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Evaluation of the EU rapid response network, crisis management and communication capacity regarding certain transmissible animal diseases

Final Report

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Submitted by:

Food Chain Evaluation Consortium (FCEC)

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Arcadia International - Van Dijk Management Consultants

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Acronyms

AA CZ:	Agricultural Association of the Czech Republic
ADIS:	Animal Disease Information System
ADNS:	Animal Disease Notification System
ADT:	Arbeitsgemeinschaft Deutscher Tierzüchter (German Animal Breeders Federation
AHES:	Animal Health Emergency System
AHS:	African horse sickness
AI:	Avian influenza
AIA:	Associazione Italiana Allevatori (Breeders Association)
ARSIA:	Association Régionale de Santé et Identification Animale (Regional Association of Health and Animal Identification)
ASF:	African swine fever
APCA:	Assemblée Permanente des Chambres d'Agriculture
AVEC:	Association of Poultry Processors and Poultry Trade in the EU countries
BE:	Belgium
BMPA:	British Meat Processors' Association
BOERENBOND:	Farmers' association (Flanders)
BPC:	British Poultry Council
BSE:	Bovine Spongiform Encephalopathy
BT:	Bluetongue
BVA:	British Veterinary Association
CA/s:	Competent Authority/ies
CD/s:	Control Directive/s
COM:	European Commission
COPA-COGECA:	Committee of Professional Agricultural Organisations and General Confederation of Agricultural Co-operatives in the European Union
CP/s:	Contingency Plan/s
CSF:	Classical swine fever
CVET:	Community Veterinary Emergency Team
CVOs:	Chief Veterinary Officers
CZ:	Czech Republic
DAFC:	Danish Agricultural Food Council
DBV:	Deutscher Bauernverband (German Farmers' Association)
DE:	Germany
DEFRA:	Department for Environment, Food and Rural Affairs
DG SANCO:	DG for Health and Consumers
DK:	Denmark
DVA:	Danish Veterinary Association
DVFB:	Deutscher Vieh- und Fleischhandelsbund (German Livestock and Meat Trade Federation)
EADP:	Australian Emergency Animal Disease Preparedness
ECDC:	European Centre for Disease Prevention and Control
ECHI:	European Community Health Indicators
EEA:	European Environment Agency
EFSA:	European Food Safety Authority
EMEA:	European Medicines Agency

EMPRES:	Emergency Prevention System for Transboundary Animal and Plant Pests and Diseases
EMRISK:	EFSA Emerging Risk Unit
EQ/s:	Evaluation question/s
EREN:	Emerging Risks Exchange Network
EU:	European Union
EU VET:	European Veterinary Emergency Team
EWRS:	Early warning and response system
FAD PReP	Foreign Animal Disease Preparedness and Response Plan
FAO:	Food and Agriculture Organisation
FAO/OIE CMC-AH:	FAO/OIE Crisis Management Centre - Animal Health
FBZPR	Federation of Agricultural Producers Union
FESASS:	European Federation for Animal Health and Food Safety
FEVEB:	Fédération Belge de la Viande (Belgian Meat Federation)
FIA:	Fédération des Industries Avicoles
FMD:	Foot-and-mouth Disease
FNGDS:	Fédération Nationale des Groupements de Défense Sanitaire GDS
FNP:	Fédération Nationale Porcine
F.N.P.A.R:	Federatia Nationala a Producatorilor Agricoli din Romania (National Federation of Agricultural Producers - Viorel Matei)
FNSEA:	Fédération Nationale des Syndicats d'Exploitants Agricoles
FR:	France
FVE:	Federation of Veterinarians of Europe
FVO:	Food and Veterinary Office (DG SANCO/F)
GLEWS:	Global Early Warning System
HPAI-P:	Highly pathogenic avian influenza in domestic poultry
HPAI-W:	Highly pathogenic avian influenza in wild birds
IHS:	Infectious haematopoietic necrosis
IT:	Italy
JRC:	Joint Research Centre-European Commission
KILW:	Krajowa Izba Lekarsko-Weterynaryjna (The National Association of Veterinarians)
LDCC:	Local Disease Control Centre
MANCP:	Multi Annual National Control Plan
MS:	Member States
NAHEMS:	National Animal Health Emergency Management System
ND:	Newcastle disease
NDCC:	National Disease Control Centre
NEPLUVI:	Nederlandse Pluimveeverwerkende Industrie (Association of the Dutch Poultry Industry)
NFU:	National Farmers' Union
NL:	Netherlands
NOP/LTO:	Association of Dutch Poultry Farmers/ Dutch Federation for Agriculture and Horticulture
NRLs:	National reference laboratories
OIE:	World Organisation for Animal Health
PL:	Poland

PVE:	Product Boards for Livestock, Meat and Eggs
RASFF:	Rapid Alert System for Food and Feed
RMA:	Romanian Meat Association
RO:	Romania
RVF:	Rift Valley Fever
SAMW:	Scottish Association of Meat Wholesalers
SCoFCAH:	Standing Committee on the Food Chain and Animal Health
SG:	Steering Group (for this evaluation)
SOP/s	Standard Operating Procedure/s
SVD:	Swine vesicular disease
TC/s:	Third Country/ies
ToR	Terms of Reference
UCPR:	Uniunea Crescatorilor De Pasari Din Romania (Romanian Poultry Producers' Association)
UECBV:	European Livestock and Meat Trading Union
UNA:	Unione Nazionale dell'Avicoltura (National Union of Poultry Farmers)
UNICEB:	Unione Importatori Esportatori Industriali Commissionari Grossisti Ingrassatori Macellatori Spedizionieri Carni Bestiame e Prodotti Derivati
UK:	United Kingdom
VDF:	Verband der Fleischwirtschaft (Meat Industry Association)
VEPEK:	Verbond voor Pluimvee, Eieren en Konijnen (Flemish Poultry, Eggs and Rabbit Association)
VHS:	Viral hemorrhagic septicaemia

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Key messages

During the last two decades the EU has experienced a number of animal health crises, the shockwaves of which have been felt economically, socially and politically. Recent outbreaks of epizootic diseases such as avian influenza (AI), foot and mouth disease (FMD) and bluetongue in previously unaffected territories of the EU have highlighted the threat posed by the sudden and unexpected emergence of infectious agents and the need for well-developed and adequately resourced counter-measures**.** The FCEC analysis indicates that over the last decade significant progress has been made in terms of the effectiveness and efficiency of the EU rapid response network. In particular:

- In spite of a significant number of primary outbreaks over the evaluation period relatively few have developed into a crisis. On the basis of the scale of the financial and economic impact, the following crises were identified: CSF (1997 DE); AI (1999/2000 IT and 2003 NL); H5N1 (2005-06); FMD (2001, UK); BT (2007/08, DE/FR/NL/BE). In the last 4 years the EU has not experienced an animal health crisis, and in particular the potential of an ASF crisis has been avoided.
- The availability of better developed and tested Contingency Plans (CP) means that in principle the EU has in place the tools which can prevent an emergency from becoming a crisis. Nonetheless, the overall effectiveness of the EU rapid response system in preventing an emergency from becoming a crisis critically depends on factors well beyond simply having tested CPs in place. Effective action relies on good cooperation and coordination within the overall rapid response network, including between the COM and MS, between laboratories and with stakeholders as well as appropriate and timely communication flows.
- The evolution of EU animal health co-financing for emergency veterinary measures has fallen from some €65 million in 2000 to €30 million in 2011, despite the fact that the EU has expanded from 15 MS to 27 MS. Over the last five years, EU co-financing has averaged €37 million, far below the average over the whole period (€91 million, 2000-2011). At the same time, the share of expenditure devoted to eradication, monitoring and control programmes has increased and has accounted for the majority of EU spending since 2005. This indicates there is now a more efficient use of funds to achieve longer term objectives such as the reinstating of disease free status for major diseases in the EU**.**
- The information exchange at SCoFCAH, is considered to be an essential and efficient element of the decision-making process and is therefore justified as is the legislative obligation for adopting emergency containment measures. Nonetheless certain cost savings measures are suggested for further consideration. FVO missions to MS to verify compliance with EU legislation, are considered to be the most effective and cost-efficient method for ensuring that the appropriate and up to date CPs are in place. It is recommended these cover all EU-27 MS within a 5 year cycle which would result in an additional requirement for 2 more inspectors in the FVO AH unit.
- The extent of the economic and social impacts, for the affected sectors and the wider economy, of major animal health emergencies/crises that have occurred in the EU27 during the last two decades is very significant. On the basis of existing studies, impacts can extend from several million € in direct losses, such as those incurred from animal culling and the destruction of materials to hundreds of millions of € or even several billion € if the indirect losses for the affected sector and the wider economy are also included. In recent years, due to improved preparedness, effective use of the lessons learnt from the management of

outbreaks and development of networks of the actors involved in the EU rapid response system, the EU 27 has no longer suffered from such extensive levels of losses.

- Nevertheless the size of the potential damage to the livestock sector, to the wider EU economy and consumer confidence, all point to the need to remain prepared and vigilant, by continuing to build and improve on the progress achieved so far. This is in line with the approach of the new Animal Health Strategy (2007-2013) "*Prevention is better than cure*" aimed at reducing the likelihood of animal disease occurrence and spread, and with the COM Action Plan to deliver the strategy's vision for the years 2007-2013 and beyond.
- Although the potential adverse impacts of animal disease crises greatly outweigh the relatively limited costs of investing in improved preparedness it remains a key challenge to address needs satisfactorily within increasing budgetary constraints, particularly in the current adverse financial climate. To overcome these constraints, it is crucial to achieve cost savings by improving the EU rapid response structures and the processes involved in order to optimise their effectiveness and efficiency. To this end, the evaluation provides detailed conclusions for each of the key components of the EU rapid response system on the basis of which recommendations are made.

Executive Summary

S.1 Background and scope of the evaluation

This evaluation of the EU rapid response network, crisis management and communication capacity regarding certain transmissible animal diseases was carried out for DG SANCO from September 2011 to June 2012 by the Food Chain Evaluation Consortium (FCEC) under the leadership of Agra CEAS Consulting.

Although the term "rapid response network" is not formally defined in EU animal health legislation, it is understood to encompass the European Commission, the Member State (MS) veterinary authorities and in a broader sense the key relevant stakeholders, i.e. private veterinarians and economic operators – especially those representing farmers and the agri-food industries. The main function of this network is to coordinate action in order to define and implement appropriate measures to effectively and efficiently address animal disease outbreaks, so as to safeguard public and animal health and minimise detrimental trade effects.

While the Commission has a coordinating role that aims to ensure proportionality, subsidiarity and non-discrimination, the MS have the main responsibility for actions in the area of emergency preparedness. Stakeholders play a key role in early detection and reporting as well as the early management of animal disease outbreaks**.** Within this EU network, MS Contingency Plans (CPs) are the core tool for implementing effective prevention and control measures. A series of disease-specific EU Control Directives provide the current EU legislative framework for harmonising control measures and establishing the minimum criteria/requirements for the CPs drawn up by MS.

The objective of this evaluation is twofold: 1) to evaluate the current legislative and non-legislative framework concerning the state of preparedness and capacity of the EU rapid response network; and 2) to clarify which aspects of current measures need to be improved and identify potential options for improvement.

The evaluation has covered a wide range of aspects of the EU network: the relevance and effectiveness of EU legislation related to contingency planning and its implementation; the added value of relevant activities of the SCoFCAH (Standing Committee on the Food Chain and Animal Health), including information exchange on the evolution of outbreaks and the adoption of emergency measures; the inspections conducted by the FVO (Food and Veterinary Office, Directorate F, DG SANCO) to verify MS compliance with EU legislation, and assistance provided by Commission services to MS; the feasibility of other/additional frameworks and/or tools for improving the control of animal disease outbreaks; and communication and dissemination capacity between all actors before and during epizootics. These elements have been addressed under seven evaluation themes (Themes A to G) as follows:

- Theme A: Legislation relating to contingency planning
- Theme B: The evaluation/approval and follow up of the CPs
- Theme C: Information exchange on outbreak evolution at SCoFCAH meetings
- Theme D: Containment measures put in place by MS CAs and endorsed by Commission Decisions

Theme E: FVO verification missions regarding CPs in peace time (including simulation exercises) and during and after outbreaks of epizootics
Theme F: The information flow in case of epizootics as well as the cooperation between MS CAs and stakeholders during CP elaboration and implementation
Theme G: The effectiveness and efficiency of the EU rapid response network

The evaluation assesses the performance of the EU rapid response network, crisis management and communication structure regarding certain transmissible diseases during the period from 1998 to 2009 and covers all 27 MS.

To address the wide-ranging objectives of this evaluation, the analysis has involved a comprehensive online survey of MS Competent Authorities (CAs) in the EU27, supplemented by extensive consultation with key stakeholders and experts at MS, EU and international level, field visits in 10 MS, a review of third country emergency preparedness systems and a literature and data review (including relevant FVO reports, financial data and national contingency plans).

S.2 Overall conclusions

During the last two decades the EU has experienced a number of animal health crises, the shockwaves of which have been felt economically, socially and politically. These crises have caused serious damage to the EU livestock sector leading to significant disruptions to markets and the wider economy. Several factors have compounded the risk of such crises – globalization and the resulting increase in trade, the intensification and concentration of production structures within the livestock producing sectors, changes in the structure and operation of the food chain downstream from the livestock production sector, the expansion of EU borders eastwards and the associated increase in the animal populations and diversity of production systems within the EU livestock sector.

Recent outbreaks of epizootic diseases such as avian influenza (AI), foot and mouth disease (FMD) and bluetongue in previously unaffected territories of the EU have highlighted the threat posed by the sudden and unexpected emergence of infectious agents, and further emphasise the need for well-developed and adequately resourced counter-measures to improve the predictability of the EU response system and to ensure rapid containment**.**

Effectively preventing and containing animal health emergencies, so as to avoid a potential crisis, is the main objective of the EU legislation in place requiring MS to have in place contingency planning so as to be prepared to prevent and/or control emergencies. In this context a crisis refers to a situation that could have been avoided if the appropriate preparedness level and measures had been in place. On this basis, the evolution over time of the number of outbreaks and of those that developed into a crisis is an indicator of the overall performance of the EU animal response system.

Based on the FCEC analysis, the following overall conclusions can be drawn on the effectiveness and efficiency of the EU rapid response network.

The availability of well developed, tested and up to date CPs, as an indicator of preparedness, can help prevent an emergency from becoming a crisis. Nonetheless, the overall effectiveness of the EU rapid response system extends to factors well beyond simply having effective CPs

in place. The effectiveness of the response also relies on good cooperation and coordination within the overall rapid response network, including between the COM and MS, regular and timely exchange of information (including scientific knowledge and advice) between laboratories and with stakeholders, and the building and maintenance of confidence and trust between all parties.

The evolution of the EU animal health co-financing indicates a downward trend in the amount of EU co-funding for emergency veterinary measures from some €65 million in 2000 to €30 million in 2011. Over the last five years EU co-financing has averaged €37 million, far below the average over the whole period (€91 million, 2000-2011[1]). This points to the more efficient use of funds to achieve longer term objectives such as the reinstating of disease free status for major diseases in the EU, as was also concluded by the recent report on the outcome of the EU co-financed animal disease eradication and monitoring programmes, which highlights notable achievements in this area, such as the effective control of CSF, bluetongue and avian influenza in the EU over the last decade (FCEC, 2011).

The comprehensive set of legislation now in place (including CPs and the EU emergency network in all its components) can be considered as a valuable shield against traditional contagious animal diseases and appears to be quite effective in terms of triggering the relevant steps and control measures to fight against emerging diseases or new "profiles" of known diseases (e.g. AI with public health risks).

As a result of this, over the evaluation period, out of a significant number of outbreaks, relatively few have developed into a crisis. On the basis of the criteria of financial cost and economic impact, the following crises were identified: CSF (1997 DE); AI (1999/2000 IT); AI (2003 NL); H5N1 (2005-06); FMD (2001, UK); BT (2007/08, DE/FR/NL/BE). In the last 4 years the EU has not experienced an animal health crisis, and in particular the potential of an ASF crisis due to the risk of re-introduction of this disease from the Caucasus region was avoided.

FVO missions and SCOFCAH meetings are two of the key components of the EU rapid response system examined in this evaluation. The evaluation has found that the information exchange at SCoFCAH is considered to be an essential element of the decision-making process and is therefore justified and that the legislative obligation for adopting emergency containment measures at SCoFCAH is seen as efficient by MS. Nonetheless, certain cost savings could be considered. FVO missions to MS to verify compliance with EU legislation, are considered to be the most effective and cost-efficient approach for ensuring that the appropriate and up to date CPs are in place.

The extent of the economic and social impacts, for the affected sectors and the wider economy, of major animal health emergencies/crises that have occurred in the EU27 during the last two decades is very significant. On the basis of existing studies, impacts can extend from several million € in direct losses, to hundreds of millions € or even several billion € if the indirect losses to the affected sector and the wider economy are also included. In recent years, due to improved preparedness, effective use of the lessons learnt from the management of outbreaks and development of networks of the actors involved in the EU rapid response system the EU 27 has no longer suffered from such extensive levels of losses.

[1] In terms of outturn payments, i.e. the sum of credits generated by a MS in a specific year.

Nevertheless the size of the potential damage to the livestock sector, the wider EU economy and consumer confidence, all point to the need to remain prepared and vigilant, by continuing to build and improve on the progress achieved so far. This is in line with the approach of the new Animal Health Strategy (2007-2013) "*Prevention is better than cure*" aiming to reduce the likelihood of animal diseases occurrence and spread, and to minimise the impact of outbreaks, and with the COM Action Plan to deliver the strategy's vision for the years 2007-2013 and beyond.

Although the potential adverse impacts of animal disease crises greatly outweigh the relatively limited costs of investing in improved preparedness it remains a key challenge to address needs satisfactorily within increasing budgetary constraints, particularly in the current adverse financial climate. To overcome these constraints, it is crucial to achieve cost savings by improving the EU rapid response structures and the processes involved in order to optimise effectiveness and efficiency. To this end, the evaluation provides detailed conclusions for each of the key components of the EU rapid response system in Themes A to G, on the basis of which recommendations are made.

S.3 Key findings per evaluation theme A-G

Based on the FCEC analysis of the collected evidence base, the following key findings and recommendations were made per evaluation theme.

Theme A: legislation relating to contingency planning

The current scope of the EU legislation is by and large considered sufficiently broad to make MS contingency planning an effective tool in achieving the goals of disease containment, control and eradication. In particular:

- Overall, there is a high level of MS compliance with the current criteria/requirements in the Annexes of the Control Directives and MS are generally satisfied with the current scope of EU legislation. The approach adopted in the FMD Control Directive in particular is considered to be exemplary and a world reference in terms of best practice on how to prepare contingency planning.
- Several MS include additional criteria in their CPs not currently laid down in the EU legislation, e.g. systematic update in light of experience gained but not all MS using additional criteria would consider it necessary to lay these down in EU legislation. This is because there is concern that putting forward more prescriptive legislation might limit MS flexibility to adopt actions which fit national conditions. In terms of the involvement of directly implicated sectors in contingency planning, this is linked with two other key aspects of the EU animal health policy, the development of cost and responsibility sharing schemes and the prioritisation of animal diseases; as both processes are currently on-going at EU level, it is considered premature at this stage to define more prescriptive legislation in this regard.
- Only about one third of MS currently include explicit provisions in their CPs on coordination with neighbouring MS in CP development (drafting, implementation and simulation), and on collaboration more generally with other MS in CP implementation**.** The current level of coordination and cooperation both between MS and with the COM is considered satisfactory and sufficient to instil confidence

amongst MS and stakeholders in the EU preparedness system. Nonetheless, MS would welcome more exchange with other MS on their specific experience with contingency planning.

- The majority (about two thirds) of MS favour a generic approach to contingency planning. MS identified several significant advantages in following a more generic approach, notably the ability to share and benefit from best practices for better planning of the organisational, logistic and legal elements that are horizontal across diseases. However, some concerns have been raised on how generic CPs should be designed. The conclusion reached is therefore that disease specific characteristics and the ability to be prepared for effective action for each specific disease need to be safeguarded, and that therefore a generic approach should aim to cover certain minimum requirements that are common across diseases**.**
- Although currently not specified in the Annexes to the EU Control Directives, different levels of action in the case of primary and secondary outbreaks are already included in the CPs of some MS. Specific practices on primary outbreaks play an important role in controlling diseases, e.g. animal traceability for BT and SVD, but only a minority of MS consider it necessary to lay down such rules as a CP requirement in EU legislation.
- The majority (over two thirds) of MS already include real-time alert exercises in both CPs for FMD and AI, as required under EU legislation, but also for other diseases for which these are not currently required. Several MS identified significant benefits in carrying out simulation exercises, in particular in terms of reviewing the applicability of the various technical provisions of contingency planning and drawing on the lessons learnt to revise and update their CPs, and contributing to practical training on the procedures to be followed during emergencies. Although real-time alert exercises are found to be time-consuming and demanding by several MS in terms of the required organisation and resources, nonetheless the majority of MS CAs consider it necessary to lay this down as a CP requirement in the EU Control Directives - in particular for CSF and ASF for which the Directives currently foresee alarm drills only. It is also noted that MS indicated that a common definition of what constitutes a simulation exercise is missing and this should also be laid down in EU legislation.

Theme B: the evaluation/approval and follow up of the CPs

- MS CPs have been systematically approved only for FMD, CSF, AI and ND. Furthermore, the procedure currently followed in these cases is in practice more of a formality rather than a substantive comprehensive review of the CPs as such.
- No subsequent approval following amendments by MS to the initially approved CPs has been carried out. This is explicitly foreseen by the legislation in some cases (e.g. FMD) although there are different requirements on both the CP review frequency and the approval of CP updates/amendments through comitology.
- The majority of MS do not consider the current procedure for the approval of the initial CPs or of their updates/amendments, to be relevant, effective or efficient for ensuring that effective CPs are in place. At the same time, most MS indicate that their *own national best interests*, the *legal obligation to have in place operational CPs as provided by the EU Control Directives*, and *the current mechanism of FVO inspections for CPs*, are the three most significant drivers for ensuring the objectives of contingency planning i.e. to achieve animal disease preparedness and rapid

reaction. Consequently, by and large, neither the COM nor MS consider that the current procedure guarantees the quality of CPs i.e. that the minimum criteria laid down in EU legislation are followed and that CPs are regularly updated/revised in the light of experience gained.

- Drawing a parallel in particular from the food and feed safety sector, the procedure foreseen by Article 13 of Regulation (EC) 882/2004 for MANCPs[2] (multi annual national control plans) does not involve SCoFCAH approval, as the Regulation foresees that MS should simply submit their MANCPs and annual reports to the COM, and in this case the COM checks via the FVO (at the end of the planning year) whether the MS system in place is effective and well-planned.
- Now that MS have developed their experience of contingency planning, it is questioned whether the CP approval procedure through SCoFCAH remains necessary and whether it offers any real added value in terms of providing the COM services with an overview of the CPs to verify their mutual effectiveness. By contrast FVO missions are regarded by the majority of MS as relevant, effective and efficient in ensuring these objectives, as they play an important role in verifying MS compliance with the legislation.
- In view of the generally low importance attached to the approval of MS CPs by SCoFCAH, the majority of MS have indicated that there is a need to review current procedures/mechanisms for the evaluation and approval of MS CPs with a view to simplification and alignment with the procedures followed for MANCPs.

Theme C: Exchange of information on outbreak evolution at SCoFCAH meetings

The current information exchange practices are by and large still adequate and efficient taking into account subsequent changes and progress regarding especially communication tools. In particular:

- The COM considers the exchange of information at SCoFCAH, taking into account both the administrative constraints involved and the existence of the ADNS (ADIS) system to be broadly efficient. The COM considers SCoFCAH and ADNS to be fully complementary: ADNS provides objective data on outbreaks, while at SCoFCAH this is accompanied by contextual information provided by MS, which cannot be made available via ADNS (or the future ADIS). ADIS will be designed to avoid overlapping, duplication and divergence that could occur from reporting events to different systems, and is thus also expected to save much effort and resource. However, the COM highlights that ADIS will not introduce a dramatic change from the current situation, as ADIS will not replace essential parts of the discussion at SCoFCAH meetings, concerning the provision of 'richer', contextual information.
- The majority of MS consider the information exchange at SCoFCAH meetings very relevant and effective both from the point of view of the MS having an outbreak (obligation to inform) and for the other parties (opportunity to obtain information). Overall MS find that SCoFCAH is an essential information exchange platform, in particular as it offers the possibility to ask and answer questions immediately, and share views and experiences at peer level. Many MS also highlight the importance of the informal exchange of information that occurs outside of the meetings. However

[2] The MANCP describes the strategy that MS develop for a certain time period in order to guarantee an efficient result in terms of controls and compliance with food legislation by operators.

some MS do not consider information exchange at SCoFCAH to be sufficiently precise or detailed, and to be relatively limited at technical level, although solutions are suggested to overcome this. Some but not all stakeholder organisations would be in favour of an equivalent stakeholder forum at EU level.

- A number of suggested potential alternative options for sharing information at SCoFCAH were considered (e.g. a technical group to facilitate discussion). No single option was put forward by any majority of MS, but some options are worth further discussion
- Most MS find the CVET missions relevant and effective as an additional tool in support of the information exchange provided at SCoFCAH. However, there may be a need to better outline CVET's role.
- Most MS find a crisis unit similar to the one laid down in Commission Decision 2004/478/EC) relevant. However, it is debatable whether this would be necessary considering the planned implementation of the crisis unit for food and feed, as the AH emergency structure is seen to already be well developed – there may simply be a need to link this emergency structure to the crisis unit planned for food and feed in cases with public health implications.

Theme D: Containment measures put in place by MS CAs and endorsed by Commission Decisions

- Current procedures for the adoption of containment measures are by and large still considered adequate by the COM taking into account subsequent changes and progress. There is also substantial flexibility in the individual steps involved in the procedure: standard templates exist for the common diseases, steps can be expedited if need be in order to implement measures within 24 hours, and the current electronic systems used by the COM for document handling should not cause unnecessary delay. Although the legal base for the adoption of measures by the COM is not appropriate for actions in all cases, this is not considered to have caused any major problems; the legal base could nonetheless be clarified and strengthened in the context of the ongoing revision of the new Animal Health law.
- Taking into account administrative/budgetary constraints, the legislative obligation for adopting emergency containment measures at SCoFCAH is considered efficient by MS. It is not considered to incur unnecessary additional administrative costs, but there may nonetheless be savings to be gained in cases where the endorsement of MS containment measures does not need to be voted on, if information provided by the affected MS is sufficient.
- The COM broadly considers the legislative obligation for endorsing containment measures to be efficient. The COM highlights that the procedure is quite flexible: votes can be conducted by email; there is a 'written procedure' whereby draft texts of legislation are sent to the MS and on which they can give their formal opinion. Legislation that needs to be voted on urgently can also be put to a vote in a non-animal health SCoFCAH meeting if need be. However, it would be difficult to reduce the number of MS participants required to be present at the meetings.

Theme E: FVO verification missions regarding CP in peace time (including simulation exercises) and during and after outbreaks of epizootics

- Several criteria are used by DG SANCO to plan FVO CP missions. Most FVO missions on animal health follow outbreaks and/or CP verification (in particular: AI, FMD, BT CSF, ASF), and follow up missions due to identified shortcomings, while a smaller number of missions are related to co-funded eradication programmes. Generally FVO CP verification missions follow animal health emergencies: following CSF (1997), FMD (2001) and AI (2003, 2006 RO), emergency preparedness missions have been carried out for these diseases in subsequent years. Although the current frequency of FVO inspection missions is considered sufficient by the majority of MS, a 5 year rotation is considered by most experts as the minimum frequency required to keep track of significant changes occurring at the level of staff in the MS CAs and other institutions and organisations involved.
- Generally, MS consider the manner of conducting FVO missions and drafting of reports fairly relevant and efficient in evaluating MS emergency preparedness, although those conducted in case of emergencies appear to be less useful than those relating to contingency planning as such. More forward-looking rather than backward-looking inspections are therefore considered most useful and could fit within a broader approach to the review of contingency planning under the MANCPs.
- FVO reporting has improved since the last evaluation of the Community Animal Health Policy (CAHP) was carried out in 2007, although it is acknowledged that there is scope for further improvements in using the FVO findings and follow up. FVO reporting serves different purposes for different readers: while the full inspection report is considered most appropriate for the MS being inspected and the other MS and third countries interested in the detailed outcome of the inspection, the COM finds the brief 'back to office' reports produced within 2-3 days of the inspection visit most useful, and uses FVO reports as background information for discussions about MS emergency preparedness at SCoFCAH.
- The majority of MS act on the FVO recommendations. In the visited case study MS, in response to FVO recommendations, all requested follow-up activities have been completed by the MS CAs. Out of 141 FVO mission reports on animal health, 439 recommendations were made of which 397 (90%) had been followed up by MS.
- Third country trading partners are mostly concerned about the effectiveness of MS CPs in practice i.e. about how MS deal with a disease outbreak when this actually occurs, as well as OIE disease-status declarations to establish freedom of disease. In this context, FVO MS inspections provide reassurance to third countries, who increasingly value their credibility and accuracy. Although in the past there appears to have been more reliance on own third country risk assessments or inspections (e.g. USA), over the last decade third country acceptance of FVO mission reporting appears to have significantly increased.

Theme F: the information flow in case of epizootics as well as the cooperation between MS CAs and stakeholders during CP elaboration and implementation

- With respect to the involvement of the various stakeholders in the conception, drafting, preparation, updating and amendment of the CP it is concluded that stakeholder involvement in MS contingency planning should be encouraged and

reinforced by the introducing of a general provision on this in the CP requirements of the Control Directives, rather than more prescriptive legislation.

- With regard to communication between MS CAs and stakeholders progress has been made, but there is still room for improvement in terms of the timing/frequency, the accuracy and scientific backing of the information provided, as well as ensuring that the appropriate level of detail is transmitted to the target audience**.**
- Broadly speaking, the improvement in cooperation/coordination between countries is expected to be paralleled by improvements in THE communication flow. In relation to communication with third country trading partners, the EU is at the forefront of applying the regionalisation concept in international trade as this has proven an effective way of managing outbreaks at the level of the affected MS or regions within MS, without the rest of the EU or an exporting third country being penalised. As a result, more recent outbreaks have generally had less impact on trade than those that occurred 20 years ago, and animal health is no longer the most controversial issue in EU negotiations with third countries. However, more has to be done to better integrate EU strategy in managing and communicating on animal health emergencies, including on improving transparency and the application of regionalisation principles.
- Communication to the wider public is generally considered sufficient, although it remains highly variable between MS. It is considered that in spite of the significant progress seen in this regard over the last decade there is scope for further improvement in the coherence, scientific quality/validity and timing of information flows**.**
- There are divergent MS CA views on the extent to which CPs should be made publicly available (on-line), with those in favour arguing that awareness and transparency in the procedures promotes rapid response in the event of an emergency, and those against concerned about the potential risks related to the release of certain sensitive information to the general public**.**

Theme G: the effectiveness and efficiency of the EU rapid response network

As has been highlighted above the EU rapid response system is considered to have improved very significantly over the last decade and to broadly work effectively and efficiently. This having been said, there is scope for improvement in some areas. More importantly it is critical to emphasise that while progress has been made in tackling outbreaks of traditional diseases (e.g. CSF) newly emerging diseases are now becoming a major risk, as demonstrated by the H5N1 and BT outbreaks. These are by definition 'low' predictability so continued efforts on these diseases will be essential. More generally, the extent of the economic and social impacts (for the affected sectors and the wider economy) of major animal health emergencies/crises that have occurred in the EU27 during the last two decades is so significant that it justifies the relatively limited costs of investing in improved preparedness. This is in line with the approach of the new Animal Health Strategy (2007-2013) "*Prevention is better than cure*" aiming to reduce the likelihood of animal diseases occurrence and spread, and to minimise the impact of outbreaks, and with the COM Action Plan to deliver the strategy's vision for the years 2007-2013 and beyond.

S.4 Recommendations

Based on the key findings presented above, a number of recommendations are presented as follows. These are grouped according to the level of support that they have received from MS:

1) Recommendation that have received widespread and unanimous support

1. Introducing a framework approach, for a generic CP laying down minimum requirements that are common across all diseases, but ensuring sufficient flexibility to adapt at an operational level to each specific disease to ensure sufficient disease focus. On the basis of the most advanced CPs in place today (e.g. FMD and generic CP models in several MS), such minimum requirements could cover: the chain of command; the establishment of NDCCs/LDCCs and expert groups; sufficient access to tools, staff, facilities and funding; cooperation between the authorities involved; cooperation between neighbouring MS/third countries; carrying out simulation exercises; and, where applicable emergency vaccination **(Theme A)**.
2. The possibility of including real-time alert exercises as a CP requirement in all the EU Control Directives should be taken into consideration, especially in the case of CSF and ASF. MS are also in favour of a common EU definition of real-time alert exercises, alarm drills and simulation exercises **(Theme A)**.
3. While the current EU rapid response system has been sufficiently reactive, thereby continuously improving by taking into account lessons learnt, it needs to be paralleled by a proactive approach, which consists of anticipating and preparing for new or emerging risks. The COM could play a key role in developing a systematic process of analysing and evaluating new risks (horizon scanning), possibly benefitting from the experience gained in the context of EFSA's work on emerging risks for food safety **(Theme A).**
4. With regard to the evaluation, approval and follow-up of CPs via the SCoFCAH procedure there appears to be MS, as well as COM, consensus on the need to improve as well as to strengthen procedures, but to avoid increasing the complexity of the requirements imposed on MS without offering any real added value.

   Consideration should be given to harmonising the approach currently followed for the approval of CPs with that of MANCPs, including the modalities of MS annual reporting on key changes made in the CPs e.g. on the chain of command (MS reporting is currently voluntary in the context of the MANCPs, but it needs to be considered whether it should be made compulsory). The majority of MS indicate the need to keep some form of COM oversight, which centres on an initial review and follow up of MS CPs by more systematic FVO verification missions, leading – but not necessarily – to some form of COM approval. The main justification for retaining some form of COM oversight over the process was the need to ensure a harmonised approach across the EU, and that all MS comply with the minimum CP requirements as laid down in the Control Directives. For those supporting this option, the idea is for the COM to create a general framework for CP drafting/updating, but to leave some degree of flexibility and freedom to MS to develop their national CPs, and to verify this via more regular peer reviewing by FVO inspections. The general framework outlined above could be established through the development by the COM of an up-to-date *'light and alive'* system of guides of good/best practices, which could fit into the development by the COM of guidelines to assist MS to adapt CP requirements to the national situation. The

added value of having in place such guidance for animal health contingency planning is illustrated for example by the *FAO Good Management Emergency Practices (GMEP)*, which appears to have been well accepted by countries supported by the FAO/OIE Crisis Management Centre for Animal Health (CMC-AH);

Other possible EU level actions aimed at ensuring high quality contingency planning and emergency preparedness throughout the EU include training and workshops, both of which can foster the exchange of experience and best practice across the EU. In this context the systematic training on contingency planning foreseen for 2012-13 is considered a very positive development. The lessons to be learnt from a more regular review of the CPs by the FVO could fit into both the BTSF training and other workshops organised on contingency planning **(Theme B).**

5. Consultation with the MS and COM services has largely indicated that the information exchange element of SCoFCAH should remain as it is **(Theme C)**. Only minor improvements have been suggested (e.g. video linking; use of CRICA for pre-and post meeting circulation of documents, additional technical groups for information exchange; template for epidemiological reports; linking future food and feed crisis unit to AH procedures and structures)**.**
6. Given the generally positive picture of the current procedure for the adoption of containment measures and their subsequent endorsement by COM decisions, only relatively minor improvements are proposed **(Theme D).** These would include the continued adaptation of the legal base for the adoption of safeguard measures by the COM to ensure its appropriateness. It would also include work to ensure the predictability of MS actions particularly by improving their capability to apply regionalisation perhaps by pre-identifying geographical units of reference for the restriction zones at the appropriate (regional level), based on common objective criteria such as administrative boundaries, livestock density and farming systems. This would help ensure consistency of the approach and its implementation across MS and improve the evidence base presented to third country trading partners.

   Having in place the current procedure for the adoption of containment measures ensures transparency. However, it is recommended to examine whether savings can be made in further restricting SCoFCAH voting on containment measures for situations where information is not sufficient or where outbreaks of 'traditional' diseases do not require long discussion. This would mean giving MS more opportunity to provide adequate information on measures taken and further encourage MS to fill information gaps or correct inadequate measures**.**
   (Theme G).
7. A 5 year cycle is considered the best approach for FVO CP verification missions in the EU27. If the FVO was to achieve a cycle of inspection missions every 5 years per MS to verify MS CPs sufficiently, this would result in an additional 5/6 missions per year. Assuming all other FVO work (e.g. missions on the monitoring and eradication programmes etc.) were to continue as at present, this would result in an additional requirement for 2 more inspectors in the FVO AH unit **(Theme E).**
8. In terms of FVO mission reporting and improving the usability of FVO reports by other COM services, in addition to the current 'back-to-office' and full inspection reports, there may be scope for a more synthetic report, for example every two years, to provide an overview of the key findings of the FVO missions undertaken, follow-up activities

and MS feedback including from training seminars. The lessons learnt from such synthesis reports could fit directly into future policy-making **(Theme E and G)**.

9. In terms of the additional costs of SCoFCAH meetings certain improvements could be considered to provide cost savings (e.g. video-linking to AH experts who are not attending the SCoFCAH meetings; the use of CIRCA by MS to facilitate the timely pre- and post-meeting circulation of relevant documents; the use of a technical group as an additional tool to information exchange at SCoFCAH; and, of a template for epidemiological reports to standardise and improve the information provided) (**Theme C and G**).

1.a) Recommended eliminations in EU legislation:

10. While the FMD CP model is considered to be the most thorough and detailed, the Control Directives for BT, ASF, AHS, CSF and AI could be revised to address the additional criteria highlighted, including animal welfare, and to take out criteria that are not considered appropriate for some diseases e.g. emergency vaccination for SVD (**Theme A).**

1.b) Issues on which harmonisation or more prescriptive EU legislation have been not recommended at present but where other potential options have been taken into consideration

11. At the moment, the best approach for reinforcing stakeholder involvement in MS contingency planning is to state the need for this as a general principle in EU legislation. More prescriptive legislation on this is perceived by the majority of MS to be both premature and potentially negative in terms of the contingency planning process in some MS. Similarly, having explicit provisions on MS collaboration laid down in EU legislation is not considered necessary by the majority of MS. Rather, it is considered more helpful to have a suitable forum for exchange of best practices, and training; to this end, an initial 1-day conference could be proposed to cover the range of issues that are relevant to contingency planning including on communication issues **(Theme A).**
12. In addition, increasing the level and detail of MS national databases providing input to ADNS/ADIS could be considered, so as to improve the availability of information which can be used to provide data to other MS and the COM in case of emergencies **(Theme F).**
13. By and large MS are satisfied with the current degree of detail on CP requirements. However, more specific guidelines could be developed, possibly by reviewing and updating those developed by the COM in 2000, to explain further the CP requirements of the Control Directives. Such guidelines are considered beneficial for adapting CP requirements to the national situation by most MS; they could also provide better guidance and more focused FVO inspections, as is the case with the FVO reports on monitoring and eradication programmes for which the COM measures on specific diseases are more prescriptive. (**Theme A**).
14. Improving the MS application of regionalisation on the basis of EU common principles and criteria on geographical demarcation of restriction zones through specific provisions in EU legislation needs to be considered **(Theme F).**

2) Recommendations that have received more divided views:

1. To improve the consistency in contingency planning across all relevant sectors and to explore potential synergies in FVO inspections for CPs and MANCPs, regular CP verification missions on the basis of a 5-year review cycle (as discussed above) could be carried out by multi-disciplinary teams to cover the broader range of fields falling under the MANCP; in addition, focused missions could be conducted on specific suspicion or evidence of shortcomings, and emergency missions (as currently conducted) in the event of outbreaks, both of which would be conducted by experts in the animal health field (**Theme E**).
2. Limited access or a filtering system may be a solution for enabling CPs to become partially public, in terms of CP information being accessed on-line only by relevant registered users (**Theme F**).
3. Promoting the opportunity for information exchange at stakeholder level, similar to that currently provided to MS CAs in the context of SCoFCAH meetings, could be further considered (**Theme F**).
4. Although the creation of a network of communicators in the field of animal health may not be the magic solution for improving communication, due *inter alia* to a generally low level of institutional memory brought about by the relatively frequent change of position of the staff involved, where possible it would be desirable to pursue further some of the useful recommendations provided by the *Conference on lessons learned from the H1N1 pandemic*. Another key lesson drawn from outbreaks over the last decade is the importance of having the information flow channelled to the outside world via a limited number of key officials, in order to ensure more coherent, scientifically based and timely messages at all levels (EU, national and regional) during epizootics (**Theme F**).
5. It needs to be considered further whether the ratio of primary to secondary outbreaks would be appropriate for MS to use as a more objective indicator of their performance in the management of certain diseases, and what the target ratio should be set at (**Theme G).**

1 Introduction and methodology

This Draft Final Report presents the main results and conclusions of the analysis in respect to the issues specified in the 43 EQs and Themes A-G of the evaluation.

1.1 Context and objectives of the evaluation

DG SANCO has launched an evaluation on the emergency preparedness of the EU rapid response network, crisis management and communication capacity concerning certain transmissible animal diseases. This evaluation is to provide an assessment of the entire relevant legislative and non-legislative framework, system and structure that both Member States (MS) and DG SANCO work within and have implemented to ensure all actors are effectively able to respond to threats and crises related to transmissible animal diseases. The study will also place the evaluation in the context of Better Regulation, by analysing the ways in which administrative burden and cost to the Commission, MS and the economic operators could be reduced.

Although the term "rapid response network" is not formally defined in EU veterinary legislation, it is understood to encompass the Commission, the responsible MS veterinary authorities and in the broader sense the main stakeholders such as those representing farmers, agro food industries and veterinarians. All these actors should work in a highly coordinated and collaborative manner in order to identify the appropriate measures to safeguard public and animal health. While the Commission coordinates the management of crises, the MS have the main responsibility for actions in the area of emergency preparedness. The Contingency Plans (CPs) are the main instrument through which MS effectively develop and implement actions against suspected or confirmed outbreaks of animal diseases in their territory.

The aim of the study is to provide an evaluation of the status of the emergency preparedness of the animal health network in the EU, with a focus on the years 1998-2009; to identify aspects of current legislative and non legislative measures, acts and processes which may require improvement or changes, and to analyse and develop policy options for the future. The study will also assess the relevance and the effectiveness of CP implementation by both MS and DG SANCO, the added value of the SCoFCAH activities including Commission legislation adopted at SCoFCAH meetings, and communication capacity between all the actors before and during epizootics. Finally the study will provide an analysis of the contribution of the EU rapid response network in maintaining a high level of sanitary protection and its impact on the trade of live animals, animal products and food of animal origin.

The rationale for evaluating the EU rapid response network consists of a number of factors as follows:

- the increasingly recognised importance of early detection and timely notification of outbreaks by MS;
- an effective and efficient flow of timely and relevant information concerning outbreaks particularly as Commission services largely rely on the EU network to effectively prepare for and manage emergencies;
- the correct implementation of disease control/eradication measures (in particular preparation of CPs both in advance and with the full cooperation with all actors

concerned); and
- good communication between all actors.

According to the Terms of Reference (ToR), the purpose of the evaluation is twofold:

1. To evaluate the current legislative and non-legislative environment as regards the state of preparedness and capacity of the EU rapid response network, in particular for the following aspects:

    a. the current emergency framework (i.e. the CP and the SCoFCAH) in tackling epizootics and the implementation of this framework by the MS;
    b. the administrative and technical controls (including FVO inspections/audit) and assistance provided by Commission Services to the MS;
    c. the feasibility of other/additional framework and/or tools improving control of certain animal disease outbreaks (collection of relevant ideas of MS and other actors, lessons learned based on existing examples or other prevention measures); and,
    d. the communication and dissemination strategy, to assess the effectiveness and efficacy of the EU rapid response network as a key tool in keeping a high level of health protection in the EU.

2. To clarify which aspects of current measures need to be improved/changed and to suggest potential options for improvement, including possible legislative amendments and future developments based, where possible, on quantitative data.

1.2 Overview of the EU rapid response network, crisis management and communication capacity

The EU rapid response network is principally composed of Commission Services and MS – specifically, the veterinary Competent Authorities (CAs) – but also private veterinarians, the economic operators concerned, especially those representing farmers, and agri-food industries (stakeholders) [3].

Its main function is to coordinate action in order to minimise the detrimental effects of disease outbreaks on the trade of live animals, and the products derived from these. In relation to trade, the focus is on establishing import conditions according to the EU's international obligations, as well as maintaining export flows by supporting Commission services in tackling any unjustified trade barriers that might arise on sanitary grounds as a defensive reaction from trading partners.

Within the network, the main responsibility for action is at MS level, while the COM has a coordinating role that aims to ensure proportionality, subsidiarity and non-discrimination. Stakeholders such as livestock farmers and food business organisations play a key role in

[3] This section is revised and completed from the earlier version presented in the Inception Report, incorporating the COM feedback on this.

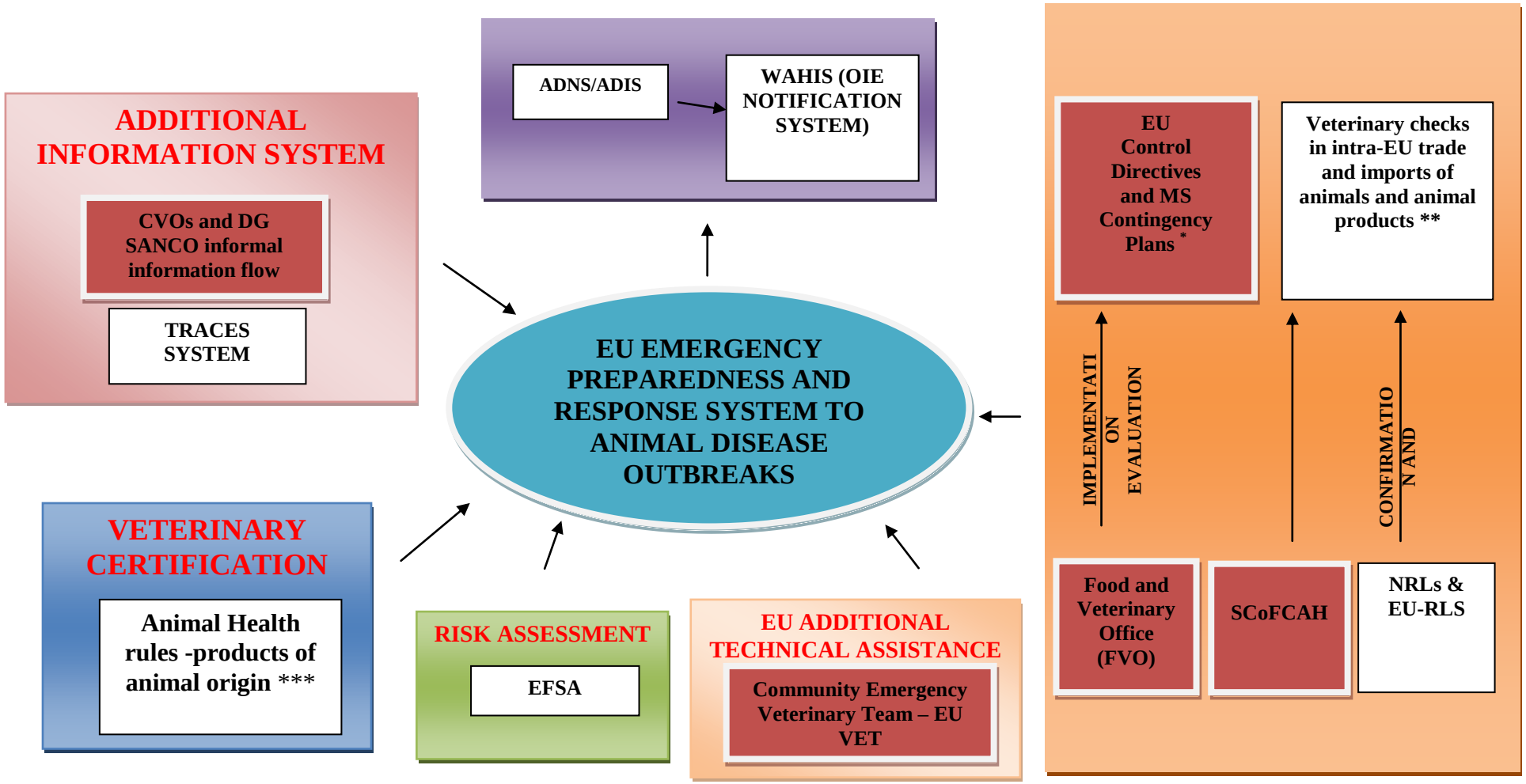
early detection and reporting as well as the early management of outbreaks, which greatly improves the likelihood of being able to control a disease in its early phases.

The **Standing Committee on the Food Chain and Animal Health (SCoFCAH)** is currently playing a key role within this system, in its regulatory/legislative function for the adoption of some of the key tools of the EU rapid response network: the Contingency Plans (CPs) put together by MS in peacetime; and the emergency containment measures taken by MS in the event of outbreaks.

Figure 1 provides an overview of the various legislative and non legislative activities, as well as complementary action carried out within the EU rapid response, crisis management and communication network, while **Figure 2** summarises the key actors and their role in the system[4].

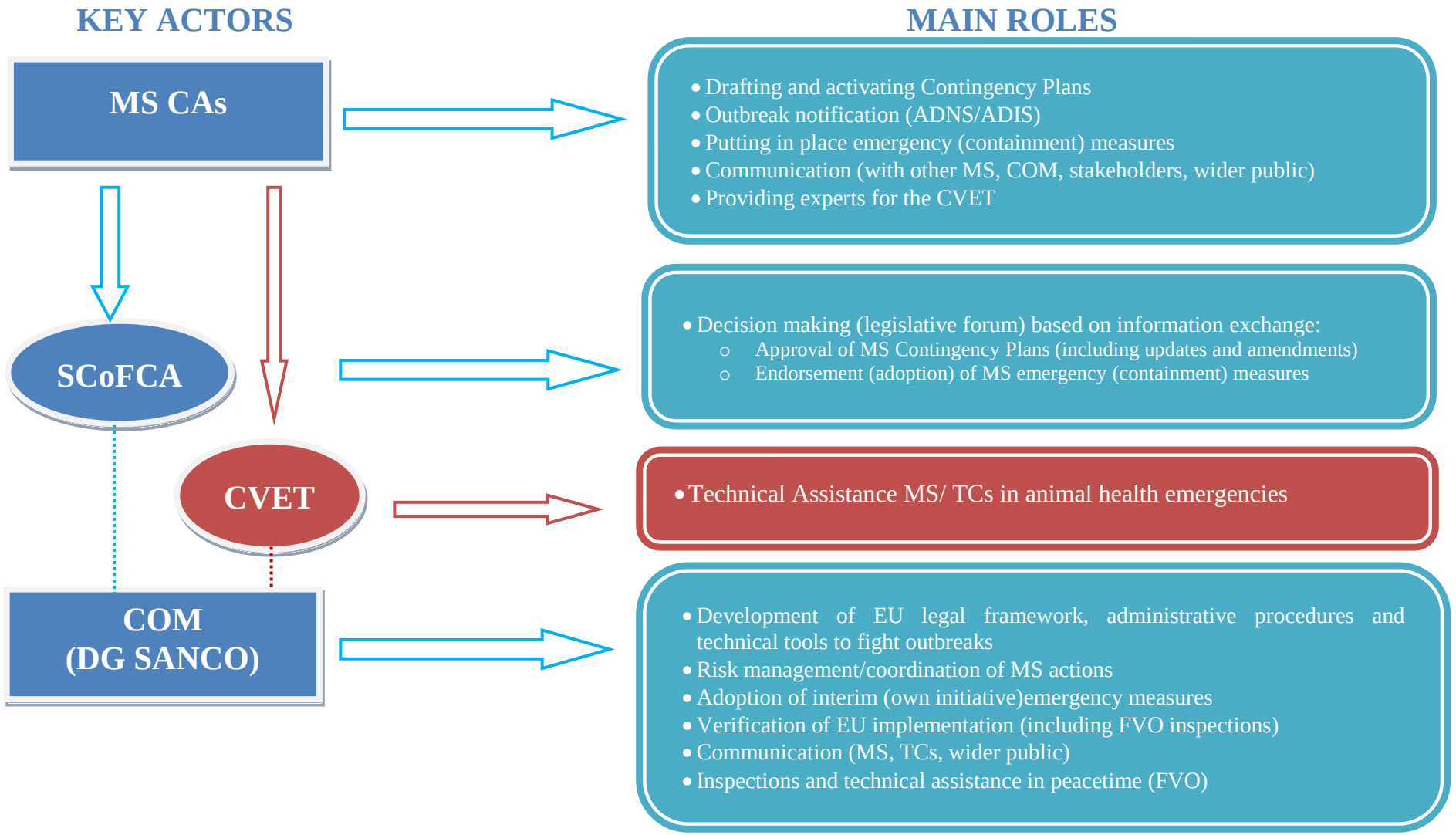
[4] Both figures are revised and completed from the earlier version presented in the Inception Report, incorporating the COM feedback on this.

Figure 1: EU emergency preparedness and response system to animal disease outbreaks



* Including animal welfare provisions (Regulation (EC) 1099/2009) and the safe disposal of animal by product (Regulation (EC) 1069/2009 and implementing rules)
** Directives 89/662/EEC and 90/425/EEC (intra-EU trade); Directives 97/78/EEC and 91/496/EEC (imports)
*** Directive 2002/99/EC

Figure 2: Key actors and roles of the EU rapid response network



The activities and cooperation of the rapid response network are regulated by both legislative and non-legislative tools. These encompass:

1. EU Control Directives: MS contingency planning

The EU Control Directives for the various diseases require that all MS should draw up a Contingency Plan (CP), to be implemented in the event of a disease outbreak, which also specifies the national measures needed to maintain awareness and preparedness. National CPs for epizootic diseases are an essential element to ensure MS outbreak preparedness, and they are a fundamental aspect of the EU rapid response network, and its crisis management and communication capacity.

Contingency plans must be submitted by the MS to the COM and approved via the comitology procedure (SCoFCAH). Once a plan has been received, the European Commission verifies whether the contingency plan allows the desired objective to be achieved; suggests to the MS concerned any amendments required in particular to ensure that the plan is compatible with those of the other MS; and approves the plans, if necessary amended in accordance with the procedure of the SCoFCAH. In the course of the implementation of a contingency plan the MS and DG SANCO also generate a two-way informal information flow, not regulated by legislation, on the measures taken and activities carried out.

2. Emergency containment measures

EU legislation (the EU Control Directives) lays down the minimum EU control measures to be implemented when an outbreak occurs, in line with the rules governing intra community trade and imports from Third Countries[5]. The aim is to reduce, through timely and effective action, the potential impact of epizootics of regulated contagious diseases[6].
The Commission and other MS may either agree or disagree with the measures taken by the affected MS:

- In the first case, the COM may (but do not have to) propose measures endorsing the situation on the ground;
- In the latter case (on very rare occasions) the Commission may consider further measures to be necessary and draft decisions in order to strengthen the applicable measures. In particular, Article 9 of Directive 89/662/EEC and Article 10 of Directive

[5] Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market.
Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market.
Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries.
Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC

[6] In addition, based on Article 5 of Council Directive 2002/99/EC, veterinary certification is required for products of animal origin intended for human consumption where provisions adopted for animal health reasons under Article 9 of Directive 89/662/EEC establishes that products of animal origin from an MS, affected by the epizootic disease, is to be accompanied by a health certificate.

90/425/EEC stipulate that the COM may, in consultation with the MS concerned and following the meeting of the Standing Veterinary Committee, take interim protective measures with regard to animals or products from the region affected by the epizootic disease or from a given holding, centre or organization.

In most cases, MS are also invited to present the evolution of animal disease presence in their territory, as well as the protective measures taken within the framework of the relevant CP at the SCoFCAH meetings. In addition, an information flow, concerning outbreak confirmation and CP implemented measures, is regularly generated between MS and the COM via the usual communication tools such as faxes and email.

3. Risk notification: ADNS/ADIS

One of the key activities of the network concerns notification of outbreak occurrence by the affected MS to other MS and the COM. In order to ensure a rapid exchange of information between the national CAs responsible for animal health and the COM on outbreaks of contagious animal diseases, the EU has provided the legal basis (Council Directive 82/894/EEC) for a computerised information system (ADNS) which alerts Commission services and MS Chief Veterinary Officers (CVOs), within 24 hours of confirmed primary outbreaks. Annex 1 of this Directive lists the animal diseases subject to notification. This system permits immediate access to information about contagious animal disease outbreaks and ensures that trade in live animals and products of animal origin are not unnecessarily affected[7].

4. Technical assistance: EU Veterinary Emergency Team

In order to improve the crisis management mechanism, in 2007 the COM adopted a Decision (Commission Decision 2007/142/EC)[8] to establish the EU Veterinary Emergency Team. This team, made up of animal health experts, is available at short notice in order to provide the support to respond rapidly to major animal disease outbreaks in the EU and third countries.

Each MS submits lists of experts they propose for the emergency team and the Commission selects ad hoc team members in the event of an animal disease crisis. At present (2011), the emergency team consists of 101 experts from several MS. Within the EU territory, the emergency team has completed several missions in the case of major crises, including of CSF, BT and FMD (see table below). In the case of the recent FMD outbreak in wild boars and domestic animals in Bulgaria, the team promptly assisted the MS by visiting the region of Burgas, where the disease outbreak had been reported, to help with further enquiries.

[7] For the risk notification on food and feed the European Commission put in place the RASFF (Rapid Alert System for Food and Feed) whereby Member States, EEA-EFTA countries and the COM share information on food and feed which may present a risk to public health.
[8] Commission Decision of 28 February 2007 establishing a Community Veterinary Emergency Team to assist the COM in supporting Member States and third countries in veterinary matters relating to certain animal diseases (2007/142/EC)

Table 1: Missions of the Veterinary Emergency Team in the EU

MS	Date	Disease
Cyprus	November 2007	FMD
Cyprus	November 2007	FMD
Slovakia	April 2008	CSF
Netherlands	November 2008	BT
Lithuania	July 2009	CSF
Bulgaria	January 2011	FMD
Bulgaria	February 2011	FMD

Source: European Commission

5. Complementary activities

Other actors and their activities also play a very important role in the management of epizootics. These include:

- EFSA which provides risk assessment advice on food and feed safety, and animal health issues, as well as animal welfare, to MS and the European Commission;

- National reference laboratories (NRLs) and EU reference laboratories (EU RLs) in the animal health field, which ensure the harmonisation and high quality of diagnostic methods as well as confirmatory diagnosis of the various diseases and uniform laboratory testing within the EU, to support the activities of the Commission in relation to risk management and risk assessment;

- In addition, TRACES, an internet-based network between veterinary authorities in the EU, provides epidemiologically important information which helps MS CAs to identify the origin of the contagion and its ensuing spread.

6. MS contingency planning

The importance of contingency planning for controlling infectious animal diseases became widely recognised in the 1990s. The objective of contingency planning is to plan the management in advance of a potential critical event that may or may not occur. In the context of infectious animal diseases, such an event would be the introduction of a highly contagious disease such as foot-and-mouth disease (FMD), avian influenza (AI), Newcastle disease (ND), classical swine fever (CSF) or bluetongue (BT).

Within the EU, legal guidance relating to contingency planning was first provided for FMD by Council Directive 90/423/EEC which states: *'Each MS shall draw up a plan of warning, specifying the national measures to be implemented in the event of an outbreak of foot-and-mouth disease'*. A list of criteria to be met by FMD contingency plans was laid down in Commission Decision 91/42/EEC and subsequently superseded by Council Directive 2003/85/EC (Annex XVII).

Contingency planning has been applied to other major infectious animal diseases. The legal framework for diseases subjected to harmonised control measures and for contingency planning within the EU is presented in the table below.

Table 2: Animal diseases subject to harmonised control measures and contingency plan

Animal disease	Legal framework	EU legislation - approval of animal disease CPs
Avian influenza	Council Directive 2005/94/EC	• for 25 MS Commission Decision 2004/102/EC • for 2 MS- Commission Decision 2007/24/EC
Classical swine fever	Council Directive 2001/89/EC	• for 15 MS- Commission Decision 1999/246/EC • for 10 MS-Commission Decision 2004/431/EC • for 2 MS-Commission Decision 2007/19/EC
Foot-and-mouth disease	Council Directive 2003/85/EC	• for 15 MS-Council Decision 93/455/EEC, • for 10 MS Commission Decision 2004/435/EC • for 2 MS- Commission Decision 2007/18/EC
Newcastle disease	Council Directive 92/66/EEC	• for 25 MS Commission Decision 2004/402/EC • for 2 MS- Commission Decision 2007/24/EC
Bluetongue	Council Directive 2000/75/EC	
African horse sickness	Council Directive 92/35/EEC	
African swine fever	Council Directive 2002/60/EC	
Other animal diseases, including swine vesicular disease	Council Directives 92/119/EEC	
Certain diseases in aquatic animals	Council Directives 2006/88/EC	

Source: European Commission

Each of the above Directives includes an annex specifying the criteria/requirements that the respective contingency plan should comply with. The specific provisions of the EU legislation covering these plans vary from one Directive to another due to the historical development of this legislation. In general, plans allow access to facilities, equipment, personnel and other necessary materials to ensure rapid and efficient containment and eradication of the outbreak, although for some diseases - CSF, AI, fish diseases and FMD- feature notable differences in terms of their requirements. The CP for AI, for example, requires specific data on the number and location of all commercial poultry holdings within the MS, and the maximum number of birds, by species, which could be present within them.

Despite such differences, the main elements to be covered by the plans are the same, namely:

- legal powers;
- financial provisions;
- the chain of command and National Disease Control Centres;
- local Disease Control Centres;
- expert groups;
- resources required for disease emergencies – personnel;
- resources required for disease emergencies – equipment and facilities;
- diagnostic laboratories;
- emergency vaccination;

- training;
- publicity and awareness;
- operational manual.

A detailed plan for emergency vaccination, and vaccine requirements needed in the event of emergency vaccination for CSF, FMD, BT, AI, ND must be indicated. In addition, Article 72 of Council Directive 2003/85/EC requires FMD CPs to set out the measures to be applied in a 'worst case scenario', in which the national CAs must control a large number of outbreaks occurring within a short time and caused by several anti-genetically distinct serotypes or strains.

For ASF and CSF, simulation exercises (alarm drills) must be organised at least twice a year. Real-time exercises must also be conducted[9]. For FMD, these take place twice within a five year period (or in combination with an exercise in a neighbouring MS or another disease).

The CPs are approved, via the comitology procedure, by Commission Decisions[10]. Significant modifications in the CP for FMD must be notified to the Commission. In any case, each MS must update its CP for most of these diseases every five years and submit it to the Commission for approval. Particularly, in the case of FMD the CP needs to take into account the experience gained during real-time alert exercises.

1.3 Overview of methodological approach

1.3.1 Structure of the assignment

The evaluation assesses the performance of the EU rapid response network, crisis management and communication structures regarding certain transmissible diseases in relation to seven specific issues[11]:

1. **Relevance and effectiveness of the current legislative and non-legislative framework** in preparing the MS to respond to possible animal health crises;
2. **Relevance and effectiveness of the implementation of the CP process by the Commission** (DG SANCO, Directorate D and F), in relation to the initial evaluation and approval of the CPs and the subsequent checking of implementation by the MS (especially with regard to FVO inspection/verification missions);
3. **Added value of the operation of the SCoFCAH** and the Commission legislation adopted at SCoFCAH meetings;
4. **Cooperation and coordination between national CAs and various stakeholders** both during the elaboration of the CPs and their implementation, including the execution of simulation exercises;

[9] Currently real time exercises are foreseen in art 73 of 2007/18/EC for FMD and. Art 62(6) of CD 2005/94/EC for AI

[10] 2007/24/EC, for AI and ND; 2007/18/EC for FMD; and 2007/19/EC for CSF

[11] This evaluation does not cover the following points: establishment of a single Animal Health Law; further development of the TRACES systems; development of an Animal Disease Information System, ADIS; reinforcement of the necessary EU antigen/vaccine banks; evaluation of the Community Reference laboratories on the field of animal health; discussion of policy on the use of authorised vaccines. These issues have been subject to other actions of the Programming document for the Strategy. However, where appropriate and relevant, reference to these issues may be made when addressing the evaluation themes and questions.

5. **Communication capacity and information flow** prior to and during epizootics between MS and the relevant stakeholders (quality, quantity, relevance to the public concerned) and the Commission Services;
6. **Relevance and effectiveness of the implementation by MS** of the framework related to CPs (in theory and in practice), and of other disease surveillance systems developed by MS in order to prevent or reduce the spread of epizootics due to known agents. Also, the capacity of MS systems to react to new agents (e.g. BT, exotic diseases), unknown agents or particular threats (bioterrorism);
7. **Capacity/effectiveness and efficiency of the EU global response system towards** the various groups of **stakeholders** (including EU trading partners).

In order to address these issues the assessment covers a set of 7 evaluation themes which consist of a total of 43 evaluation questions (EQs).

The assignment was structured according to three main tasks: structuring, data collection, and synthesis. The synthesis assesses **the relevance, effectiveness, efficiency, and sustainability** of the EU rapid response network, crisis management and communication capacity for certain transmissible disease, with a view to identifying possible areas for improvement.

1.3.2 Intervention logic

The intervention logic of the EU-rapid response network, as positioned within the EU animal disease risk prevention and management system, was developed by the FCEC and approved by the SG during the inception phase of the evaluation; this is presented in **Figure 3.**

Disease containment, control and eradication is a wider objective served by a range of tools, including surveillance, diagnostics and the rapid response network CPs. CPs are a component of the rapid response system. In the short term, an effective CP will contribute to containing the disease; this, in the long term will contribute to control and eradication.

1.3.3 Judgment criteria and indicators

The analysis of Themes A-G and the 43 EQs of the TOR were based on the judgement criteria and indicators presented in **Annex 1**.

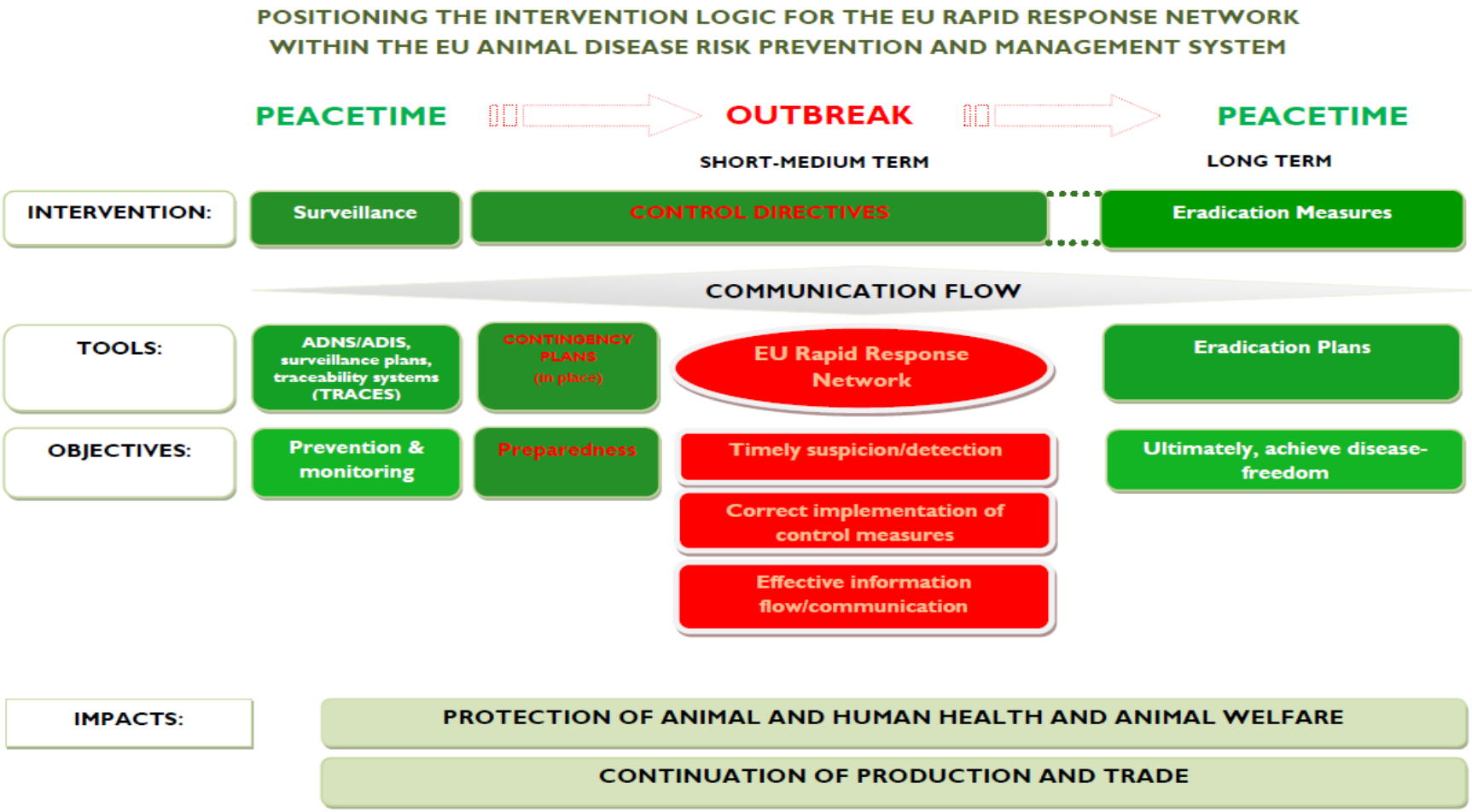
In particular, once the judgment criteria were defined, the identification and selection of quantitative and qualitative indicators was based on the following two main criteria:

1. The relevance of the indicators in the context of the evaluation in terms of providing fully justified answers to the evaluation questions; and,
2. The existence and availability of data to determine the feasibility of using the indicators identified as being relevant.

In this process, the scarcity of relevant quantitative indicators for an evaluation of this nature was noted. On the basis of the above two criteria, a limited number of quantitative indicators were identified as most appropriate to include, and these are summarised in the analysis of Theme G. Furthermore, a range of 'quasi-quantitative' indicators qualitative indicators were developed.

The analysis of the indicators has drawn on the results of the key methodological tools used in this evaluation: an EU-27 survey of MS Competent Authorities (CAs), the 10 MS case studies and in-depth interviews with an extensive range of relevant stakeholders. An overview of the consultation process followed in the study is provided in **Annex 2.**

Figure 3: Intervention logic for the EU rapid response network



2 Theme A: legislation relating to contingency planning

2.1 Background

The EU Control Directives for the various diseases require that all MS should draw up a Contingency Plan (CP), to be implemented in the event of a disease outbreak, which also specifies the national measures needed to maintain disease preparedness. National CPs for epizootic diseases are an essential element to ensure MS preparedness to address outbreaks, and they are a fundamental aspect of the EU rapid response network, and its crisis management and communication capacity.

The legal framework for animal diseases subjected to harmonised control measures and for contingency planning within the EU is presented in **Table 2**[12].

The specific objective of this theme is to evaluate the relevance and effectiveness of the current legislative framework in preparing MS to respond to potential animal health emergencies, with a view to achieving the goals of disease containment, control and eradication. The current legislative framework refers, in particular, to the Control Directives which *inter alia* lay down the minimum requirements for drawing national CPs.

The FCEC has screened the legislation and identified the following key criteria for determining whether a CP is relevant and effective. On this basis, the FCEC has examined, in the survey of MS CAs and in the case studies, the extent to which these criteria are endorsed by MS, whether they are considered to be detailed enough and whether other relevant criteria that are currently not listed should be included in the Control Directives.

[12] Newcastle disease and aquatic animal diseases are coved respectively by Control Directive 92/66/EEC and Control Directive 2006/88/EC. The aim in both cases is to achieve a disease free status for facilitation of trade. In agreement with DG SANCO, diseases of aquatic animals have been excluded from this evaluation for the following reasons: a) disease control and spread of disease in particular in fish living in the open sea differs significantly from that of terrestrial animals; b) these diseases are only on very rare occasions requiring a rapid emergency response; and c) in some MS there are very few establishments that are concerned. Although disease control measures and contingency plans are in place for these diseases, it is up to the MS to decide whether and how to implement these. In the case of Newcastle disease (ND), it can be reasonably assumed that any MS ready for avian influenza is also ready for ND.

Table 3: CP criteria laid down in EU legislation

	DISEASE						
CRITERIA	**ASF**	**CSF**	**AHS**	**SVD**	**BT**	**AI**	**FMD**
Organisation:							
Chain of command[13]	√	√					√
Staff details & responsibilities			√	√	√	√	
NDCC/LDCC	√[14]	√[15]	√	√	√	√	√
Permanent operational expert group	√[16]	√[17]				√[18]	√
Cooperation between all relevant authorities						√[19]	√
Cooperation with neighbouring MS in real time alert exercises							√ [20]
Legal powers for implementation	√	√	√	√	√	√	√
Access to financial resources	√	√					√
Practical implementation[21]:							
Detailed instructions on action including for safe disposal			√	√	√	√	
Operational manual	√	√					√
Tools:							
Availability of equipment & materials	√	√	√	√	√	√	√
Diagnostic labs facilities & capacity for rapid diagnosis	√	√	√	√	√	√	√
Emergency vaccination		√	√	√	√	√	√
Capacity for safe disposal							√
Capacity for rapid communication:							
Between CAs and with stakeholders	√[22]	√[23]	√	√	√	√	√
With the general public						√	√
Other criteria							

[13] The full chain of command includes staff details and responsibilities, and also the NDCC/LDCC network. The Control Directives (CDs) for AHS, ND, SVD, and BT require "Staff details & responsibilities" for CPs while in the CDs for CSF, ASF, and FMD a chain of command is explicitly laid down as a criterion. The chain of command is a broader requirement than staff responsibility, as it also explicitly specifies the ability/right of CVOs to activate CPs.
[14] Art 22 CD **2002/60/EC**
[15] Art 23 CD **2001/89/EC**
[16] Art 22 CD **2002/60/EC**
[17] Art 23 **CD 2001/89/EC**
[18] Art 62(6) of CD 2005/94/EC establishes that: '*In addition to the measures provided for paragraphs 1 to 4, further rules to ensure a rapid and efficient eradication of avian influenza, including provisions on disease control centres, **expert groups** and **real-time alert exercises**, may be adopted in accordance with the procedure referred to in Article 64(2)'.*
[19] Art 62 (3) of CD 2005/94/EC establishes that: '*Provisions shall be in place for close cooperation **between the competent authorities responsible** for the different sectors, particularly those in charge of animal health, public health, environmental matters and health and safety of workers, in particular to ensure proper risk **communication to farmers, workers in the poultry sector and the publ**ic'.*
[20] Annex XVII of CD 2003/85 *: by way of derogation from paragraph 11.2.1 and subject to appropriate provisions in the contingency plan, **MS** with a limited population of animals of susceptible species arrange for the **participation in and contribution to real-time exercises carried out in a neighbouring MS** [..]'.*
[21] Some Control Directives (ASF, CSF, FMD) explicitly require an operational manual, while for the other diseases the legislation simply lays down "detailed instructions on action" as a criterion. The former is broader, as an operational manual includes a detailed range of instructions.
[22] Art 22 CD 2002/60/EC. The type of communication is not specified.
[23] Art 23 CD 2001/89/EC. The type of communication is not specified.

	DISEASE						
CRITERIA	**ASF**	**CSF**	**AHS**	**SVD**	**BT**	**AI**	**FMD**
Training [24]	√	√	√	√	√	√	√
Real Time Alert Exercise						√[18]	√
Alarm drills	√	√					
Worst case scenario							√
Holding registration and identification of high density areas		√[25]				√	√[26]

Source: FCEC, based on the criteria/requirements in the Annexes to the disease specific Control Directives.

2.2 Findings

2.2.1 Assessment of the current scope of the EU legislation (EQ A/1)

A/1 To what extent is the CP scope broad enough in current legislation to make it an effective tool in achieving its goals such as disease containment, control and eradication?

This evaluation question addressees the extent to which the scope of current EU legislation on contingency planning, as laid down in EU Control Directives for notifiable diseases, is broad enough to achieve the goal of disease containment, control and eradication.

The containment, control and eradication of animal diseases are a wider objective served by a range of tools, including surveillance, diagnostics and contingency planning. The Contingency Plans (CPs) are an essential component of the rapid response system. In the short term, an effective CP will contribute to contain a disease outbreak; in the longer term, this will contribute to disease control and eradication.

According to experts, a standard ideal format for an animal disease CP as such does not exist, as each CP needs to be tailored to each country's own distinctive specificities as well as the disease characteristics (FAO Good Emergency Management Practice: The Essentials, 2012). Nonetheless, it is still possible to identify some key elements which are crucial for a correct and effective implementation of CPs in the event of emergency diseases.

In particular, for CPs to be an effective tool (in achieving the objectives of disease containment, control and eradication), certain minimum criteria or requirements on their scope and contents should be in place. These are already defined for certain priority notifiable diseases[27] in the Annexes to the EU Control Directives[28], with the obligation for MS to draw

[24] Training is in some cases explicitly specified at different levels, such as at administrative and field level, and in other cases not defined at all. In the case of the CD on FMD, one specific criterion is training in communication. Training in communication is also mentioned in the CD on aquatic diseases.
[25] Art 22 (b) of Council Directive 2001/89/EC establishes that '*the contingency plan for CSF should give a precise indication of the regions where areas with a high density of pigs may be found in each Member State, in order that in these regions a higher level of disease awareness and preparedness is ensured.'*
[26] FMD Directive 2003/85/EC in Annex X point (3) provides a definition of Densely Populated Livestock Areas (DPLA), referring to art 2 (u) of CSF Directive 2001/89/EC when deciding for vaccination.
[27] In particular, those diseases covered by the old list A (notifiable diseases) of the OIE.
[28] Some CP requirements are also laid down within the articles of Control Directives – for example, the requirement to have in place a NDCC is included in article 22 of Control Directive 2002/60/EC for ASF and

their CPs according to certain criteria. However, there is significant variation in coverage and detail between the criteria laid down for the various diseases; this is due to historical reasons, in particular the progressive development of the Control Directives.

A number of indicators capturing a range of parameters were developed by the FCEC to evaluate the breadth of the scope of EU legislation.

Indicator 1: MS compliance with the criteria/requirements currently laid down in EU legislation

The FCEC has screened the legislation and identified the key criteria for contingency planning, as listed in the Control Directives for each of the diseases. This exercise provided the basis for examining the extent to which these criteria are endorsed by all 27 MS, whether they are considered to be detailed enough, and whether other relevant criteria that are currently not explicitly listed in the Control Directives should be included.

With regard to the requirements laid down in each disease-specific Control Directive, the results of our survey show that, overall, the level of MS compliance is high: on average, 22 MS comply with each requirement laid down in each of the Control Directives. However, the average level of MS compliance with the EU requirements varies greatly between diseases: while in the case of CSF, FMD and AI CPs, the average level of MS compliance is very high (25 MS comply with each requirement), in the case of AHS and SVD the average level of MS compliance is significantly lower (15 and 17 MS, respectively, comply with each requirement) **(Table 4**).

For some of those MS which do not fully comply with all of the criteria laid down in EU legislation, this appears to be due to budget/administrative constraints. This is the case, for example, with the requirements for a '*permanent operational expert group'* in Portugal, '*alarm drills'* for CSF in Slovakia, and '*training'* for AHS and SVD in Estonia (source: survey results). In other cases, the lack of compliance with some criteria featuring in EU legislation stems from the fact that they are not considered relevant to MS needs. For example, this is the case for Lithuania in terms of the '*cooperation with neighbouring MS in real time exercises', 'capacity for safe disposal', 'real time alert exercises'* and *'worst case scenario';* for Poland, elements not covered in the CPs are regarding '*capacity for rapid communication between the CA and stakeholders'*, as this is assured in internal procedures on relations with the public and regulations on access to public information.

article 23 of Control Directive 2001/89/EC for CSF; the requirement to ensure cooperation between all relevant authorities, to carry out real time alert exercises and to have in place an expert group are included in article 62 of Control Directive 2005/94/EC for HPAI.

Table 4: Extent of MS compliance with the CP criteria/requirements laid down in EU legislation

Criteria laid down in CONTROL DIRECTIVE 2002/60/EC-ASF	N. of MS
Access to financial resources	22
Alarm drills	14
Availability of equipment & materials	23
Communication between CAs and with stakeholders	22
Chain of command	23
Diagnostic labs facilities & capacity for rapid diagnosis	23
Legal powers for implementation	22
NDCC/LDCC	22
Operational manual	19
Permanent operational expert group	21
Training	20
Average level of compliance	21

Criteria laid down in CONTROL DIRECTIVE 2001/89/EC- CSF	N. of MS
Access to financial resources	26
Alarm drills	16
Availability of equipment & materials	26
Communication between CAs and with stakeholders	26
Chain of command	27
Diagnostic labs facilities & capacity for rapid diagnosis	27
Emergency vaccination	20
Holding registration and identification of high density areas	24
Legal powers for implementation	27
NDCC/LDCC	26
Operational manual	26
Permanent operational expert group	27
Training	25
Average level of compliance	**25**

Criteria laid down in CONTROL DIRECTIVE 92/35/EEC - AHS	N. of MS
Availability of equipment & materials	16
Between CAs and with stakeholders	16
Detailed instructions on action including for safe disposal	16
Diagnostic labs facilities & capacity for rapid diagnosis	15
Emergency vaccination	10
Legal powers for implementation	16
NDCC/LDCC	15
Staff details & responsibilities	16
Training	13
Average level of compliance	**15**

Criteria laid down in CONTROL DIRECTIVE 92/119/EEC - SVD-	N of MS
Availability of equipment & materials	19
Between CAs and with stakeholders	19
Detailed instructions on action including for safe disposal	19
Diagnostic labs facilities & capacity for rapid diagnosis	19
Emergency vaccination	9
Legal powers for implementation	19
NDCC/LDCC	18
Staff details & responsibilities	20
Training	14
Average level of compliance	**17**

Criteria laid down in CONTROL DIRECTIVE 2000/75/EC- BT-	N. of MS
Availability of equipment & materials	25
Between CAs and with stakeholders	25
Detailed instructions on action including for safe disposal	24
Diagnostic labs facilities & capacity for rapid diagnosis	25
Emergency vaccination	24
Legal powers for implementation	26
NDCC/LDCC	24
Staff details & responsibilities	26
Training	24
Average level of compliance	**25**

Criteria laid down in CONTROL DIRECTIVE 2005/94/EC- AI	N. of MS
Availability of equipment & materials	26
Between CAs and with stakeholders	26
Cooperation between all relevant authorities	27
Detailed instructions on action including for safe disposal	27
Diagnostic labs facilities & capacity for rapid diagnosis	27
Emergency vaccination	17
Holding registration and identification of high density areas	24
Legal powers for implementation	27
NDCC/LDCC	25
Permanent operational expert group	23
Real Time Alert Exercise	22
Staff details & responsibilities	27
Training	25
With the general public	26
Average level of compliance	**25**

Criteria laid down in CONTROL DIRECTIVE 2003/85/EC- FMD	N. of MS
Access to financial resources	26
Availability of equipment & materials	27
Between CAs and with stakeholders	26
Capacity for safe disposal	25
Chain of command[1]	27
Cooperation between all relevant authorities	27
Cooperation with neighbouring MS in real time alert exercises	17
Diagnostic labs facilities & capacity for rapid diagnosis	27
Emergency vaccination	23
Legal powers for implementation	27
NDCC/LDCC	26
Operational manual	26
Permanent operational expert group	23
Real Time Alert Exercise	25
Training	27
With the general public	27
Worst case scenario	22
Average level of compliance	**25**

Source: FCEC survey of 27 MS CAs

On average, 22 MS consider necessary all of the minimum CP criteria currently included in the EU legislation. Again, the analysis by disease and type of criterion shows that MS views vary largely between criteria. Some of the criteria concerning organisational aspects, such as '*chain of command including staff details and responsibilities', 'cooperation between all relevant authorities', 'access to financial resources'* and *'legal power for implementation'* are considered necessary by 24 MS. In the case of FMD, HPAI, and CSF these criteria are considered necessary by an average number of 25 MS (for more details on the *chain of command* see the box below). Almost all MS (25) focus on the availability of appropriate tools such as '*availability of equipment and materials'* and '*diagnostic labs facilities & capacity for rapid diagnosis'*. It is interesting to note that despite being explicitly included only in the case of the Control Directive on FMD, the *'capacity for safe disposal'* is perceived as an important requirement for all of the listed diseases (Q 3.b- FCEC survey results).

On the other hand, some other criteria are not considered necessary by a large number of MS - e.g. only few MS consider it necessary to lay down in EU legislation the requirement to include '*emergency vaccination'* provisions in the CPs for SVD (9 MS) and AHS (15 MS). During the MS case studies, some MS (Italy, Poland, Denmark) indicated that, as vaccines do not exist for these diseases[29] (in the case of AHS, the vaccine is not officially authorised in the EU), it is not necessary to lay down in EU legislation the requirement to include emergency vaccination in the national CPs for these two diseases. This explains also why the majority of MS do not comply with this criterion in the case of SVD and AHS (**Table 4**).

While real time alert exercises are considered necessary by the majority of MS (23), alarm drills are perceived as less useful, even for CSF and ASF for which this CP requirement is already laid down in EU legislation. Some MS have adopted alarm drills at local rather than at national level. In Denmark, the DVFA explained that alarm drills were not included in the CPs as they are performed at regional level; regions must perform five simulations or alarm drills per year covering such aspects as provision and assessment of equipment, design of modus operandi, etc. They also use alarm drills as a tool whenever they have a suspicion; according to the DVFA, there can be up to 250 or more suspicions per year (DK case study). Similarly, in Italy, real time alert exercises have been performed by the Ministry of Health, while alarm drills are carried out by LDDCs (through the local sanitary services, the ASL - Aziende Sanitarie Locali) (IT case study).

Except for the above criteria on which there is a relatively homogeneous opinion of MS, the view on the need for certain other criteria varies depending on MS characteristics, for example:

- The UK (generic) CP complies with all the criteria laid down in EU legislation, except for *'cooperation with neighbouring MS in real time exercises'*, which is not considered necessary for this country as such due to its geographic position and not very relevant for vector borne diseases (UK case study);
- In Italy, the identification of Densely Populated Livestock Areas (DPLA) and registration of holdings for CSF CP and FMD CP are considered not necessary as the country has developed a GPS system which allows the IT CA to quickly identify

[29] Also in the case of ASF there is no vaccine, but in this case emergency vaccination is not laid down in Control Directive 2002/60/EC.

holdings and DPLAs, thus defining protection and surveillance zones in case of disease occurrence (IT case study);

- In the Czech Republic, the criteria which are not included in the country's CPs are '*cooperation with neighbouring MS in real time alert* for SVD and AHS, '*operational manuals*' for SVD and AHS, '*emergency vaccination*' for AHS, '*real time alert exercises*' for BT and AH, and '*worst case scenario*' for BT, SVD, AHS. For diseases that have never been reported in the country (SVD and AHS), the SVA did not consider necessary the criteria listed above (CZ case study).

The chain of command

The value of **the chain of command** has been highlighted by the COM services, stakeholders and international organisations consulted: a pre-defined clear structure and understanding of who will be responsible for what activities empowers CVOs to implement decisions in the event of outbreaks, overcoming internal pressures at national level, and increasing their ability to fully activate the CPs. On the other hand, an insufficiently clear chain of command can create friction between different services and thus reduce the availability of the necessary tools and overall ability to handle an emergency. There is, therefore, a need to link closely the chain of events to the chain of command.

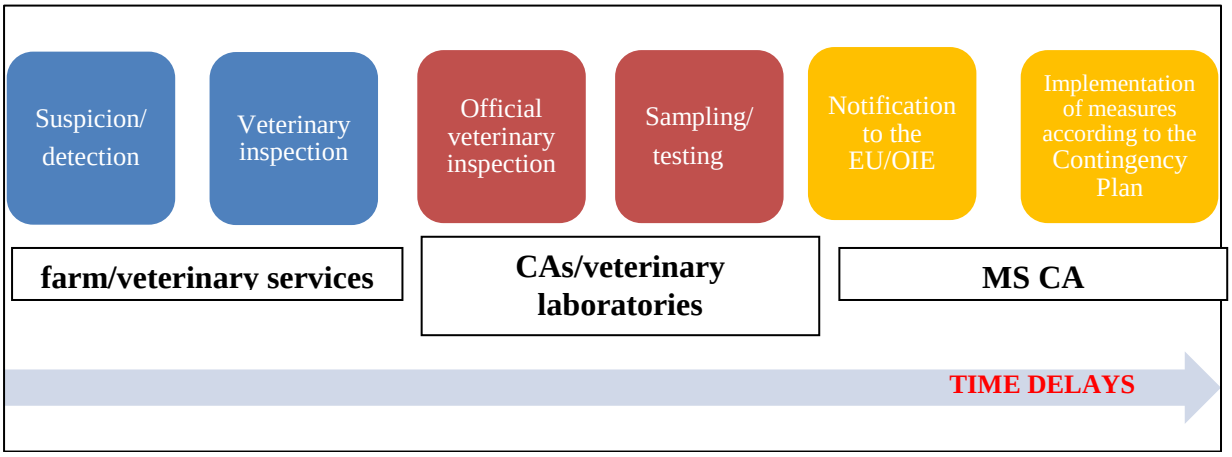
At the level of the COM services, the chain of command has already been established. DG SANCO has developed specific templates for reacting to crises for known diseases. For FMD, these are shared with MS to assist them in taking actions which are additional to those foreseen in the Control Directive 2003/85/EC – e.g. safeguard decisions drafted on the basis of the template with additional details, rules, information not included in the Directive, which strengthen the chain of command in a MS. For example, during the recent FMD outbreak at the Turkish-Bulgarian borders, DG SANCO helped Bulgaria to block animal movement in some regions (see also theme D on the SCOFCAH procedure for the adoption of containment measures).

The need to define a well-structured chain of command has been also internationally recognised. According to the head of the FAO/OIE Crisis Management Centre for Animal Health, defining a clear chain of command is crucial in making CPs effective, along with a good communication flow and the separation between a strategic and tactical approach in managing emergencies,. Since its inception, the Centre has introduced the **Incident Command System (ICS)**; allowing for a good management and reporting system to avoid potential confusion, this has proved useful in establishing certain best practices to adapt and apply in a UN context.

According to stakeholders, the chain of command requires that all relevant actors meet and plan in advance the CP, taking into account all relevant and concerned agencies and bodies to involve. Failure to ensure coordination during peacetime between the various parties involved can result in lack of cooperation in the event of emergencies. Indeed, some stakeholders indicated that problems in the chain of command during emergencies resulted in a lack of trust, and coordination/collaboration between relevant actors (the CAs and stakeholders).

It is noted that in some cases, due to the characteristics of a disease, delays in the chain of command during an emergency are linked to delays in the chain of events, e.g. delays during the detection/suspicion to confirmation phase. This is the case of CSF, a disease particularly difficult to manage due to its long incubation period with no visible symptoms; it may take 6 weeks for a farmer to detect (or suspect) a CSF outbreak, although the diagnosis is relatively quick (1 or 2 days depending on farm location). Another difficult disease to detect is FMD in sheep, which partly underlies the 2001 FMD crisis in the UK; DG SANCO amended the FMD legislation due to the difficulty to diagnose the disease on sheep. There have also been improvements in diagnostic tools which allow quicker results: for example, during an AI suspicion in the Netherlands in 2011, new laboratory tests gave quick results and the authorities were able to inform DG SANCO rapidly, and created a restriction zone to avoid panic.

Figure 4: Chain of events and chain of command



Source: FCEC

Indicators 2 and 3: the use and need for additional criteria/requirements to those currently laid down in the EU legislation

A number of criteria/requirements are used by MS in their national CPs that are additional to those currently laid down in the EU legislation. The most extensively used is the '*systematic update in light of experience gained*'. The majority of MS (18-20 MS, depending on the disease) include this requirement in their CPs for FMD[30], AI, CSF and BT; 15-16 MS include it in their CPs against ASF, AHS, SVD (Q 3.c- FCEC survey results). Positive examples of the use of this criterion have been reported by several MS*:*

- The UK generic CP is reviewed annually[31] taking into consideration lessons identified from exercises and incidents handled, together with responses to a public consultation (posted in DEFRA website);
- The IT CP against AI includes a systematic update in light of experience gained, following in particular the 1999 crisis which has helped the IT CA to establish in advance the number of vaccines needed and define the zones under restrictions;
- The FR CP for BT is currently being revised as the existing version, addressing emergencies in a free status country, is largely obsolete for France being affected by BTV-1 and BTV-8. Various recommendations for the improvement of the BT CP have been provided by the *Groupements de Défense Sanitaire* (GDS) in their 2010 report on the BT crisis, including the need to plan for various scenarios of outbreaks and for the emergence of new serotypes on the French territory, and to build the emergency response approach on the basis of cost-benefit analysis.

[30] In the case of FMD, this requirement is partly defined in article 72.10 of Control Directive 2003/85/EC which establishes: *"In any case, every five years each Member State shall update its contingency plan in particular in the light of real-time alert exercises referred to in Article 73, and submit it to the Commission for approval in accordance with the procedure referred to in Article 89(2)."*

[31] To meet the provisions of Section 14a of the Animal Health Act 1981 (as amended by section 18 of the Animal Health Act 2002).

'*Cooperation with stakeholders*' and '*explicit lines of communication with the EC'* are the second most frequently used additional criteria, applied respectively by 13-15 and 9-12 MS (range depends on the disease; Q 3.c- FCEC survey results).

Not all the MS using these additional criteria consider them necessary to include in EU legislation. Indeed, a smaller number of MS see the need to have requirements for '*systematic update in light of experience gained*' and '*cooperation with stakeholders*' explicitly laid down in EU legislation compared to the number of MS actually using them in their CPs. Only in the case of the '*explicit lines of communication with the EC*', more MS than those actually using this criterion in their CPs consider this necessary to lay down as a CP requirement in EU legislation (Q 3.c and Q 3.d- FCEC survey results).

It is noted that some of the criteria currently included in the Control Directives for certain diseases are considered by MS CAs to be necessary for ensuring an effective CP against other diseases as well, as highlighted in **Table 5** below (Q 3.b –FCEC survey results).

Table 5: Criteria currently laid down in EU legislation for certain diseases that are considered necessary by MS CAs for ensuring an effective CP for other diseases

Criterion	Requirement currently laid down in Control Directives for:	Number of MS considering it necessary for ensuring an effective CP
Cooperation between all relevant authorities	FMD and HPAI	• 24- 25 MS for CPs against CSF, ASF, FMD, HPAI and BT; • 21-22 MS for CPs against AHS and SVD;
Capacity for safe disposal	FMD	• 24 - 25 MS for CPs against CSF, ASF, FMD, HPAI; • 22 MS for CPs against BT [(a)] and SVD, and 20 MS for CPs against AHS
Detail instructions on action including for safe disposal	SVD, BT, AHS, and HPAI	• 22 -24 MS for CPs of CSF, ASF, FMD and HPAI and BT; • 21 MS for CPs against AHS and SVD.
Communication with the general public	FMD and HPAI	• 23 - 24 MS for CPs against CSF, ASF, FMD, HPAI and BT; • 21 - 22 MS for CPs against SVD and AHS.
Real time alert exercises	FMD and HPAI	• 19- 23 MS for CPs against CSF, ASF, FMD BT and HPAI; • 15-16 MS for CPs against SVD and AHS
Permanent operational group	FMD, HPAI, CSF and ASF	• 20 - 22 MS for CPs against CSF, ASF, FMD, HPAI and BT; • 18 MS for CPs against AHS and SVD
Cooperation with neighbouring MS in real time alert exercises	FMD	• 18 - 19 MS for CPs against CSF, ASF, FMD, HPAI and BT; • 16 MS for CP against AHS and SVD.
Alarm drills	ASF and CSF	• 14 - 17 MS for CPs against CSF, ASF, FMD, HPAI and BT; • 13 MS for CPs against AHS and SVD

Criterion	Requirement currently laid down in Control Directives for:	Number of MS considering it necessary for ensuring an effective CP
Worst case scenario	FMD	• 15 - 18 MS for CPs against CSF, ASF, FMD and HPAI; • 11and 13 MS for CPs against BT, AHS and SVD.
Holding registration and identification of high density areas	FMD, HPAI and CSF	• 24-22 MS for CPs against CSF, ASF, FMD, HPAI and BT. • 18 and 20 MS for CPs against SVD and AHS

(a) In the case of BT, Italy pointed out that requirements for safe disposal are not necessary as the carcasses of animals killed, following BT outbreaks, are in fact not infected.

Source: FCEC survey of 27 MS CAs

In this context, it is also noted that the FMD model for contingency planning is considered the most 'modern' and thorough as it introduces new elements such as the requirement to be prepared for a worst case scenario and to cover various communication/cooperation aspects. An indication of the significance of the FMD model is that the FVO is preparing a template for the reports of the CP verification missions in 2012 (to cover LT, PT, BG, FI, and RO) and this template will use as a model the 14 requirements laid down in the Control Directive for FMD as this legislative framework is deemed to be the most developed of all diseases (as also discussed under EQ E/4). This does not necessarily imply that the FMD model is considered relevant or applicable to follow as such for all diseases; the FMD Control Directive is the most exhaustive due to nature of the disease (FMD affects multiple species and has a high transmission speed) and the experience gained from repeated FMD emergencies in the EU. The FMD model provides therefore a best practice for contingency planning of animal diseases, to the extent this is relevant and applicable in the context of other diseases.

Finally, some MS have indicated a number of other criteria considered relevant to lay down in EU legislation as necessary for an effective CP. These are:

- The identification of contact persons along the food chain (indicated in Belgium, by both stakeholders and the CA);
- The availability of the financial budget (CZ CA);
- The revision of all CPs for all the diseases covered (PT CA).

Indicator 4: the need to have more prescriptive EU legislation

The majority of MS (22) do not consider it necessary to have more prescriptive rules laid down in the Control Directives (Q4- FCEC survey results). This is mainly justified in that, according to some MS, there is already good understanding of how the legislation is intended. Other MS believe that CPs need to be adapted as much as possible to the national context, therefore more prescriptive rules would make emergency measures more difficult to implement.

However, some MS noted that guidelines illustrating different chapters might be beneficial as they have the advantage of allowing MS to adapt them to their own national situation. The value of such an approach is also highlighted by the fact that, when drafting their CPs, 22 MS

have used the EU guidelines produced in 2000 (Q5- FCEC survey results). This aspect is further covered in EQ A/10.

Indicator 5: the need to define stakeholder involvement (for all stakeholders)

One key aspect for assessing how 'broad' the CP scope should be defined in the legislation is the extent to which there is a need to define the level of involvement/participation of the various directly and indirectly implicated sectors in the rapid response system. This is the case, in particular for directly relevant stakeholders, in the current legislation on CPs in the field of food and feed safety. *A priori*, the definition of responsibility provided in Regulation (EC) 178/2002 and Regulation (EC) 882/2004 covers the entire animal health chain and all Food Business Operators (FBOs). Article 42(2) (j) of Regulation (EC) 882/2004 provides: '*The organisation and operation of contingency plans for animal or food-borne disease emergencies, feed and food contamination incidents and other human health risks*'. Article 13(4) (CPs for food and feed) of Regulation (EC) 882/2004 specifies that, if necessary, implementing measures may be adopted (by comitology), including defining the role of stakeholders, thus providing the legal basis for more prescriptive legislation on this in the food and feed sector.

With regard to the current situation, nearly half of MS (13-15 MS, range depends on the disease) currently include the requirement for cooperation between the relevant CAs and the wider range of stakeholders in the CPs against all of the listed diseases. However, not all of these MS (only 8-9 MS) would like to see this requirement explicitly laid down in EU legislation (Q 3.c and Q 3.d- FCEC survey results).

MS positions are different with regard to directly relevant stakeholders (i.e. those representing farmers and agri-food industries), for which 15 out of 27 MS CAs consider it necessary to have clearly defined rules laid down in EU legislation on involvement in CP development (Q 6.b - FCEC survey results). The extent and need for the involvement of directly relevant stakeholders are discussed further in EQ A/2.

An extensive range of stakeholders (as well as other CAs) may be directly included within the chain of command, if this is needed. The case studies have demonstrated that this has tended over time to extend over an increasingly wider range of directly and indirectly implicated sectors, including civil society and the wider public in affected areas, and that this is in part due to the experience gained in managing emergencies (e.g. the UK with FMD, France with BT, Italy with AI, NL and BE with various diseases). Therefore, if required by the nature of the emergency, an extensive range of directly and indirectly implicated sectors may be involved. For example, in the 1999 AI crisis, the IT CA included hunters associations and animal welfare organisations within the national and local disease crisis centres; the UK and France involved civil society and the public in affected communities, during the FMD and BT crises, respectively.

The FCEC consultation with the MS CAs and stakeholder organisations indicates an overall positive consensus on the need for stakeholder involvement in CP development. The main advantages of a more participatory approach were identified as follows:

- Improves stakeholders' acceptance of new measures and their willingness to implement the agreed measures during emergencies, by identifying those measures that ensure the right balance of an adequate level of bio-security without being excessive detrimental to the livestock industry, therefore building trust and confidence in the overall system;
- CPs are better adjusted to field conditions, which makes them more effective.

On the other hand, the main disadvantage of stakeholder consultation identified by several MS is the substantial amount of time it takes to prepare and hold meetings and to process the results and the risk that this could slow down both the drafting and implementation process. Several MS also pointed to the different and potentially conflicting interests of CAs and stakeholders, particularly when the financial stakes are high, while differences in the level of expertise and knowledge on disease containment and eradication may also give very different viewpoints. It was noted, however, that these disadvantages could be overcome by well defined rules on stakeholder involvement and obligations that clarify responsibilities and actions of each party involved during emergencies.

Nonetheless, despite the positive impacts of stakeholder involvement, as noted above, not all the MS which currently involve the wider range of stakeholders welcome a clear rule on this in EU legislation. Although stakeholders are fully engaged in almost all aspects of contingency planning and their involvement has proven successful in recent outbreaks of FMD, AI and BT, several MS CAs and national stakeholder organisations (e.g. in the UK, France, Germany) noted that allowing MS to decide the appropriate level of involvement maintains flexibility to fit national conditions and disease specificities.

Therefore, in the view of these MS and stakeholders, EU legislation needs only to state the principle and not the detail, while legislation that is too prescriptive could in fact be damaging to the CP process as industry practices, administrative processes and industry representative organisations vary greatly between MS. Similarly, MS with decentralised administrations (e.g. Germany) indicated that cooperation and participation of stakeholders should be performed following national rules to ensure that MS and regional specificities are respected.

Indicator 6: generic versus disease-specific CPs

Currently, the majority of MS have in place disease specific CPs. All of the responding MS (25 MS) have in place CPs for FMD, HPAI, CSF and BT. Several MS (7-11 MS, range depends on the disease) have in place disease-specific CPs that are part of a generic CP. It is noted that not all of the MS have in place CPs for all the diseases covered by this evaluation, while there are also several MS that have in place CPs covering diseases in addition to those covered by this evaluation[32] (Q1- FCEC survey results).

Further discussion on current trends and the advantages/disadvantages of each approach is provided in EQ A/5.

[32] These are in particular: Newcastle disease, diseases of aquatic animals, Rinderpest, Epizootic haemorrhagic of deer, sheep and goat pox, Vesicular Stomatitis, Lumpy Skin Disease, viral and exotic diseases of fish, scrapie and BSE, Small Hive Beetle, Brucellosis, wild animal diseases, West Nile Fever, Rift Valley Fever, Leucosis, Contagious Peripneumonia, Peste des petits ruminants, Trichinellosis, Rabies, Tuberculosis. Infectious Haematopoietic Necrosis (IHN), Viral hemorrhagic septicaemia (VHS) and Infectious salmon anaemia (ISA).

In terms of **disease coverage**, it was pointed out that some other diseases should be covered in EU legislation and more action should be taken to anticipate emerging diseases and new risks. For example, Q fever and West Nile Fever are considered endemic by several of those consulted: in the NL there were a large number of Q fever outbreaks two years ago and many people got infected; West Nile Fever outbreaks occurred in Hungary in 2008. Italy suggested that Rift Valley fever should be also included in EU legislation. Poland indicated Anthrax due to the concern of bio-terrorism. Within the COM there are several working groups on specific diseases (e.g. rabies), but not on emerging diseases. MS would benefit from an EU working group through which they can share practices and learn from the experience of other MS, and this is of particular importance in the case of zoonotic diseases.

Indicator 7: coverage of animal welfare issues

Although animal welfare is not explicitly featuring currently in the CP requirements of any Control Directive, the integration of animal welfare provisions into contingency plans for contagious diseases is indeed foreseen by Regulation (EC) 1099/2009[33] (replacing Council Directive 93/119/EEC) to enter into force in 2013. This Regulation (article 18) provides for requirements to be included in the CPs in the case of depopulation and emergency killing, which will have an impact on the culling operations and preparedness needs of MS: '*the stunning and killing methods planned and the corresponding standard operating procedures for ensuring compliance with the rules laid down in this Regulation shall be included in the contingency plans required under Community law on animal health, on the basis of the hypothesis established in the contingency plan concerning the size and the location of suspected outbreaks'.*

The majority of MS already include animal welfare provisions in their CPs (14-25 MS, depending on the disease), while 20-25 MS (range depends on the disease; in the case of HPAI, CSF and FMD, 25 MS) consider it necessary to include explicitly as a requirement in the Control Directives (Q 3.a and Q 3.b- FCEC survey).

The FVO general report in 2008 presents an overview of the implementation of EU requirements for animal welfare at the time of slaughter and culling in several MS where FVO missions were carried out between 2006 and 2007: Denmark, Czech Republic, the Netherlands, Slovenia, France, Spain, and the United Kingdom. It was noted that with regard to culling in disease outbreak situations, the level of preparedness was generally high in these MS. In particular, the report pointed out that realistic simulation exercises allowed MS to better understand the importance of external partners and adequate staff for animal handling and culling; the CA to assess the appropriateness of the different methods of culling and the extent to which animals could be humanely destroyed. It also indicated that comprehensive assessments of the practicalities and advantages/disadvantages of the different culling methods were more likely to be included in simulation exercises of MS where the CAs had already extensive experience in dealing with large scale outbreaks (FVO report 2008).

As clarified during the interview with DG SANCO AW Unit, the main AW issue relates to the applied slaughter practices (including pre-slaughter transport conditions) when mass

[33] Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing.

culling of animals is the measure taken to deal with emergencies. With regard to this, the following examples can be given in some MS that are more advanced in the development of more humane slaughter techniques:

- In the case of the Netherlands, all CPs include the mandatory establishment of an independent "Animal Welfare Commission", reporting to the NL CA during notifiable animal disease outbreaks. The 2006 FVO report of mission to assess animal welfare at slaughter concluded that *'several legislative measures and procedures impose a higher standard than the corresponding EU requirements'*[34].

- In the case of the UK, within DEFRA, the Animal Welfare Policy Team is responsible for providing policy advice on animal welfare on farm and during culling. The MS has put a lot of pressure to include newly developed poultry stunning methods that involved minimum handling of birds (the Containerised Gassing Unit - CGU) in OIE guidelines.

- Considerable experience on AW has been gained in Lower Saxony, where there have been some developments in in-house gassing of poultry without handling, offering the advantage of no pre-slaughter transport/handling. From an animal welfare perspective BMELV found this to be very important. However, it would not be necessary to include this in EU legislation – as it is a rather technical point. Nonetheless, BMELV pointed out that CO_2 culling will be increasingly applied in Germany – it is in fact already included in the general part of the CP. Gassing is included in the CPs, along with other methods (since gassing only concerns certain situations e.g. when depopulating a barn).

Indicator 8: Overall scope

Overall, MS are satisfied with the current breadth of scope of the EU legislation on CPs. Nearly all MS (25) consider the current scope to be broad enough to make them an effective tool in achieving containment, control and eradication of animal diseases (Q8 –FCEC survey). It is also noted that the EU approach to contingency planning is highly regarded by third countries, for example the detailed requirements provided by the FMD Control Directive are considered the reference best practice for contingency planning.

One general conclusion that comes from the interviews and case studies is that the EU rapid response system to date has been progressively developed in *'learning by doing'*. This suggests that the approach has been mainly reactive, i.e. adjusting the system where weaknesses are identified and lessons learnt after a disease outbreak or a simulation exercise. While this ensures that the system has the potential to continuously improve, it needs to be paralleled by a proactive approach, which consists in anticipating and preparing for new or emerging risks. This is considered particularly important today in a rapidly changing world, where countries are frequently confronted with unforeseen crises as well as longer term challenges arising from a broad range of new threats, as demonstrated by emerging vector borne diseases such as BTV-8 or the Schmallenberg virus (SBV). As a consequence, it has become increasingly important for policy makers to have robust systems in place to identify

[34] Although some concerns were raised at the time regarding the electrical stunning of pigs.

emerging risks at their early inception and to put in place strategies for prevention and control, in an effort to prevent potential crises.

There are some examples of a more proactive approach at MS level, e.g. the UK foresight analysis of the detection and identification of infectious diseases (UK Government's Foresight project, Infectious Diseases: preparing for the future), and in the Netherlands, both of which are based on emerging risks identification systems already in place in areas as diverse as plant and animal health, agriculture or wildlife. This is an area where there is scope for improvement in the EU: to date, the COM has not developed a systematic process of analysing and evaluating new risks (horizon scanning), except to some extent discussions on new threats that may occasionally take place in the context of SCoFCAH meetings. The European Food Safety Authority (EFSA) is currently developing a methodological framework for the identification of emerging risks for food safety, which could provide useful inputs to the COM on this[35]. Also, in 2010 an internal mandate was issued by EFSA for establishing an Emerging Risks Exchange Network (EREN) to exchange information between EFSA and the MS on possible emerging risks for food and feed safety; EREN is currently composed of delegates from 20 MS designated through the EFSA Advisory Forum[36].

2.2.2 Involvement of stakeholders in contingency planning (EQ A/2)

A/2 To what extent should the role of stakeholders participating in the establishment and operation of CPs, especially those representing farmers (economic and or/and sanitary interest) and agro food industries, be laid down in the EU legislation?

The extent to which stakeholders should be involved in the various phases of CP development and whether this should be explicitly established in EU legislation has also been discussed at a broader level under EQ A/1; the analysis here focuses more on the directly implicated stakeholders in particular farmers and food business operators (FBOs),

As outlined in the context of EQ A/1 (indicator 5), defining the role of stakeholders is contingency planning is already envisaged in the food and feed safety field through the provision for potential implementing legislation under Article 13.4 of Regulation (EC) 882/2004: '*Where necessary, implementing measures may be adopted in accordance with the procedure referred to in Article 62(3). Such measures shall establish harmonised rules for contingency plans to the extent necessary to ensure that such plans are compatible with the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002.* ***They shall also indicate the role of stakeholders in the establishment and operation of contingency plans****' (see also EQ A/1).* EU food safety legislation also establishes key obligations of FBOs; this encompasses requirements under feed and food law, animal heath and animal welfare rules, which need to be fulfilled by business operators at all stages of production, processing and distribution (see box below).

[35] EFSA is developing a methodological framework, including a data monitoring capacity, data filtering methodology and networking structures to identify emerging risks and drivers of emerging risks in a timely fashion and to communicate these to the risk manager. This work is in the context of the definition and description of "emerging risks" within the EFSA's mandate, adopted by the Scientific Committee on 10 July 2007 (EFSA/SC/415 Final).

[36] Annual report on the Emerging Risks Exchange Network 2011, EFSA, Parma, Italy.

THE KEY OBLIGATIONS OF FOOD AND FEED BUSINESS OPERATORS
(as laid down in Regulation (EC) 882/2004)

SAFETY
Operators shall not place on the market unsafe food or feed
RESPONSIBILITY
Operators are responsible for the safety of the food and feed which they produce, transport, store or sell
TRACEABILITY
Operators shall be able to rapidly identify any supplier or consignee
TRANSPARENCY
Operators shall immediately inform the competent authorities if they have a reason to believe that their food or feed is not safe
EMERGENCY
Operators shall immediately withdraw food or feed from the market if they have a reason to believe that it is not safe
PREVENTION
Operators shall identify and regularly review the critical points in their processes and ensure that controls are applied at these points
CO-OPERATION
Operators shall co-operate with the competent authorities in actions taken to reduce risks

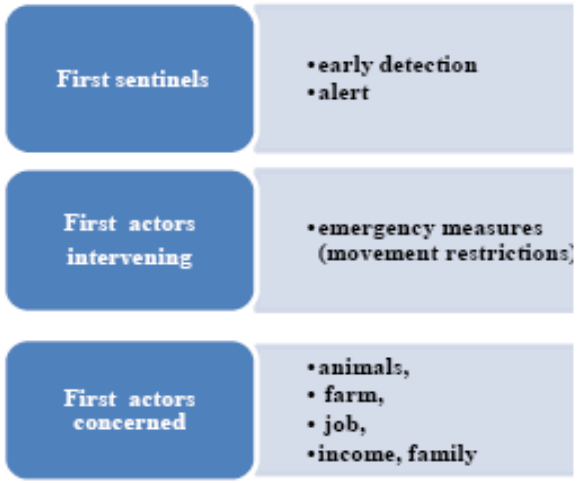
As **Figure 4** (EQ A/1) shows, a critical point in managing outbreaks is the pre-notification period (i.e. from significant/strong suspicion to official notification); the ability to minimise this period depends on the level of preparedness. People on the ground, i.e. farmers and veterinarians, therefore play a crucial rule in the initial phases of an outbreak event.

Farmers are the first sentinel of animal disease events, the first actor to intervene in implementing emergency measures, as well as, the first economic operator directly affected by animal disease outbreaks (**Figure 5**). Veterinarians also play a central role, in providing the crucial link between animals, animal holders and society, therefore balancing the different interests involved.

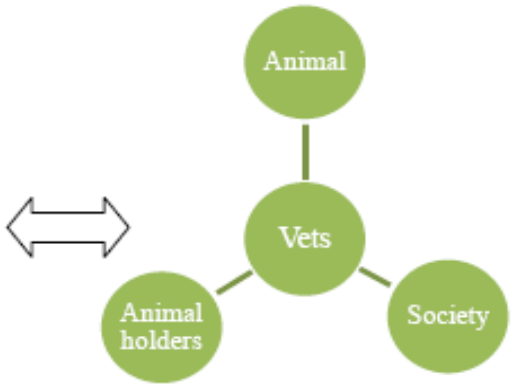
In this respect, the professional organisations representing farmers and veterinarians play an essential role as the only structure reaching all farmers, therefore key in ensuring that an animal health emergency is appropriately managed by all actors of the chain of command (from farmers to CVOs and the COM). Stakeholder organisations (in particular, COPA-COGECA, FESASS and the FVE) have noted during our consultation and on other occasions[37] that, being closer to livestock producers, they are able to provide input on the feasibility of measures and to ensure their smooth implementation through joint planning, the clarification of respective roles and responsibilities and coordinated communication. The collective involvement of farmers positively contributes to the enforcement of the emergency measures; risk raising awareness and training; the use of shared means; the communication to farmers and consumers; and the support to farmers in the event of a crisis.

[37] For example, presentations of these organisations at the DG SANCO Conference on Crisis management in the Food Chain, Brussels - 19-20 May 2011.

Figure 5: The roles of farmers and veterinarians in the first phase of AH emergency management



Source: FESASS' presentation at Crisis Management Conference 19-20 May 2011, Brussels



FVE's presentation at Crisis Management Conference 19-20 May 2011, Brussels

Indicator 2 – the current extent of stakeholder involvement

In 14 MS, stakeholders are engaged in CP development. While the majority of these MS engage stakeholders in simulation exercises (10 MS), implementation (9 MS) and updating (8 MS), in few MS stakeholder participation is reported in the pre-drafting consultation (5 MS) and drafting (4 MS) phases.

The degree of stakeholder involvement varies significantly across MS. In some MS, stakeholder organisations are involved in all CP development phases (e.g. NL and UK) and take active part in national and local crisis centres (as evidenced also by FESASS and some MS case studies), while other MS cooperate with stakeholders on ad-hoc basis for the application of specific measures in specific cases/diseases such as vaccination.

The FCEC interviews and consultation with the MS CAs and stakeholder organisations identified several benefits of stakeholder involvement in contingency planning, as also discussed briefly under indicator 5 of EQ A/1. These are fully outlined as follows:

- Ensuring feasibility of the measures, as these are more tailored and adjusted to field conditions;
- Ensuring the acceptance of measures taken by all levels of the chain, which is a condition for good implementation: stakeholder involvement reassures stakeholders, encourages engagement as well as building trust and confidence in the overall system;
- Ensuring a rapid response at all levels with an operational network on the ground. As pointed out by all of the consulted EU stakeholder organisations, by being involved, stakeholders know exactly what the measures are and how they can increase their effectiveness;

- Improving communication: several MS pointed out that stakeholder involvement in all phases of the CPs contributes to the circulation of correct information in the event of emergencies, and maintains a consistent plan of actions in crisis situations which also contributes to delivering a reliable and consistent message to the general public;

However, collaboration with stakeholders has also been portrayed as challenging. As already indicated, a key challenge of stakeholder involvement is the substantial amount of time it takes to prepare and hold meetings and to process the results and the risk that this could slow down both the drafting and implementation process. Also, some MS indicated that during an emergency, the CAs have to play the difficult role of mediator between several stakeholders with conflicting interests.

Indicators 1 and 3: the need to have clearly defined rules in EU legislation for stakeholder involvement; advantages and disadvantages

An introduction to this issue was already made by indicator 5 in EQ A/1. This indicator shows that 15 out of 27 MS CAs consider it necessary to have clearly defined rules laid down in EU legislation for the involvement of directly relevant stakeholders (i.e. those representing farmers and agri-food industries) **(**Q 6.b- FCEC survey results).

In terms of the various phases of CP development, the majority of these MS indicate that they welcome clear rules on stakeholder involvement for simulation exercises (11 MS), CP implementation (9 MS) and CP updating (8 MS). A smaller number of MS favour stakeholder involvement at the pre-drafting and drafting phases (5 and 4 MS, respectively) (Q 6.b- FCEC survey results).

In several MS where stakeholders are currently involved, both the CAs and the consulted stakeholder organisations reported that the involvement of stakeholders in the implementation of CPs has proven very relevant. This is generally considered particularly relevant and useful when carrying out simulation exercises: some MS indicated that the participation of stakeholders in simulation exercises helps identify strengths and weaknesses of both the CAs and stakeholder organisations and find solutions in case of outbreaks of animal diseases. On the other hand, in some MS both parties agreed that the CA should take the initiative and play the leading role in the preparation of CPs, and that involving stakeholders at this stage could distort objectivity**.**

More generally, in terms of promoting better prevention and management, both MS CAs and stakeholder organisations representing farmers/the veterinary profession indicated that, as a general principle, involving farmers from an early stage in the process ensures industry support, and this in turn helps identify practical and workable solutions and results in better achievement of the final goals. COPA-COGECA highlighted that farmers should not just be considered the target of the measures but also part of the solution (particularly in terms of improving prevention via bio-security measures). In addition, FESASS pointed out the need for CAs to work together with the collective involvement of farmers on their national approach to anticipate and plan. The association has encouraged this collaboration more generally in the context of the EU Animal Health Law.

Defining clear rules within the EU legislation for the involvement of directly relevant stakeholders is considered to offer the following advantages:

- Given the current differences in the degree of involvement of stakeholders among MS, ensuring that farmers are involved in CP development and implementation across all of Europe;
- Clarifying the role and responsibilities of the parties involved and actions to be taken during animal health emergencies. Sharing responsibility gives farmers incentives for timely reporting of disease outbreaks, and can thus contribute to minimising notification delays and improving the speed of response[38];
- Ensuring that the available tools and means of all parties involved are recognised, taken into account and mobilised;
- Encouraging the development of specific technical skills and the creation of collective involvement of farmers, working in partnership with the public services in MS (particularly in those MS where gaps are identified in technical knowledge and skills).

In addition, MS and stakeholders noted that the selection of the appropriate stakeholders is the key to successful stakeholder involvement in the CP process. Collaboration between stakeholders and MS CAs during CP development is considered to be most effective when only those relevant stakeholders representing the affected industry with common interests and expertise in the sector are involved, and that their participation needs to be ensured both at national and at local levels. For example, when outbreaks have an impact on mixed farms (arable/livestock), or remote communities, it is important to ensure that these stakeholders are also included; capturing those stakeholders is not always easy and great care needs to be paid to this aspect, as the success of the entire CP implementation may depend on it.

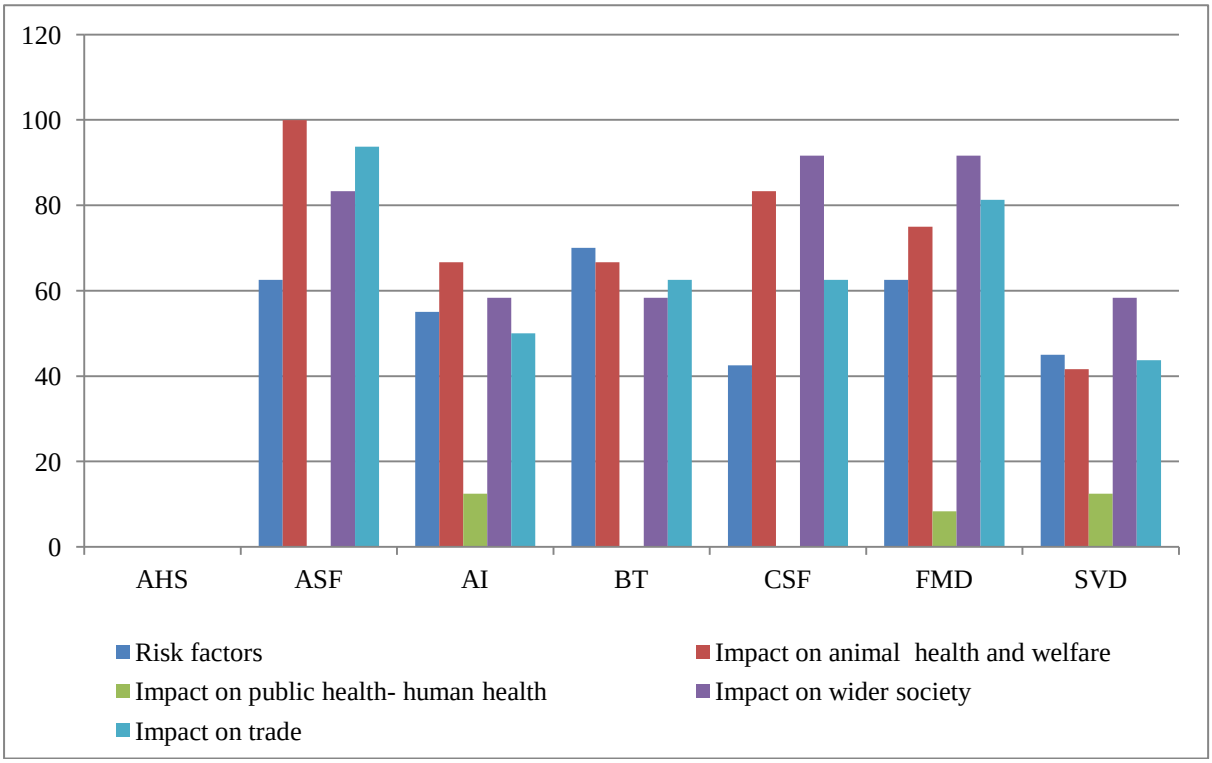
On the other hand, as also discussed in indicator 5 of EQ A/1, not all the MS which currently involve stakeholders welcome a clear rule on this in EU legislation. Despite the perceived benefits, concerns were expressed by both CAs and stakeholders that more prescriptive legislation on the involvement of stakeholders might limit MS flexibility to adopt actions which fit national conditions and disease specificities and thus might hinder those MS where collaborative structures between the CAs and stakeholders are established and have proven successful. These MS CAs and stakeholders emphasise the need to have flexibility to adapt the approach to take into account differences in organisational structures of the national livestock industry and in MS animal health systems and administrative structures, including the chain of command, as well as disease specificities. Therefore, in the view of these MS and stakeholders, EU legislation needs only to state the principle and not the detail; legislation that is too prescriptive could be damaging to the CP process.

The involvement of directly implicated stakeholders is also interlinked with two other key aspects of the EU animal health policy: the development of cost and responsibility sharing schemes, and the prioritisation of animal diseases. The definition of criteria for the

[38] With regard to the relationship between the speed of response and stakeholder involvement, it is pointed out that the ability to minimize delays, for example in the pre-notification period, is not necessarily linked to what is established in a CP, but reflects rather the overall preparedness of a MS to face outbreaks. Such delays are also dependent on the nature of diseases: for some diseases, e.g. CSF and FMD on sheep, it may be difficult to shorten the pre-notification period due to the inherent difficulties in the disease diagnosis.

prioritisation of animal diseases is an ongoing process both at MS and at EU level; in this context, DISCONTOOLS[39] is developing criteria and a scoring system for the classification of animal diseases, the results of which to date - as summarised in the following table – indicate the high importance attached to the diseases currently covered by contingency planning rules. As both processes are currently on-going at EU level, it would be premature at this stage to define more prescriptive legislation on the involvement of directly implicated sectors in contingency planning.

Figure 6: Prioritisation of animal diseases (DISCONTOOLS scoring system)



Source: FCEC elaboration on the basis of results to date of the scoring system of DISCONTOOLS

2.2.3 Collaboration between and within MS (EQ A/3, A/4)

A/3 To what extent are the CPs compatible and coordinated with those of neighbouring MS?

This evaluation question investigates the extent to which neighbouring MS undertake cooperation actions in ordered to make their CPs compatible and coordinated. In particular, cooperation is examined when drafting/reviewing CPs and carrying out simulation exercises.

[39] The DISCONTOOLS project is a joint initiative of industry and a wide range of stakeholders including the research community, regulators, users and others. It is actively encouraged and funded by the European Commission services. Starting from the 1st of March 2008, it will be carried out over four years and will provide a mechanism for focusing and prioritising research that ultimately delivers new and improved vaccines, pharmaceuticals and diagnostic tests. This model was developed in the context of an OIE/DG SANCO study on the listing and categorisation of priority animal diseases, including those transmissible to humans, published in September 2010. This tool is being tested on a sample of diseases. Quantitative criteria for economic and human health impacts are included in this model.

Currently, the FMD Control Directive in particular foresees Cooperation with neighbouring MS in real time alert exercises. More generally, the current CP approval procedure (as discussed under Theme B) foresees that MS CPs are reviewed and approved by SCoFCAH, and the rationale for this appears to be *inter alia* to ensure that desired objectives can be attained and that CPs are compatible with those of other MS.

Indicators 1 to 3: coordination/collaboration between neighbouring MS during CP development (drafting, implementing and simulation).

The *cooperation with neighbouring MS in real time alert exercises* is explicitly foreseen only in the case of FMD contingency planning, although in the FCEC survey the majority of MS indicated to have such a provision in place in their CPs for CSF, ASF, FMD, HPAI and BT (14-17 MS, depending on the disease), and 7-8 MS have this provision in place in their CPs for SVD and AHS (Q 3.a - FCEC survey results).

However, full *coordination between neighbouring MS in both CP drafting and simulation exercises* appears to take place in fewer MS: 8 MS coordinate with other neighbouring MS for CP drafting and simulation in the case of FMD, and 7 MS for CPs against CSF, ASF and HPAI; an even smaller number of MS cooperate on CPs for SVD, BT an AHS (5-6 MS, depending on the disease). Similarly, 8 MS indicate to include *collaboration between MS on CP implementation* in their CPs against CSF, FMD, while 7 MS for CPs against HPAI, BT and SVD and 5-6 MS for ASF and AHS. Nonetheless, a larger number of MS consider it necessary to lay down this requirement in the EU legislation on contingency planning for CSF, FMD, HPAI (14 MS), for BT (13MS), and for ASF, SVD and AHS (11MS) (Q 3.c- FCEC survey results) (Q 3.c- FCEC survey results). According to the COM and stakeholders, cross-border cooperation is particularly relevant when there are zoning issues to be discussed and agreed.

A number of positive cases of cooperation between neighbouring MS in CP development and, more generally, of collaboration on animal health emergencies were identified during the MS case studies, as follows:

- Cross border real-time alert exercises were carried out by Germany, the Netherlands, Belgium and Luxembourg in 2010, Romania and Bulgaria in 2011, and by Nordic and Baltic countries for several years (simulation exercises are discussed in EQ A Q/8);
- There is a Memorandum of Understanding between the Nordic and Baltic countries to exchange personnel in case of emergencies;
- The Netherlands and Germany have a good collaboration concerning vaccinations of livestock and poultry against notifiable diseases. During the CSF and FMD emergencies, bilateral consultations have proven to be very effective for a rapid response to the outbreaks;
- The Czech Republic, Poland and Slovakia hold meetings to monitor rabies in the Carpathian region each year. This co-operation consists of an exchange of information and allows the three MS to co-ordinate simulation exercises. Through the meeting, problems with rabies in the region can be identified and better understood. For example, in 2011 there was an increase in rabies in all three MS; through the meeting the three MS realised that this was due to the floods which washed away the baits;

- Belgium, the Netherlands Luxembourg have established the Benelux Committee through which issues of animal health emergencies are discussed;

With regard to cooperation between MS and neighbouring third countries in the context of contingency planning, this mainly occurs at the stage of simulation exercises. Some examples have been presented during our MS field visits. Poland indicated that transboundary cooperation is normally at a regional level, with its regional and district CPs containing provisions for co-operation during simulation exercises with neighbouring MS and third countries. Romania reported an FMD simulation exercise in 2009 where Ukraine, Serbia, Moldova were invited; it also participated in an international simulation exercise for Newcastle Disease (ND). Bulgaria has cooperation activities with Turkey on FMD. However, some of these MS also pointed out that there are some issues in terms of lack of commitment or communication of neighbouring third countries which might jeopardise their cooperation, it is therefore important to endeavour to continue these efforts (further details on this subject are provided in EQ F/3 and F/4).

A/4 To what extent does the current legislation sufficiently impose collaboration between MS when implementing CPs in case of epizootics?

General legislation - the Control Directives, Regulation (EC) 882/2004 and the guidelines for MANCPs including contingency planning - provides in some cases for cooperation between CAs in a MS when implementing a CP, but it does not foresee cooperation between MS. Only the FMD CD specifies that MS should cooperate with neighbouring MS in carrying out real time alert exercises.

Indicator 1: the need for cooperation/collaboration between MS in CP implementation in case of epizootics

As indicated above (EQ A/3), few MS have already included in their CPs provisions for the *collaboration with neighbouring MS in CP implementation*, although a larger number of MS consider it necessary to lay down this requirement in the EU legislation on contingency planning (Q 3.c- FCEC survey results).

Cooperation between MS is seen a useful instrument to exchange experiences and make rapid implementation of measures to restore trade in the country in accordance with health rules. Some MS also indicate that the lack of informal contact and communication flows between MS technical experts, e.g. on disease management or killing methods at the time of crisis might have reduced the effectiveness of animal health emergency actions.

For this reason, some MS CAs and national stakeholders consider that the collaboration between MS for CP development should be a provision laid down in the EU legislation and that there is scope for the COM to promote and reinforce this further.

However, not all MS having in place cooperation activities with other MS consider this provision necessary to include in EU legislation. Some MS justify their position on practical grounds, pointing out that collaboration is relevant only with neighbours with whom they have economic and trade relations, and that MS should therefore have the choice on whether and with which neighbouring MS they wish to collaborate.

It was also noted that the degree of cooperation and coordination in CP implementation between MS is also related on disease specific characteristics and the regional cooperation context. For instance, it was not considered necessary by the UK CA in their case as geographically isolated and not very relevant for vector borne diseases; the position is different for Northern Ireland as it is in the same epidemiological zone as the Republic of Ireland and close collaboration/coordination is therefore essential. More generally, it was noted that it would be good to have a forum for exchange on this issue, and training could also be provided (e.g. in the context of BTSF); a conference between the EU-27 MS dedicated on this subject might help to start the process. An exchange between MS on best practices and lessons learnt from CP development is indeed considered important, and this needs to cover the wider spectrum of issues involved including on communication.

Several examples of successful cooperation between MS and with the COM in addressing animal health emergency situations more generally were identified during the MS case studies, as follows:

- The recent concerted effort of MS and the COM for addressing the Schmallenberg virus (SBV) was indicated as a good example of successful cooperation; furthermore, this is partly attributed to the availability of generic contingency planning to deal with unpredictable emerging diseases. The SBV emergency demonstrates how the EU was able in 5 months to build up a policy on a totally new emerging disease. It demonstrates how the animal health policy and network put in place in the EU over the last 20 years, for example the building of cooperation between EU laboratories to improve diagnosis, is contributing to better dealing with unpredictable diseases. The dedicated €3 million fund that was relatively rapidly put in place to improve knowledge on the Schmallenberg virus was provided by several MS as a good example of cooperation between MS for preventive action against new threats[40].
- Training activities for MS on contingency planning, animal health prevention and the control of emerging animal diseases are currently organised under the "Better Training for Safer Food" (BTSF) programme to improve the dissemination of knowledge and awareness of EU law in these fields and to promote a harmonised approach to the operation of EU and national control systems. In total, 8 weeks of training on contingency planning are foreseen during the period April 2012 to October 2013.

While it is generally acknowledged that coordination and cooperation both between MS and with the COM has significantly improved over the period and is currently satisfactory, as also demonstrated by the significant progress made in addressing the recent outbreaks of the Schmallenberg virus, this has not always been the case during the last decade. Looking back, there are also some negative examples of the lack of collaboration/coordination between MS in CP implementation and communication on epizootics which have resulted in incompatible

[40] The Commission has earmarked €3 million to carry out scientific studies on Schmallenberg virus. The fund supports 14 projects involving seven different eligible MS: Belgium, Germany, Spain, France, Italy, the Netherlands and the UK The studies will be co-financed by the Commission at the rate of 50 % of eligible costs for the period 1 April 2012 to 31 December 2013 with up to a maximum amount of €438,615 for Belgium, €595,883 for Germany, € 146,590 for Spain, €589,380 for France, €124,120 for Italy, €639,342 for the Netherlands and €371,811 for the United Kingdom. These will focus on the causes of the infection, the ways of disease transmission and how best to carry out large-scale testing.

actions in dealing with a number of diseases, including FMD, BT and AI, leading to significant delays and confusion for stakeholders; MS reported that communication channels with other MS have been found to be extremely formal in the past and this has delayed to lack of clarity or delays in feeding back information. However, MS and the COM have learnt from these gaps or weaknesses, and the current level of collaboration/coordination is largely considered to be satisfactory and to instil confidence amongst MS and stakeholders in the EU preparedness system. Despite these achievements, the COM and MS acknowledge the need to continuously take stock of lessons learnt, and in this context the recent SBV emergency provides a good opportunity to fine-tune the mechanism, in terms of risk communication and management, and how to improve the system to prevent adverse reactions of TCs (this issue is discussed under EQ F/3).

Indicator 2: the use of EU financial contribution for MS' active collaboration in controlling outbreaks.

Although relevant provisions exist in Article 3.3 of Com Decision 2009/470[41], there have been no cases where the use of this article has been made to request EU co-financing of such collaboration initiatives.

2.2.4 Generic versus disease-specific CPs (EQ A/5)

A/5 To what extent a generic CP for a country could achieve the same objectives as several disease-specific CPs, especially in light of the very similar generic minimum requirements in most of the directives and the foreseen AH Law structure

Indicator 1 and 2: the current extent and the need for a generic contingency plan

Although most MS currently have disease-specific CPs in place (as discussed under indicator 6 in EQ A/1), several MS are moving towards a generic CP approach combined with specific CPs. A similar approach has been already adopted in other sectors, e.g. Hygiene package (Directive 853/2004) and Regulation 882/2004 on official controls.

Indeed, the trend is growing across the EU for a more generic approach in animal disease contingency planning. Several MS have recently completed or are currently in the process of revising their approach to this end, while the majority of MS (19) believe that a generic CP is able to achieve the same objectives as several disease specific CPs (Q2- FCEC survey results). In particular, a generic plan is considered to have the following advantages:

- Improving the consistency of the strategy and of the chain of command;
- Using and adapting best practices across diseases;

[41] Article 3.3: "*The Member State concerned shall also qualify for a Community financial contribution where, on the outbreak of one of the diseases listed in paragraph 1, two* ***or more Member States collaborate closely to control the epidemic****, particularly in carrying out an epidemiological survey and disease surveillance measures. Without prejudice to the measures provided for under the common organisation of markets concerned, the specific Community financial contribution shall be decided on in accordance with the procedure referred to in Article 40(2).*" This provision existed in the previous vet expenditure legislation, Council Dec 90/424.

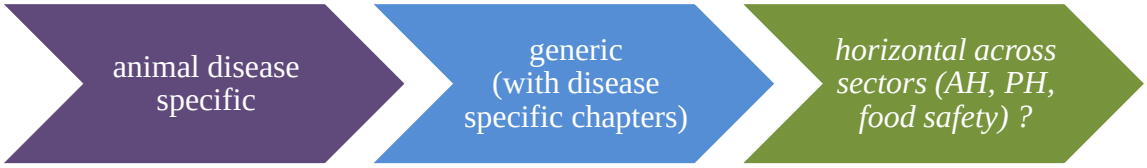
- Providing a framework which gives flexibility to add new CPs, especially for emerging/re-emerging diseases and currently unpredictable risks. This is particularly the case for vector-borne diseases, such as the Bluetongue 2007 outbreaks and the recent Schmallenberg virus outbreaks; and
- Minimising the number of documents to be kept and reviewed, thus facilitating access and usability, and avoiding unnecessary repetition.

While several MS are currently developing a generic CP in combination with specific CPs (FR, IT, PL, RO), others have already adopted this generic CP approach (DK, the UK, DE). The approach in most of these cases involves a generic plan outlining emergency response actions common to all diseases, such as organisational, logistic and legal elements that are horizontal across diseases – e.g. the chain of command, control structures, communication and contact with press, financial compensation system - and, as a complement, special chapters or operational instructions for the individual animal diseases providing specific measures in dealing with each disease (e.g. emergency vaccination, disposal measures).

Belgium has adopted a middle position, by creating a roadmap framework (Global Contingency Plan) for the development of specific plans in the event of any animal disease outbreak. The GCP includes the necessary tools for CP drafting: risk assessments for emerging diseases, ensuring the availability of resources in terms of laboratories and experts that could survey specific areas and regions across the territory. The advantage of the GCP according to the BE CA is that it helps to improve preparedness for a more rapid response to emergencies (BE case study).

It can be concluded therefore that, over the last decade, animal health emergency response in the EU has evolved from an exclusively disease-specific approach to a more horizontal disease approach, drawing potential synergies, complementarities and best practices in order to provide a common general framework for addressing animal diseases. As such, emergency preparedness is therefore considered to have entered a more mature phase, by drawing lessons learnt over the past decade. According to some MS and the COM, it merits further reflection whether the next step in this process might be to develop a broader horizontal approach across sectors (animal health, plant health and food safety). This trend is depicted in the figure below. Key drivers behind this process are the need for robust financial planning in the context of the current adverse economic climate, but also the ongoing development of public-private partnerships and responsibility-sharing in these sectors.

Figure 7: Evolution of the process of contingency planning in the EU



Source: FCEC

Those MS that continue to favour specific CPs per disease are concerned that a generic approach may be of less practical use if the CPs become too large to manage, and therefore may be diluted in precision in terms of developing specific actions for specific diseases.

Moreover, diseases for which CPs are in place can vary considerably in pathogenesis/ epidemiology, reporting obligations, applicable disease control measures, sector organisation, thus making disease specific CPs more appropriate for practical application, especially at local level. Several MS indicated that grouping CPs may be applicable for some diseases but not all. There are also concerns that a change into a generic CP would increase administrative burden for MS, particularly in MS where significant effort has been made to develop the CPs for specific diseases.

To overcome these concerns, a generic approach will need to maintain flexibility to allow sufficient disease focus. Such a model would involve a generic approach laying down certain generic minimum requirements applicable across all animal diseases but with the possibility to adapt the approach on the requirements of each disease, which is the model followed in most of the MS that have developed generic CPs. On the basis of the most advanced CPs in place today (e.g. FMD Control Directive; generic CP models in several MS), such minimum requirements could cover: the chain of command; the establishment of NDCCS/LDCCS and expert groups; sufficient access to tools, staff, facilities and funding; cooperation between the authorities involved; cooperation between neighbouring MS/third countries; the carrying out of simulation exercises; and, where applicable emergency vaccination.

Similarly, a more horizontal approach across all sectors would involve identifying those elements that constitute the common overarching principles of effective contingency planning, such as ensuring early detection and timely notification, communication to the parties involved and cooperation between CAs and with stakeholders.

2.2.5 National and regional CPs (EQ A/6)

A/6 To what extent a national CP for a decentralised country could achieve the same objectives as a set of coherent regional CPs?

A priori, a national approach to contingency planning in a decentralised country is expected to offer potential advantages in terms of:

- Avoiding overlap and ensuring consistency between regional CPs;
- Ensuring consistency/coordination in the approach followed and implementation across regions (which currently tends to vary considerably);
- Pooling the regional and national resources available throughout the country, in terms of staff, experts, funding and tools, to optimise their use;
- Using lessons learnt from CP development and operation across regions; and
- Providing an existing framework which gives flexibility to add new CPs especially for emerging diseases / currently unpredictable risks.

On the other hand, a risk inherent in a federal CP is the distance from the action that needs to be taken on the ground and potential overlap or confusion in terms of the chain of command, which might undermine the effectiveness of the response.

The analysis has focused on those MS that have in place a federal structure to address animal health emergencies, in particular Germany[42]. The case study in Germany shows that the current federal approach to contingency planning for animal health, as this has evolved over the years, is overall considered satisfactory both in terms of achieving the benefits and in avoiding the risks associated with a federal CP.

Germany has currently in place an approach for AH contingency planning whereby there is a 'uniform umbrella' at federal level regarding CP drafting and emergency measures[43] to be taken, under which the Länder have the competence to decide how to allocate responsibilities within their own structures. There are also certain elements of the CPs that are implemented jointly, such as the Mobile Crisis Centre, which no Länder would have established on its own.

Since 2007, both the federal government and the Länder use a unique internet-based CP consisting of a generic part for all diseases and specific parts dealing with certain diseases and certain emergency actions e.g. culling and disinfection[44]. Through the internet-based platform, each level (local veterinary office, Länder, federal) can view the measures that it needs to take in the case of a suspected outbreak and in the case of a disease scenario that affects more than one Länder, the internet platform allows Länder officials to view which laboratory is competent for a given experiment or diagnosis.

2.2.6 Different levels of action in case of a primary or secondary outbreak (EQ A/7)

A/7 To what extent are the criteria for CP relevant and effective, such as different levels of actions in CP in case of a primary or secondary outbreak?

This evaluation question examines the extent to which different levels of actions for primary and secondary outbreaks are considered a relevant and effective criterion to be included in animal disease CPs[45].

Different levels of action are not currently specified in the Annexes of the EU Control Directives for any of the diseases.

A third or less of MS consider it necessary to lay down this requirement as a provision in the CPs for CSF (9 MS), for ASF, AI, BT and SVD (8 MS), and for AHS (6 MS). A similar number of MS indicate that they actually use this requirement in their CPs for BT (9 MS), for

[42] Case studies were also carried out in other MS with decentralised administration, in particular Italy and the UK. As Italy has in place a national CP that it is implemented by the Regions under the authority of the CVOs, while in the UK the administration of England - Animal Health and Veterinary Laboratories Agency (AHVLA) prepares and maintains the DEFRA Contingency Plan and the devolved administrations of Scotland, Wales and Northern Ireland have similar and complementary plans.

[43] BMELV stressed that emergency measures do need to be incorporated into a federal CP, as diseases can travel across Länder borders.

[44] The most important diseases have a dedicated specific part, but few are yet to be implemented. One important specific part however has already been completed, namely the one for CSF. This chapter details the reporting pattern required for CSF, special information concerning the transport of CSF disease samples as well as other aspects unique to the fight against CSF.

[45] The extent to which the ratio between secondary and primary outbreaks could be used as a suitable indicator to assess CP preparedness and animal health management in crisis situations is examined in EQ G (indicator 3).

CSF and SVD (8 MS), for ASF, AI, FMD (7 MS), and for AHS (6 MS) (Q 3.c and Q 3.d-FCEC survey**)**. Furthermore, the case studies revealed that some MS that define different levels of action for managing primary and secondary outbreaks do not, nonetheless, consider it necessary to include such an obligation for all MS in the EU legislation.

During the MS case studies, some MS indicated that they use this differentiated approach depending on the disease. For example, Italy uses it for BT and SVD, as for these diseases vigilant traceability of animals and data on the origin of the animals play a crucial role in controlling the disease and allowing secondary outbreaks to be more easily identifiable. For FMD, AI and CSF this distinction is not required due to the epidemiological nature of these diseases, e.g. FMD secondary outbreaks may cause primary outbreaks.

A key difference in action indeed concerns the enforcement of traceability requirements: in MS where differentiated action is taken, as soon as a primary outbreak is identified, traceability tools are activated to identify possible secondary outbreaks. Other differences in action may concern culling and vaccination strategies and compensation provisions, which may be higher in the case of primary outbreaks but on a more cost-sharing basis in the case of secondary outbreaks.

Some MS indicated that, although not making a distinction between levels of action, in the case of primary outbreak they require the outbreak to be declared on solid and detailed evidence, and that in the case of a secondary outbreak action is generally quicker since most procedures have already been put in motion following the primary outbreak.

2.2.7 The need for real time alert exercises for all listed notifiable diseases (EQ A/8)

A/8 To what extent are real-time alert exercises, currently only required for FMD, needed for other diseases?

This evaluation question examines the extent to which real-time alert exercises should be included in CPs for all other OIE listed (notifiable) diseases.

Currently, real-time alert exercises are explicitly required only in the Control Directives for FMD and AI[46]. The FMD CD requires MS to carry out real-time alert exercises twice within a five-year period, or during "*the five year period after the outbreak of a major epizootic disease has been effectively controlled and eradicated*"[47]. Some other CDs (CSF, ASF) refer to regular alarm drills (twice a year) as criterion for the CP[48].

Simulation exercises aim to test CPs in order to ensure that they provide an effective response when they put into practice; they are also a useful tool for training staff in emergency procedures. Indeed, simulation exercises should create a realistic scenario which may occur in a country, by carrying out disease control and administrative actions as these would be performed during a real outbreak situation.

[46] Art. 73 of CD 2003/85/EC for FMD and Art. 62(6) of CD 2005/94/EC for AI.
[47] Point 11.2.2. in Annex XVII of CD 2003/85/EC
[48] Annex VII of CD 2001/89/EC for CSF and Annex VI of CD 2002/60/EC

Westergaard (2007) identifies the control measures that should be covered during simulation exercises (see box below) and provides an overview of potential tasks to be performed during simulation exercises for FMD, CSF and AI.

Real time alert exercises, alarm drills and simulation exercises are not defined as such in EU legislation. However, in literature some definitions have been proposed. Real time alert exercises involve full scale simulation, whereas alarm drills are more theoretical and tend to deal with disease situations on a more limited scale. The term 'Simulation exercise' is commonly used as synonym for both real time alert exercise and alarm drills[49]. Both types of exercise have their uses. Due to its scale, real-time simulation may involve long procedures, with multiple meetings to build the appropriate scenario, and therefore entail a higher cost; on the other hand, desk exercises are easier and lower cost to organise.

Elements of a simulation exercise

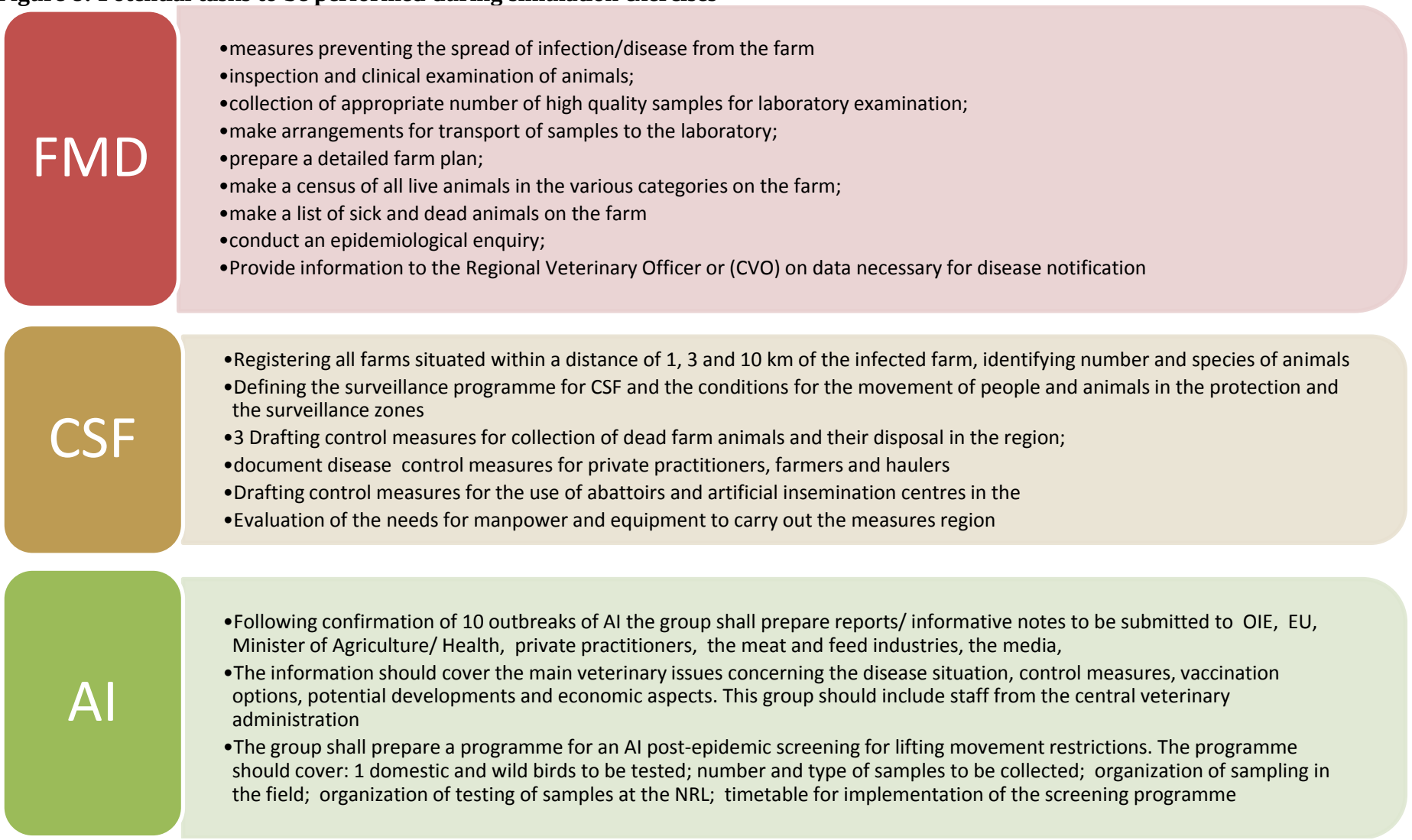
Disease control measures	**Administrative measures**
1 Disease investigation, including tracing and identification of the index case.	1 Payment of compensation to farmers.
2 Collecting samples for laboratory examination and transport of samples to the laboratory.	2 Recruitment of staff – payments, lodging, transport, etc.
3 Stamping-out of infected herds/flocks.	3 Procurement of equipment, disinfectants, protective clothing and vaccine
4 Disposal of carcasses.	4 Financial aspects related to killing and disposal of animals
5 Cleansing and disinfection.	5 Preparation of legal texts related to movement restrictions and trade
6 Establishment of movement restrictions.	6 Drafting documents with information on the disease situation for submission to national and international authorities and the press.
7 Pre-emptive slaughters.	
8 Emergency vaccination, where relevant.	
9 Restocking of depopulated holdings.	
10 Post-epidemic screening	

Source: Westergaard 2007

[49] Westergaard (2007) has suggested the following definitions

- '**Real time alert exercise'** means a model of the course of events related to one or more disease outbreaks where the participants of the exercise have no prior information about the time and the scenario prepared for the exercise;
- **Alarm drill'** or '**Fire drill'** means practice in dealing with a disease situation at the level of a livestock holding, a region or country. This practice can take place with or without prior notice;
- **Simulation exercise:** usually this term simply substitutes for 'real-time alert exercise' and 'alarm drill. It denotes *'an organised and controlled scenario-driven event carried out with the aim of: training personnel designated to be involved in an emergency situation related to the control of potentially rapid spreading animal diseases, and testing, reviewing and up-dating contingency plans, disease eradication strategies and capabilities at local, regional and national level'* (pp.37).

Figure 8: Potential tasks to be performed during simulation exercises



Source: Westergaard 2007

Indicator 1: current MS requirements for real-time alert exercises

With regard to real-time alert exercises, overall, the majority of MS comply with this requirement as laid down in the Control Directives for FMD and AI: 25 and 22 MS indicate that real-time exercises are included in the CP against FMD and AI, respectively. Real time alert exercises are also used by MS for other diseases, although this is not explicitly required in the Control Directives for these diseases: 22 MS include this requirement in their CPs against CSF, 19 MS in CPs against ASF, 16 MS in CPs against BT and 10 MS in CPs against SVD and AHS (Q 3.a – FCEC survey results).

Table 6 presents an overview of the number of MS carrying out simulation exercises since 2001, although the definition of what this constitutes is not homogenous across the EU[50]. Most MS (24 MS) carried out real-time alert exercises for FMD. In 2010 Germany carried out a real-time alert simulation for FMD together with the Netherlands, Belgium and Luxemburg, while in 2011 a simulation exercise took place at the Bulgarian border including Romania. Several MS carried out simulation exercises for HPAI, CSF and ASF (10, 6 and 2 MS, respectively). Simulation exercises have been also performed for other diseases, such as ND and Equine Infection Anaemia.

Table 6: Number of MS carrying out simulation exercises in the EU since 2001

Disease	Number of MS
Foot and Mouth Disease	24
Avian Influenza	10
Classical Swine Fever	4
African Swine Fever	2
African Horse Sickness	1
Other diseases	ND (2), Equine Infection Anaemia (1)

Source: FCEC, based on FCEC case studies, FVO inspection reports and FAO 'Inventory of web accessible recent FMD Real-time Alert Exercises carried out by the European and other countries in the past 15 years and OIE website-Disease Introduction simulation exercises.

Indicator 2: the need for real-time alert exercises

Although MS generally indicated that the preparation and implementation of real-time alert exercises is time-consuming as it requires considerable organisation capacity to prepare, execute and evaluate them, the majority of MS consider them necessary to be laid down in the EU legislation for ensuring an effective CP. For the most part, MS have also indicated that there is a need to develop a common definition of what a simulation exercise is, and that it would be helpful if this was also laid down in the EU legislation.

Nonetheless, the position of MS on the need to include in the Control Directives the requirement of real time alert exercises varies significantly between diseases: 21-23 MS consider them necessary to include in the case of CSF, AI, FMD and ASF; 15-19 MS see the need to have them included in the case of BT, SVD and AHS (Q 3.b – FCEC survey results). In one MS that has experienced significant outbreaks in the last 10 years, simulation

[50] Due to the lack of a clear definition of real-time alert exercise, alarm drills in EU legislation, in some cases the term simulation exercise is used which may refer to alarm drills instead of real-time alert exercises.

exercises although considered important and beneficial are not carried out by the CA due to the significant resources and time required.

Examples of the positive contribution from the implementation of real time alert exercises have been reported by several MS, in terms of:

- **Assessing the national animal health system in place, identifying lessons to be learnt**. In the UK, preparedness against FMD has been tested by the GB-wide FMD exercise called 'Silver Birch' in November 2010; lessons of this exercise have been incorporated in the 2011 CP. The exercise demonstrated the benefits of changes introduced since the 2001 and 2007 FMD outbreaks - for example, the immediate ban on livestock movements on confirmation of disease, and the standstill on all livestock movements - both of which helped to prevent or slow down disease spread; it also highlighted potential room for improvement, e.g. to ensure better IT connectivity for stakeholders and refine vaccination plan. Following *Silver Birch*, the focus has been on tightening processes and making them more rigorous: while veterinarians should be in the network for technical aspects, wider expertise is needed for organisational processes and logistics aspects, i.e. the emergency response network should be multi level, multi-agency and multi disciplinary. Belgium indicated that on average it carries out a simulation exercise every 2 years (for a specific disease selected according to needs each time), which is then evaluated and leads to the revision and updating of the CPs for that disease. In Poland, simulation exercises were implemented a part of post accession transition with EU funding: in total, 16 simulation exercises were completed at regional level and 2 at national level, covering four diseases, and leading to the updating of the CPs for these diseases.
- **Enabling practical training on the emergency procedures and administration required during outbreaks**. In France, in 2010, 61 exercises were realised at Departmental level, of which 22 were simulation exercises against FMD, to cover practical issues (e.g. setting up a disinfection unit), and 1 national simulation exercise ('*Perce-neige'*) was carried out to test the automatic transmission of an alert. Germany indicated that recent desktop simulation exercises helped identify reasons of the delays in communication channels. In Czech Republic, the simulation exercises carried out with the Czech Integrated Rescue System (IRS) have simulated the movement of people, and equipment as well as the transport of samples to laboratories, while requirements of the CPs were adapted so that they could be fulfilled by all farmers. Also, the FVO general report in 2008 pointed out that realistic simulation exercises allowed MS to better understand the importance of external partners and adequate staff for animal handling and culling (see indicator 7: coverage of animal welfare issues, EQ A/1).
- **Identifying areas for improvement in the legislation.** Italy carried out a simulation exercise for AHS in 2011, where shortcomings regarding the EU compensation mechanism for stamping out were identified and communicated to the COM.

Simulation exercises also provide a useful tool in providing the context for engaging in dialogue and cooperation with stakeholders on how best to respond to emergencies; this was clearly indicated to be the case in the MS that carry out simulation exercises that involve stakeholders, as discussed in EQ A/2.

Finally, the number of simulation exercises carried out was proposed by several MS as an objective indicator of the performance of the preparedness and rapid response system (as discussed under EQ A/9).

2.2.8 Use of objective performance indicators (EQ A/9)

A/9 What would be the relevance and possibility to define and lay down in legislation objective performance indicators (including costs and benefits) in assessing crisis preparedness and management capacities of the MS. Is it possible to identify good practices in this area?

Indicator 1: current use of objective performance indicators by MS in assessing crisis preparedness and management capacities

The majority of MS (20 MS) indicated that they use objective performance indicators to assess their crisis preparedness and management capacities (Q 7.a- FCEC survey results). A range of indicators are used, some of which are quantitative and some qualitative, including: disease prevalence; animal morbidity and mortality; the zoonotic nature of the infection (transmission risk to humans or other species); evaluation of risk of transmission via trade; the occurrence of outbreaks of dangerous diseases in neighbouring countries and in the world; and, cost-benefit analysis on specific courses of action for specific diseases such as emergency vaccination strategies and control measures.

On the other hand, 7 MS indicate that they do not use some of the more quantitative performance indicators such as disease prevalence or cost-benefit analysis, either due to lack of means (in particular budget constraints, lack of expertise) or to other reasons such as being located in a low risk area. However, even amongst these MS, some more qualitative performance indicators are being used, such as the number of simulation exercises carried out, the number of trained officers and the frequency with which contingency plans are updated; this type of indicators is indeed used by most MS.

MS highlight the relevance of a disease-specific approach in developing such indicators. In particular, the assessment of crisis preparedness and management capacity is not considered to be homogeneous for all diseases as it should take into account specifics related to the nature of each disease (e.g. transmissibility, involvement of invertebrate vectors etc.) and to the national control policy in place (e.g. vaccination, no vaccination etc.). Hence, indicators tend to be defined each time in view of the disease and epidemiological context in the MS at the time of the assessment. This has implications in terms of the feasibility of laying down in EU legislation objective performance indicators, as discussed below.

Indicator 2: relevance and possibility of laying down objective performance indicators in the legislation

MS are fairly divided with regard to the need and feasibility of laying down in EU legislation objective performance indicators (Q 7.b- FCEC survey results).

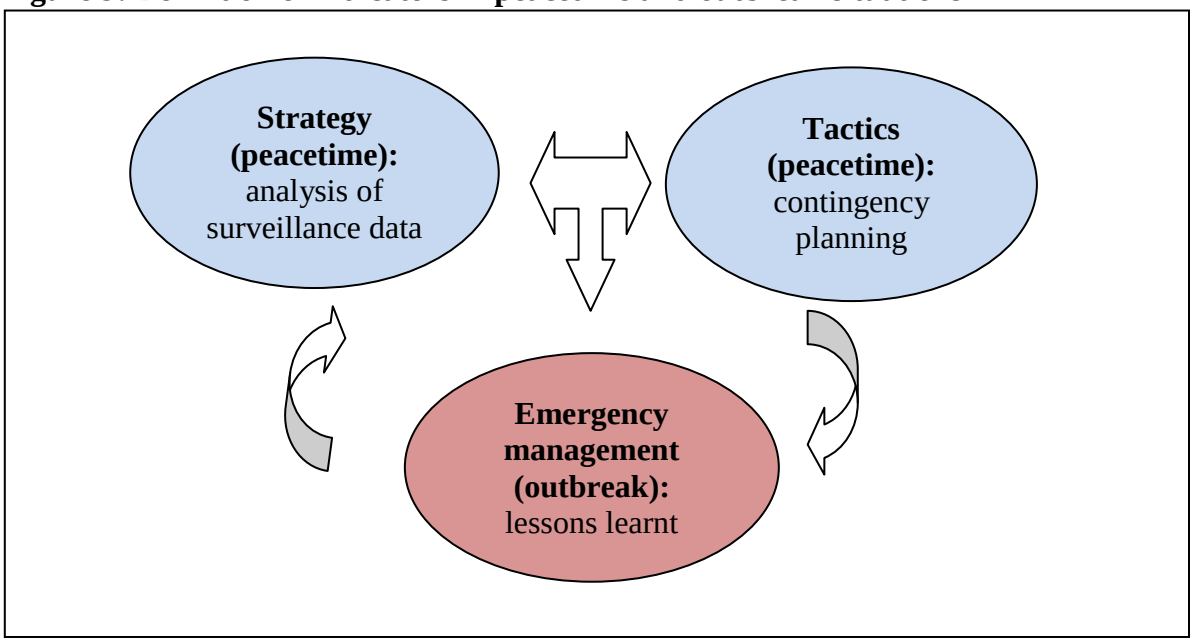
Half of the MS (14) consider it relevant and possible to lay down such indicators in the EU legislation. However, most MS note that performance indicators can have a common basis

but should be tailored to be disease-specific taking into consideration the nature of each disease, the national policy adopted regarding its control and the epidemiological situation. As a result, the assessment should not be exclusively based on these indicators but also on the specificity of each disease and the national context.

A number of performance indicators, considered to be relevant and possible, have been provided by MS in the survey and case studies. The FCEC has analysed and developed these to fit into a more holistic approach of defining a strategy and tactics towards animal diseases in peacetime, to the ability to learn from crisis management in outbreak situations (**Figure 9**). Appropriately defined indicators could be developed to fit in this context, on the basis of the suggestions made by MS, as follows:

- **General indicators to define strategy (peacetime surveillance)**. These cover the broader risk factors for the occurrence of the various diseases, as identified by surveillance activities, such as: disease prevalence, disease incidence, the zoonotic nature of the infection, prioritisation and categorisation of animal diseases through assessment of key risk factors (e.g. risk profile of trading partners, volume/intensity of trade, and the transmission rate of the disease through animal movements);
- **General indicators to define tactics: level of preparedness to implement CPs (peacetime)**. These include: resources available at any moment for a given disease CP, indicating the minimum level of preparedness compared to optimal levels, to be balanced with the importance/relevance of the agricultural activity for the MS, for instance minimum staff and equipment available per livestock unit; number of simulation exercises performed; rate of update of CPs; availability of funds; and, costs and benefits analysis of the measures to be taken for the containment and eradication of diseases (e.g. preventive culling, vaccination strategies), to assist in particular the decision-making process (in peacetime and during outbreaks);
- **Indicators to assess emergency management (outbreak)**. These include: time delays (e.g. the time between the outbreak and the start of the CP, the time for laboratories to confirm a suspicion, the time taken for vaccines to be available); the economic impact.

Figure 9: Definition of indicators in peacetime and outbreak situations



Source: FCEC elaboration

The other half of MS (13) consider that laying down performance indicators in the EU legislation is not relevant or possible. The majority of these MS (9) consider that this is neither relevant nor possible given the variety of epidemiological situations that may arise at MS level; this indicates there are similar concerns as in the case of those MS that consider it relevant and possible, i.e. that indicators need to be disease-specific to be of relevance. Other reasons cited by some of the opposing MS, include the increased complexity and lack of flexibility that the addition of indicators in the EU legislation would incur (again, mostly related to the fact that some indicators may only be relevant for some diseases), but also the administrative burden and budget constraints in monitoring and reporting on these indicators.

The majority of MS, both amongst those that are in favour and those that oppose the use of indicators therefore appear to be concerned on the general use of such indicators, without appropriate due consideration of the specificities and context of a particular disease and the circumstances in which this may occur and develop. MS therefore specify that the choice of particular indicators should be left to MS, so that indicators are better suited to agricultural activities (e.g. animal species, concentration of livestock) and readily available data at MS level. In this way, performance indicators can be appropriately adapted from lessons learnt in a particular context, but need also to be evaluated regularly to assess the extent to which they are relevant and useful.

Indicator 3: Identification and analysis of specific good practices across countries

In the EU, MS that have experienced outbreaks of diseases that have had a severe economic impact and/or public health relevance (e.g. UK: FMD; DE: CSF; NL/IT: HPAI) have generally had the opportunity to develop more their approach on the definition and use of appropriate indicators to assess their strategy, tactics and lessons learnt from outbreak management. Although caution is drawn to the need to re-assess and possibly adapt indicators if these are to be used in other contexts (within the same MS or other MS; for the same

disease or for other diseases), the exchange of good practices on this between MS should be encouraged as it can provide valuable ideas and inputs to other MS to develop the indicators best suited in their own contexts.

For example:

- During the case studies the UK CA indicated that cost benefit analysis, risk and impact assessments are taken into account when reviewing the country's emergency preparedness. A dedicated team within the CA (AHVLA: Veterinary Risk Group, composed of 7 experts) reviews the evidence base for risk, on the basis of various data and tools. The Group holds a meeting every month that produces a series of management strategies, on the basis of their risk assessment, which is destined to the CVOs for the UK and the devolved administrations (England, Wales, NI and Scotland). In their risk assessments, the Group use EFSA risk categories, based on both quantitative and qualitative definition of risk. Risk modelling and assessment, carried out in the context of academic research, provides the basis from which to determine the cost and benefit of different control policies and emergency preparedness.
- The DE CA (BMVEL) has indicated during the case study that it follows a similar approach, developed particularly after the CSF outbreak of 2006 when the need to study in depth the costs of outbreaks versus the cost of control strategies including vaccination.
- The FR CA also acknowledges the fact that cost benefit analysis of the strategy to be followed for the containment and eradication of diseases should be used, but that this is presently not carried out; the lack of cost-benefit analysis has also been highlighted in France by stakeholders in a 2010 report on the French BT crisis[51], where it is recommended that the state and the industry should get together to create a national Observatory to collect data on the cost of animal health emergencies, and that this initiative reaches out at EU level, as an important pre-requisite for defining future strategies in fighting against diseases.

Although the above MS CAs attach great importance to the use of such tools, they consider that MS should be left to use tools and indicators that are readily available and relevant to the livestock sector and administrative organisation in their countries, and therefore it would not be relevant or possible to lay down common indicators in EU legislation.

Beyond the EU, the Crisis Management Centre for animal health (CMC-AH), the joint initiative from the OIE and FAO providing assistance to countries facing or threatened by animal disease outbreaks, indicates that assessments of the disease risk situation and the capacity of the country to respond to an animal disease outbreak are carried out during missions. However, the CMC-AH notes that it is doubtful whether common performance indicators can be used to assess crisis management. The relevance and possibility of such indicators is questioned given the large range of disease/country-specific situations globally.

[51] GDS (Groupements de Défense Sanitaire) France: Mission Prospectives Sanitaires, Rapport d'étape n°2 sur le FCO, July 2010. *"La Mission recommande que l'Etat et la Profession s'accordent pour créer un Observatoire national du coût des crises sanitaires et souhaite que cette initiative soit relayée au niveau européen. La disposition de données précises aurait permis de réaliser une étude estimative sur le rapport coût/bénéfice des différentes stratégies pouvant être mises en œuvre."*

Disseminating guides of good practices and training are considered more useful tools in this context, and the CMC-AH has to this end developed and disseminated a guide of Good Emergency Management Practices (GMEP guide – see also EQ B/3); the guide *inter alia* includes key indicators of progress in managing outbreaks, which are based on the analysis of epidemiological data and time delays within the outbreak management detection-to-response sequence.

Broadly speaking, as also noted under indicator 8 of EQ A/1, the EU veterinary system is seen as a model in other world regions, including EU developed trading partners. In particular, experience and lessons learnt in the EU from FMD outbreaks appear to have provided incentives and is being used as a model for review of CPs in the US and Australia. The EU approach and in particular the detailed requirements provided to MS under the FMD Control Directive are considered the reference in terms of best practice available on how to prepare contingency planning.

2.2.9 The need for EU implementing rules and/or guides of good practices (EQ A/10)

A/10 Is there a need to lay down implementing EU (Commission) rules in the area of contingency planning and/or guides for good practices?

As discussed under indicator 4 of EQ A/1, overall, MS are satisfied with the current degree of detail on CP requirements in the EU legislation and do not see the need for more prescriptive implementing rules. The majority of MS (22 MS) do not consider it necessary to have more prescriptive rules on contingency planning in the EU legislation (Q4- FCEC survey results). This is either because, according to some MS, there is already good understanding of the legislation, or because MS consider that more prescriptive rules would make emergency measures more difficult to implement because contingency plans need to be adapted as much as possible to the national circumstances, including industry practices and administrative procedures.

Only a minority of MS (5 MS) believe that more detailed and prescriptive rules should be laid down at EU level and that these should include almost all of the minimum criteria currently specified in the EU legislation. Some of the new MS in particular have noted that having more prescriptive EU legislation contributes to the acceptance of certain measures at national level and that implementing rules along the same lines as Regulation 882/2004 for food and feed would be useful to ensure a harmonised approach to disease control. MS have different views on the need to lay down detailed provisions on rules regarding the diagnostic laboratory facilities/capacity for rapid diagnosis and the requirement for emergency vaccination, which according to one MS do not need to be laid down in EU legislation, but according to another MS are needed for emergency vaccination for CSF, FMD, BT and AHS.

The FVO notes that most MS are prepared in terms of first reaction to emergencies without having to consult immediately the CP (the first 24-36 hour response is conducted by people on the ground). The CP is however critical as a central reference document and consulted for details and continuation of the action (e.g. setting up control centres, supply in IT equipment, contacting additional staff, responsibilities, contact people, sampling, etc). Overall, the FVO does not consider it necessary for MS to have more prescriptive EU legislation; although it

could have the advantage to better focus FVO inspections therefore improve the efficiency of the inspections.

On the other hand, guidelines illustrating different aspects of contingency planning might be beneficial for allowing MS to adapt CPs to their own national situation. This is highlighted by the fact that, when drafting their CPs, 22 MS have used the EU guidelines produced in 2000 (Q5- FCEC survey results). The FVO indicates that currently there is no harmonised guideline as the Control Directives had been developed over a long period (1992-2006), therefore CP requirements for some diseases (e.g. for FMD) are more detailed than others (as discussed also under EQ A/1).

2.3 Conclusions and recommendations (Theme A)

Based on the FCEC analysis of the collected evidence base, the following overall conclusions can be drawn on the relevance and effectiveness of the current EU legislation related to contingency planning (as specified in particular in the Annexes to the disease specific EU Control Directives).

Key findings

The current scope of the EU legislation is by and large considered sufficiently broad to make MS contingency planning an effective tool in achieving the goals of disease containment, control and eradication (**EQ A/1**). In particular:

- Overall, there is a high level of MS compliance with the current criteria/requirements in the Annexes of the Control Directives (**indicator 1**) and MS are generally satisfied with the current scope of EU legislation (**indicator 8**). The current FMD CP model is considered by MS to be the most thorough and detailed, while the EU approach and in particular the detailed requirements provided to MS under the FMD Control Directive are considered to be exemplary and a world reference in terms of best practice available on how to prepare contingency planning.
- Several MS include in their CPs additional criteria not currently laid down in the EU legislation, e.g. systematic update in light of experience gained (**indicator 2**). Nonetheless, not all MS using additional criteria would consider it necessary to lay these down in EU legislation (**indicator 3**). For example, although the active participation of stakeholders during emergency situations is considered to be an advantage by both MS and stakeholder organisations (**EQ A/2**), and the majority of MS CAs consider it necessary to have clearly defined rules laid down in EU legislation for the involvement of directly relevant stakeholders (i.e. those representing farmers and agri-food industries), several MS CAs have expressed concerns on putting forward more prescriptive legislation on this (**indicator 5**). A key concern is that more legislation might limit MS flexibility to adopt actions which fit national conditions and disease specificities and thus might hinder those MS where collaborative structures between the CAs and stakeholders are established and have proven successful. Stakeholder involvement is also linked with two other key aspects of the EU animal health policy: the development of cost and responsibility sharing schemes, and the prioritisation of animal diseases. As both processes are currently on-going at EU level,

it is considered premature at this stage to define more prescriptive legislation on the involvement of directly implicated sectors in contingency planning.

- The majority of MS already include animal welfare provisions in their CP and welcome the full integration of such provisions as a CP requirement in the EU Control Directives, as foreseen by Regulation (EC) 1099/2009/EC (**indicator 7**).

Only about one third of MS currently include explicit provisions on coordination with neighbouring MS in CP development (drafting, implementation and simulation) in their CPs, and to collaborate more generally with other MS in CP implementation **(EQ A/3 and EQ A/4).** Nevertheless positive examples of cooperation/coordination activities in contingency planning and, more generally, in addressing animal health diseases have been reported by most MS, as well as the fact that this has been reinforced over the last decade as a consequence of the lessons learnt from the negative impacts of the previous lack of cooperation/coordination. The current level of coordination and cooperation both between MS and with the COM is considered satisfactory and sufficient to instil confidence amongst MS and stakeholders in the EU preparedness system. This was more recently demonstrated by the significant and relatively rapid progress in addressing the outbreaks of an emerging and unpredictable vector borne disease in the form of the Schmallenberg virus. This response was a result of the effective animal health network which has been put in place in the EU over the last 20 years, for example by building cooperation between EU laboratories to improve diagnosis. Nonetheless, MS would welcome more exchange with other MS on their specific experience with contingency planning. MS are quite divided in their views on whether more specific provisions on cooperation/coordination between neighbouring MS for contingency planning need to be laid down in EU legislation, with those MS against arguing that this should be left to individual MS.

The majority (about two thirds) of MS favour a generic approach to contingency planning; although this is a more recent trend, as generic plans are currently only available in about a third of MS. This reflects the fact that by drawing on the lessons learnt over the past decade the approaches taken have reached a certain maturity (**EQ A/5**). MS identified several significant advantages in following a more generic approach, notably the ability to share and benefit from best practices for better planning of the organisational, logistic and legal elements that are horizontal across diseases. However, some concerns have been raised on how generic CPs should be designed. The conclusion reached is therefore that disease specific characteristics and the ability to be prepared for effective action for each specific disease need to be safeguarded, and that therefore a generic approach should aim to cover certain minimum requirements that are common across diseases**.**

Although currently not specified in the Annexes to the EU Control Directives, different levels of action in the case of primary and secondary outbreaks are already included in the CPs of some MS. Specific practices on primary outbreaks play an important role in controlling diseases, e.g. animal traceability for BT and SVD, but only a minority of Member States consider it necessary to lay down such rules as a CP requirement in EU legislation. (**EQ A/7**)

The majority (over two thirds) of MS already include real-time alert exercises in both CPs for FMD and AI, as required under EU legislation, but also for other diseases for which these are not currently required (over two thirds of MS include this requirement in their CPs for CSF and ASF; about one third of MS in the CPs for the other diseases) (**EQ A/8**). Several MS

identified significant benefits in carrying out simulation exercises, in particular in terms of reviewing the applicability of the various technical provisions of contingency planning and drawing on the lessons learnt to revise and update their CPs, and contributing to practical training on the procedures to be followed during emergencies, but also identifying areas for improvements in the legislation as such. Real-time alert exercises are, however, found by several MS to be time-consuming and demanding in terms of the required organisation and resources. Nonetheless, the majority of MS CAs consider it necessary that this be laid down as a CP requirement in the EU Control Directives (CDs) - in particular for CSF and ASF for which the CDs currently foresee alarm drills only. It is also noted that MS indicated that a common definition of what constitutes a simulation exercise is missing and this should also be laid down in EU legislation.

The majority (about two thirds) of MS indicated that they use objective performance indicators to assess their crisis preparedness and management capacities (**EQ A/9**). A range of indicators are used, some of which are quantitative and some qualitative, including: disease prevalence; animal morbidity and mortality; the zoonotic nature of the infection (transmission risk to humans or other species); evaluation of the risk of transmission via trade; the occurrence of outbreaks of dangerous diseases in neighbouring countries and in the world; and, cost-benefit analysis on specific courses of action for specific diseases such as emergency vaccination strategies and control measures. Although these MS CAs attach great importance to the use of such tools, they consider that MS should be left to use what is readily available and relevant to the livestock sector and administrative organisation in their countries, and therefore it would not be relevant or possible to lay down common indicators in the EU legislation.

MS are by and large satisfied with the degree of detail in the current EU legislation on CP requirements, and do not wish to see more prescriptive rules (**EQ A/10**). However, guidelines further explaining the legislation might be beneficial for assisting MS to sufficiently and effectively adapt the CP requirements, as laid down in the Control Directives, to their own national context.

Recommendations

Given the generally positive picture of the current setup, potential improvement would require soft corrective measures, as follows:

1. While the FMD CP model is considered to be the most thorough and detailed, the Control Directives for BT, ASF, AHS, CSF and AI could be revised to address the additional criteria highlighted, including animal welfare, and to take out criteria that are not considered appropriate for some diseases e.g. emergency vaccination for SVD (**EQ A/1**).
2. Introducing a framework approach, for a generic CP laying down minimum requirements that are common across all diseases, but ensuring sufficient flexibility to adapt at an operational level to each specific disease to ensure sufficient disease focus (**EQ A/5**). On the basis of the most advanced CPs in place today (e.g. FMD and generic CP models in several MS), such minimum requirements could cover: the chain of command; the establishment of NDCCS/LDCCS and expert groups; sufficient access to tools, staff, facilities and funding; cooperation between the authorities involved;

cooperation between neighbouring MS/third countries; the carrying out of simulation exercises; and, where applicable emergency vaccination. A generic approach can improve overall preparedness to deal with new emerging diseases: the successful concerted effort of MS and the COM for addressing the recent outbreaks of the Schmallenberg virus (SBV) (as discussed under EQ A/4) was partly attributed to the availability of generic contingency planning to deal with unpredictable emerging diseases.

3. More specific guidelines could be developed, possibly by reviewing and updating those developed by the COM in 2000, to explain further the CP requirements of the Control Directives. Such guidelines are considered beneficial by most MS, for adapting CP requirements to the national situation, therefore ensuring effective contingency planning. However, more prescriptive legislation is not considered necessary (**EQ A/10**).
4. At the moment, the best approach for reinforcing stakeholder involvement in MS contingency planning is to state the need for this as a general principle in EU legislation (**EQ A/2**), as more prescriptive legislation on this is perceived to be both premature and potentially damaging to the contingency planning process in some MS.
5. Having explicit provisions on MS collaboration laid down in EU legislation is not considered necessary by the majority of MS (**EQ A/3** and **A/4**). Rather, it would be good to have a suitable forum for exchange of best practices, and training could also be provided; to this end, an initial 1-day conference on this subject could be proposed to cover the range of issues that are relevant to contingency planning including on communication.
6. The possibility of including real-time alert exercises as a CP requirement in all the EU Control Directives should be taken into consideration, especially in the case of CSF and ASF. MS are also in favour of a common EU definition of real-time alert exercises, alarm drills and simulation exercises (**EQ A/8**).
7. It is not considered necessary to define different levels of action in case of primary and secondary outbreaks for all MS in EU legislation (**EQ A/7**).
8. While the current EU rapid response system has been sufficiently reactive, thereby continuously improving by taking into account lessons learnt (**EQ A/1**), it needs to be paralleled by a proactive approach, which consists in anticipating and preparing for new or emerging risks. The COM could play a key role in developing a systematic process of analysing and evaluating new risks (horizon scanning), possibly benefitting from the experience gained in the context of EFSA's work on emerging risks for food safety.

3 Theme B: the evaluation/approval and follow up of the CPs

3.1 Background

According to the current rules laid down in the disease specific Control Directives, CPs must be submitted by the MS to the COM for approval via the comitology procedure (Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002 – SCoFCAH).

The specific objective of theme B is to analyse the relevance (added value) and the effectiveness of the EU mechanism for evaluation/approval, at the level of SCoFCAH, both of the initial CPs and of their subsequent updates/ amendments. It also aims to identify other potential mechanisms/processes and/or additional tools for CP evaluation/ approval which may be more effective and efficient in achieving the intended goals of disease containment, control and eradication. This includes consideration of the advantages and disadvantages of a number of alternative potential mechanisms (listed under EQ B/3), such as COM approval without SCoFCAH, peer review at SCoFCAH without approval, a strengthened/increased role for FVO missions to verify MS CP implementation, and approval by an independent body; and/or additional tools (listed under EQ B/3 and EQ B/6, and also under EQ A/10), in particular, having in place a 'light and alive' system of guides of good practices, possibly supplemented by training. The efficiency is determined in terms of the administrative costs/burden involved to organise and attend SCoFCAH meetings for this purpose, in comparison with the identified alternatives and/or additional tools.

3.2 Findings

3.2.1 Assessment of the current (comitology) procedure foreseen by the legislation (EQ B/1, B/2 and B/4)

B/1 To what extent is the EU approval procedure of CP by comitology relevant and efficient?

A number of indicators were developed by the FCEC to assess the relevance and efficiency of the current EU approval procedure. These include the level of current compliance to the procedure foreseen by the legislation, the extent to which and justification why this is considered relevant/efficient by the MS/COM, and advantages/disadvantages of the procedure (which need to be assessed, in particular, against procedures followed in other sectors, and against potential alternative mechanisms achieving the same objectives – EQ B/3).

Indicator 1: current level of compliance with the procedure foreseen by the legislation

The CPs for AI, ND, FMD and CSF have been approved for all 27 MS. CPs for other diseases have never been approved. Indeed, there are currently 3 categories of CPs:

- Obligation for EC approval exists and CPs are approved (FMD, CSF, AI, ND);
- Obligation exists but CPs are not approved (e.g. BT, ASF);

- Obligation to approve does not exist (all the rest of OIE listed notifiable diseases).

Although also foreseen by the legislation, no subsequent approval following amendments by MS to the initially approved CPs has been carried out by the COM, due to lack of staff resources (see also EQ B/2).

The current level of compliance, in terms of the number as such of approved CPs, in combination with other indicators, allows conclusions to be drawn on the relevance and efficiency of the approval procedure.

In following the procedure foreseen by the legislation only for some key diseases, the COM and MS are indeed prioritising the use of SCoFCAH to this end, in view of the time and resource constraints both at the level of the COM and of the MS. According to the COM/MS, approval is not based on a substantive and comprehensive review/evaluation of the submitted CPs by SCOFCAH, but remains rather a formality. This is also evidenced by the fact that there is little exchange or time provided for MS to review the submitted CPs prior to SCoFCAH meetings, as the procedure is usually completed in one day.

Indicator 2: MS/COM assessment of the relevance and efficiency of the procedure currently foreseen by the legislation

Only 3-5 MS consider the current procedure to be *very* relevant, effective and efficient, while a further 8-11 MS consider it to be *fairly* relevant, effective and efficient (Q 9.a - FCEC survey results). On the other hand, 9-11 MS consider the current procedure to be *not very* or *not at all* relevant, effective and efficient. However, the interviews carried out at the level of MS CAs during the case studies revealed that there has been some confusion in answering this question, and that the actual number of MS that consider the procedure to be *not very* or *not at all* relevant, effective or efficient is actually higher, with indeed many MS indicating that they were not even aware that the CP review and approval procedure is taking place at SCoFCAH. In answering these questions in the survey, those MS were referring rather to the current actual situation, whereby the CP approval procedure is a formality rather than a substantive CP review/evaluation process.

The relatively low importance attached by MS to the procedure currently foreseen by the legislation is also highlighted by the survey response on the factors that are considered to contribute to ensuring the objectives of contingency planning i.e. to achieve animal disease preparedness and rapid reaction (Q 10 - FCEC survey results).

By and large, the majority of MS (25-27 MS) indicated that *own national best interests*, the *legal obligation to have in place operational CPs as provided by the EU Control Directives*, and *the current mechanism of FVO inspections for CPs*, are the three most significant drivers for effective contingency planning. National best interests are determined, in particular, by the experience of previous outbreaks and awareness of future threats, and the strong desire to ensure that the country is prepared for possible future outbreaks in view of the potential impacts of an outbreak and the economic significance of maintaining/achieving a disease-free epidemiological status.

By comparison, the *current procedure of CP approval by comitology* is considered to be *fully* contributing to ensuring the objectives of contingency planning by only 3 MS and *partly* by 18 MS, while according to 6 MS it is *not at all* contributing to this objective. Several MS highlighted the fact that their limited knowledge or understanding of other MS specificities, legal framework and administrative set up makes it impossible for them to evaluate effectively other MS CPs, as would require a real voting procedure at SCoFCAH. In any case, the COM and MS would only be able to verify whether a CP document exists, but not whether it is implementable or sufficient, due the fact that the operations manual is the most important document and usually available only in the national language.

During the case studies, several of the MS CAs highlighted the fact that there is no evidence that approved CPs are better than non-approved CPs, therefore, in their view the current procedure does not guarantee as such the quality of CPs (EQ B/1: indicator 4).

Indeed, the interviews carried out both at the level of the COM and at the level of MS revealed that this procedure is still in place largely for historical reasons. In particular, two decades ago, MS needed to build up trust in each other's animal health contingency systems, and the COM needed to keep close control of MS implementation. Now that MS have developed their experience of contingency planning, it is questioned whether the CP approval procedure through SCoFCAH remains necessary and whether it offers any real added value.

On the other hand, as also indicated above, FVO inspection missions to verify the state of preparedness and contingency planning in the MS are considered to offer real added value and to be relevant (this point is further discussed in EQ B/3). Even in the case of MS that were in favour of the initial CP approval by SCoFCAH, this was considered relevant and useful if followed by regular follow up by the FVO. Although MS CAs admitted that FVO inspections provided a challenge and a cost in terms of the organisation, time and effort required on behalf of the CA, they were nonetheless considered to be very relevant and useful in providing a good picture of the effectiveness of the animal disease emergency system in place in the inspected MS, as the expertise of the FVO is generally highly regarded and respected by MS.

Indicators 3 to 5: advantages/disadvantages of the procedure currently foreseen by the legislation

As already indicated, neither the survey nor the MS case studies and COM/stakeholder interviews revealed any significant advantages or tangible benefits of the procedure for CP approval by SCoFCAH as currently foreseen by the EU legislation. The primary objective of ensuring effective contingency planning appears to be better ensured by MS' own national best interests, the legal obligation as such, and FVO verification missions, rather than by the CP approval at SCoFCAH (results of Q 10 – FCEC survey, as reported above). Also, the historical justification for the procedure at SCoFCAH, notably the need to develop a climate of trust between MS and vis a vis the COM, by and large no longer appears to be as significant. Furthermore, the procedure currently followed is - for the various reasons outlined above - more of a formality rather than a substantive comprehensive review of the CPs as such, while there is no evidence that approved CPs are better than non-approved CPs.

It is noted, nonetheless, that some form of oversight by the COM (including FVO CP verification inspections, as discussed under EQ B/3) is still largely considered relevant and useful, as a way of facilitating the exchange of information between MS, encouraging MS to draft a good CP, and also for the COM to keep an eye on how MS are preparing themselves to face outbreaks. In particular, for those MS that consider CP approval by SCoFCAH to be very/fairly relevant, effective and efficient, the main rationale is that it enables some form of dialogue between MS for knowledge sharing on this subject; this objective can nonetheless be fulfilled by other means, as discussed under EQ B/3 and EQ B/6.

On the other hand, the main disadvantage of the procedure currently foreseen by the EU legislation is considered to be administrative burden, in comparison to the perception that it offers no real added value, as it competes for time and resources (both at COM and MS level) with what is considered to be the main rationale for and mandate of SCoFCAH, notably the tasks relating to the development, adoption and follow up of implementation of animal health legislation including of emergency measures, which are therefore seen as the highest priority and most significant work of SCoFCAH (see Theme D). The additional costs involved in attending SCoFCAH meetings are discussed under Theme C. In particular, regarding the costs of SCoFCAH meetings in general, background information is provided under EQ C/2; our interviews indicate that the legislative obligation to approve CPs does not currently result in additional costs to the costs of regular meetings, but this could be the case if it were to be systematically followed for the approval of initial CPs and revisions.

Drawing a parallel from the food and feed safety sector (EQ B/1: indicator 5), the procedure foreseen by Regulation (EC) 882/2004 for MANCPs (multi annual national control plans) does not involve SCoFCAH approval, as the Regulation foresees that MS should simply submit to the COM their MANCPs and annual reports, with voluntary notification of key changes made to the MANCPs[52]. There is therefore no need to approve MANCPs as such, and in this case the COM checks via the FVO (at the end of the planning year) whether the MS system in place is effective and well-planned. The MANCPs are seen as a benchmark for MS to ensure they have followed the criteria/requirements set out in the legislation.

Article 13 of Regulation (EC) 882/2004 on contingency planning in the food and feed safety sector is under review. In the context of food and feed crisis management, DG SANCO is trying to create a fully integrated system along the food chain which will include food and feed safety, plant health and seeds thus allowing full control. The COM wants to streamline other relevant legislation in this field, e.g. by deleting the approval procedure on MS action for the control on the residues of veterinary medicines[53] and making it part of the MANCP. In this context, potential synergies at the level of FVO inspections for CPs and MANCPs could be explored (see EQ E/4).

[52] MS reporting is currently voluntary in the context of the MANCPs, but it needs to be considered whether it should be made compulsory.
[53] DG SANCO is examining the possibility of introducing some mandatory requirements on the minimum frequency of control as there should be some harmonisation at MS level

B/2 Is the EU approval procedure by comitology for updates and amendments of CP needed and efficient?

The initial CPs may be amended to take account changing requirements in the different Directives, compulsory updates every 5 years (e.g. the case for FMD, as required by Article 72.10 of Council Directive 2003/85/EC)[54], and updates in case of significant change or any amendment in the measures taken against the specific diseases. It is generally foreseen by the legislation that subsequent amendments to the CPs must be submitted by the MS to the COM and be approved via comitology procedure, although the wording of the different directives is not identical in this regard.

The indicators used by the FCEC to assess the relevance and efficiency of the EU procedure for the approval of updates and amendments to the initial CPs include the level of current compliance to the comitology procedure foreseen by the legislation, the extent to which and justification why this is considered relevant/efficient by the MS/COM, and the extent to which MS review/revise their CPs in line with the provisions foreseen in the EU Control Directives.

Indicator 1: current level of compliance with the procedure foreseen by the legislation

As indicated already in the introduction, no subsequent approval following amendments by MS to the already approved plans has been carried out by SCoFCAH. This is largely due to the relatively low importance attached to this procedure, coupled with the lack of staff resources both at the level of the COM and of the MS.

Indicator 2: MS/COM assessment of the relevance and efficiency of the procedure currently foreseen by the legislation

Only 2-3 MS consider the current procedure to be *very* relevant, effective and efficient, while a further 10-13 MS consider it to be *fairly* relevant, effective and efficient (Q 9.a - FCEC survey results). On the other hand, 9-12 MS consider the current procedure to be *not very* or *not at all* relevant, effective and efficient. Again (as in the case of the approval of the initial CPs), the interviews carried out at the level of MS CAs during the case studies revealed that there has been some confusion in answering this question, and that the actual number of MS that consider the procedure not to be at all relevant, effective or efficient is actually higher, with indeed many MS referring rather to the current actual situation, whereby the procedure foreseen for the approval of CP amendments and updates is a formality rather than a substantive review/evaluation process.

In the interviews and case studies, both the COM and MS have largely confirmed that there is no need to apply the comitology procedure for the approval of the updated CPs, as multilateral trust in the system is now seen as having been developed. A key argument put forward against the procedure is, once more, the burden this puts on the use of MS and COM

[54] Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC. Article 72.10**:** '*In any case, every five years each Member State shall update its contingency plan in particular in the light of real-time alert exercises referred to in Article 73, and submit it to the Commission for approval in accordance with the procedure referred to in Article 89(2).'*

resources, in relation to the little added value conferred by this procedure. On the other hand, FVO inspection missions to verify the state of preparedness and contingency planning in the MS are considered to offer real added value and to be relevant also for following up the progress and updates made by MS to their initial CPs (as further discussed in EQ B/3). Several MS noted that this is particularly relevant for the follow up of revisions and updates to the CPs, for which current mechanisms in place are considered not to provide sufficient incentive to MS to regularly review their contingency planning approach (a point that is therefore considered to need improving).

Indicator 3: extent to which MS update their CPs

For some of the diseases, in particular CSF, FMD, BT, HPAI, and (to a lesser extent) ASF, by and large the majority of MS have indicated that they review and revise/update their CPs in line with the provisions foreseen in the EU Control Directives (Q 10 and Q 11, FCEC survey results), in particular the requirement to undertake an update in view of the experience gained following simulation exercises and/or the evaluation of the response to actual outbreaks. In comparison, in the case of SVD and AHS, for which the review and revision is not compulsory under the EU Control Directives, just over half of MS do so (those MS that have not reviewed/revised their CPs for these diseases indicated that this is mainly due to the prolonged absence of the disease from their territory and therefore the relatively lower priority attached to these diseases).

In some cases, MS indicated that CPs are continuously updated in real time on-line, following debriefing between those services involved in the implementation of a CP that has been activated in the case of an emergency, on the basis of which strengths and weaknesses of the activated CP could be identified.

The relatively high figure of compliant MS suggests that, in the event the comitology procedure was followed for the approval of revised/updated CPs, potential requirements in terms of COM/MS resources would be relatively high.

B/4 Does the current CP evaluation provide the Commission services with an overview of the CPs in order to verify their mutual effectiveness, especially regarding the neighbourhood issue?

The extent to which the current CP evaluation provide the Commission services with an overview of the CP in order to verify their mutual effectiveness is related to the ability of the COM to evaluate a CP and in particular to the extent to which the COM currently reviews the CPs (EQ B/1 indicator 2). In terms of enabling the COM to verify the effectiveness of CPs on the neighbourhood issue, including via FVO CP verification inspections, this is also related to the extent to which the legislation as such foresees cooperation between neighbouring MS; currently, the cooperation with neighbouring MS is only foreseen in the case of FMD and in the context of real time alert exercises (as discussed under EQ A/4), although about one third of MS currently include in their CPs explicit provisions to coordinate with neighbouring MS in CP development (drafting, implementation and simulation) (EQ A/3).

Clearly, the conclusion reached from our interviews with the COM and MS is that the current CP evaluation process via comitology offers no added value in terms of providing the COM

services with an overview of the CPs, including on their mutual effectiveness regarding the neighbourhood issue. By contrast, FVO inspections play an important role in verifying MS compliance with the EU legislation (EQ B/3), to the extent that relevant provisions in the legislation exist to enable the FVO to address this issue. As noted under the conclusions of Theme A, MS are currently quite divided on whether explicit provisions on this issue should be included in the CP requirements of the EU Control Directives, but there is more consensus on the need to develop more guidelines on CP development and these could include recommendations for cooperation between neighbouring MS where applicable.

3.2.2 Alternative mechanisms and additional tools for CP evaluation and/or approval (EQ B/3, B/5 and B/6)

In view of the generally low importance attached to the approval of MS CPs by SCoFCAH, 13 out of 27 MS indicated in the survey that there is a need to improve current procedures/mechanisms for the evaluation and approval of MS CPs (Q 9.b - FCEC survey results). As indicated in the previous section, our interviews with MS CAs in the context of the case studies revealed that the actual number of MS that do not consider the approval by SCoFCAH to be relevant or efficient, and therefore see the need to improve the current system, is actually higher, due to certain confusion in answering survey Q 9.a (relevance, effectiveness and efficiency of the current procedure) and Q 9.b (need for improvement). Several MS in fact perceived the procedure foreseen for the approval of CPs as a formality of little added value, rather than a substantive CP review/evaluation process, and therefore identified the need to improve current procedures/mechanisms[55].

B/3 What would be the other possible mechanisms for CP evaluation and/or approval?

During the inception phase of the evaluation, potential alternative options were identified to the current comitology procedure foreseen by the EU legislation, as follows:

- Commission approval without SCoFCAH;
- No SCoFCAH approval – to be replaced by:
    - Peer review by SCoFCAH;
    - An up-to-date system of guides of good practices;
    - Accreditation by an independent body at international or national level.

Both the survey and the case studies revealed that, while the majority of MS agree on the need to improve the current procedure for the evaluation, approval and follow up of CPs, the views on potential alternative mechanisms that could be used to replace the current procedure are quite divided. A point where there appears to be MS, as well as COM, consensus is on the **need to ensure that procedures remain relatively rapid and simple**, and to avoid increasing the complexity of the requirements imposed on MS without offering any real added value in the process.

[55] The survey data presented below are based on the responses of 13 MS indicating there is a need for improvements to the current procedures. Although the actual number of MS considering the need for improvements has been higher, it has not been possible to adjust the survey response data. The responses of those MS that indicated otherwise in the survey have nonetheless been taken into account in a more qualitative manner in the analysis of the relevant EQs of Theme B.

Thus, 7-9 MS consider some form of COM approval, but without SCoFCAH, to remain *very*/*fairly* relevant, effective and efficient (Q 9.c - FCEC survey results[55]). The main justification for retaining some form of COM oversight over the process was the need to ensure a harmonised approach across the EU, and that all MS comply with the minimum CP requirements as laid down in the Control Directives. The key benefit of this option is that it could enable the COM to identify best practices amongst the reviewed CPs and to potentially play a role in facilitating the transfer of this knowledge to all MS (e.g. via systematically updated guides of good practices, as discussed in the next point), but also to identify and take corrective action for MS that are performing poorly in terms of animal disease preparedness. For those supporting this option, the idea is for the COM to create a general framework for CP drafting/updating, but to leave some degree of flexibility and freedom to MS to develop their national CPs. In this framework, a strengthened safeguard role of the COM - both for effective contingency planning and for the implementation of detailed measures - is considered crucial by MS supporting this option. For instance, several MS noted that no effective action is currently taken to penalise MS that have not put in place CPs, and no incentives are provided to keep these updated. In terms of detailed measures, a MS CA indicated that the COM should be stronger in imposing on MS the full implementation of EU legislation regarding animal traceability, e.g. to imports of live animals from another key supplier MS; similarly, the COM is expected to intervene in ensuring the sufficient availability of appropriate vaccines, particularly against new strains, e.g. BTV-8 for which MS experienced problems finding the vaccine quantities needed as this was not commercially available.

In this context, the option most favoured by MS as an alternative – or a complement - to COM approval is to strengthen the role of the FVO in the evaluation of MS CPs, as the **FVO inspections** were by and large indicated by both the MS and the COM as the most appropriate mechanism for assessing national CPs. FVO inspections, which provide high level peer reviewing and are therefore widely respected and accepted, are considered to be very relevant, effective and efficient in ensuring that MS meet the EU requirements on contingency planning (see EQ B/1 and EQ B/2; also, Q 9.a and Q10, FCEC survey results). By making FVO CP verification missions more periodical, CPs in all 27 MS could be evaluated and assessed in 5 years. As discussed in Theme E (EQ E/3), if FVO involvement for CP verification were to be increased, with all other FVO work continuing as currently, it would require 2 more inspectors at the FVO AH unit. It is noted that one critical issue with FVO audits of CPs highlighted by several MS is that they are perceived to be relatively 'narrow' in scope in that they examine the CPs in isolation of actual outbreaks occurred, and this point may require further reflection if the FVO's role in the evaluation of CPs was to be further reinforced.

The second most 'preferred' alternative option appears to be an up-to-date system of guides of good practices. This option, which was identified as *very*/*fairly* relevant, effective and efficient by 5-6 MS, would be a *'light and alive'* system outlining good or best practices to guide MS in their drafting, review and updating of CPs (as discussed under EQ A/10, MS by and large consider such guidelines beneficial for allowing MS to adapt sufficiently and effectively the CP requirements, as laid down in the Control Directives, to their own national context), and could be used in conjunction (indeed provide assistance) to FVO inspections,

but it also could be possibly supplemented by additional tools such as training and workshops (see EQ B/6).

The EU has already taken action to provide guidance to MS on how to draft their CPs**:** ***guidelines for contingency plans against notifiable diseases*** had been circulated by DG SANCO to MS in May 2000 (and in 2003 for AI and ND). The majority of MS (22 MS) have indicated that they have used these guidelines when drafting their national CPs (Q 4.last point, FCEC survey results), and in the case studies the CA in several MS have confirmed that they have found these guidelines to be very useful, thus highlighting the importance of having in place such a guide.

Beyond the EU, an interesting case of the benefits of having in place such a guide is provided by the ***FAO Good Management Emergency Practices (GMEP***[56]). The GMEP aims to assist and facilitate country preparedness to respond effectively and efficiently to animal disease outbreaks, in particular – but not exclusively - of transboundary animal diseases (TADs). It covers the whole cycle of contingency planning, from preparedness and prevention, to detection, response and recovery. The language used in the GMEP is simple so all countries can easily understand the issues involved. The joint FAO-OIE Crisis Management Centre for animal health (CMC-AH) has disseminated the GMEP to member countries in CDs or pen drivers: a base manual and other material are provided as part of the GEMP package including a GEMP checklist. The GMEP has now become a standard of good practices and it provides a good example of how the Centre provides assistance for preparedness, e.g. the instant command system approach which is generally considered as a best practice for emergency management around the world.

On the other hand, the options involving peer review of the MS CPs by SCoFCAH, or their accreditation by an independent body at international or national level, received little support, with the majority of MS that responded to this question (7-8 MS) indicating that these options would be *not very/not at all* relevant, effective or efficient. In particular, the accreditation by independent bodies is not considered to be a good alternative as they are generally perceived to offer more of a formal, rather than a substantive, procedure.

An alternative option that was provided by a new MS was in the direction of the change in the system foreseen for the evaluation of animal disease eradication and monitoring programmes. Previously, the assessment of eradication and monitoring programmes was carried out by dedicated working groups at COM level; in the future it will be done by groups of experts in the MS. A similar solution could be possible for CPs by appointing 'accredited' teams of MS experts with relevant experience to allow them to make recommendations on the submitted CPs that would be accepted by the MS.

B/5 Could other or additional tools or practices be considered more effective and efficient to achieve the same goals for both parties (MS CAs and COM services)?

This is analysed under EQ B/3 in terms of the CP evaluation/approval procedure and under EQ B/6 in terms of technical assistance and other additional tools.

[56] Honhold N. et al (2011): Good emergency management practice: the essentials. A guide to preparing for animal health emergencies. FAO Animal Production and Health, Rome, 2011.

B/6 What would be the need of other possible EU level actions in ensuring high quality contingency planning and emergency preparedness?

Following on from the suggestions already presented in this EQ on potential EU level actions to provide guidance, other than the guides of good practices discussed as an alternative option under EQ B/3, the following potential additional tools were identified during the inception phase of the evaluation:

- Training;
- Workshops;
- Missions either to MS or third countries facing epizootic diseases, in order to maintain the know-how in this field (including CVET missions and FVO inspections).

All of the above EU level actions were considered to be *very/fairly* relevant, effective and efficient by the majority of MS (8-12 MS) that responded to this question in the survey; training scores the highest, followed by workshops, and missions to MS/TCs (Q 9.c - FCEC survey results[55]). It is noted that these tools can be used in parallel, and can complement each other (e.g. training can be tailored to specific issues identified via workshops).

While these tools are highly valued by MS, they were largely missing from the system and tools in place over the last decade. Several MS indicated that the COM should give incentives to MS for the identification and sharing of good practices and, in this context, both training and workshops are regarded as relevant and effective tools. It was noted under EQ B/1 that for those MS that consider CP approval by SCoFCAH to be very/fairly relevant, effective and efficient, the main rationale put forward is that it enables some form of dialogue between MS CAs, as well as between MS CAs and the COM, for knowledge sharing on this subject; this objective could alternatively be fulfilled through training and workshops, and could be facilitated also by some COM oversight as discussed under EQ B/3. In this context, it is also noted that several MS complained for the current absence of effective feedback by the COM on the submitted CPs (i.e. any more detailed feedback than the simple notification of CP approval), which MS welcome as it contributes to useful dialogue and exchange on the subject.

Regarding training, a positive development is considered to be the systematic training on contingency planning as such, for which the BTSF foresees a total 8 weeks of training during the 2012-13 period. Some MS consider compulsory training as a good initiative while others prefer it to be offered on an optional basis. In this context, the '**Better training for Safer Food'** is seen as a useful programme which allows MS CAs to share and harmonise MS practices; According to the COM, training may be difficult to implement in practice on a compulsory basis. The COM is concerned that providing this type of training is quite difficult in that the trainees must have firsthand knowledge of dealing with animal disease emergencies, particularly for less prevalent or emerging diseases. The level and the quality of training depend on the experience of the MS in dealing with such emergencies (e.g. in the Netherlands the veterinary profession is generally considered to be very well trained due to the significant practical experience acquired during emergencies experienced in the past, such as CSF (1997/8), FMD (2001), AI (2003)). According to the EU professional veterinary association (FVE), the non harmonised level of professional training and qualifications of veterinarians across the EU continues to be an issue of concern. The COM has experienced

this in practice: when circulating DVDs among official veterinarians during the AI crisis, the COM realised that the usefulness of the information depended on the level of base training and practical experience of the veterinarians which was very uneven amongst MS.

Workshops, in particular if they involve knowledge sharing / transfer of know-how from MS that have experienced the implementation of CPs during actual outbreak situations, are considered to be another important additional tool for ensuring high quality contingency planning and emergency preparedness. The lessons to be learnt from a more regular review of the CPs by the FVO, as discussed under Theme B, could fit into both the BTSF training and other workshops organised on contingency planning.

3.3 Conclusions and recommendations (Theme B)

Key findings

Based on the FCEC analysis of the collected evidence base, the following overall conclusions can be drawn on the relevance, effectiveness and efficiency of the procedure currently foreseen by the disease specific Control Directives for the approval of MS CPs (comitology procedure):

- MS CPs have been systematically approved only for FMD, CSF, AI and ND. Furthermore, the procedure currently followed in these cases is in practice more of a formality rather than a substantive comprehensive review of the CPs as such (**EQ B/1: indicator 1**).
- No subsequent approval following amendments by MS to the initially approved CPs has been carried out. This is explicitly foreseen by the legislation in some cases (e.g. FMD) although there are different requirements on both the CP review frequency and the approval of CP updates/amendments through comitology (**EQ B/2: indicator 1**).
- The majority of MS do not consider the current procedure, for the approval of the initial CPs or for updates/amendments to the initial CPs, to be relevant, effective or efficient for ensuring that effective CPs are in place. In following the procedure foreseen by the legislation only for some key diseases, the COM and MS are indeed prioritising the use of SCoFCAH to this end, in view of the time and resource constraints both at the level of the COM and of the MS (**EQ B/1: indicators 2-5; EQ B/2: indicators 2-3)**.
- At the same time, most MS indicate that their *own national best interests*, the *legal obligation to have in place operational CPs as provided by the EU Control Directives*, and *the current mechanism of FVO inspections for CPs*, are the three most significant drivers for ensuring the objectives of contingency planning are obtained i.e. to achieve animal disease preparedness and rapid reaction. Furthermore, there is no evidence that approved CPs are better than non-approved CPs. Consequently, by and large, neither the COM nor MS consider that the current procedure guarantees the quality of CPs (i.e. that the minimum criteria laid down in EU legislation are followed), and that CPs are regularly updated/revised in the light of the experience gained (**EQ B/1: indicators 2-5; EQ B/2: indicators 2-3**).
- Drawing a parallel in particular from the food and feed safety sector (**EQ B/1: indicator 5**), the procedure foreseen by Article 13 of Regulation (EC) 882/2004 for

MANCPs[57] (multi annual national control plans) does not involve SCoFCAH approval, as the Regulation foresees that MS should simply submit their MANCPs and annual reports to the COM , and in this case the COM checks via the FVO (at the end of the planning year) whether the MS system in place is effective and well-planned.

- The current procedure for the approval of CPs in the animal health sector appears to be still in place largely for historical reasons. In particular, two decades ago, MS needed to build up trust in each other's animal health contingency systems, and the COM needed to keep close control of MS implementation. Now that MS have developed their experience of contingency planning, it is questioned whether the CP approval procedure through SCoFCAH remains necessary and whether it offers any real added value in terms of providing the COM services with an overview of the CPs to verify their mutual effectiveness (**EQ B/4**), while a key argument put forward against the procedure is the burden this can potentially entail on the use of MS and COM resources (**EQ B/1: indicators 2-5; EQ B/2: indicator 2**). By contrast FVO missions are regarded by the majority of MS as relevant, effective and efficient in ensuring these objectives, as they play an important role in verifying MS compliance with the legislation (**EQ B/3**).

In view of the generally low importance attached to the approval of MS CPs by SCoFCAH, the majority of MS have indicated that there is a need to review current procedures/mechanisms for the evaluation and approval of MS CPs with a view to simplification and alignment with the procedures followed for MANCPs.

Recommendations

A starting point where there appears to be MS, as well as COM, consensus is on the need to improve as well as to strengthen procedures, but to avoid increasing the complexity of the requirements imposed on MS without offering any real added value in the process. From our review of the evidence base, the following conclusions can be reached on potential improvements to the current system:

1. Consideration should be given to harmonising the approach currently followed for the approval of CPs with that of MANCPs, including the modalities of MS annual reporting on key changes made in the CPs e.g. on the chain of command (MS reporting is currently voluntary in the context of the MANCPs, but it needs to be considered whether it should be made compulsory) (**EQ B/1**).
2. The majority of MS indicate the need to keep some form of COM oversight, which centres on an initial review and follow up of MS CPs by more systematic FVO verification missions, leading – but not necessarily – to some form of COM approval (**EQ B/3**). The main justification for retaining some form of COM oversight over the process was the need to ensure a harmonised approach across the EU, and that all MS comply with the minimum CP requirements as laid down in the Control Directives. For those supporting this option, the idea is for the COM to create a general framework for CP drafting/updating, but to leave some degree of flexibility and freedom to MS to develop their national CPs, and to verify this via more regular peer reviewing by FVO inspections:

[57] The MANCP describes the strategy for a certain time period that MS develop in order to guarantee an efficient result of controls and compliance with food legislation by operators.

- The general framework outlined above could be established through the development by the COM of an up-to-date *'light and alive'* system of guides of good/best practices, which could fit into the development by the COM of guidelines to assist MS to adapt CP requirements to the national situation (see recommendation 2 of Theme A). The added value of having in place such guidance for animal health contingency planning is illustrated for example by the *FAO Good Management Emergency Practices (GMEP)*, which appears to have been well accepted by countries supported by the FAO/OIE Crisis Management Centre for Animal Health (CMC-AH)[58];
- The call for more FVO involvement in the review of CPs could be addressed by making FVO CP verification missions more frequent, so that CPs in all 27 MS could be evaluated and assessed over a 5 year period. This would result in an additional requirement of 2 more inspectors at the FVO AH unit (see recommendation 1 of Theme E).

3. Other possible EU level actions aimed at ensuring high quality contingency planning and emergency preparedness throughout the EU include training and workshops, both of which can foster the exchange of experience and best practice across the EU. In this context the systematic training on contingency planning foreseen for 2012-13 is considered a very positive development (**EQ B/6**). The lessons to be learnt from a more regular review of the CPs by the FVO could fit into both the BTSF training and other workshops organised on contingency planning.

[58] The Centre is set up by the FAO/OIE to provide a rapid response mechanism for transboundary animal disease emergencies. It provides technical and operational assistance to help governments, particularly in developing countries, develop and implement solutions to prevent or rapidly control disease spread.

4 Theme C: Exchange of information on outbreak evolution at SCoFCAH meetings

4.1 Background

The specific objective of this theme is to assess the added value of SCoFCAH in terms of providing an opportunity for exchange of information and communication. It also includes sub-questions concerning the relevance and effectiveness of the EU Veterinary Emergency Team and the relevance/utility of adding any other support mechanisms to SCoFCAH such as the introduction of a crisis unit for animal health similar to that in place for food/feed crisis management.

The SCoFCAH has a regulatory/legislative role, which includes the approval of CPs (theme B), and the endorsement of containment measures put in place by MS (theme D). In carrying out this role, the SCoFCAH provides also the opportunity for information exchange, on the basis of which decisions are taken. Therefore, themes B, C and D of the evaluation are interlinked, in particular when considering efficiency issues.

4.2 Findings

4.2.1 Assessment of the relevance and efficiency of the current exchange of information on outbreak evolution at SCoFCAH meetings (EQ C/1, C/2, C/3 and C/4)

C/1 To what extent are the procedures still adequate taking into account subsequent changes and progress regarding especially communication tools?

Indicator 1: MS considering the procedures can be improved and reasons why

The results of the FCEC survey show that, overall, MS are satisfied with current procedures for the exchange of information on outbreak evolution at SCoFCAH meetings; as a result, 20 MS do not consider there is a need to improve current procedures, whereas 7 MS consider there is a need (Q 13.b – FCEC survey results). From the case studies, the majority of MS CAs visited (6 out of 10 MS) do not consider there is a need to improve the current process of exchanging information. This is further discussed in EQs C/5 to C/8.

Indicator 2 and 3: Advantages and disadvantages of potential communication tools and of potential improvements

The COM considers SCoFCAH irreplaceable, but sees that the information provision may need to be streamlined (e.g. by videoconferencing; presentations/relevant documents circulated in CIRCA; EFSA real time updates). These tools are discussed below.

In particular, in view of progress regarding especially communication tools, the possibility to replace part or whole of the physical meetings by videoconferencing was raised; it was therefore important to test MS response to this possibility. However, some doubts were

expressed regarding the feasibility of videoconferencing with 27 MS, due to the reasons below:

- Potential legal impediments to decision making, due to uncertainty as to the legal status of video-voting as such;
- Problems in the clarity of communication due to the lack of translation and body language;
- Potential training required for participants inexperienced with videoconferencing.

Some smaller-scale potential improvements of the meetings were also raised during the interviews, regarding online information. At present much email communication occurs between the COM and MS, e.g. invitations to the meeting, the sending of presentations by MS before the meeting and the posting presentations after the meetings. The COM explained it was currently looking at the possibility of using CIRCA, the Commission intranet, for exchanging information internally and organising the exchange of information prior to SCoFCAH meetings.

In more detail, the following potential improvements in communication tools were analysed:

a) Communication via email

Some MS indicate that if a single decision needs to be voted then this could also be achieved by email, and that information exchange on outbreaks could also occur by email. However, email should not be relied upon alone according to other MS: at present, these MS often receive information from the COM by both email and fax. They consider it beneficial to receive information by both media; given the very large number of emails that the CVO receives, it is possible that information sent by email is not seen immediately, thus sending information by fax acts as a safety net.

b) Communication via videoconferencing

Despite the possibility suggested by the COM of replacing part or all of the SCoFCAH meetings with videoconferencing, many MS do not find that videoconferencing would be an adequate complement or substitute. Many MS highlight the importance of informal sharing of views, achieving comprise, knowledge exchange and networking that can only be achieved in person.

More specifically regarding the advantages and disadvantages of videoconferencing from our case studies:

- Several MS report that it is much more comfortable to meet in person as there is substantial added value in networking outside of the meeting, and it is easier to reach a compromise when participants are present in the same room. In addition, MS cite useful discussions with the microphone switched off between both the COM and MS as well as amongst MS, which would not be possible in a video conference. Further, other MS find there could be technical difficulties with videoconferencing; or that videoconferencing is not adequate when too many participants are present, as was the case during the BT outbreaks in 2007 according to one MS.

- On the other hand, some MS favour the use of videoconferencing as an additional tool. They note that unlike SCoFCAH meetings in person, several competent staff of the animal health unit in the MS CAs can participate in a videoconference and ask questions that cover various aspects of the situation. An argument that may support use of videoconferencing is a successful example of teleconferencing that one MS notes of conferences organised at the level of the technical committee following the E. coli crisis, which allowed a continuous exchange in real time between large numbers of participants: meetings were conducted on a daily basis for roughly 2 weeks and on average 1 hour/day, to which at least 2 experts from each MS of all EU-27 (therefore in excess of 50 people) participated. Nonetheless, these MS note that the use of this tool should go hand in hand with good preparation and steering on the part of the COM/participants, as well as reliable technology, also because there could be problems with translation.

The COM confirms the added value of meeting in person in terms of easily exchanging information during and outside meetings, as well as engaging in bilateral discussions, which would be difficult with videoconferencing. The COM also notes that videoconferencing could create interpretation problems. If the agreed language is English, there may be loss of expertise from MS experts who are not competent in English, which would not occur when meeting in person thanks to interpretation services.

The COM further reports that there is already substantial flexibility in modes of communication. The COM possesses an exhaustive list of MS contacts to contact in cases of emergencies via email and fax. In addition, teleconferences are already in use (if rarely): if, for example, there is a limited number of MS that need to exchange views, a teleconference can be organised via the 'Arkadin' system. The COM suggests however that videoconferencing could be required when an urgent outbreak has occurred concerning a small number of MS, and there is not sufficient time for any other procedure.

Nonetheless, one area where video communication could be used to increase efficiency is in video-linking to experts located in MS, the COM suggests. Considerable savings could be achieved if experts could provide their input via video-link instead of physically attending the meeting- especially in the case of a short contribution. Video-links are in fact already used by EFSA within certain committees. Indeed certain conference rooms used by SCoFCAH are equipped for video-links; as such this would be easily implementable.

c) Use of CIRCA for document handling and circulation

Contrary to videoconferencing, no MS from the case studies is doubtful about the potential greater efficiency from further use of CIRCA, the Commission intranet, in order to facilitate the circulation of documents. A number of MS consider that pre-meeting circulation of documents in CIRCA would improve the exchange of information at the meetings, since in the past the relevant documents have sometimes arrived too late to be reviewed before the meetings. CIRCA may therefore be a quicker form of circulation.

The COM also considers CIRCA could be further made use of on animal health issues, as it has already proved efficient when used by other committees. Each MS would have access to the intranet via a password, which would allow the MS to upload documents to the database.

This would increase efficiency as almost all documents could be circulated to MS prior to the meetings, with only last-minute documents being distributed at the meeting. Also, currently MS usually either bring their presentations to the meetings on a memory stick or send them via email, but memory sticks can be lost, and a key problem with email exchange is the size of documents that can be sent. Uploading presentations to CIRCA prior to the meeting would solve these problems. Finally, no legal change would be required to use CIRCA for these purposes, simply a change in practice.

C/2 To what extent do MS consider efficient this legislative obligation regarding the exchange of information taking into account the administrative constraints involved (pros and cons)?

The objective of MS attending the SCoFCAH meetings is to take decisions (voting). This is done on the basis of information distributed and exchanged between COM/MS prior to the meeting as well as on the basis of MS presentations (by the MS having the outbreak) and information exchange (with the COM and other MS) during the meeting. The purpose of this question is to understand how much more time and costs this information exchange requires.

Usually, one AH SCoFCAH meeting is organised per month. However, in times of crisis the frequency can as high as twice a week. Therefore the main *additional* costs for both MS and COM are the meetings that occur in addition to the regular meetings.

The costs associated to SCoFCAH meetings include administrative costs for the COM (in particular translation costs) and the MS, and travel costs for one representative of the MS to attend the meetings (which is fully reimbursed by the COM; additional experts may attend but at the cost of the MS):

- The total cost of reimbursement of travel is between €10,000 and €15,000 per meeting.
- An interpreter is reported to cost €442 for half a day. As typically an AH committee meeting lasts two days, and 2 interpreters are required per language at the same time, and a standard of 6 languages are covered (English, French, German, Italian, Spanish and Dutch), then total interpretation costs per AH meeting could theoretically amount to €21,216.

Furthermore, efficiency should take into consideration both administrative and budgetary constraints/costs. Also, to properly determine the efficiency, the additional costs of information provision at SCoFCAH need to be compared against the benefits of this activity, i.e. its added value (which is further discussed under EQ C/4).

Indicator 1: MS considering the legislative obligation to exchange information efficient given administrative constraints (obligations to update) and budgetary constraints (e.g. travel to Brussels).

The FCEC survey indicates that taking into account technological progress, regarding communication tools in particular, as well as administrative/budgetary constraints, a majority of MS consider '*Information exchange (SCoFCAH) for MS having an outbreak (obligation to inform)'* as currently taking place at SCoFCAH meetings to be very efficient (14 MS, with another 8 MS finding it fairly efficient).

However, a number of MS from the case studies note that there are certain costs to attending the meetings that could thus reduce the efficiency of this legislative obligation to provide information. As the COM only reimburses travel expenses for one representative, MS wishing to send additional representatives are required to bear the expenses themselves. Some MS therefore only send one participant, due to budgetary constraints. This in spite of the fact that several MS highlight the need for more than one participants to attend: they consider that one representative is not sufficient to undertake all the discussions, and would generally send two representatives (e.g. because some subjects may require knowledge that goes beyond one participant's competencies or expertise, and it regularly happens that e.g. details concerning draft texts have to be discussed bilaterally with the COM or other MS during the session).

Other MS report that significant time and costs are involved in providing information at the meetings (e.g. in preparation of information, and afterwards for follow-ups and informing colleagues who did not participate) but this time is generally considered to be well spent, and the obligations to update on national animal health status at the meetings is generally not considered a source of inefficiency.

Finally, some MS indicate that in some cases due to the information exchange at SCoFCAH, the meetings last longer than expected and thus MS representatives miss their return flights or, more important, have to delegate their vote to another MS, which can result in missing strategic decisions in some cases.

C/3 To what extent do Commission services consider efficient this legislative obligation regarding the exchange of information taking into account the administrative constraints involved (pros and cons) and the existence of the ADNS (ADIS) system?

One of the key activities of the rapid response network concerns notification of outbreak occurrence by the affected MS to other MS and the COM. In order to ensure a rapid exchange of information between the national CAs responsible for animal health and the COM on outbreaks of contagious animal diseases, the EU has provided the legal basis (Council Directive 82/894/EEC) for a computerised information system (ADNS) which alerts COM services and MS CVOs, within 24 hours of confirmed primary outbreaks. Annex 1 of this Directive lists the animal diseases subject to notification. This system permits immediate access to information about contagious animal disease outbreaks and ensures that trade in live animals and products of animal origin are not unnecessarily affected.[59]

A particular issue to examine in this EQ is the difference between the information provided at SCoFCAH and that available at the level of ADNS, bearing in mind that it is important to avoid duplication of efforts made to provide this type of information. Exploratory interviews showed that *a priori* the information provided at SCoFCAH appears to be complementary to that provided by ADNS – although MS have full access to ADNS, ADNS is not a forum of information exchange, it is not interactive. However, ADNS in itself is evolving to the new ADIS (Animal Disease Information System) which will eventually replace the current

[59] For the risk notification on food and feed the European Commission put in place the RASFF (Rapid Alert System for Food and Feed) whereby MS, EEA-EFTA countries and the COM share information on food and feed which may present a risk to public health.

ADNS. The COM suggested that the ADIS will be a broader database (of which, ADNS will be one part), and will present data in a more accessible way. Therefore one possible option raised was that ADIS (when currently pilot ADIS becomes operational) could be built and developed on purpose to also replace elements of SCoFCAH. For example, a possibility would be to further develop ADIS to add presentations; and then later include information given in response to questions by MS CAs (i.e. make it more interactive).

ADNS is to be replaced by ADIS (Animal Disease Information System), in 2014. Its stated objectives are to improve the collection, the processing and the use of information on animal health; provide for a one entry platform with no duplication for MS; manage data on animal health that are compatible and fit for use for different purposes; achieve standardisation and harmonisation of information on animal health; and facilitate EU MS to fulfil their obligations towards the OIE as regards WAHIS. The future users of ADIS are to be EU MS / members of the OIE that submit data to the system; officials of the European Commission, the OIE and the MS that process the data; officials that use information from ADIS; and stakeholders and general public that consult the information on the public domain. It will bring systems from both the European Commission (e.g. Animal Disease Notification System, EU co-financed programmes, reporting of diseases under Directive 64/432, AI surveillance reporting) and the OIE (WAHIS Immediate Notifications, WAHIS Reporting on presence/absence of animal diseases) under its scope.[60]

Indicator 1: Type of information exchanged at SCoFCAH that could not be made available through ADNS (ADIS); reasons why.

The COM considers SCoFCAH and ADNS to be fully complementary. It indicates that the substance of the information provided by the two means regarding outbreaks is identical, however the information submitted through ADNS is objective, 'hard' data (e.g. regarding number of animals affected, farms concerned, which pathogenic agent was present), whereas when presented at SCOFCAH, it is accompanied by contextual information. The COM reports that MS at SCOFCAH 'add layers of information' to complement the objective information provided by ADNS in order to obtain a fuller picture (e.g. by offering hypotheses about how outbreaks occurred, presenting the information in a certain manner on a map, etc.). It is this contextual information provided by MS that could not be made available by ADNS (or the future ADIS), as it depends on MS' interpretations and the exchange of opinions.

Indicator 2: Elements of information exchanged at SCOFCAH that could be replaced by the future ADIS.

ADIS will be a tool that will allow MS to report through a single window all information related to animal diseases that is currently reported through different systems such as ADNS and WAHIS (OIE) and other EU notification or reporting systems (see background above for further information). The COM considers it will avoid overlapping, duplication and divergence that could occur from reporting events to different systems, and thus will also save much effort and resources.

[60] Information from European Commission 2012, Animal Health Advisory Committee 14 February, Animal Disease Information System.

However, the COM highlights that ADIS will not induce a dramatic change from the current situation. The functions of ADIS and SCoFCAH will still be complementary, as in particular ADIS will not replace essentials parts of the discussion at SCoFCAH meetings, concerning the provision of 'richer', contextual information.

The information relating to outbreaks will still be presented with geo-coordinates as it is now in ADNS and WAHIS, and the system is intended to be a decision-making tool by making the link between the system of notification of diseases and the TRACES system. The COM specifies that ADIS is not intended for handling and circulating documents. Nonetheless, the final form of ADIS is still to be determined; only a prototype has been completed to date.

C/4 What are the relevance and effectiveness of SCoFCAH as information exchange forum both from the point of view of a MS having an outbreak (obligation to inform) and from the other parties (opportunity to get information)?

Interviews with the COM indicate that SCoFCAH's added value includes:

- technical epidemiological discussion;
- sharing of experience and in-depth scientific discussion at peer level;
- information provided at meetings is considered official (although it may not be necessarily public) and subsequently informs the decision-making;
- it provides room for clarifications;
- direct contact allows informal exchange between MS.

SCoFCAH was considered relevant (it offers an added value) and effective (i.e. decisions can be taken, only following/based on the information exchange); however, not necessarily efficient.

A key issue for this EQ was therefore to examine whether MS share the views of the COM on the added value of this information exchange. Another issue to explore was whether stakeholders had the intention of creating an analogous forum for information exchange in the case of emergencies, and whether/how they benefit from the information that emanates from the SCoFCAH meetings.

Indicator 1: The extent to which MS and COM consider SCoFCAH relevant and effective as an information exchange forum for a) MS having an outbreak (obligation to inform); b) other MS (opportunity to get information on outbreaks); c) for further use by MS/COM of the information obtained in the discussion/ communication with TCs and stakeholders; arguments for and against the procedure

The majority of MS consider information exchange as currently taking place at SCoFCAH meetings to be very relevant, whether it be for '*Information exchange (SCoFCAH) for MS having an outbreak (obligation to inform)'* (21 MS, with 3 finding it fairly relevant), '*Information exchange (SCoFCAH) for other MS (opportunity to obtain information on outbreaks)'* (22 MS, with 3 finding it fairly relevant), or '*Information exchange (SCoFCAH) for further use by MS/COM of the information obtained in the discussion/ communication with TCs and stakeholders'* (15 MS, with 10 finding it fairly relevant) (Q 13.a – FCEC survey). There are only slightly fewer MS finding the information exchange for the above

criteria to be very effective: *Information exchange (SCoFCAH) for MS having an outbreak (obligation to inform)'* (20 MS, with 4 finding it fairly effective), '*Information exchange (SCoFCAH) for other MS (opportunity to obtain information on outbreaks)'* (21 MS, with 3 finding it fairly effective), and '*Information exchange (SCoFCAH) for further use by MS/COM of the information obtained in the discussion/ communication with TCs and stakeholders'* (13 MS, with 11 finding it fairly effective). It should also be noted that both from the point of view of a MS having an outbreak (obligation to inform) and from the other parties (opportunity to get information), no more than 2 MS consider the exchange to be less than fairly relevant and fairly effective.

From the case studies, overall MS find that SCoFCAH is an essential information exchange platform, in particular as it offers the possibility to ask and answer questions immediately, and share views and experiences. One MS notes that if, for example, a MS had to organise the slaughter of a large number of animals during a small period of time, SCoFCAH provides the opportunity for the other MS to know how this was achieved in practical terms. Also, as discussed in EQ C/1, many MS also highlight the importance of the informal exchange of information that occurs outside of the meetings (e.g. during breaks or after the meetings). The COM also highlights the advantages above, while noting in addition the possibility of engaging in bilateral discussions as well, and the fact that MS have the flexibility to make use of the meetings as they choose.

However, some MS do not find SCoFCAH as a meeting for information exchange particularly effective in fulfilling the obligation of the MS having the outbreak to inform and for the other MS to be informed**.** In particular, these MS do not consider information exchange at SCoFCAH to be sufficiently precise or detailed and is relatively limited at technical level. Furthermore, these MS find that information exchange is inevitably constrained by the timing (e.g. too much information for one day) and the frequency of the SCoFCAH meetings. One MS also finds that at present the amount of information at SCoFCAH which has to be analysed and discussed is considerable: often there are as many as 30 points to be discussed during a meeting, and this may include very long draft legal acts. Finally, another MS finds that SCoFCAH meetings as an opportunity for information exchange are not very relevant for an MS actually undergoing an outbreak, as this information could easily be relayed by that MS by email.

Further, several MS note that it can be difficult to read all documents before the meeting; documents are commonly received roughly ten days in advance, but sometimes they are received only one day in advance or even during the meeting (see answer to EQ C/1 regarding possible improvements to this via use of CIRCA).

The COM acknowledges that the running of SCOFCAH requires much effort and resources from the COM and MS. For example, if the agenda is too long, especially if there is a mixture of points of discussion and points for vote, MS may have difficulty following it, especially if they do not have the necessary expertise (as discussed in answer to EQ C/2). In terms of potential efficiency gains, the COM reports that it is working on trying to make the meeting days shorter (e.g. instead of 2 days, 1 day and a half or 1 day) and save resources by reducing the number of meetings. However the COM considers that the current number of meetings during crisis situations (e.g. 2 or 3 times per month) is indeed necessary.

One key issue that one unit of the COM raises is whether a committee designed to have legislative power such as SCoFCAH should also be a place for information exchange. The institutional duties of SCoFCAH may not be clear enough, and the primary legislative function of the committee could become diluted by its additional de facto function as a place for information exchange. There may therefore be a need for a more strict separation between the information exchange aspect of the meeting (which would still need to occur in some manner for MS to make informed decisions, the COM highlights) and the voting function.[61]

As an example of other possibilities for information exchange, the COM notes that in the more general framework of crisis preparedness, there are mechanisms for the exchange of general information from MS and COM, as part of food and feed crisis management. If AH is relevant in that context, then the exchange of information can take place through standard operating procedures in the general plan. Regarding the sharing of more technical information, a group of experts may be better placed for this (e.g. a technical working group – see EQ C/5 for further discussion of this by MS), the COM suggests.

Nonetheless, if the COM finds that in principle it could be possible to divide the information exchange and voting functions of the committee, it may also be preferable to keep them together as they currently are, for a number of reasons indicated below:

- Firstly, because MS can discuss with one another in order to have the necessary information to make informed choices about legislation e.g. containment measures.
- Through such discussion, a MS can gain credibility in the information exchanged in order to influence a vote in its favour (e.g. regarding lifting restrictions in this MS). In particular, a point of discussion earlier in the meeting could create the necessary confidence to influence a point of vote later in the meeting.
- When exchanging information there is almost always a decision to be made. It can be regulatory (e.g. endorsement of a draft legislative text), or it can be choosing to take no action (e.g. because an MS having an outbreak has made a credible and reliable presentation of the containment measures taken). In the latter case this can still be considered an action, because there is an exchange of information that has induced discussion, but the COM may not need to submit a text to a vote if the discussion is deemed sufficient.

Finally, the COM highlights that even if there were no information exchange, one would still have to have a monthly meeting for SCoFCAH e.g. for the prolonging of legislation, endorsing interim protection measures taken by the COM. It may not necessarily be emergencies, e.g. deciding on measures to take about outbreaks from distant TCs. Hence, placing the information exchange aspect elsewhere than SCoFCAH may not necessarily create efficiency gains.

[61] The COM stresses that this is more of a concern for issues not related to the adoption of emergency containment measures, since in the case of emergencies information exchange is vital for the voting of legislation.

Indicator 2: Evidence of past cases where the information exchange at SCoFCAH has made an impact in managing an emergency situation, that could not have been achieved in another way (in particular through reliance on ADNS/ADIS only)

According to one MS, information provided at SCoFCAH has been found crucial in all major crises. For instance, in the cases of FMD in the UK and AI in the Netherlands, the exchange of information at SCoFCAH helped the MS CA analyse all information systems and activate the traceability of live animals and animal products. This allowed it to assess the risk and send local veterinarians for controls.

Benefits from the exchange of information at SCoFCAH have been also found in the recent outbreak of the Schmallenberg virus. The information provided has allowed the above MS CA to identify the number of breeding animals imported from the affected MS. This information has been then communicated to the local authorities, which have carried out controls in the holdings containing the animals coming from the affected MS.

The exchange of information at SCoFCAH is also considered good for MS adopting measures to see if other MS are satisfied with them. During the 1999 AI crisis, the Italian CAs wanted to understand whether the other MS were satisfied with the measures taken in Italy.

Other MS note that the SCoFCAH meetings have also proven useful in the case of an outbreak of a non-notifiable animal disease. During the Q fever crisis and the more recent outbreak of the Schmallenberg virus in the Netherlands, the SCoFCAH organised a meeting with all MS where new guidelines were discussed and a fund for research was allocated.

Finally, one MS gives the example of the BT crisis where BT experts at SCoFCAH explained to the CA the outbreak, the evolution of the disease and the latest information in details - information that the CA would have otherwise obtained with difficulty since BT did not break out in that MS. The CA highlights that it is important to be well informed about other diseases such as BT, in case it had broken out in its MS.

Most MS visited consider that SCoFCAH provides the opportunity for much more detail than ADNS, in particular on measures taken and CAs' interpretation of the situation, and being able to interact with the speaker and ask questions. Some MS find ADNS should be more exhaustive in order for MS to depend less on the information provided at SCoFCAH. ADNS is indeed still seen to be inadequate information for the purposes of making decisions, meaning that without information from SCoFCAH CAs would run the risk of taking disproportionate measures.

Indicator 3: Extent to which stakeholders have benefitted, during emergency situations, from information provided through SCoFCAH

Overall, stakeholder organisations consulted in each of the MS find the information on outbreak evolution provided through SCoFCAH useful. Stakeholder organisations generally obtain information from the SCoFCAH meetings either from the MS CA or from the association representing their interests at EU level in Brussels, whether this would be a formal or informal procedure.

National stakeholder organisations as well as European-level stakeholder organisations broadly find that SCoFCAH's communication had improved: they cited the example of the Schmallenberg virus outbreak, for which SCoFCAH was found to be quick to provide detailed information (as opposed to during the outbreak of BT in 2007, according to some national stakeholder organisations). Another example is the presentation at SCoFCAH provided during the of FMD outbreak in Bulgaria in 2011, for which one national stakeholder organisation outside this country indicated that the complete information allowed their members to verify that the disease was well managed.

However, the main problems cited by some national stakeholder organisations included the late publishing of minutes of the meetings, and little information from their respective CA as to the outcomes of meetings. Stakeholders were also in broad agreement that it would be useful if they could receive dedicated information. Sometimes they found that information could arrive with a few days' delay or that information in the media is quicker. Stakeholder organisations also indicated that the SCoFCAH website could be improved, e.g. by being more user-friendly, by having a dedicated section for stakeholders, and by more clearly marking updates. Also, EU stakeholders report they are not able to join SCoFCAH meetings which limit access and the sharing of more targeted information. They consider further participation of EU stakeholders during specific outbreaks could ensure a better exchange of views with MS authorities, and help disseminate information across to national-level stakeholders

Indicator 4: Extent to which stakeholders find an equivalent forum at EU stakeholder level for information exchange on outbreak evolution necessary, and, if yes, what form could this take.

Stakeholder organisations consulted in the MS case studies are divided as to the need for an equivalent forum at EU stakeholder level for information exchange on outbreak evolution. Those national stakeholder organisations that do not support such a forum consider such an arrangement is already possible on stakeholders' own initiative in an informal manner through stakeholders' EU representative associations, that there are enough platforms in place and there is no need to create additional ones, and that it was better to receive official information from one source (SCoFCAH).

On the other hand, those national stakeholder organisations that do find an equivalent forum at EU stakeholder level necessary for information exchange generally support the creation of a working group within the SANCO Animal Health/Animal Welfare Advisory Committee. The main advantage of such a working group would be to receive precise information from the COM and CAs more quickly, to allow MS CAs and stakeholders to 'learn from each other' (e.g. by exchanging knowledge from areas where they are respectively more competent), and having a direct line into/link to SCoFCAH, as for one several stakeholder organisations it is particularly important that the grassroots impacts of SCoFCAH decisions were well understood. This would be further facilitated if stakeholders could be given observer status at SCoFCAH meetings.

4.2.2 Other tools for information exchange (EQ C/5)

C/5 What other more appropriate, effective, efficient and less time consuming systems for *crisis communication* and sharing information could be suggested? (CVO meetings, technical group, creation of a special unit with countries concerned by a specific disease in view to coordinate actions, template for an epidemiological report, video conference, on line information)?

In terms of crisis communication as such, this is a different issue from information exchange - refer to theme F for communication issues.

Indicator 1: MS that consider the listed systems appropriate, efficient and effective for sharing information; arguments for and against each of the suggested systems

At present, only a minority of MS indicate that current procedures could be improved (7 MS) (Q 13.b – FCEC survey); of those, 5 MS consider a '*Technical group (COM/MS)*' to be a very relevant alternative option in providing the required background to the decision-making process at SCoFCAH, 4 MS find it would be very effective, and 3 MS find it would be very efficient (Q 13.c.1 – FCEC survey). The second most preferred addition to provide the required background to the decision-making process is a '*Template for the epidemiological report provided at SCoFCAH',* with 3 MS finding it very relevant, 3 MS finding it very effective and 3 MS finding it very efficient. The other options considered ('*CVO meetings (including information exchange)', 'Creation of a special unit with countries concerned by a specific disease to coordinate actions',* and *'Video conference')* are not found to be particularly relevant, effective or efficient in providing the required background to the decision making process (with no more than 1 MS finding them either very relevant, very effective or very efficient).

The case studies revealed different preferences from MS as to potential alternative options to provide the required background to the decision-making process. However, most MS visited do not find that that any of the suggested potential alternative options would be replacements to current information exchange practices at SCoFCAH (as also concluded by the FCEC survey), but some may be complementary to the existing practices (see also indicator 2 of EQ C/5).

Some MS find that none of the potential alternatives listed could replace the information exchange at SCoFCAH, but suggested a *technical group at COM level* would be most useful as an additional tool in providing the required background for the decision-making process. It reported that sometimes MS may have a very different point of view on a topic, both from each other and from the COM, and therefore have difficulty coming to consensus during the SCoFCAH meeting, often because the MS representatives at SCoFCAH at any given point are competent and responsible in only certain areas. There may therefore still be need for discussion beyond SCoFCAH meetings, in which case it could be useful to submit a draft text to a working group, where the relevant experts are invited to participate in order to clarify issues and provide an objective standpoint. A positive example provided by MS is the technical group convened during the BT outbreak in 2007. Finally, the COM considers technical groups serve as a useful additional tool; they have proved useful when organised on an ad hoc basis, whenever the COM sees the need for additional input, and increasingly via audio conferences through the 'Arkadin' system.

For other MS, developing a template for the epidemiological report provided at SCoFCAH is considered as the best option to improve the relevance, the effectiveness and the efficiency of the exchange of information at SCoFCAH, as it allows information to be standardised and objective for all MS CVOs and to be communicated at local level. Also, this gives the opportunity to MS to be prepared in advance and thus overcome some terminology issues due to the translation. Some MS have often received information by emails and faxes in the language of the MS affected, which could not be understood. It would therefore be good to have a template with information in English. A reporting template is indeed already in use by the UK and there is also a high level briefing paper (CRIP[62]) for domestic use which responds to this need; the use of this template could be applicable at EU level, but EU guidance on how to use it would be needed. It is also noted that using a standard template for the reporting improves the process of exchange of information, although this cannot on its own replace SCoFCAH meetings, and has to be in addition to putting into place a technical group COM/MS.

The other options considered to be the least relevant, effective or efficient in providing the required background to the decision making process were '*CVO meetings (including information exchange)', 'Creation of a special unit with countries concerned by a specific disease to coordinate actions',* and *'Video conference'*, as follows:

- *Information exchange during CVO meetings* is considered not very effective or efficient by some MS, as CVOs may not always be available at short notice and the discussion at CVO meetings cannot be at the level of technical detail required and/or may not achieve the goals at reasonable cost. Further, concerns are voiced by the COM that a CVO meeting would not necessarily be more useful for information exchange as this would not allow measures to be voted on as a CVO meeting is not a standing committee. It is stressed that CVO meetings are essentially the opportunity to discuss policy and reach consensus. But the COM also notes that CVO meetings can be useful if there is a dispute regarding a text at SCoFCAH, in which case the discussion can be elevated to a more political level at CVO meetings.

- Regarding the *ad hoc creation of a special unit for countries concerned by a certain disease*, the COM reports that such an approach has already been undertaken following the recent Schmallenberg virus outbreak. It was delegated by SCoFCAH, and this unit would then report back to either SCoFCAH or the concerned CVOs. Such a unit was found useful because a SCoFCAH meeting would not normally allow for more than one hour of discussion on a given disease among MS, therefore further discussion among concerned MS could take place in the context of such a unit. Such special units are seen to be straightforward and simple to organise by the COM, and have worked well.

- The use of *videoconferencing* is also largely not favoured by MS, many of which have not had good experiences with videoconferencing, as further discussed under EQ C/1 indicator 2.

[62] The Commonly Recognized Info Picture (CRIP) – applicable to all types of emergencies – is provided in ppt form to give basic data and info on the emergency; this is the briefing paper for the highest political level (Minister/Prime Minister).

On the other hand, some MS called strongly for additional platforms and/or tools to facilitate the current information exchange at SCoFCAH, as a real network to handle emergencies at EU level is seen to be missing. According to these MS CAs, despite SCoFCAH meetings and bilateral ad hoc contacts with SANCO or between MS in the case of emergencies, valuable time can be wasted in that these meetings by definition pass through higher political levels (e.g. CVO or SCoFCAH or SANCO) and there is less direct and informal technical exchange between desk officers at MS and SANCO level. They therefore see the need for other additional platforms and/or tools that would provide a more regular and detailed technical exchange (such as on the implementation of the measures e.g. culling and disposal methods). In this context, the role of the EU Veterinary Emergency Team and the establishment of a crisis unit similar to that for food and feed safety were explored further under EQ C/6 and EQ C/7, respectively. A *rapid alert system* such as that presently in place for food safety emergencies is indicated as a potential example to follow for animal health emergencies. In particular, this would include a RASFF[63]-type tool to share information and a rapid alert team (i.e. a crisis unit as discussed in EQ C/7). This rapid alert system would be designed to work harmoniously with SCoFCAH, to avoid the risk of having in place parallel structures that do not communicate or overlap with each other.

Indicator 2: MS considering the listed systems above could partly or totally replace the current information exchange through SCoFCAH

Of those MS that find that that current procedures could be improved (7 MS), 3 MS find that a '*Technical group (COM/MS)'* could fully replace the current information exchange procedure at SCoFCAH, and 3 partly replace it (Q 13.c.2 – FCEC survey). Next, 1 MS finds that '*CVO meetings (including information exchange)'* could fully replace the current information exchange procedure at SCoFCAH, and 5 partly replace it. Other options, *Template for the epidemiological report provided at SCOFCAH', Creation of a special unit with countries concerned by a specific disease to coordinate actions',* and *'Video conference',* were less preferred as either 2 or 3 MS find that these options would not at all replace the current information exchange procedure at SCoFCAH (as opposed to 1 MS for the above two).

Overall, most MS consider that the suggested options could only serve a complementary role to current information exchange practices at SCoFCAH, but not a replacement.

4.2.3 Additional mechanisms and/or structures for providing support to the information exchange currently provided at SCoFCAH (EQ C/6, C/7 and C/8)

C/6 What are the relevance and effectiveness of the existence and missions of the Community Veterinary Emergency Team (Commission Decision 2007/139/EC)?

In order to improve the crisis management mechanism, in 2007 the COM adopted a Decision (Commission Decision 2007/142/EC)[64] to establish the Community Veterinary Emergency

[63] Rapid Alert System for Food and Feed
[64] Commission Decision of 28 February 2007 establishing a Community Veterinary Emergency Team to assist the COM in supporting MS and third countries in veterinary matters relating to certain animal diseases (2007/142/EC).

Team (CVET; now EU-VET). This team, made up of animal health experts, is available at short notice in order to provide the support to respond rapidly to major animal disease outbreaks in the EU and third countries.

Each MS submits lists of experts they propose for the emergency team and the Commission selects ad hoc team members in the event of an animal disease crisis. At present (2011), the emergency team consists of 101 experts from several MS. Within the EU territory, the emergency team has completed several missions in the case of major crises, including of CSF, BT and FMD (**see Table 1**). In the case of the most recent outbreak, the FMD outbreak in wild boars and domestic animals in Bulgaria in 2011, the team promptly assisted the MS by visiting the region of Burgas, where the disease outbreak had been reported, to help with further enquiries.

Indicator 1: The extent to which MS and COM consider the CVET missions relevant and effective, and reasons why

According to the FCEC survey, most MS find CVET missions relevant and effective: 10 MS find CVET missions very relevant and 13 fairly relevant in providing additional support to the information exchange (from a total of 23 responses); and 8 MS consider CVET missions very effective and 14 fairly effective in providing additional support to the information exchange (from a total of 24 responses).

However, some MS consider there may be a need to better outline the CVET's role i.e. whether its purpose is to assist in crisis management or monitor whether all legislation has been laid down according to the Directives. Some MS also consider CVET missions to be excessively time consuming as they take too long to set up; therefore they are not found to be appropriate for immediate emergencies. But MS note the importance of the CVET missions as providing an objective point of view on an outbreak, independently of the information the MS in question provides at SCoFCAH, and thereby it provides other MS with more certainty. The information flow from the CVET missions to SCoFCAH may need to improve though, as one MS reports that information from CVET missions is not communicated to SCoFCAH.

The COM reports that the small number of CVET missions so far is related to the relatively tranquil AH situation of the past few years, not that MS are not satisfied by them. The COM's experience with CVETs has so far been good, in terms of feedback from MS where CVETs were active. The COM supports the now formal coverage of the CVETs, whereby CVET experts are chosen in an institutional manner. However the COM admits there is no hard evidence to show that CVET missions have prevented outbreaks from becoming a crisis. The CVET's functions will be institutionalised in the new Animal Health Law.

Indicator 2: Concrete examples/cases where the CVET missions have played a key role in MS' response to an outbreak

During the BT crisis in 2008, the CVET carried out a mission in the Netherlands;[65] specifically to study the presence of the new serotype BTV type 6. This mission is recalled as

[65] European Commission **http://ec.europa.eu/food/animal/diseases/controlmeasures/docs/BT_netherlands_report.pdf**, retrieved on 25 February 2012

very helpful and it led the Dutch CA to provide a well-balanced and appropriate response to the outbreak.

CVET missions are considered very relevant by some MS due to the very experienced personnel who can guide the less experienced CAs in difficult situations. As an example, the Romanian CA cites the situation in Bulgaria with wild boars in late 2011 – the actual sequence of events was better understood thanks to the CVET team having visited Bulgaria. It is also indicated that it is very useful for MS to have this tool available in case the relevant experts for a given disease are not present in the MS at the time of the disease outbreak.

C/7 What is the relevance of additional/support mechanisms and/or structures for SCoFCAH (such as establishment of a crisis unit similar as laid down in Commission Decision 2004/478/EC)?

COM Dec 2004/478 foresees the establishment of a crisis unit (involving COM, EFSA and MS) to deal with 'crisis situations' in food and feed safety. However, the standard operating procedures of this unit are still being finalised.

Indicator 1: Extent to which MS and COM consider a crisis unit to be a relevant mechanism in addition to SCoFCAH; arguments for and against

According to the FCEC survey, 10 MS find a crisis unit would be very relevant in providing additional support to the information exchange currently provided at SCoFCAH, and 11 fairly relevant (from a total of 22 responses).

The French CA considers that a crisis unit would indeed be a relevant mechanism in addition to SCoFCAH as part of a rapid alert system such as that presently in place for food safety emergencies (in an improved form, as suggested by the French CA after the *E.coli* crisis – see answer to EQ C/5 for more details). In particular, it suggests: a rapid alert team at the level of SANCO, composed of experts on emergency planning and crisis management, to coordinate and manage at EU level animal health emergency response - an equivalent of the 'Food Crisis Unit'. This SANCO team would be active both at peacetime and in case of emergencies. Its activities during peacetime would include advice and guidance on the implementation of the CPs, which necessitates a larger exchange between MS for the benefit of all MS; this can be done in thematic working groups to which MS can contribute their experiences (as is currently the case in the field of food safety), for example on how to be prepared in terms of staff and equipment, how to carry out vaccination or culling operations etc. This work could then be shared between all MS, in the form of guidelines, notably to transfer experience and lessons learnt to MS that are less advanced in this field. In case of outbreaks, the team would coordinate emergency response and facilitate the necessary bilateral technical exchange between MS on the implementation of measures for emergencies affecting several MS (by bringing together technical experts from MS in the context of ad hoc working groups created at the moment of crisis). For example, such an ad hoc group was put together at the time of the *E. coli* crisis by experts from the MS most concerned by the crisis to deal in more detail with traceability issues, since these issues did not concern all MS. However, another MS is not of the opinion that an additional crisis unit would necessarily provide additional assistance to MS activities, but it could be helpful in accelerating the information flow between the MS and e.g. third countries or facilitating/ coordinating the creation of common

views concerning certain problems affecting several MS in the same way (e.g. unjustified export restrictions due to the Schmallenberg virus).

On the other hand, the COM finds that the creation of an instrument that is only activated when there is a crisis may not be very relevant. Rather than implement another crisis unit, it suggests linking the AH emergency structure to the crisis unit for food and feed in cases of public health emergencies. Indeed, the COM notes that there is already a well-defined AH crisis structure (AHES manual) and DG SANCO internal procedure which is very clear regarding roles and responsibilities.

Indicator 2: Examples of cases and impacts: lessons learnt from the crisis unit for food and feed, if any.

None, as the crisis unit for food and feed is yet to be implemented.

C/8 What would be the need for other or additional tools or practices to efficiently achieve the same goals (MS CA and Commission service)?

In the context of this question it was important to identify the goals of the COM against those of the MS in terms of what their expectation is from this information exchange, what they hope to achieve from it. Views differ at the COM as to the expectations from SCoFCAH: some find that the information exchange function should be maintained as an indispensable component of SCoFCAH's ability to reach informed decisions, while others are more in favour of streamlining SCoFCAH's functions (see EQs C/3 and C/4 for more detail).

4.3 Conclusions and recommendations (Theme C)

Key findings

Based on the FCEC analysis, the following overall conclusions can be drawn on the exchange of information regarding outbreaks at the SCoFCAH meeting:

- The current information exchange practices are by and large still adequate taking into account subsequent changes and progress regarding especially communication tools (**EQ C/1**). Most MS do not consider there is a need to improve the exchange of information on outbreak evolution at SCoFCAH meetings (**indicator 1**). Email communication could be used more frequently for short exchanges but should not be relied upon. Videoconferencing is not supported by most MS, mainly due to the added value of meeting in person. However considerable savings could be achieved if experts could provide their input via video-link instead of physically attending the meeting-especially in the case of a short contribution. Pre-meeting circulation of documents in CIRCA would improve the exchange of information at the meetings, since in the past the relevant documents have sometimes arrived too late to be reviewed before the meetings (**indicator 2**).
- Despite the administrative constraints involved, most MS consider the exchange of information at SCoFCAH efficient (**EQ C/2).** Although additional time and costs are involved in providing information and updates at the meetings, this time is generally

considered to be well spent. However, some MS highlight the need for multiple participants, in order to cover more areas of competence and interact better with other MS and the COM simultaneously. The fact that the COM only reimburses one participant per MS is an obstacle to this for some MS. Information exchange may make meetings longer than needed, thus forcing some MS to delegate their vote to another MS if it cannot attend the whole meeting.

- The COM also considers the exchange of information at SCoFCAH, taking into account both the administrative constraints involved and the existence of the ADNS (ADIS) system to be broadly efficient **(EQ C/3)**. The COM considers SCoFCAH and ADNS to be fully complementary. ADNS provides objective data on outbreaks, while at SCoFCAH, this is accompanied by contextual information. It is this contextual information provided by MS that could not be made available via ADNS (or the future ADIS) (**indicator 1**). ADIS will be designed to avoid overlapping, duplication and divergence that could occur from reporting events to different systems, and is thus also expected to save much effort and resource. However, the COM highlights that ADIS will not introduce a dramatic change from the current situation, as ADIS will not replace essential parts of the discussion at SCoFCAH meetings, concerning the provision of 'richer', contextual information (**indicator 2**).
- A majority of MS consider the information exchange at SCoFCAH meetings very relevant and very effective both from the point of view of the MS having an outbreak (obligation to inform) and from the other parties (opportunity to obtain information) (**EQ C/4**). Overall MS find that SCoFCAH is an essential information exchange platform, in particular as it offers the possibility to ask and answer questions immediately, and share views and experiences at peer level. Given this the amount of information and length of the meetings are not considered to be excessive. As such, the information exchange is found to facilitate the voting procedure. Many MS also highlight the importance of the informal exchange of information that occurs outside of the meetings; however some MS do not consider information exchange at SCoFCAH to be sufficiently precise or detailed, and to be relatively limited at technical level, although solutions are suggested to overcome this (**indicator 1**). Many examples exist of information exchange at SCoFCAH that has made an impact in an emergency situation (**indicator 2**). Many examples also exist of MS CAs and stakeholder organisations benefiting from the information provided at SCoFCAH (**indicator 3**). Although some stakeholder organisations would be in favour of an equivalent stakeholder forum at EU level, not all would be in support of this option (**indicator 4**).
- The majority of MS do not find that any of the suggested potential alternative options for sharing information would be replacements to current information exchange practices at SCoFCAH, but some MS find them to be complementary to the existing practices **(EQ C/5)**. A technical group is the additional tool that is most preferred by MS CAs, in order to facilitate further technical discussion, if necessary on an ad hoc basis. The second-most preferred tool is a standard template be used for epidemiological reports to ensure these are more clear and focused. CVO meetings, the creation of a special unit for countries concerned by a certain disease, and videoconferencing are generally not supported by MS.
- Most MS find the CVET missions relevant and effective as an additional tool in support of the information exchange provided at SCoFCAH (**EQ C/6**). However, there may be a need to better outline the CVET's role. Examples of the CVET's intervention in MS or neighbouring MS are seen as positive by the visited MS.

- Most MS would find a crisis unit similar to the one laid down in Commission Decision 2004/478/EC) relevant **(EQ C/7)**. However, it is debatable whether this would be necessary considering the planned implementation of the crisis unit for food and feed, as the AH emergency structure is seen to already be well developed – there may simply be a need to link this emergency structure to the crisis unit planned for food and feed in cases of public health implications.

Recommendations

The main outcome of the analysis of Theme C is that our consultation with the MS and COM services has largely indicated that the information exchange element of SCoFCAH should remain as it is. Given the positive overall picture of the current information exchange practices at SCoFCAH meetings, only minor improvements can be suggested as follows:

1. Video-linking to AH experts who are not attending the SCoFCAH meetings is a cost-effective answer to the need for multiple participants from each MS to be present at the meetings. As the facilities already exist at the COM for video-linking, this could be implemented quite quickly.
2. CIRCA could be used by MS to facilitate the timely pre- and post-meeting circulation of relevant documents.
3. As some MS find SCoFCAH meetings to be lacking in detail, and as a technical group is one of the most favoured additional tools for information exchange at SCoFCAH, technical groups could be called upon more frequently in order to provide further detail and resolve technical problems.
4. A template for epidemiological reports could be envisaged to standardise and streamline the presentation of information on outbreaks.
5. When the crisis unit for food and feed is implemented, it would be useful to examine in which way this can be linked to the existing animal health crisis structures.

5 Theme D: Containment measures put in place by MS CAs and endorsed by Commission Decisions

5.1 Background

The specific objective of this theme is to analyse the extent to which procedures related to containment measures implemented by MS and approved by SCoFCAH are adequate and efficient. This also relates to the evaluation of the effectiveness, relevance, and efficiency, of SCoFCAH as a legislative forum. It is noted that the objective of this theme is *not* to analyse the relevance and effectiveness of the measures as such but of the procedure followed by the COM/SCoFCAH for their adoption.

EU legislation (the EU Control Directives) lays down the minimum EU control measures to be implemented when an outbreak occurs, in line with the rules governing intra community trade and imports from third countries.[66] The aim is to reduce, through timely and effective action, the potential impact of epizootics of regulated contagious diseases.[67]

The Commission and other MS may either agree or disagree with the measures taken by the affected MS:

- In the first case, the COM may (but does not have to) propose measures endorsing the situation on the ground;
- In the latter case (on very rare occasions) the COM may consider further measures to be necessary and draft decisions in order to strengthen the applicable measures[68]. In

[66] Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market.
Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market.
Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries.
Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC

[67] In addition, based on Article 5 of Council Directive 2002/99/EC, veterinary certification is required for products of animal origin intended for human consumption where provisions adopted for animal health reasons under Article 9 of Directive 89/662/EEC establishes that products of animal origin from an MS, affected by the epizootic disease, is to be accompanied by a health certificate.

[68] There are also other important reasons that lead to the COM decision to adopt protection measures at EU level, even when the affected MS are already applying appropriate disease control measures, as outlined in the Animal Health Emergency System manual:

1. Generally in case of extremely highly contagious diseases (FMD, CSF, HPAI) that have also a major impact on trade as there is a need of maximum transparency and the EC legal acts are giving additional assurances to other MS and TCs that disease control measures applied by the affected MS are backed up by the EC. In addition by publication of the protection measures in the Official Journal of the European Union (OJ) they are available in all official languages of the EU. Usually they clearly describe the area under restrictions and the provisions that apply to intra-EU trade and exports.
2. If the first epidemiological inquiries indicate a potential for wider spread of the infection within that MS or to other MS or TCs;
3. More than one MS are involved in the outbreak;
4. The disease poses a serious risk to public health;
5. New or emerging disease that poses unknown or not yet fully understood risks to animal and/or human health;

particular, Article 9 of Directive 89/662/EEC and Article 10 of Directive 90/425/EEC stipulate that the COM may, in consultation with the MS concerned and pending the meeting of the Standing Veterinary Committee, take interim protective measures with regard to animals or products of animal origin from the region affected by the epizootic disease or from a given holding, centre or organization.

In most cases, MS are also invited to present the evolution of animal disease presence in their territory, as well as the protective measures taken within the framework of the relevant CP at the SCoFCAH meetings. In addition, an information flow, concerning outbreak confirmation and CP implemented measures, is regularly generated between MS and the COM via the usual communication tools such as faxes and email (as discussed in Theme C).

There are variations in the safeguard decisions depending *inter alia* on disease epidemiological factors. Safeguards have been established for ASF, CSF, AI, and FMD; for Newcastle disease (ND) usually no safeguard measures are taken, because most MS (except SE and FI) routinely vaccinate their poultry flocks against that disease resulting in reduction of susceptible populations and therefore very limited impact of outbreaks.

5.2 Findings

5.2.1 Adequacy of the current (comitology) procedure (EQ D/1)

D/1 To what extent are the procedures still adequate taking into account subsequent changes and progress?

A key issue examined in the context of EQ D/1 is the adequacy of the SCoFCAH procedure given the new electronic systems developed at the level of the COM in the last 4-5 years, which require a strict step-wise process for implementing legislative procedures. The adoption of emergency measures falls under the 'urgent' legislative procedure and the COM has taken the necessary steps (mainly, through the development of standard templates to be used for the legal texts) to ensure that COM adoption can follow within 24 hours of the notification of the measures. However, it was also suggested that in the event of an unpredictable outbreak scenario (for which changes may also be needed to the standard templates), the automation of the process through the more recent electronic systems would make it a concern whether adoption can take place within the current short deadlines.

This question also refers to the appropriateness of the legal base used for the procedure, which is currently under review in the context of the new Animal Health Law. The mechanism for the management of animal diseases is currently based on the EU legislation related to veterinary checks in intra-EU trade and imports of animals and animal products (Council Directives 90/425/EEC, 89/662/EEC, 97/78/EC, 91/496/EEC)[69] which foresee

6. EU protection measures are already foreseen in the disease specific legislation (e.g. for HPAI H5N1);
7. Determination of level of action.

[69] As mentioned previously, the current legal basis for the emergency (¨safeguard¨) measures taken in the case of outbreaks are the following Council Directives:
• Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market

taking protective measures by SCoFCAH approval and interim protective measures by the COM alone.[70] From our interviews it was revealed that, while at the time of the adoption of this legislation, the legal base was considered appropriate for the adoption of such measures, the situation has since evolved and that not all the conditions foreseen in those Directives are longer met. In particular, these Directives envisage that the COM needs to approve measures if the COM has not previously been informed of the measures taken by MS or if the measures taken by MS are inadequate. In practice, safeguard measures are, for the most part, taken in collaboration with MS, and are often subject to lively discussion at SCoFCAH level (e.g. the decision to introduce in 2001 vaccination for FMD). The COM is currently drafting a new Animal Health Law which is expected to contain provisions for amending the legal base for these containment measures.

Apart from this issue, the SCoFCAH procedure of adoption of safeguard measures is considered to be working very well. There have been no problems relating to inadequate justification of the safeguard actions taken as such. COM legal services point out that the urgency of the situation at time of serious outbreaks or risks to animal and public health, coupled with the risk involved in terms of the speed and extent of potential spread of highly contagious diseases provides sufficient justification for the COM to retain powers to adopt protective measures in such cases. The short delays in reacting in the timeline of actions for AI and FMD were cited as good examples of this. It was also pointed out that the measures need to be adopted by COM Decisions in the interest of visibility towards MS and third countries.

Indicator 1: Experience gained by the COM in practice; cases where the system might fail to produce quick decisions

The experience gained by the COM in practice is analysed in terms of the following three issues:

a) Potential concerns regarding the speed of adoption of measures relating to standard templates and legal framework

For emergency situations, standard decision texts have been agreed on between the COM Legal Services, the Secretariat General DG AGRI, DG TRADE, and DG SANCO for interim decisions to be taken by the COM which need minimal adjustment according to the specificities of each outbreak (mainly MS name and areas under restrictions). These texts can be presented within a very quick time frame to SCoFCAH for adoption and require minimal work for the translation services. In that sense the COM deems that the standard procedure

- Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra- Community trade with a view to the completion of the internal market {concerns products of animal origin}
- Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
- Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC

[70] Control and precautionary measures are laid down in Art 9 Directive 89/662/EEC-animal products (e.g. determination of buffer zones (zoning). Requirement for zoning is laid down in the Control Directives, however it is possible to enlarge these zones by a safeguard decision, if the COM or other MS deem that the measures taken are not sufficient and interim measures Art. 10 of Directive 90/425/EEC- live animals. .

can easily be expedited. The Legal Services DG AGRI, DG TRADE and the Secretariat General are contacted by DG SANCO, and are requested to give their agreement to the texts. It still remains a formal procedure, usually taking from 24 to 48 hours, but can be expedited to be implemented within 24 hours if need be.

The COM acknowledges that in the case of a non-standard event, more time would be required, due to the need for a non-standard template. But this would not necessarily make the procedure that much slower – as staff would be working more intensively in this case. As an example, the *E.coli* crisis took 3-4 days to react to as there was no template, however the COM stresses that even without a template, at least on animal health issues the reaction would be fairly quick as the structures are better defined (e.g. the surveillance and protection measures are the same).

Further, if quick action needs to be taken and does not 'fit' the standard framework, these can be addressed by COM interim protection measures and subsequent confirmation of the measures at SCoFCAH. There is also the possibility for MS to vote on measures by email.

In any case, so far the main diseases have been covered with these templates. But the COM notes that nonetheless in the past 4-5 years the procedure has not been properly tested due to the relatively good animal health situation, so the efficiency of this aspect is still uncertain. The COM also highlights that when the COM is closed there is a special mechanism that engages special contact points to attend to urgent matters.

In addition, the COM underlines the importance of having scientific evidence, as overly hasty measures could lead to a disproportionate reaction that would disrupt trade. Therefore, what could slow down the procedure is the availability of scientific evidence. Still, precautionary measures can be taken even if there is no scientific basis, if a significant threat is posed.

On this basis, it can be concluded that there is no indication that current COM procedures for endorsing containment measures are not functioning well. However, it acknowledges that so far there has been no major crisis to test this.

b) Potential concerns regarding the speed of adoption of measures due to the new electronic systems used by COM procedures (EGREF and POETRY):

The implementation of the new electronic systems used by the COM (EGREF and POETRY) was designed to improve efficiency[71]. In the context of the adoption of containment measures, the first step of the step-wise process followed by the COM is the inter-service consultation; the system allows either the inter-service consultation to be inputted manually into EGREF (e.g. individual comments from emails are inputted), or DGs can input comments on texts themselves directly into EGREF. Next, the vote on the text at SCoFCAH only occurs once inter-service consultation is complete. Once the vote is complete and MS have provided their opinions, the text then goes back via EGREF to the cabinet and then the

[71] EGREF is an electronic system for the handling and uploading of official documents and POETRY is the system for translation, which is now integrated into EGREF. A text therefore now goes directly to DG Translation after being uploaded to EGREF; the line units themselves no longer deal with translation. EGREF is, as the COM indicates, 'synonymous with adoption procedure', i.e. it is the system governing the step-wise process for the formal adoption of legislation by the Collège (all Commissioners).

Secretariat General for final adoption. On average the whole procedure can reportedly take ca. 7 days. However, the procedure can be accelerated for urgent matters. For example, when staff is made aware of an emergency they can contact DG Translation and the publication office to notify them of the urgency. Following negotiations and sufficient notification to other services of a text having been uploaded to EGREF, the procedure can be expedited in order for a text to be implemented within 24 hours (as explained above concerning the standard texts, and in the case of emergency interim protection measures, the procedure does not need to incorporate a SCoFCAH vote).

Overall, the EGREF system is considered by the COM to be quite flexible and useful in that data can be inputted into the system at different stages of a text's adoption timeline, and the progression of the text can be followed step by step. The COM reports that no major problems have been experienced with the EGREF system to this date.

c) Appropriateness of the legal base for the adoption of interim protection measures:

The COM confirms that usually the MS take the necessary measures and that these are then endorsed through COM decisions, in accordance with the texts providing the legal basis for the adoption of these measures. The COM generally acts where there is a lack of information or the MS have not addressed an outbreak correctly.

In such cases, the COM considers it appropriate that it adopt interim measures that go beyond what is outlined in the relevant Control Directives (e.g. in terms of the geographical area of application of the measures), as it is important to reassure third countries by acting as a single entity – i.e. through the COM – rather than individually. A particular issue, as also noted under Theme F (EQ F/4), would also include work to ensure the predictability of MS actions particularly by improving their capability to apply regionalisation perhaps by pre-identifying geographical units of reference for the restriction zones at appropriate (regional level), based on common objective criteria such as administrative boundaries, livestock density and farming systems.

The COM acknowledges that currently the wording in the existing legislation is not an appropriate legal base for its application of interim protection measures, or for a consistent approach in the adoption of control measures by MS in certain cases e.g. on regionalisation.

Although the COM does not report any substantial legal problems owing to this lack of clarity and it is not an issue of dispute between MS and the COM, clarifying these issues would improve the acceptability of measures by third countries. A revision of the legal base for COM interim protection measures is planned for the new AH law scheduled for the third quarter of 2012, which would provide the opportunity for dealing with these issues.

5.2.2 Efficiency of the current (comitology) procedure (EQ D/2, D/3)

In case the COM decides to implement interim protection measures, within 10 days the measures must be reviewed and the 'definitive' measures are adopted by SCoFCAH, which then may remain in force for an extended period of time and may be adapted to the concrete epidemiological and/or risk situation. Discussions in SCoFCAH on the development of the measures are of great interest to MS, as indicated by the COM (e.g. the decision to introduce

emergency vaccination for FMD in 2001), as this exchange contributes to the wealth of experience for all veterinary services in the EU.

In terms of efficiency issues, the administrative burden of the current procedure for adoption of containment measures is not considered to be significant, when compared to the benefits of having transparent, real and official exchange at peer level of information on the outbreaks on which the SCoFCAH can then build decisions, and the added value of the currents procedure as outlined by the COM (see below).

In particular, regarding the costs of SCoFCAH meetings in general (see background information under EQ C/), the time taken by the legislative obligation to vote on containment measures does not tend to result in additional costs to the costs of regular meetings.

D/2 To what extent do MS consider this legislative obligation efficient taking into account the administrative constraints involved (pros/cons)?

Indicator 1: MS that consider the legislative obligation for adopting containment measures efficient given the administrative and budgetary constraints involved

The results of the FCEC survey show that all MS, taking into account administrative/budgetary constraints, consider the current procedure for adopting emergency containment measures at SCoFCAH meetings very or fairly efficient (9 MS and 18 MS, respectively).

The case studies showed that in general there are no unnecessary additional administrative costs for the procedures, and that current procedures are broadly considered efficient. One MS finds the decision-making process rather long but also that there are no real possibilities to speed up the process due to the high number of parties involved. As an alternative, another MS suggests voting on containment measures is typically an area where decisions might be achieved by email, if only one urgent decision has to be made.

The procedure for adopting containment measures are indeed connected to additional costs, because they require additional experts, according to one MS. This is because, often, MS demand details in SCoFCAH meetings to justify the containment measures, which requires additional expertise to provide sufficient answers (see EQ C/2 for further discussion). Another MS supports this view in that it considers that in case of diseases that are fully regulated, voting is only needed for additional measures, for which a clear rationale should be agreed on.

During the case studies, MS generally agreed with the COM view that the added value of the approval of containment measures at SCoFCAH is in terms of:

- Safeguarding against the threat of MS taking unilateral measures;
- Providing flexibility to adopt quick and well-defined additional measures, over and above what is foreseen by the Control Directives (which, by definition, cannot include measures for every possible scenario). As an example, the COM cites the short delays in the timeline of the actions for AI and FMD;
- Empowering CVOs to overcome internal pressures at national level (chain of command). For example, during the 1999 AI, the Italian CA asked the COM to

endorse the measures adopted in order to encourage stakeholders and other national authorities to accept them;

- Providing international reassurance on the EU management of animal outbreaks;
- Coupled with FVO inspections and the discussions at SCoFCAH (twice per week in case of emergency), the process ensures enforcement by MS;
- Contributing to the improvement of legislation (safeguard measures are almost always subsequently incorporated in the revised Control Directives). Several examples given. The German CA reports the example of COM decisions regarding containment of CSF and the slaughter of pigs in certain zones; this has been incorporated into the legislation following this experience, and the German CA now relies on these legislative tools. The Danish CA reports the example of the vaccination of cattle in the Netherlands in 2001 against FMD. At this time, SCoFCAH made a decision to forbid the transport of cattle beyond the Netherlands. The principles of the containment measures in this decision were then incorporated into a directive in 2003. The COM also reports one example where the transfer of safeguard measures into legislation was quite clear: measures taken to control the AI outbreak in 2006. These measures – including the prevention of the import of feathers into the EU without treatment – were then incorporated into the AI Control Directive.

D/3 To what extent do Commission services consider this legislative obligation efficient taking into account the administrative constraints involved (pros/cons)?

Indicator 1: Extent to which the COM considers the legislative obligation for adopting containment measures efficient given the administrative and budgetary constraints involved.

The COM broadly considers the legislative obligation for endorsing containment measures efficient. Having in place the current procedure for the adoption of containment measures also ensures transparency.

The COM highlights that the procedure is quite flexible. The COM also has a 'written procedure' at its disposal whereby it sends draft legislation to the MS by fax (plus scanned as e-mail) and requests them to express their formal opinion in writing (fax/e-mail), within a 24-hour deadline in the case of emergencies. This written procedure fully replaces a SCoFCAH meeting in person. Alternatively, if there is an urgent need for an AH meeting, the relevant MS representatives can also meet during a food safety SCoFCAH meeting. The MS representatives would then liaise with their animal health experts located in their respective MS.

The COM finds it may not be possible to simplify the current procedure further without losing some detail. On some specific trade aspects the COM reports that one could potentially have meetings with fewer MS, but as it is a single market all MS would need to be aware of decisions made. Often the outcome is important for all MS: even if an only few MS need to be involved for the details, all MS need to be involved e.g. for impacts in certification requirements, and other MS need to know what restrictions apply. Communication of the restrictions is seen as one of the main benefits of the current procedure. Therefore the COM considers it would be difficult to reduce the number of MS required to be present at the

meetings. It is also noted that possibility of reducing the number of MS attending SCoFCAH meetings for this procedure is very limited as one MS can at most vote for only one other MS and thus the minimum legal number of MS required at the meeting is fifty per cent of all MS plus one.

The COM also highlights the substantial costs that could accrue from trade disruptions if all MS are not aware of decisions.

The COM underlines that the current procedure is efficient because interim measures can be decided on quickly by the COM, then SCoFCAH can confirm at its next meeting – there is no need to quickly organise a meeting of all 27 MS.

5.2.3 Relevance and effectiveness of current (comitology) procedure (EQ D/4)

D/4 What is the relevance and effectiveness of SCoFCAH as legislative forum and of the emergency decisions, from the following points of view: - to protect animal and human health,- to ensure free movement (trade) of animals and goods from the non-affected areas, - to prevent over-reaction from third countries having an impact on EU export, - to ensure transparency, publicity, and EU level accessibility for the measures taken by the MS having the outbreak?

The involvement of SCoFCAH is considered by the COM to be effective and relevant in emergency decisions for ensuring free movement of animals and goods from non-affected areas, since when outbreaks occur, the emergency measures adopted by the COM fill the gap by providing these specific instructions. The example of the FMD outbreak in 2001 was given, where the measures defined additional movement conditions in regions outside the restriction zones (the measures defined high risk and low risk areas for the purposes of animal movement and exports). According to COM services, the case of the FMD outbreak demonstrated that the emergency measures taken worked very well and were appreciated by MS and third countries as it was clear to all what action to take (this Decision has now expired and its validity has not been extended, as there was not enough interest to do this).

As regards preventing over-reaction from third countries having an impact on EU exports, containment measures appear to act as reassurance to third countries that the outbreak is effectively managed within the EU. For example, in 2001 following the UK FMD outbreak, the adopted safeguard measures also included rules banning export /re-import and surveillance; this allowed trade from the non-affected areas of the Community to re-establish as MS/regions started progressively obtaining freedom from the disease. Similarly, at the time of the BSE crisis, measures were taken to prevent the export of contaminated animals to third countries and re-import. In the case of the HPAI outbreak, the COM took a further approach by adopting a preventive Decision, so that at the moment of first notification this would be immediately enforceable. As area where further improvement could be sought is the MS application of regionalisation (as also discussed under EQ D/1 and EQ F/4).

Indicator 1a: MS considering SCoFCAH as a legislative forum and the emergency decisions relevant and effective to protect animal and human health; concrete examples where the procedure has had an impact.

Most MS consider the current procedure for adopting emergency containment measures at SCoFCAH meetings very relevant (21 MS) and very effective (15 MS) in terms of '*Protecting animal and human health'*. The IT CA reports that for BT, these measures allowed Italy to distinguish between affected and safe territories and thus protect animal health within the country.

Indicator 1b: MS considering SCoFCAH as a legislative forum and the emergency decisions relevant and effective to ensure free movement (trade) of animals and goods from the non-affected areas; concrete examples where the procedure has had an impact

The FCEC survey shows that from the point of view of '*Ensuring free movement (trade) of animals and goods from the non-affected areas'*, 16 MS find the current procedure for adopting emergency containment measures at SCoFCAH meetings very relevant, and 12 MS very effective.

The following concrete examples illustrate this:

- The German CA reports the example of COM decisions regarding containment of CSF and the slaughter of pigs in certain zones, as a good example of how SCoFCAH emergency measures ensured free-movement of pigs from non-affected areas (concerning intra community trade); the German CA considers SCoFCAH very relevant and effective for this.
- Also, the Danish CA reports the positive example of the FMD outbreak in Bulgaria in 2011. The entire country was initially closed: It then progressively lifted restrictions to only the affected regions, then finally to the outbreak zones alone.
- The French CA reports the case of the gradual regionalisation process following the BT outbreak in France (BTV 1 and 8) which allowed the continuation of safe animal movements from the progressively re-defined restricted zones[72] (in application of Commission Regulation (EC) No 1266/2007[73]), and the various measures adopted at EU level during the AI crisis.
- The Italian CA reports that for the recent FMD in Bulgaria and AI in Romania, this procedure has allowed trade restrictions to be limited to high risk zones only. Due to the assurance coming from the SCoFCAH procedure, MS did not consider it necessary to restrict the entire countries.

Indicator 1.c: MS considering SCoFCAH as a legislative forum and the emergency decisions relevant and effective to prevent over-reaction from third countries having an impact on EU export; concrete examples where the procedure has had an impact.

13 MS consider the procedure very relevant and 10 MS very effective at *'Preventing over-reaction from third countries having an impact on EU export'* (from a total of 26). The following concrete examples illustrate this:

- The German CA reports that there have been SCoFCAH decisions in the past that did not go beyond the contents of the relevant directives, but were nonetheless a signal towards the MS that the outbreaks were under control. In particular, the COM

[72] Since end of 2008 the whole of the country is defined as one restricted zone.
[73] Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue.

was able to demonstrate that no animals would be moved from the restriction zones to the third countries. The German CA sees this as a good demonstration of transparency as well as an important example of how SCoFCAH acts in certain scenarios. It thus served to prevent loss of third countries' confidence in EU exports.

- The Danish CA concedes that preventing over-reaction from third countries having an impact on EU export is always difficult. It found that there is always an over-reaction from third countries. However SCoFCAH in general may well have contributed to attenuating such an over-reaction.
- The Italian CA reports the example of the case of FMD in 1993, where the containment measures adopted guaranteed a constant flow of the exports of Parmigiano Reggiano and Grana Padana. However, the Italian CA does not consider this procedure to be very effective in preventing TCs – e.g. Russia, Canada, U.S and Japan - from adopting restrictive measures against MS.

Indicator 1.d: MS considering SCoFCAH as a legislative forum and the emergency decisions relevant and effective for ensuring transparency, publicity, and EU level accessibility for the measures done by the MS having the outbreak; concrete examples where the procedure has had an impact.

14 MS find the procedure very relevant and 12 very effective at *'Ensuring transparency, publicity, and EU level accessibility for the measures done by the MS having the outbreak'* (from a total of 25). The Italian CA reports measures adopted in France in 2003 and in the UK in 2007 establishing the compulsory traceability of all commercial stocks coming from the affected areas, in order to be controlled. This protected the Italian livestock resources.

Indicator 2: Potential elements for replacement, and advantages/disadvantages (including from an efficiency point of view).

No major potential elements for replacement are suggested as the system is broadly deemed relevant, effective and efficient from the four points of view set out.

5.3 Conclusions and recommendations (Theme D)

Key findings

Based on the FCEC analysis, the following overall conclusions can be drawn on procedures for the adoption of containment measures by MS and endorsed by Commission decisions:

- Procedures are by and large still considered adequate by the COM taking into account subsequent changes and progress (**EQ D/1**). There is also substantial flexibility in the individual steps involved in the procedure: standard templates exist for the common diseases, steps can be expedited if need be in order to implement measures within 24 hours, and the current electronic systems used by the COM for document handling should not cause any unnecessary delay in the procedure. The legal base for the adoption of measures by the COM is not appropriate for actions in all cases Although this is not considered to have caused any major problems, the legal base on this could be clarified and strengthened in the context of the ongoing revision of the new AH law in the third quarter of 2012.
- Taking into account administrative/budgetary constraints, the legislative obligation for adopting emergency containment measures at SCoFCAH is considered efficient by MS (**EQ D/2**). In general there are no unnecessary additional administrative costs for the procedures. There may nonetheless be savings to be gained in cases where the endorsement of MS containment measures does not need to be voted on, if information provided by the affected MS is sufficient. Most MS also agree that there is significant and real added value in the approval of containment measures at SCoFCAH as opposed to other means, in particular relating to the improvement of legislation, for which MS provide many examples.
- The COM broadly considers the legislative obligation for endorsing containment measures to be efficient (**EQ D/3**). The COM highlights that the procedure is quite flexible: votes can be conducted by email; there is a 'written procedure' whereby it sends draft texts of legislation to the MS to which they can give their formal opinion. Legislation that needs to be voted on urgently can also be put to a vote in a non-AH SCoFCAH meeting if need be. However it would be difficult to reduce the number of MS participants required to be present at the meetings.
- Overall, MS consider the current procedure for adopting emergency containment measures most relevant and effective, primarily for protecting animal and human health, but also for ensuring free movement (trade) of animals and goods from the non-affected areas **(EQ D/4)**. Many concrete examples are provided by MS to illustrate the relevance and effectiveness of the current procedure.

Recommendations

Given the generally positive picture of the current procedure for the adoption of containment measures and their subsequent endorsement by COM decisions, only relatively minor improvements can be suggested, as follows:

1. Continue adaptation of the legal base for the adoption of safeguard measures by the COM to ensure its appropriateness. It would also include work to ensure the predictability of MS actions particularly by improving their capability to apply

regionalisation perhaps by pre-identifying geographical units of reference for the restriction zones at the appropriate (regional level), based on common objective criteria such as administrative boundaries, livestock density and farming systems. This would help ensure consistency of the approach and its implementation across MS and improve the evidence base presented to third country trading partners (as discussed under EQ D/1, EQ D/4, and EQ F/4).

2. Investigate whether savings can be made in further restricting SCoFCAH voting on containment measures for situations where information is not sufficient. This would mean giving MS more opportunity to provide adequate information on measures taken, and further encouraging MS to fill information gaps or correct inadequate measures.

6 Theme E: FVO verification missions regarding CP in peace time (including simulation exercises) and during and after outbreaks of epizootics

6.1 Background

This evaluation theme has the specific objective of analysing the effectiveness and relevance of the FVO (Food and Veterinary Office, Directorate F, DG SANCO) activities and verification missions. FVO verification missions are carried out regarding CP implementation in MS in peace time (including the verification of simulation exercises) and during/after outbreaks of epizootics (to verify implementation of emergency measures by MS).

A key issue to examine under this theme is the extent to which the FVO reports and recommendations are used and followed up by the various relevant actors, including the various COM services, the MS (those inspected and the others), third country trading partners and stakeholders, and which lessons can be learned for future improvement.

6.2 Findings

6.2.1 Criteria for prioritising the FVO CP missions (EQ E/1)

E/1 To what extent are the criteria used by DG SANCO relevant to plan the FVO CP missions or mission series to MS?

FVO missions are performed in the framework of the DG SANCO mission programme; the FVO inspections follow the main lines of the EU requirements regarding CP set up and operation.

The criteria used for prioritising the FVO missions are drawn up by the FVO. In March each year the FVO sends to the DG SANCO hierarchy a draft setting out the broad lines of the inspection programme for the following year. This defines such aspects as the share of missions between MS and third countries and the subject focus (e.g. food safety, import controls). Although a risk assessment is difficult to do in quantitative terms, the FVO uses some qualitative criteria to determine risk, such as when the last visit was to a MS or particular risks of concern in relation to CPs (e.g. ASF risk from Russia, for which FVO is planning a mission to Finland in 2012). The prioritisation of FVO missions will also depend on other FVO activities such the obligation to do missions in relation to the eradication programmes; there are generally competing demands for the FVO inspection services and a prioritisation between these in view of the FVO animal health resource constraints needs to be made. The draft programme is then sent, following consultation with the SANCO hierarchy, to the SANCO cabinet which may propose amendments, although generally very few amendments are proposed[74].

The FVO indicates that the following criteria for planning FVO CP missions are currently used (listed below in no order of priority):

- Likelihood of disease occurrence;

[74] An internal audit carried out within SANCO looked at FVO mission prioritisation and the extent to which this is risk based versus other obligations (e.g. missions for eradication programmes) or political considerations.

- Obligation in relation to other FVO animal health inspection activities, e.g. in relation to eradication programmes;
- Cover MS other than those which were visited most recently;
- Emergency situations;
- Specific MS requests.

The following table represents the main FVO missions carried out during the period covered by this evaluation, in relation to the criteria used for prioritising the FVO missions.

Table 7: Number of FVO missions in relation to FVO prioritisation criteria

	Likelihood of disease occurrence	Obligation in relation to other FVO animal health inspection activities	Cover MS other than those which were visited most recently	Emergency situations
Year		**Preparedness missions**		**Emergency Missions**
1998				4 x CSF
1999		3 EU MS on CPs for CSF/FMD)	6 missions to applicant countries	5 (1x ASF, 3x BTV, 1x SVD)[(a)]
2000	1 (unidentified disease in dairy cattle)	5 EU MS on CPs for CSF/FMD)		6 (FMD, BTV, 2x HPAI, NCD, ISA)
2001		2 EU MS on CPs for CSF/FMD)		7 x FMD, 1x CSF [(a)]
2002		5 EU MS on CPs for CSF/FMD)		2 x CSF
2003		13 EU MS (on CPs for FMD, CSF, BTV, HPAI, NCD)		1 x HPAI, 1x CSF
2004		3 EU MS (on CPs), 1x ASF, 5x Brucella, 1x bovine TB, 3x Rabies		
2005	1 (HPAI suspicion)	9 x CPs [(c)]		1x NCD
2006	2 x CSF, 3x BTV [(d)]		1 candidate MS on CP for HPAI	1x HPAI
2007		5 x (CPs for HPAI and NCD, CSF)		1x UK FMD
2008	3 x CSF	3 x CP (FMD, CSF, BTV)		3 x BTV
2009		7 x CPs (multiple diseases)		

(a) FVO 1999 annual report indicates 7 emergency missions but CSF emergency mission to Germany in 1999 could not be confirmed, first CSF mission is in 2000 nr 1097, and only 5 mission reports could be traced.
(b) FVO annual report 2001 mentions 8 emergency FMD mission but a FMD mission to Greece could not be confirmed.
(c) FVO annual report 2005 mentions 10 CP missions to new MS and Romania but CP mission to Romania could not be confirmed.
(d) FVO annual report 2006 mentions 3 CSF missions, of which one to Hungary, but the mission report could not be retrieved.
Source: FCEC, based on FVO annual reports 1999-2008

In the beginning of the period, following the CSF outbreaks, 4 emergency missions were executed in 1998. Subsequently, CP inspection missions were held systematically in all MS, first in the EU15 MS, and later in the context of enlargement in the new MS. The FMD outbreaks in 2001 urged for further CP missions. Overall, FVO missions on animal health tend to follow disease outbreaks and subsequent CP verifications missions (in particular: AI, FMD, BT CSF, ASF and other diseases), and follow up missions due to identified shortcomings; the remainder is related to co-funded eradication programmes.

Overall, it can be concluded that the FVO missions are scheduled by prioritising according to the risk. When disease outbreaks occur, the FVO is flexible to change the mission planning accordingly, but evidently planned missions may be delayed, as was the case in 2001, when a series of inspections to all MS was changed due to the FMD outbreaks and resulting emergency missions.

6.2.2 FVO CP missions and animal diseases outbreaks (EQ E/2)

E/2 Has consideration been given by DG SANCO (mainly Directorates G and F) to current disease outbreaks when planning to carry out relevant CP missions (series) by the FVO to evaluate MS preparedness against those diseases for which there have been significant outbreaks (e.g. AI)?

Before 2008 (i.e. until the AH unit was created in the FVO) the missions were mostly covering mammals; since 2008, they also cover birds and aquatic animals. This has influenced the focus of the FVO CP verification missions in terms of disease coverage. For example, in 2009 verification missions for the CPs covering birds and aquatic animals were also included.

From the FVO interviews and FVO inspection mission analysis, the number of FVO inspection missions for the verification of CPs (as well as emergency measures) following significant disease outbreaks were considered as an indicator of the relevance of the missions (in particular: AI, FMD, BT CSF, ASF and other diseases) (source: FVO mission reports).

As already indicated, the FVO CP verification missions generally follow animal health emergencies. Examples of such missions over the past decade are provided in the table below:

Table 8: FVO verification missions following animal health emergencies

Year	Objective of the FVO mission
1998	After the outbreaks of CSF, 4 emergency missions were conducted
1999	3 MS were visited to assess the CPs of FMD and CSF. Also, applicant EU MS were visited to assess the ability of veterinary services to monitor and control animal disease outbreaks
2000	5 further inspections on CPs for FMD and CSF were carried in Germany, Sweden, Finland, Austria, and Portugal
2001	2 inspection missions were carried out on CPs of FMD and CSF; in France and Spain. The threat for an FMD introduction in the EU via Turkey led to an FVO mission to review the FMD vaccination programme in place
2002	After outbreaks of FMD in Europe in 2001, the series of inspections on CPs for FMD and CSF was completed

Year	Objective of the FVO mission
2003	After outbreaks of HPAI, 13 MS were visited to assess CPs dealing with epizootic disease outbreaks
2004	A series of inspections was held to evaluate the EU CPs in pre-enlargement MS was completed
2005	9 inspection missions were carried out on CPs in new MS
2006	Missions to Bulgaria and Romania were carried out concerning CPs for HPAI;
2007	5 missions were conducted on CPs, for HPAI, NCD, and CSF
2008	3 inspections were carried out to evaluate emergency preparedness by evaluation of CPs in Estonia, Poland and Spain
2009	Further audits of the control of epizootic diseases involving CPs was conducted in 7 countries for multiple diseases

Source: FVO website, FVO annual reports 1999-2008

Hence, it can be concluded that a series of CP inspection missions have followed animal health emergencies (CSF, FMD, HPAI), and in most cases in the same year as the outbreak. Only in Romania, the outbreaks were reported in 2005 and the FVO mission took place in 2006. There is a tendency to audit for more than one disease, and to combine missions, and to incorporate into a General Audit, such as in 2008 in Estonia, Poland and Spain.

6.2.3 Frequency of FVO missions (EQ E/3)

E/3 To what extent is the frequency of such inspection missions and the criteria and rationale supporting decisions regarding this frequency relevant?

Indicators 1 and 2: current frequency of FVO missions and identification of the optimal frequency

The current frequency of FVO missions is such that the FVO aim to visit each MS within 5 years, which is in line with the current timing of CP updates[75]. Until now, the FVO has more or less met this target. However, in future, the FVO could be constrained to follow up the CPs in all 27 MS, as from circa 2013 verification missions will be due for CPs in all 27 MS. The FVO has done 3 missions per year on average since 1999, as follows:

- 1999-2002: 15 missions in 15 MS (CPs for CSF/FMD)
- 2002-2003: 15 follow-up missions
- 2005: 10 missions in NMS
- 2008/9: follow-up missions in 8 NMS
- 2012: CP missions are planned for 2012 (FI, RO, PL), including AW aspects of emergency slaughter for disease control purposes.

[75] A discussed under Theme B, CPs are supposed to be updated in the light of the experience gained, although the exact frequency is only specified in the case of FMD, for which the EU legislation foresees compulsory updates every 5 years (as required by Article 72.10 of Council Directive 2003/85/EC).

For 2012, the FVO has planned to carry out verification missions in LT, PT, BG, FI, and RO. In Eastern/NE European MS, such as RO, LT, FI, the FVO will primarily check the MS preparedness on ASF due to the risk of re-introduction of this disease from the Caucasus region. In PT, they will check the preparedness on PPR (Peste des petits ruminants) and risk of introduction of the disease from Morocco. In BG the focus will be mainly on FMD and CSF. The FVO indicates that all missions will include the check on compliance to AW aspects (especially procedures in use for animal culling).

The indicators used here are the number and frequency of FVO CP (as well as emergency measures) inspection missions in each MS since 1998, and the number and % of MS that consider the current frequency of FVO inspection missions to be sufficient. In the table below, the FVO animal health inspection missions are presented for the EU 27.

Table 9: Current number and frequency of FVO inspection missions to MS to verify CP compliance

EU 27	**Evaluation period**	**years**			
	1998-2009	**12**			
	Number of FVO reports (FVO website)	**Animal health reports (a)**	**AVG nr of reports/yr**	**Inspections involving animal health CPs (b) (FVO report nr)**	**calculated CP verification cycle (years)**
Austria	48	7	0.6	2 (1094, 9079)	6
Belgium	73	6	0.5	1 (1019, 1071)	6
Bulgaria	36	10	0.8	3 (7483, 7527, 7800, 8306, 8210)	2.4
Cyprus	27	7	0.6	2 (7618, 8253)	6
Czech Republic	35	5	0.4	1 (7574)	12
Denmark	50	6	0.5	2 (1215, 9101)	6
Estonia	19	5	0.4	3 (7250, 7616, 8600)	4
Finland	52	6	0.5	2 (1097, 9100)	6
France	104	17	1.4	2 (3381, 9151)	6
Germany	101	18	1.5	3 (1097, 8308, 7797)	4
Greece	104	15	1.3	2 (8851, 9185)	6
Hungary	41	8	0.7	3 (7619, 7798)	6
Ireland	75	15	1.3	2 (8511, 9193)	6
Italy	116	28	2.3	2 (1143, 9078)	6
Latvia	36	6	0.5	2 (7617, 8259)	6
Lithuania	37	6	0.5	2 (7621, 9265)	6
Luxembourg	37	6	0.5	2 (8655, 9190)	6
Malta	14	2	0.2	1 (7620)	12
Netherlands	77	12	1.0	2 (8535, 9196)	6
Poland	50	8	0.7	2 (7612, 7789)	6
Portugal	102	28	2.3	2 (1245, 9102)	6
Romania	37	10	0.8	3 (7526, 7482, 7618)	4

EU 27	**Evaluation period**	**years**			
	1998-2009	**12**			
	Number of FVO reports (FVO website)	**Animal health reports (a)**	**AVG nr of reports/yr**	**Inspections involving animal health CPs (b) (FVO report nr)**	**calculated CP verification cycle (years)**
Slovakia	31	7	0.6	2 (7609, 8313)	6
Slovenia	34	6	0.5	1 (8267)	12
Spain	94	26	2.2	2 (9084, 8347)	6
Sweden	43	5	0.4	2 (1108, 9197)	6
United Kingdom	112	19	1.6	2 (8545, 7267)	6

(a) Including BSE, and general audits
(b) FVO animal health inspection missions during 1998-2009 in the EU27, with inspection missions involving specifically CPs
Source: FCEC (VetEffect)

The number of FVO inspection missions varies widely among MS, but is related to the value of the livestock sector (France, Germany, Italy, Netherlands, UK), and/or disease risks and co-financed disease eradication programmes (Italy, Greece, Portugal, Spain). Also the outbreaks of CSF, FMD, HPAI and Bluetongue initiated multiple FVO missions.

The CPs are evaluated every 6 years in most of the EU MS, however, it should be noted that not all the CPs for all notifiable diseases were evaluated. Key diseases for which CPs were evaluated were FMD and CSF and, for new MS, CPs for multiple diseases were evaluated.

Hence it can be concluded that the number and frequency of FVO inspection missions in each MS since 1998 demonstrates that the focus has been on countries with outbreaks, and cases of non-compliant CPs.

The majority of MS (21 out of 25 MS) indicated that the current frequency of FVO inspection missions regarding CPs in peace time and during/after outbreaks of epizootics has been sufficient, with several MS indicating that, although useful, FVO missions put a significant burden on the CAs and should therefore be conducted only to the extent they are necessary. At the same time, the majority of MS consider the FVO inspections very relevant and effective in verifying and improving MS emergency preparedness, as discussed below under EQ/4, while 4 MS considered the current frequency not sufficient, with 3 MS indicating that the conducting of inspection missions every 5 years, and for 1 MS even more frequently, would be more appropriate (Q 16.b and 16.c – FCEC survey results).

However, the need to improve frequency becomes more evident when considering that the CPs of the EU-15 MS were last reviewed in 1999-2003, while those of the new MS were reviewed at the time of their accession to the EU; verification missions for the CPs on all diseases for all 27 MS are therefore due to be carried out from 2013. In this context, it is important to foresee a reinforced frequency of CP verification missions. Another justification for improving the frequency of FVO missions is the fact that significant change tends to occur at the level of staff in the MS CAs and other institutions and organisations involved; a 5 year rotation is considered by most experts as the minimum period required to keep track of

significant changes and to ensure that the 'institutional memory' is safeguarded as this is important to deal with new emergencies.

If this increased involvement of the FVO to achieve a cycle of inspection missions every 5 years to verify sufficiently MS CPs was to result in an additional 5/6 missions per year, and all other FVO work (e.g. missions on the monitoring and eradication programmes etc.) was to continue as currently, it would result in an additional requirement for 2 more inspectors in the FVO AH unit.

6.2.4 Relevance and effectiveness of FVO missions and reports (EQ E/4)

E/4 To what extent is the way of conducting FVO missions and drafting of reports relevant and effective, aiming at a) evaluating the MS emergency preparedness, b) improving the quality of the MS CP and c) providing input for their regular review?

Indicators 1 and 2: relevance and effectiveness of FVO missions and reports

The FVO reporting format changed in 1999 and has developed substantially since then, due also to new quality control procedures. Directly after the mission, FVO inspectors prepare the so-called 'back to office' reports; these contain first impressions and recommendations, and are most used by DG SANCO officers (see also EQ E/5). The final official FVO inspection reports including MS comments usually take several months to be published.

Nearly all of the responding MS consider the way of conducting FVO missions and drafting of reports sufficiently relevant and effective in achieving all of the above aims. However, MS CAs generally tend to consider the way of conducting FVO missions as such more relevant and effective than the drafting of FVO reports (Q 16.a and 16.d respectively – FCEC survey results), for which some improvements are suggested.

The relevance and effectiveness of the FVO inspections and reports was further analysed in terms of fulfilling the key aims, as follows:

a) Evaluating MS emergency preparedness

While overall FVO inspections are seen as a very relevant and effective tool in evaluating MS emergency preparedness, those conducted in case of emergencies appear to be less useful than those relating to contingency planning as such. In terms of improving the relevance and effectiveness of FVO missions, more forward looking rather than backward looking inspections may improve emergency preparedness, and in this context, CP verification mission are considered to better serve this purpose.

The reported shortcomings of FVO inspections, and in particular the FVO reports, are that they tend to focus on legal analysis and formal aspects of compliance to the EU legislation. Moreover, these reports are a snapshot of the situation at the moment when the mission is taking place; if a MS is not acting correctly during an emergency, the FVO inspections cannot change the situation when dealing with that particular emergency, although the FVO findings, e.g. on shortcomings identified, could be useful *ex post* in the context of future emergencies. Concerns have also been raised by the industry about the fact that these reports

are usually published months after the occurrence of outbreaks and thus the information contained therein may no longer be relevant for stakeholders.

The FVO points outs that currently the objective as laid down in the FVO mandate is to undertake inspections to evaluate what action has been taken to respond to an emergency, but in the context of emergencies, action is often taken at the highest political level in a MS and it goes beyond the FVO role or power to analyse and assess such action.

b) Improving the quality of the MS CP
c) Providing input for their regular review

Nearly all of the responding MS consider the way the FVO missions and reports sufficiently relevant and effective in achieving both of these aims, although more in terms of improving the quality of contingency planning in the MS and less in providing input for regular CP review (Q 16.a and 16.d respectively – FCEC survey results), As also discussed under Theme B, FVO inspections are considered particularly relevant and effective in the process of CP evaluation and follow up (Q 9.a – FCEC survey results), and indeed are a key factor that contributes to ensuring the improvement of contingency planning in the MS (Q 10 – FCEC survey results).

The verification by the FVO in its peer reviewing role is considered crucial for ensuring effective contingency planning across the EU. The FVO CP verification missions carried out in peacetime are indeed considered important for the technical advice they provide and thus improving preparedness in MS, therefore the COM is encouraging MS to use them regularly. These reports have been used more for example by MS engaged in significant trade (e.g. DK, NL). Stakeholders (e.g. Copa-Cogeca) have been consulting them on animal welfare aspects.

The FVO is preparing a template to be used for the reports of the CP verification missions in 2012, using as a model the 14 requirements laid down in the Control Directive for FMD as this the most developed in terms of CP requirements (as already discussed under indicator 3, EQ A/1). The FVO is prioritising requirements for reporting which, at the moment, stand as follows:

- How are exotic diseases dealt with in the MS?
- How are MS prepared for emergency vaccination?
- Are simulation exercises carried out and how?

On the last point in particular, simulation exercises are seen by the FVO as a crucial aspect of contingency planning as they allow MS to see the extent to which CPs are working; un-tested (non-simulated) CPs can in practice be considered as useless (the importance of simulation exercises is discussed further under EQ A/8).

The discussion with MS CAs during the case studies revealed that further support and guidance to improve CPs is welcome; however, the MS do not believe that more prescriptive legislation as such can improve CPs (as also discussed under EQ A/10). The FVO does not consider it necessary either to have more prescriptive EU legislation, as the role of an EU intervention in this field is considered to be to provide general guidelines and leave leeway to MS to adapt to their own circumstances. Also, it has been pointed out that, for the most part,

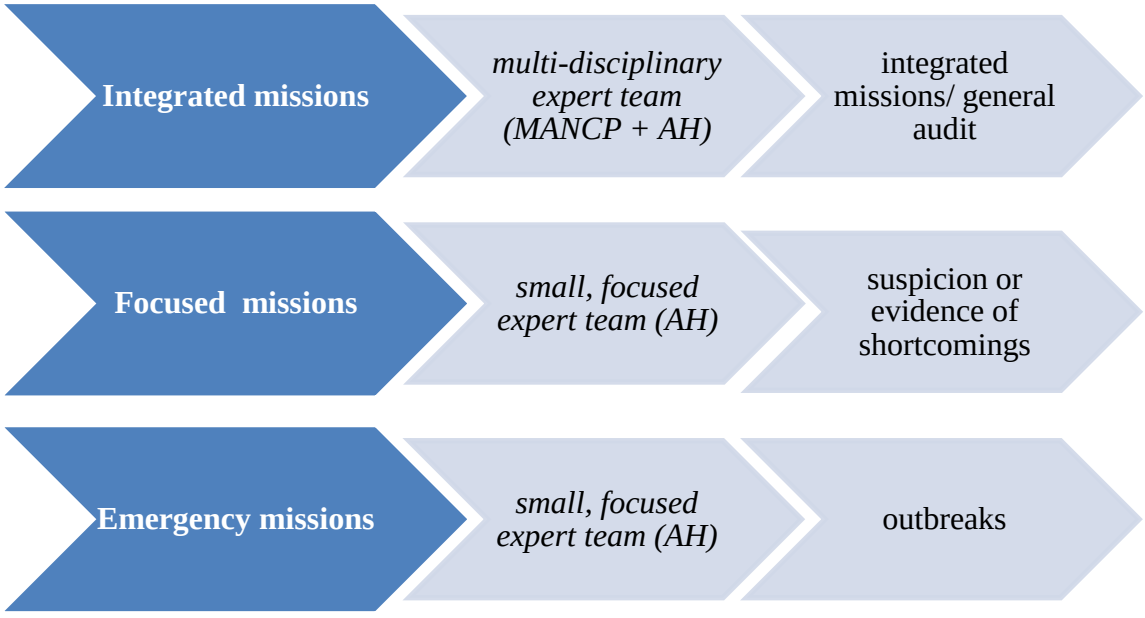
a CP is very useful in the first 36 hours in terms of guidance, for example, where to set up the control centres, where to access phones, IT equipment and staff, who is in overall charge, who should be contacted; and, at local level, what samples to take, what restrictions to impose immediately etc.. Thereafter, MS will proceed on the basis of the evolution of the outbreak.

Having in place some guidelines could also provide better guidance and more focused FVO inspections therefore improving the efficiency of the inspections. For example, the FVO reports on MS implementation of monitoring and eradication programmes are more detailed, and this reflects the COM measures on specific diseases such as BT, CSF FMD which are much more prescriptive.

Moving forward, it was noted that MANCPs are checked via the FVO (at the end of the planning year) to verify whether the MS system in place is effective and well-planned. As, there are links between CPs and MANCPs, for a more consistent approach for the review of contingency planning across the food safety and animal health fields, potential synergies at the level the FVO inspections currently carried out in these sectors there could be explored.

In this case, regular CP verification missions on the basis of a 5-year review cycle (as discussed in EQ E/3) could be carried out by multi-disciplinary teams to cover the broader range of fields falling under the MANCP. In addition, focused missions could be conducted on specific suspicion or evidence of shortcomings, and emergency missions (as currently conducted) in the event of outbreaks, both of which would be conducted by experts in the animal health field. The different levels of the potential FVO missions, their aims and required team expertise, are summarised in the following figure.

Figure 10: Potential levels of FVO inspection missions



Source: FCEC

6.2.5 Use of FVO CP verification reports (EQ E/5 and EQ E/8)

E/5 To what extent are individual CP FVO reports and general reports used by Commission's services to effectively evaluate MS emergency preparedness?

An internal audit carried out in 2006 within DG SANCO recommends that *Directorate D* [the AH Directorate at the time of audit] *should ensure that it benefits fully from FVO expertise in the process of risk assessment and risk management of animal disease outbreaks. The FVO's overall involvement in this process should be clearly described in Directorate D's SOPs.*

Also, the evaluation on the CAHP carried out by the FCEC in 2006 concludes that:
'*'The use of FVO reports in the Commission policy and the decision-**making process appears to be relatively limited** at present and is therefore an issue worth pursuing. Some interviewees mentioned that FVO reports could be more useful if they would give priorities with regard to the risks and provide quantifiable indicators. Also suggestions were made to extend the scope of the FVO to include the provision of advisory services (e.g. to third countries) and the appraisal of the relevance of the legislation. Currently the position is that the objective of the FVO as laid down in its mandate is to undertake inspections, so any extension to its role and scope would imply a change to its mandate. More generally, more effective control of the implementation of EU rules would involve actions that go beyond the FVO inspections as such, including increasing collective knowledge of emerging risks and training/awareness-raising of stakeholders and operators to understand risks. It would also involve constant-coordination and information exchange between DG SANCO, other relevant Commission services (DG AGRI, Trade, TAXUD, OLAF) and the national authorities*''.

The FCEC has sought to understand whether there has been any improvement since the above conclusions of the internal SANCO audit and the FCEC evaluation of the CAHP. This EQ is linked to EQ E/4.

Our findings indicate that several aspects have improved in the consultation of FVO reports by the COM. In particular, the various SANCO units tend to use extensively the 'back to office' briefings, which are drafted immediately after the mission and give a summary of key points (as the final report including MS comments can take months to be published). As in this report key information is already presented, the relevant DG SANCO units confirmed that they take up the key messages in their further actions towards the MS and in discussions at SCoFCAH. In case of severe shortcomings, so-called 'safeguard cell' meetings are held, with representatives of the FVO and the legal and enforcement units of DG SANCO, to take appropriate actions.

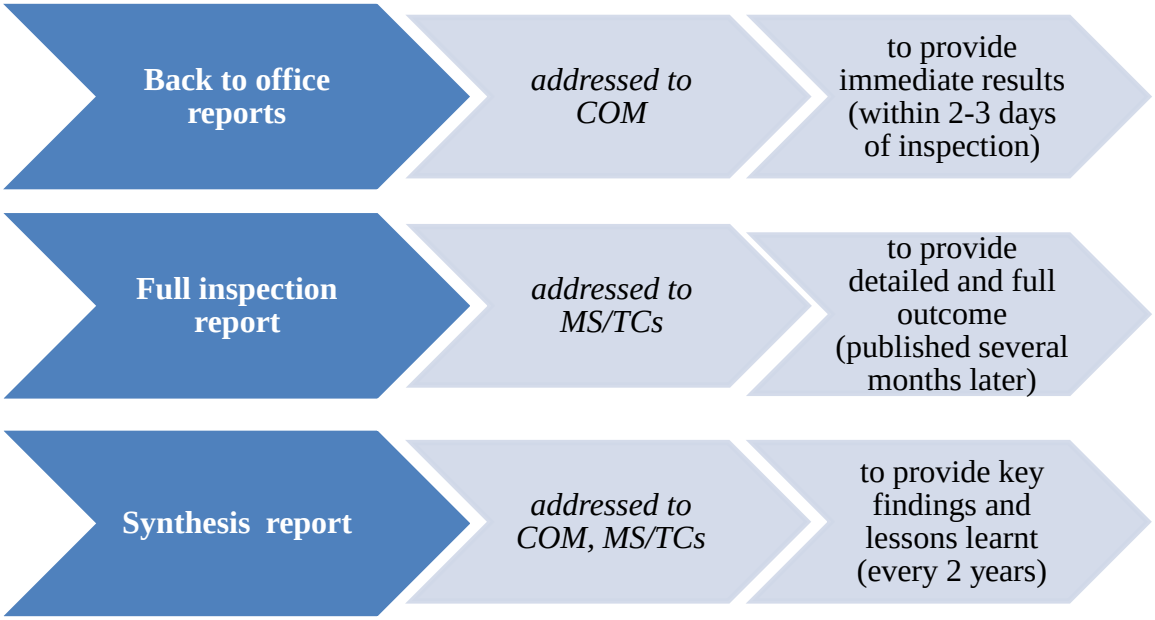
At the level of the FVO, in assessing the preparedness and level of response action in MS, before a mission the FVO consults its reports on other missions carried out, e.g. for the purposes of identification/traceability and the MS country profiles, to check outstanding recommendations (i.e. those FVO recommendations from other FVO reports which have not yet been dealt with) and the progress made; the FVO also cross-checks BT laboratory bio-security preparation reports, which are not published.

It is noted that FVO reporting serves different purposes for the different readers. While the full inspection report is considered most appropriate for the MS being inspected and the other MS and third countries interested in the detailed outcome of the inspection, the COM finds

most useful, for the reasons outlined above, the short 'back to office' report. However, the COM acknowledges that there may be scope for a more synthetic report, to be produced for example every two years, to provide an overview of the key findings of the FVO missions undertaken, follow-up activities and MS feedback including from seminars. The objective would be to retain the main messages from the work carried out by the FVO and exchanges with the MS over the past 2 years, and to eventually enable comparison over time, thus serving once more the collective institutional memory both of the COM and of the MS. As such, the lessons learnt from the synthesis report could directly fit into future policy-making.

These different levels of potential FVO reporting and their use are presented in the following figure.

Figure 11: Potential levels of FVO reporting



Source: FCEC

E/8 To what extent FVO activities and the way it is used in this framework (missions, actions taken, follow up) contribute to support demonstration of the effectiveness of CP to other trading partners?

As noted under Theme A, the EU veterinary system is seen as a model in other world regions, including EU developed trading partners. For example, the experience and lessons learnt in the EU from FMD outbreaks appear to have provided incentives and is being used as a model for the review of CPs in the US and Australia. The EU approach and in particular the detailed guidelines to MS for FMD are today considered the reference in terms of best practice available on how to prepare contingency planning.

Third country trading partners are mostly concerned about the effectiveness of MS CPs in practice i.e. about how MS deal with a disease outbreak when this actually occurs. Nonetheless, the current system of FVO controls on MS contingency planning provides reassurance to third countries, who value the credibility and accuracy of the results of FVO

missions, because the FVO is seen to be an independent third body reviewing the actions of MS CAs, i.e. the credibility of the FVO comes from providing independent analysis of MS situations and actions.

This has not always been the case, a t least not with all third countries. For example, back in 2004 at the accession of the 10 new MS, the US and Canada did not rely on FVO reports on the animal health situation in the new MS and sent their own inspectors to these MS to check their animal health system, and the application of Control Directives and contingency plans. However, the US position is not necessarily followed by other third countries. Other third countries, such as NZ, accepted the EU assessment of the animal health situation in the new MS. Another example is in the late 1990s, when two positive risk assessments on the EU situation on CSF were carried out by the US competent authorities, which were nonetheless not accepted by Australia.

Concerning freedom from animal diseases, third country trading partners tend to rely mainly on the OIE declarations of freedom from disease. Where there is absence of such provisions, they do rely on their own risk assessments, or even own inspections (e.g. USA). Although the credibility of FVO reports seems to have increased, both for stakeholders and for third countries, stakeholders in particular indicate that there appears to be less follow up by the EU of the recommendations of FVO missions in the case of third countries compared to the case of EU MS. Pursuing a stricter follow up of the third country shortcomings identified by FVO reports is considered by these stakeholders important in facilitating trade, and as such there is a call for the COM to give more attention to this matter.

6.2.6 Follow-up activities and lessons learnt from FVO reports (EQ E/6 and EQ E/7)

E/6 To what extent have follow-up activities been completed by Commission services regarding their own area of activity and by the MS CAs, in response to these reports, e.g. follow-up missions in the field further to action plans?

The evaluation of the CAHP carried out by the FCEC in 2006 reports that:
"FVO inspections play a key role in verifying the implementation of the Community rules on animal health in the MS and third countries. While overall these are appreciated, there is an apparent lack of sufficient follow-up to the missions, and apart from the infraction procedure there are no readily usable or proportionate sanctions in cases where competent authorities do not implement the recommendations of the FVO report''.

The FCEC has sought to understand whether there has been any improvement since the above conclusions of the FCEC evaluation of the CAHP.

The current follow-up process of the FVO is as follows: an initial follow-up is carried out (to clarify points in the MS action plan or to request a response to issues that have not been addressed) and assessed internally to propose actions and suggestions on how recommendations may be further followed-up. The MS country profiles (published on the FVO website) provide information and records of FVO recommendations and how MS react: only outstanding issues are reported in the MS country profiles.

The majority of MS act on the FVO recommendations. In the visited case study MS, in response to FVO recommendations, all requested follow-up activities have been completed by the CAs. Out of 141 mission reports on animal health 439 recommendations were made of which 397 (90%) had been given follow up by MS (source - FVO country reports). Hence, FVO recommendations have been given follow up by MS CAs in the vast majority of cases.

It is noted that this indicator should be used carefully. The FVO country profile report for Poland emphasises that ''*the number of recommendations in this overview does not represent, of itself, a measurement of the degree of responsiveness by the Competent Authorities or of the seriousness of problems. Some recommendations may be related to minor technical aspects while others may refer to more problematic, systemic, issues''*

The use of FVO reports by the COM in its policy- and decision-making process continues to improve (as also outlined in EQ E/5): FVO reports are targeted mainly to the EU MS, and the COM tends to use the brief mission conclusions prepared shortly after the visit reports as the full reports, including MS CA feedback, are published several months later.

E/7 What lessons have been learnt from these mission reports and possible follow-up on MS CA activities and what was their impact on a) current legislation and on the new AH Strategy, especially in terms of possible additional tools to those already existing, and b) on FVO inspection mission practices or role?

FVO CP missions on BT in EL, IT, ES, PT in 2006 are all cases demonstrating that more stringent requirements for BT surveillance were introduced in the EU legislation (the Control Directive for BT was revised) based on the FVO recommendations to these countries. FVO reports are considered in conjunction to scientific advances on the various diseases for providing input to review EU directives, as is the case for example with the incorporation of surveillance of low pathogenic AI strains into the relevant EU legislation, but also with surveillance for BTV.

The FVO may raise the attention of DG SANCO on some legislative aspects in case, during MS missions, gaps are found in EU legislation. These aspects are discussed internally within DG SANCO. Although the FVO makes suggestions for development/improvements in EU legislation, this activity does not fall under its mandate.

Lessons learnt from previous experience are important in updating CPs. The adaptability of CPs depends in practice on the MS context and the disease. For example, CPs for BT were adapted following the 2008/09 outbreaks; some MS are generally better than others in updating their CPs based on previous outbreak experiences.

6.3 Conclusions and recommendations (Theme E)

Key findings

Based on the FCEC analysis of the collected evidence base, the following overall conclusions can be drawn on the FVO verification missions regarding CP in peace time (including simulation exercises) and during and after outbreaks of epizootics:

- Several criteria are used by DG SANCO to plan the FVO CP missions (**EQ E/1**). Most FVO missions on animal health follow outbreaks and/or CP verification (in particular: AI, FMD, BT CSF, ASF), and follow up missions due to identified shortcomings, while a smaller number of missions are related to co-funded eradication programmes.
- Generally FVO CP verification missions follow animal health emergencies: following CSF (1997), FMD (2001) and AI (2003, 2006 RO), emergency preparedness missions have been carried out for these diseases in subsequent years (**EQ E/2**).
- Although the current frequency of FVO inspection missions is considered sufficient by the majority of MS (**EQ E/3**), this is not sufficient when considering three other indicators. These are: a) the importance attached by MS to FVO inspections for verifying and improving MS emergency preparedness; b) that verification missions for the CPs on all diseases for all 27 MS are due to be carried out from 2013 (the CPs of the EU-15 MS were last reviewed in 1999-2003, while those of the new MS were reviewed at the time of their accession to the EU); and, c) a 5 year rotation is considered by most experts as the minimum frequency required to keep track of significant changes occurring at the level of staff in the MS CAs and other institutions and organisations involved.
- Generally, MS consider the manner of conducting FVO missions and drafting of reports fairly relevant and efficient in evaluating MS emergency preparedness (**EQ E/4**), although those conducted in case of emergencies appear to be less useful than those relating to contingency planning as such; more forward-looking rather than backward-looking inspections are therefore considered most useful and could fit within a broader approach to the review of contingency planning under the MANCPs.
- FVO reporting has improved since the last CAHP evaluation was carried out in 2007, although it is acknowledged that there is scope for further improvements in using the FVO findings and follow up (**EQ E/5**). FVO reporting serves different purposes for different readers: while the full inspection report is considered most appropriate for the MS being inspected and the other MS and third countries interested in the detailed outcome of the inspection, the COM finds the brief 'back to office' reports produced within 2-3 days after the inspection visit most useful, and uses FVO reports as background information for discussions about MS emergency preparedness at SCoFCAH.
- The majority of MS act on the FVO recommendations. In the visited case study MS, in response to FVO recommendations, all requested follow-up activities have been completed by the CAs. Out of 141 FVO mission reports on animal health, 439 recommendations were made of which 397 (90%) had been followed up by MS (**EQ E/6**).
- FVO reports are considered in conjunction with scientific progress and provide input for reviewing EU directives (HPAI, BTV) (**EQ E/7**). Lessons learnt from previous experience are also important in updating CPs, although in practice the adaptability of CPs depends on the MS context and the disease.
- Third country trading partners are mostly concerned about the effectiveness of MS CPs in practice i.e. about how MS deal with a disease outbreak when this actually occurs, as well as OIE disease-status declarations to establish freedom of disease. In this context, FVO MS inspections provide reassurance to third countries, who increasingly value their credibility and accuracy. Although in the past there appears to have been more reliance on own third country risk assessments or inspections (e.g. USA), over the last

decade third country acceptance of FVO mission reporting appears to have significantly increased (**EQ E/8**).

Recommendations

On the basis of the above conclusions, certain potential improvements to FVO inspections and reporting could be recommended as follows:

1. Following the conclusions of **EQ E/3**, a 5 year cycle is considered the best approach for FVO CP verification missions in the EU27. If the FVO was to achieve a cycle of inspection missions every 5 years per MS to verify MS CPs sufficiently, this would result in an additional 5/6 missions per year, and assuming all other FVO work (e.g. missions on the monitoring and eradication programmes etc.) were to continue as at present, this would result in an additional requirement for 2 more inspectors in the FVO AH unit.
2. Although more prescriptive EU legislation on CP requirements is not considered appropriate, having in place some guidelines to further explain the CP requirements of the Control Directives (see Theme A) could also provide better guidance and more focused FVO inspections thereby improving the efficiency of the inspections (**EQ E/4**) This is the case with the FVO reports on monitoring and eradication programmes, for which the COM measures on specific diseases are more prescriptive.
3. To improve consistency in contingency planning across all relevant sectors potential synergies in FVO inspections for CPs and MANCPs (Multi Annual Control Plans) could be explored. In this case, regular CP verification missions on the basis of a 5-year review cycle (as discussed above) could be carried out by multi-disciplinary teams to cover the broader range of fields falling under the MANCP; in addition, focused missions could be conducted on specific suspicion or evidence of shortcomings, and emergency missions (as currently conducted) in the event of outbreaks, both of which would be conducted by experts in the animal health field (**EQ E/4**).
4. In terms of FVO mission reporting and improving the usability of FVO reports by other COM services, in addition to the current 'back-to-office' and full inspection reports, there may be scope for a more synthetic report, for example every two years, to provide an overview of the key findings of the FVO missions undertaken, follow-up activities and MS feedback including from seminars (**EQ E/5**). As such, the lessons learnt from the synthesis report could fit directly into future policy-making.

7 Theme F: the information flow in case of epizootics as well as the cooperation between MS CAs and stakeholders during CP elaboration and implementation

7.1 Background

The specific objective of this theme is to evaluate the degree of stakeholder involvement and coordination between MS CAs and stakeholders in preparing and updating the CPs and during implementation (including simulation exercises); and, the MS communication systems in case of epizootics between neighbouring MS and with neighbouring third countries, towards third country trading partners and towards different groups of stakeholders (farmers, agro-food industries, and also, citizens/consumers).

Some of these issues have been extensively addressed in Theme A, in particular the extent to which stakeholders are involved in the different phases of CP development (EQ F/1) and cooperation between neighbouring MS and/or third countries (EQ F/3). Therefore, the analysis here focuses more on the information flows between the different actors during animal health emergencies.

7.2 Findings

7.2.1 Involvement of stakeholders in CP development (EQ F/1)

F/1 To what extent have MS CAs involved the various stakeholders in the conception, drafting, preparation, updating and amendment of the CP to facilitate their effective cooperation and coordination during implementation (eventual reasons of an absence of cooperation)?

This aspect has already been addressed in **EQ A/1** (**indicator 5**) and **EQ A/2**, by highlighting the advantages and disadvantages of the current stakeholder involvement in CP development as well as the need for having a clear and defined rule on this in the EU legislation.

Our analysis shows that the participation of stakeholders contributes in several ways to improving the quality of contingency planning. It concludes that, at the moment, stakeholder involvement in MS contingency planning can be encouraged and reinforced through the introduction of a general provision on this in the CP requirements of the Control Directives, rather than more descriptive legislation.

7.2.2 Communication between the CAs of neighbouring MS and/or third countries (EQ F/3)

F/3 To what extent is the MS CA communication with the CA of neighbouring MS (or neighbouring third countries) on epizootics appropriate and what additional measures should be taken?

One of the key activities of the rapid response and emergency network is the notification of outbreak occurrence by the affected MS CA to the CA of other MS and/or third countries and

the COM. In order to ensure a rapid exchange of information between the national CAs responsible for animal health and the COM on outbreaks of contagious animal diseases, the EU has provided the legal basis (Council Directive 82/894/EEC) for a computerised information system (ADNS/ADIS) which alerts Commission services and MS Chief Veterinary Officers (CVOs), within 24 hours of confirmed primary outbreaks. Annex 1 of this Directive lists the animal diseases subject to notification. With regard to third countries, this usually occurs through the EU via notification to the OIE WAHID (World Animal Health Information Database) interface. While further details on ADNS/ADIS as an information tool are provided in Theme C, this EQ examines the communication and information flows between MS.

The improvement in cooperation/coordination between countries is expected to be paralleled by improvements in the communication flow. Although this has generally been the case, as discussed below, there is still scope for improvement, particularly between MS that have not as yet developed a tradition of cooperation and with third countries.

As also reported under **EQ A/3 and EQ A/4**, over the last decade significant progress has been made to reinforce cooperation/coordination activities between MS CAs, as a consequence of the lessons learnt from the negative impacts of the lack of cooperation/ coordination. An initial 1-day conference on coordination between MS CAs, including communication during epizootics, has been identified as a potential suitable improvement (see recommendation 5, Theme A). In case of epizootics, regular reports are also published in the SCoFCAH website within 24 hours from the end of emergency session of the SCoFCAH, which provides the framework for the COM to work in cooperation with the affected MS (and where needed with neighbouring third countries), so as to ensure the maximum transparency on the evolution of disease outbreaks.

A number of recent positive cases of cooperation/coordination activities between MS confirming this encouraging trend have been provided in Theme A (EQ A/3). In particular, as mentioned in EQ A/4 (indicator 1), the recent Schmallenberg outbreak has provided the opportunity to fine-tune the mechanism of risk communication between the affected MS and the COM. Several incentives have been undertaken which have improved the information flows between the MS, such as the creation of a specific website with all the relevant information on SBV2, the organisation of a one-day scientific seminar on the "Management of the Schmallenberg Virus", and the sharing of the latest scientific findings with the OIE.

On the communication side, several elements have been, however, identified by some MS CAs, as well as by EU stakeholders in need of improvement, such as increasing the speed and transparency of the information flow, avoiding or overcoming the conflict of interest between the economic and health interests, and establishing principles regarding the communication flow across EU MS and with relevant stakeholders.

In terms of additional tools to improve communication flows between MS, one MS indicates that it would be good if the COM encourages MS to improve the level and detail of their

databases providing also input to ADNS/ADIS[76], which in case of emergencies can be used to provide data to other MS and the COM.

Although cooperation between MS and neighbouring third countries has improved over the years (with several positive examples identified in EQ A/3), communication has sometimes proven more difficult for some MS due to a lack of commitment or communication of neighbouring third countries.

Beyond the communication in the context of cooperation initiatives between specific MS and neighbouring third countries, communication with third countries on animal health issues is mainly conducted at MS and EU level via the OIE. Over the years, the EU has developed a number of instruments and incentives in the animal health field which have increased its pro-active, transparent, and timely role in cooperation/coordination with neighbouring third countries during emergencies. Some of these instruments directly involve the development of animal disease CPs, others are related to cooperation activities which cover specific element of contingency planning (e.g. vaccine bank for FMD, and BTSF training). In particular, the following initiatives are currently running:

- In the context of the European Neighbourhood Policy (ENP)[77], an individual ENP Action plan, including approximation to EU animal health legislation, is drafted jointly by the COM and the partner state. Also for the Eastern Partners (Armenia, Azerbaijan, Belarus, Georgia, Moldova and Ukraine) one initiative has been started by the COM in 2008 and inaugurated in Prague in 2009. Its main goal is to provide these countries with an institutionalised forum for discussing free trade deals and strategic partnership agreements with the EU's eastern neighbours. In the trade field, Deep and Comprehensive Free Trade Agreements (DCFTA) are foreseen to be negotiated with different eastern partners, where a special SPS chapter including animal health is envisaged. DCFTAs are a part of broader Association agreements foreseen to be negotiated and signed with some of these countries. Ukraine is ready to sing a DCFTA this year, while the COM is planning to start negotiations on such as agreements with Georgia and Moldova next year.
- Support to draft CPs: This activity currently takes place in the context of twinning programmes or EU advisory groups in Ukraine, Georgia, Armenia and Moldova.
- BTSF: training of officials and veterinaries in third countries. The initiative includes: field, laboratory and diagnostic training and ad-hoc training (e.g. on ASF in Ukraine).
- Cooperation between the EU and neighbouring third countries on specific diseases[78]: several examples of cooperation on FMD, ASF, CSF, rabies and PPR. Under the EuFMD[79] several actions, including the supply of FMD vaccines by the EU vaccine

[76] This MS has recently developed an Animal Disease Information System which gathers all information on outbreaks, suspect or confirmed cases by specifying date, place and number of infected animals. All local and national authorities have direct access to this database.

[77] This covers East European countries and Maghreb/Middle East (Algeria, Armenia, Azerbaijan, Belarus, Egypt, Georgia, Israel, Jordan, Lebanon, Libya, Moldova, Morocco, the Occupied Palestinian Territory, Syria, Tunisia and Ukraine).

[78] See also GF-TADs for Europe - Regional Activity Report 2010/2011. The GF TADs (Global Framework for the progressive control of Transboundary Animal Diseases) is a joint FAO/OIE initiative

[79] The EuFMD is a regional body specialised in supporting member countries (currently 36) in the European region to prevent FMD, through actions co-ordinated with those of the EU through DG-SANCO. The EuFMD Commission supports risk reduction in the European neighbourhood, under the Co ordination mechanism of the

bank to the Caucasian region (e.g. Turkey and Georgia); cooperation with eastern European third countries on ASF[80]; cooperation activities on rabies[81]; on CSF, EU project in Western Balkans under the EU pre-accession mechanism; on PPR, EU support to Turkey for animal identification & mass vaccination;

- Early Warning system: disease notification is made directly to SANCO;
- TAIEX: workshops and expert missions at the request of the trading partner. A TAIEX expert mission was carried out in September 2011; another mission is foreseen in Armenia in 2012. Also, a workshop on future challenges for veterinarians in the EU and neighbouring countries was organised in Budapest in April 2011 by the EU presidency and TAIEX;
- Potsdam Group: in the context of the European Council, this Group deals with certain veterinary agreements with third countries. It is made up of MS that, for particular reasons, have consolidated relations with TC partners and they represent all 27 MS in negotiations.

The expectation of both MS and of the COM is that communication can improve further, as bilateral and multilateral relations improve, promoted *inter alia* by an approximation between the EU27 and neighbouring third countries in the context of the above initiatives.

7.2.3 Communication between the CAs of MS and third country trading partners (EQ F/4)

F/4 To what extent is the MS CA communication on epizootics with the CA of trading partners (to which animals or risk products has been exported) appropriate and what additional measures should be taken?

Indicators 1 and 2: Current information flows with trading partners during epizootics

As already discussed under EQ F/3 in relation to communication with neighbouring third countries, primarily this role is left to the EU. As a routine, DG SANCO informs all DGs concerned and certain third countries - the candidate MS, countries with which the EU has concluded trade and cooperation agreements, and the other main trading partners[82]. The

West Eurasia FMD Roadmap which aims to achieve FMD control by 2020 in 14 countries which have endemic FMD in all or part of their territories. It has developed the Progressive Control pathway (PCP) for FMD to assist national and regional actions in this region. The EuFMD implements projects in the Caucasus, Turkey, Syria, Iran and Egypt aimed at progressive FMD control and thereby reducing risk to EuFMD member countries.

[80] EU VET mission in Ukraine (Aug. 2010); EU BTSF sustained training missions in November 2011 in Belarus, Ukraine and Moldova; EU BTSF laboratory training workshop in Vilnius, Lithuania, for Russia, Ukraine, Moldova, Belarus, Georgia and Armenia (December 2011); EU ASF Risk research programme (Ended September 2011).

[81] EU eradication projects are on-going in the countries bordering the EU to the north-east, and on-going EU project in Western Balkans.

[82] Within the COM, there is a division of competences between DG SANCO and DG TRADE for export matters. When a veterinary agreement or an agreement with an SPS chapter exists (i.e. currently with the US, Chile, Canada, Russia, New Zealand), DG SANCO has full competence, including communication. Veterinary agreements help ensuring a well-structured dialogue between the EU and third countries. When the export competence is with DG TRADE, this DG is also competent for the communication. In both cases, use is also made of the EU Delegations in third countries to ensure proper communication with the third country CAs and

notification of animal diseases to all other third countries occurs through the EU via notifications to the OIE. Further information on the evolution of the outbreak is provided in the reports published in the SCoFCAH website within 24 hours from the end of an emergency session, and this can provide transparent and validated information for the COM to work in cooperation with the affected MS (and where needed with neighbouring third countries or third country trading partners).

The appropriateness of the current information flow between exporting MS CAs and destination third country CAs can be established by assessing whether this fulfils the main objectives for which the communication exists. One of the ultimate objectives of the EU animal disease risk prevention, management and communication system is to guarantee the continuation of production and trade of the EU livestock sectors and to contribute to the economic sustainability of the sector directly or indirectly affected by an animal disease outbreak, including the impact of the EU measures taken to control outbreaks.

Animal diseases and their control have had a significant impact on EU meat trade in the last two decades (for example, outbreaks of BSE, FMD, AI etc.). The EU however remains a large player in meat trade exporting more than 3.8 million tonnes in 2010. The net trade position of the EU varies between livestock sectors, as **Table 10** shows.

Table 10: Exports of the EU key livestock sectors to third countries, 2010 ('000 tonnes)

	Imports	Exports	Net trade
TOTAL meat & meat preparations (SITC-01)	**1, 413**	**3,821**	**2,407**
Bovine meat	203	212	8
Sheep or goat meat	196	12	-184
Pig meat	19	1,260	1,242
Poultry meat & edible offal	165	1,124	959

Source: Eurostat (Comext)

A key aspect of the EU and MS communication with trading partners is related to whether there is recognition of EU regionalisation procedures, which has become an essential element of the EU rapid response management.

The EU is at the forefront of applying in practice the regionalisation concept in international trade and continues to encourage all trading partners to follow regionalisation principles and to recognise its advantages in minimising trade disruptions while ensuring high animal health status. A number of third countries has indeed been increasingly recognising EU regionalisation policy[83], in accordance with SPS and OIE guidelines and standards, while animal health is no longer the most controversial issue that could potentially block progress

industry. In cases of big crisis, DG SANCO has created a task force with DG TRADE to also manage the communication issues.

[83] With the US, the EU regionalisation policy is now accepted for 19 MS for CSF; UK regionalisation policy is fully accepted for FMD, helped also by the close relation between the two countries. For SVD, the US has recently regionalised Italy, but continuing to apply its own rules to re-open trade. During the AI outbreaks in 2006 both the US and Canada applied regionalisation in response to AI outbreaks occurred in France, Sweden and Germany at the beginning of 2006 and imports restrictions were limited to the affected areas.

in EU trade negotiations[84]. As a result, outbreaks that occurred over the last decade (e.g. CSF and FMD) have had less impact on trade than those of 20 years ago.

International organisations have a very positive view of the EU approach and the progress made; the OIE considers the EU as a model[85] in terms of prevention and control of animal diseases and for the good governance of veterinary services (harmonised legal framework; adoption of safeguard measures; import regulations; etc). The successful experience over the last decade in containing, controlling and eradicating epizootics, such as FMD, CSF and AI in affected MS or in regions within MS has demonstrated that control disease measures and regionalisation procedures are integrated together. EU legislation and the MS national CPs are considered an essential element in reinforcing and strengthening the correct implementation of regionalisation principles in the event of disease outbreaks, by improving transparency, exchange of information, predictability, confidence and credibility with its trading partners.

Despite the significant progress achieved in the last decade, there are still some issues of concern. Some third countries call for additional guarantees on MS exports, which are however usually demanded on diseases for which there are no harmonised EU measures, or may unilaterally impose export conditions - which in some cases are not compatible with the principles of the functioning of the EU single market - because of a perceived lack of harmonisation in the measures taken across the EU[86] or the disproportional reaction of third country trading partners. The latter, in particular, justifies the need to continue efforts to improve cooperation with certain third countries, including via the conclusion of trade and cooperation agreements with a veterinary (or SPS) chapter, but also by improving the predictability of MS contingency planning to react to new emerging threats as the recent relatively rapid MS response to the SBV outbreaks has demonstrated (this issue has been discussed in Theme A).

[84] The EU has concluded a series of new FTAs with SPS chapters with Peru, Colombia, and South Korea while the negotiation is still open with MERCOSUR, Singapore, Malaysia, Ukraine and India.

[85] Some groups of third countries have been trying to mirror/replicate elements of the EU approach on animal health management. The Union Economique et Monétaire Ouest Africaine (UEMOA) have created a Permanent Veterinary Committee – Comité Vétérinaire Permanent (CVP) – which is based on the EU model; in 2004-2005 they have also harmonised food safety legislation. A WAEMU strategy for the reinforcement of veterinary services in the region was elaborated based on a regional analysis of the OIE PVS evaluation results carried in all countries of the region.

[86] The rationale of this position is based on certain third countries' view that rules for the functioning of the single market or control rules for animal diseases are not implemented by MS in harmonised way.

7.2.4 Communication towards stakeholders and citizens/consumers (EQ F/5, F/6, F/2)

F/5 To what extent is the MS CA communication on epizootics appropriate and what measures should be taken, e.g. quantity, quality, right messages to various categories of people, right time to communicate on urgent measures, especially with the most concerned stakeholders representing farmers (economic or/and sanitary interest) and agro food industries?

Indicators 1 and 2: MS communication capacity towards relevant stakeholders

During the MS case studies, national stakeholder organisations indicated that the current level of communication from the MS CA is considered generally satisfactory. Over the years, progress has been made in improving the communication at national, regional and local level in several MS, also as a consequence of the lessons learned in addressing outbreaks:

- In France the role of stakeholders, including in particular the GDS, has been reinforced following the large consultation ('*Etats Généraux du Sanitaire'*) carried out in 2010, which resulted in the introduction of a specific structure for relevant stakeholders' involvement and information exchange in the context of epidemio-surveillance, as well as the development of a framework for responsibility sharing. It raises the level of acceptance of the FR CA's decisions by local actors, as farmers' professional organisations internally communicate to their local members.
- In Germany, two stakeholders emphasised being well informed and up to date and also underlined that communication had improved since the outbreak of BT in 2007.
- In the UK, some of the consulted stakeholders highlighted the FMD outbreaks in the UK in 2007 where the sharing of information, and clear and regular communication between all parties, resulted in a more coordinated and effective response. The communication system has been further improved after the *Silver Birch* recommendations (2010 simulation exercise for FMD), by extending to the LDCCs communication at regional and local press on the basis of a single briefing document prepared at central level by the NDCC under the CVO.
- In Romania one stakeholder organisation cited positive examples where over the past few years the National Sanitary Veterinary and Food Safety Authority (NSVFSA) circulated information regarding AI, FMD and CSF.

Nonetheless, consultation with national and European stakeholders and the MS CA have highlighted that there is still room for improvement. Several MS stakeholders indicated that necessary improvements would *inter alia* include better timing/frequency of the information flow, and greater accuracy and scientific backing of the information provided. Examples of a lack of precise information have been identified in Q fever in the Netherlands, and the 2005 AI outbreaks in Italy. At EU level, one stakeholder organisation indicated that problems may arise from the fact that some countries do not make a distinction between the communication for stakeholders and communication destined to the general public. Similarly, some MS indicated that the communications system could improve by ensuring that the appropriate level of detail is transmitted to the targeted audience. A solution proposed by two national stakeholders in one MS would be to adopt a more proactive approach where stakeholders and journalists are informed upfront about the people in the sector to contact for trustworthy information. The use of up to date communication tools, such as SMS services for updates on

outbreaks, and videos on the CA's website, showing the specific clinical signs of a relevant disease, was also suggested by one MS.

In terms of having a forum at stakeholder level for information exchange (similar to the that taking place in the context of SCoFCAH meetings), during the MS case studies and interviews there were divergent views between the various organisations consulted on both the necessity and method to follow for information exchange. For most of the relevant stakeholders at EU level, it would be good to have a more planned and regular information exchange between DG SANCO and key stakeholders; also, in five MS the majority of stakeholders consider it important to have an equivalent 'forum' at stakeholder level for information exchange on outbreak evolution. At present, co-operation takes place on an ad-hoc basis. A more structured way of cooperation would provide both parties with better opportunities of discussing and understanding current issues both in peace time and in emergency situations. The most favoured options were the creation of *a special WP within AH/AW Advisory Committee* followed by a stakeholder's own forum. On the other hand, in other MS national stakeholders indicated that there are enough platforms representing stakeholders at EU level and thus there is no need to create additional ones; they also preferred to receive information from a unique and official source such as SCoFCAH meetings.

F/6 What is the level of risk communication capacity of MS towards citizens/consumers in time of crisis in general?

Indicators 1 to 3: MS communication capacity towards citizens

All MS CAs reported that they are broadly satisfied with the current communication flow towards citizens/ consumers: 14 MS consider this to be fully sufficient, with the remaining 13 MS considering it partly sufficient (Q19 - FCEC survey**)**. However, communication to the wider public tends to be highly variable between MS.

Some MS have indeed reported that, in the past, the lack of an appropriate level of communication towards consumers and citizens resulted in unnecessary concerns. However, they also indicated that over the last decade significant improvements have been made on this, in light of the experience gained. In particular:

- Since the 2005 AI outbreak, the IT CA decided that only the spokespersons of the Ministry of Health could release information on animal diseases in order to ensure a consistent and scientifically based message at time of crisis. This new approach of communication has been highly appreciated especially by those stakeholder organisations for which a lack of scientific approach to communications in 2005 caused significant communication costs.
- In the UK the LDCCs cover the regional and local press on the basis of the single briefing document prepared at central level by the NDCC under the responsibility of the CVO; this was improved after the *Silver Birch* exercise (2010) recommendations, where delegation for local/regional briefing was given to the LDCCs but on the basis of this single briefing document.

- In France in the case of FMD and CSF, all official press releases had the obligation to mention the absence of health risk to the population, and stakeholders confirmed that this had a positive impact in reassuring the public.
- In Belgium, the communication policy was revised during the last 5 years as a consequence of the over-communication problems experienced immediately after the creation of the national food safety agency (the AFSCA). Today, both the national CA and stakeholder organisations indicted a balanced communication flow has been established between them and towards the wider public. AFSCA also carried out in 2010 a survey to evaluate consumers' perception of its services for the control of food chain in Belgium AFSA (2010). Although the survey did not address specifically issues related to animal health emergencies, the results demonstrated that citizens' confidence in the system has improved. Generally speaking, Belgian consumers (1,321 respondents) considered the actions of AFSCA to be effective and food security to have improved throughout the decade, and 90% of respondents considered the service provided through ASFCA to be useful to society (Houins, 2010).

An appropriate information flow and coordination of communication between the COM and MS is also fundamental for ensuring an adequate level of risk communication capacity towards citizens and consumers.

DG SANCO officials, as well as the consulted MS CAs during the case studies, indicated that the communication of the COM has also improved over the last decade. The relationships that the COM has established with the MS and, inter-institutionally, with EFSA have been, in most cases, effective in providing scientific validation to communication messages issued by the COM, thus contributing to preventing unnecessary speculation. However, the 2006 AI outbreak and the more recent *E. coli* crisis have indeed demonstrated the importance of having the information flow channelled to the outside world via a limited number of key officials, in order to ensure more coherent, scientifically based and timely messages at all levels (EU, national and regional) during epizootics. This, however, cannot completely discount the increased complexity of preventing information leakages and controlling speculation.

At the time of the AI crisis, DG SANCO's Public Health Directorate had set up the Health Security Committee (HSC Communicators network in November 2008)[87], a network of communicators on pandemic preparedness (human health). Such a network appears easier to establish for public health and food borne diseases rather than for animal health, due also to some historic difficulties in lack of communication with some MS veterinary services.

Lessons learnt from the AI crisis were reviewed at the *Conference on lessons learned from the H1N1 pandemic*, which was held in Brussels on 1 and 2 July 2010. The table below presents the main conclusions reached at the conference in the field of communication; this

[87] Today the network includes all 27 MS, the 3 EEA countries, and the following EU agencies and international health organisations: ECDC, EFSA, EMA, ECHA, WHO EUROPE and WHO HQ. The network has met 4 times since its establishment. Ad hoc expertise (OIE, FAO, etc) could be invited for specific events when needed and depending on the topics under discussion. The network has established links with the Global Health Security Action Group GHSAG communicators' network and with the WHO communicators' network (under IHR).

was an interesting case on how to develop a process/system of taking into account lessons learnt in terms of crisis communication management, especially with regard to the first two points. It is noted, however that, although useful in the short run, the duration of the impact of messages coming out of this type of conferences tends to be rather short, while the fact that press officers move frequently tends to result in an overall low level of institutional memory.

Finally, it has also been noted by most of the relevant EU stakeholders that currently many EU consumers/citizens are unaware of the fact that EU standards relating to animal health and welfare are among the most stringent in the world. It is therefore vital that the EU animal health and welfare policy is communicated and explained adequately to consumers/citizens through appropriate information campaigns.

F/2 To what extent should CPs be made publicly available (evaluation of benefits of transparency and public awareness vs. possible risk of bioterrorism)?

MS are quite divided on the extent to which CPs should be made publicly available (on-line).

In particular, the CAs in 13 MS take the position that CPs should be published in their entirety, while the publication only of summaries of CPs is not considered sufficient by these MS. Their position is justified on the grounds that public awareness and transparency promote rapid response in case of emergency. Making CPs publicly available improves the access to information and ensures a better preparedness regarding the actions to take.

The CAs of the other 14 MS understand the above position but consider that only summaries of CPs should be made publicly available. Although transparency and an easy access to CPs are deemed important, these MS point out at the potential risks related to the release of certain information to the general public, in particular with regard to the confidentiality of sensitive information such as contact details, the existing level of expertise and technical aspects of the action plan, but also from a potential bioterrorism point of view (e.g. publication of maps).

To address these concerns, a limited access or a filtering system may be a solution for accessing CP information only by relevant registered stakeholders.

Table 11: Main conclusions in the field of communication at the Conference on lessons learned from the AI (H1N1) pandemic in Brussels July 2010

Communication
1. The HSC Communicators' Network, which played a key role in harmonising the Member States during the pandemic, while providing **support and advice to each other in the writing of common guidelines as well as in the development of the messages on key subjects.** In decision-making on future policies, the HSC must take into account communication factors, which can be obtained through the **collection of the comments, the feedback and the experiences of the HSC Communicators' Network**. The existing tools available to the Network must be improved and adjusted (like HEDIS and Medisys).
2. Surveys of the members showed the possibility of using stakeholders and the media to communicate both to the population in general and to specific target groups. **Identifying and establishing a relationship with stakeholders and the media before a pandemic is essential.** Establishing relationships of trust with journalists before a crisis begins is judged to be essential to better guarantee good working relationships during a crisis. **The existence of a select group of available experts to answer questions from journalists at all times**, as well as the **availability of a spokesperson**, are both considered essential.
3. Global analyses of the target groups, including their use of the media, their consumer behaviour, the information sources they trust and which they consider credible, would be useful in order to develop key messages that are tailored and personalised for the respective target groups. Furthermore, polls and surveys are considered to be essential tools for understanding the perceptions and behaviours of our citizens in a health crisis. These methods make it possible to monitor changes in behaviour and, consequently, to assess whether we are passing on the right messages. A plan for conducting polls / surveys must be established before a crisis. The polling methods, the models and the results should be shared between countries as a source of information and the exchanging of good practices.
4. The use of new social media (Web 2.0) is increasing ever more rapidly and will offer new possibilities for reaching specific target groups. The possibility exists to monitor and analyse the activity of these groups and by so doing to spot the early warning signs of alarm and trends. The current trend should continue and cannot be ignored or left out of any communication plan. Social media is managed by the users and is a two-way form of communication. The institutions must get involved in these recent developments and learn to communicate "with" and not "to" the public so that there is rapid response. In this way, the key messages can be adjusted according to what is being said online

Source: Council conclusions on Lessons learned from the A/H1N1 pandemic – Health security in the European Union

7.3 Conclusions and recommendations (Theme F)

Key findings

Based on the FCEC analysis of the collected evidence base, the following overall conclusions can be drawn on the information flow in case of epizootics as well as the cooperation between MS CAs and stakeholders during CP elaboration and implementation:

- The involvement of the various stakeholders in the conception, drafting, preparation, updating and amendment of the CP (**EQ F/1**) has been extensively analysed in Theme A. It is concluded that stakeholder involvement in MS contingency planning should be encouraged and reinforced through the introduction of a general provision on this in the CP requirements of the Control Directives, rather than more prescriptive legislation (EQ A/2 and recommendation 4 of Theme A).
- With regard to communication between MS CAs and stakeholders progress has been made, but there is still room for improvement in terms of the timing/frequency, the accuracy and scientific backing of the information provided, as well as ensuring that the appropriate level of detail is transmitted to the targeted audience (**EQ F/5).**
- Broadly speaking, the improvement in cooperation/coordination between countries is expected to be paralleled by improvements in the communication flow. A number of recent positive cases of cooperation/coordination activities between MS CAs confirming this encouraging trend have been provided in Theme A. Regarding neighbouring third countries, a number of initiatives are in place aiming to reinforce cooperation activities, whereby beneficial effects are also expected in terms of improving communication (**EQ F/3**).
- In relation to communication with third country trading partners, the EU is at the forefront of applying the regionalisation concept in international trade as this has proven an effective way of managing outbreaks at the level of the affected MS or regions within MS, without the rest of the EU or an exporting third country being penalised (**EQ F/4**). As a result, more recent outbreaks have generally had less impact on trade than those that occurred 20 years ago, and animal health is no longer the most controversial issue in EU negotiation with third countries. However, more has to be done to better integrate EU strategy in managing and communicating on animal health emergencies, including on improving transparency and the application of regionalisation principles.
- Communication to the wider public is generally considered sufficient, although it remains highly variable between MS **(EQ F/6)**. It is considered that in spite of the considerable progress seen in this regard over the last decade there is scope for further improvement in the coherence, scientific quality/validity and timing of information flows**.**
- There are divergent MS CA views on the extent to which CPs should be made publicly available (on-line), with those in favour arguing that awareness and transparency in the procedures promotes rapid response in the event of an

emergency, and those against concerned about the potential risks related to the release of certain sensitive information to the general public **(EQ F/2).**

Recommendations

From our review of the evidence base, the following conclusions can be reached on potential improvements to the current system:

1. Limited access or a filtering system may be a solution for accessing CP information on-line only by relevant registered users (**EQ F/2**).
2. Regarding MS communication with neighbouring MS, an initial 1-day conference between MS CAs, has already been identified as a potential way forward to improve coordination in CP development, including communication during epizootics (recommendation 5, Theme A). In addition, increasing the level and detail of MS national databases providing also input to ADNS/ADIS could be considered, so as to improve the availability of information which in case of emergencies can be used to provide data to other MS and the COM (**EQ F/3**).
3. Promoting the opportunity for information exchange at stakeholder level, similar to that currently provided to MS CAs in the context of SCoFCAH meetings, could be further considered (**EQ F/5**).
4. Improving the MS application of regionalisation on the basis of EU common principles and criteria on geographical demarcation of restriction zones through specific provisions in EU legislation needs to be considered. (**EQ F/4**).
5. Although the creation of a network of communicators in the field of animal health may not be the magic solution for improving communication, due *inter alia* to a generally low level of institutional memory brought about by the relatively frequent change of position of the people involved, where possible it would be desirable to pursue further some of the useful recommendations provided by the *Conference on lessons learned from the H1N1 pandemic*. Another key lesson drawn from outbreaks over the last decade is the importance of having the information flow channelled to the outside world via a limited number of key officials, in order to ensure more coherent, scientifically based and timely messages at all levels (EU, national and regional) during epizootics (**EQ F/6**).

8 Theme G: the effectiveness and efficiency of the EU rapid response network

G/1 To what extent is the EU rapid response network an effective and efficient tool in keeping a high level of sanitary protection in the EU and achieving defence of this status towards trade partners in order to minimise negative effects on trade of live animals, animal products and food of animal origin?

8.1 Background

This is an over-arching evaluation theme. Following on from the analysis of specific parts of the EU rapid response network (themes A-F), this theme has the specific objective of evaluating the effectiveness and efficiency of the network as a whole in protecting animal and public health as well as minimising the negative effects on trade of live animal and animal products. It therefore assesses the extent to which the EU rapid response network has been effective and efficient in achieving the objectives for which it was set up.

A number of indicators were used by the FCEC to assess EQ G/1, some of which have already been covered in the analysis of Themes A-F, as follows:

1. The **number of emergencies (outbreaks) over the period** under review, and **how many of these developed into a crisis**. The trend/pattern over time is an indicator of the effectiveness of the rapid response network including contingency planning.
2. **The extent to which outbreaks occur outside established restriction zones**, as determined by the ratio of primary to secondary outbreaks. Under certain conditions this could be an indicator of the effectiveness of the system.
3. **Trend in the level of EU emergency funding over time**. The costs of emergency measures and level of EU emergency funding, as such and when compared to the level of animal health funding on eradication and control programmes, can be used to determine the extent to which contingency planning and the rapid response network contribute to minimise the cost of emergencies due to the speed and effectiveness of the action taken. This is therefore an indicator of both the effectiveness and the efficiency of the rapid response system, as this has evolved over the period under review.
4. **Additional costs of SCoFCAH meetings and FVO missions**[88]. These costs, borne by the COM and MS, can be considered against the added value in terms of results obtained. Such costs are in particular analysed with reference to:
    i. The cost of **SCoFCAH meetings** (with reference in particular to information exchange and the adoption of containment measures, covered respectively in Themes C and D);
    ii. Improving the frequency of **FVO inspection missions** to MS to verify CP compliance with the relevant legislation (as recommended in Theme E).

[88] The purpose of this indicator is not to cover the full costs of running the EU rapid response network (for the COM and MS), which did not form part of the evaluation, but only to cover certain key components of the EU rapid response system that are important for the implementation of certain processes in place, the effectiveness and the efficiency of which have been the subject of detailed analysis under Themes A-F.

5. The **economic impact of an animal health crisis**, as a more general indicator of the counterfactual in the absence of effective rapid response.

It is noted that the evaluation has aimed to identify suitable quantitative indicators to analyse the effectiveness and the efficiency of EU rapid response network. This has proven difficult for two main reasons:

- A key issue is the scarcity of data to develop relevant quantitative indicators for an evaluation of this nature;
- Furthermore, even when data exist, these are not always relevant or indicative of causality. For example, the reduction/increase in the number of primary outbreaks over time may to some extent be linked to the effective/ineffective operation of the emergency network, but also to other risk management options such as effective surveillance and prevention, as well as to changing external risk factors such as changing patterns of trade, the evolving epidemiology of a disease etc. In this case, it is difficult to attribute direct causality to the intervention under review, i.e. the extent to which the intervention has contributed to achieving the reduction in the number of outbreaks compared to other contributing factors. Similarly, it is difficult to establish the counterfactual, i.e. to know what would have been the number of outbreaks and potential impact if there had been no government intervention or if the existing rapid response system was not sufficiently effective to contain the spread of an outbreak, as again other factors such as disease epidemiology and industry structures can influence the evolution of an outbreak.

It is therefore important to contextualise the above quantitative indicators, on the basis of a qualitative assessment incorporating our findings under Themes A-F, to establish the conclusions that can be drawn within the context of this specific evaluation.

8.2 Findings

8.2.1 Overview of EU animal health emergencies developing into a crisis

In the analysis below, the number of outbreaks refers to the number of emergencies, while the number of crises refers to emergencies that developed into a crisis i.e. a situation of major financial, economic and/or public health impact. Effectively preventing and containing animal health emergencies, so as to avoid a potential crisis, is the main objective of the EU legislation in place. A crisis refers to a situation that could have been avoided if the appropriate preparedness level and measures had been put in place. On this basis, the evolution over time of the number of outbreaks and of those that developed into a crisis is an indicator of the overall performance of the EU animal health emergency response system.

The past twenty years have seen the EU experiencing several animal health crises, the shockwaves of which have been felt economically, socially and politically. These crises have caused serious damage to livestock sector and significant disruptions to markets and

the wider economy. Several factors have compounded the risk of such crises – globalization and the resulting increase in trade, the expansion of EU borders to the East, and the development and increase in the animal populations of the EU livestock sector.

Recent outbreaks of epizootic diseases such as avian influenza (AI), foot and mouth disease (FMD) and bluetongue in previously unaffected territories of the EU have highlighted the threat posed by sudden and unexpected emergence of infectious agents, and further emphasise the need for well-developed and adequately resourced counter-measures, to ensure rapid containment**.**

Table 12 presents an overview of the animal disease outbreaks that have occurred in the ten most affected MS over the period 1997-2009. It shows the extent to which the severity of the diseases presence has varied among these MS. Over this period outbreaks of avian influenza mainly affected Germany, Italy, and the Netherlands; FMD crises were severe particularly in the UK in 2001 and more recently in Bulgaria[89]; several bluetongue outbreaks were confirmed in France, Italy, Netherlands and Germany. Data on disease outbreaks (for the key diseases) in the MS covered by the field visits are also provided in **Annex 3**; these indicate the significant reduction over time of major animal disease outbreaks in the majority of cases.

As indicated by the recent Report on the outcome of the EU co-financed animal disease eradication and monitoring programmes in the MS and the EU as a whole (FCEC, 2011), at EU level there are indeed several notable achievements over the last decade, in particular with regard to the animal diseases covered by this evaluation:

- Classical swine fever (CSF) in domestic pigs has been eradicated all over Europe, with the sole exception of large outbreaks in domestic pigs (in 2006 and 2007) in Romania;
- The successful implementation of large-scale vaccination campaigns against the responsible serotypes has contributed to the sharp decrease in the number of bluetongue outbreaks in 2009 and 2010 through the reduction of the virus circulation. This has made possible in recent years (after 2007) to move animals vaccinated for the present serotype(s) from restricted areas into free areas;
- In the case of avian influenza, in 2008 and 2009 the decrease in the number of both domestic birds and wild birds is related to the positive trend in the number of outbreaks occurring which has shown a significant decline since 2007 both for domestic and wild birds.

Table 12: **Disease outbreaks reported in selected MS, 1997-2009**

MS	HPAI	FMD	CSF	BT	ASF	SVD*
Belgium	8		8	7612		

[89] Foot and Mouth Disease (FMD) was first diagnosed in a wild boar shot by hunters at the end of 2010 in the region of Burgas in southeast Bulgaria, close to the border with Turkey, and later testing of samples from farmed animals produced positive FMD results

Czech Republic	4			14		
Denmark	1			16		
Germany	9		89	24798		
France	1	2	1	54137		
Italy	426		90	16188	596	634
Netherlands	241	26	429	6332		
Poland	9					
Romania	198		355			
United Kingdom	4	2038	15	135		

Source: ADNS (data provided by DG SANCO).

In terms of the number of outbreaks reported, **relatively few crisis situations have developed during the evaluation period.** In particular, on the basis of the criteria of financial cost and economic impact, the following crisis situations were identified: CSF (1997 DE); AI (1999/2000 IT); AI (2003 NL); H5N1 (2005-06); FMD (2001, UK); BT (2007/08, DE/FR/NL/BE). In the last 4 years the EU has not experienced an animal health crisis, while the potential of an ASF crisis due to the risk of re-introduction of this disease from the Caucasus region was avoided.

The evaluation has also aimed to identify **the extent to which the availability of a CP, as an indicator of preparedness, can prevent an emergency from becoming a crisis**. The conclusions reached by the analysis suggest this to be the case. In particular:

- The analysis of Theme A concludes that having CPs in place indeed contributes to a more effective response to controlling animal diseases outbreaks. An important condition, however is that these are operational i.e. cover the range of relevant criteria, are supplemented by the necessary technical, human and financial resources and are tested in simulation exercises. All of the MS (that responded to the FCEC survey: 25 MS) currently have CPs in place for the key diseases which have caused a crisis in the EU over the last 10 years: FMD, CSF, AI and BT. Moreover, the testing and updating of CPs, including through simulation exercises and lessons learnt from past crises (e.g. FMD in the UK, CSF in DE, AI in NL and IT, BT in NL and BE), have improved over the evaluation period both in the MS that suffered these crises and in an increasing number of other MS.
- The evaluation in Theme B has also looked at the extent to which CPs can be more effective when they are approved by the SCoFCAH. There is no evidence to suggest this to be the case, also due to the fact that in practice this process is only followed for some diseases. On the other hand, FVO inspection missions are considered to be more effective and efficient in verifying MS preparedness.
- Furthermore in Theme A, the evaluation has looked at the effectiveness of generic versus disease specific CPs; from this analysis it can be concluded that the generic approach can improve both the effectiveness and the efficiency of contingency planning. Indeed, over the last decade, animal health emergency response in the EU

has evolved from an exclusively disease-specific approach to a more horizontal disease approach, drawing potential synergies, complementarities and best practices in order to provide a common general framework for addressing animal diseases. Key drivers behind this process are the need for robust financial planning in the context of the current adverse economic climate, but also the ongoing development of public-private partnerships and responsibility-sharing in these sectors.

The overall effectiveness of the EU rapid response system in preventing an emergency from becoming a crisis extends beyond the availability of CPs as such, to the cooperation and coordination within the overall rapid response network, including cooperation between the COM and MS, between laboratories and with stakeholders.

8.2.2 Outbreaks outside established restriction zones

The effective management of an animal health emergency can also be assessed by the number of secondary outbreaks occurring outside the zones of primary outbreaks (ratio of primary to secondary outbreaks).

This indicator is used internally in the SANCO Management Plan, establishing that for AI and FMD an effective management of animal health crisis is indicated by the percentage of secondary outbreaks outside the regions of primary outbreaks, for which targets have been set at 8% by 2013 and 0% by 2015, respectively [90]. SANCO analysis of MS notification data from the ADNS/ADIS database indicates that the EU has been well below this target in the last few years.

Further analysis on the ratio between primary and secondary outbreaks was sought on a case by case basis for the 10 case study MS. It was not possible to obtain any data on this, further than what is already available in ADNS, while none of the visited MS uses this as an indicator of the performance of their ability to effectively manage and respond to emergencies; furthermore, questions were raised on the suitability of the indicator as such, and the suitability of using the existing notification data as the basis for the assessment. In particular, it was noted that primary and secondary outbreaks are not always possible to distinguish for introduction into the ADNS system, also due to the obligation of MS to report within 24 hours. There may also be a need to collect more detailed data on epidemiological criteria, rather than just on a geographical/administrative basis as is currently the case with MS notification data reported to ADNS.

Both MS and COM experts agree that the analysis on primary and secondary outbreaks should take into consideration the differences in epidemiology of each animal disease (e.g. vector-borne diseases such as bluetongue are more difficult to contain than SVD; CSF symptoms are more difficult to detect compared to those of other animal diseases

[90] The baseline result compared to which the 2013 target applies was 13% in 2007. The 2015 favourable results should be considered with due caution as the overall number of outbreaks in 2010 were low (2 AI and 0 FMD).

due to its long incubation period; FMD in sheep has proven more difficult to detect[91]) and MS context (e.g. the speed of spread of a disease such as HPAI may be higher where there is high density in poultry farms). It was indeed noted that data on secondary outbreaks are not always revealing, as they need to be combined with other qualitative analysis which help contextualise the management of animal health emergencies.

It is therefore concluded that it needs to be considered further whether the ratio of primary to secondary outbreaks would be appropriate for MS to use as a more objective indicator of their performance in the management of certain diseases, and what the target ratio should be set at.

8.2.3 EU funding for animal health emergencies

The current financial system of the EU Animal Health policy is laid down in Decision 2009/470/CE[92] regarding certain expenses in the veterinary sector. The budget allocated is given under three different budget lines:

- **17.040101**: Animal disease eradication and monitoring programmes and monitoring of the physical conditions of animals that could pose a public-health risk linked to an external factor;

- **17.040201:** Other measures in the veterinary, animal welfare and public-health field;

- **17.040301:** Emergency fund for veterinary complaints and other diseases of animal contaminations which are a risk to public health

For the purposes of this evaluation only the veterinary measures under the emergency fund (line 17.040301**)** are relevant and therefore taken into account. No allocated budget is foreseen at EU level for activities related to national contingency plans, the costs of which are entirely covered by MS.

Following outbreaks of several infectious diseases - avian influenza, bluetongue, classical swine fever, and others listed in Chapter of Council Decision 2009/470/EC - on the territory of MS, the EU provides financial support (50% EU contribution) to affected MS for specific costs directly related to the certain emergency measures taken, such as:

- Compensating owners for the slaughter and destruction of animals and their products;

[91] An example is the FMD crisis in 2001: the UK Parliament Inquiry highlighted that the effects of the disease outbreak were '*far from conventional. The way in which the disease had spread before its discovery and had disproportionately affected sheep were both unprecedented'* (Anderson CBE, 2002 pg. 23). FMD in sheep is difficult to diagnose, as they usually present mild symptoms, whereas cattle can act as sentinels and show obvious signs of disease infection. Therefore, FMD symptoms in sheep were only possible to detect after that sheep came into contact with pigs at the slaughterhouses and the vet had been called out to inspect the cattle (Anderson CBE, 2002).

[92] Council Decision of 25 May 2009 on expenditure in the veterinary field.

- The cleaning and disinfecting of holdings and equipment;
- The destruction of the contaminated feedingstuffs and contaminated equipment;
- Supply of the vaccine (100% EC contribution) and the costs incurred in carrying out vaccination, when vaccination has been decided in accordance to an EC Decision.

The costs of emergency measures and level of EU emergency funding, on a case by case basis, could under certain conditions serve as an indicator of the effectiveness of the rapid response system in specific cases: in theory, the more effective i.e. the earlier and the more rapid the response, the lower the level of funding; however, in practice, an effective policy which may involve mass culling can be high cost (e.g. FMD or AI). It is also noted that, when using the emergency funding as an indicator, care needs to be given to inherent biases in some cases: for example, in managing the FMD case in the UK, the EU continued to pay for animal culling despite the proposed vaccination which was accepted at EU level, and finally the UK decided not to resort to it.

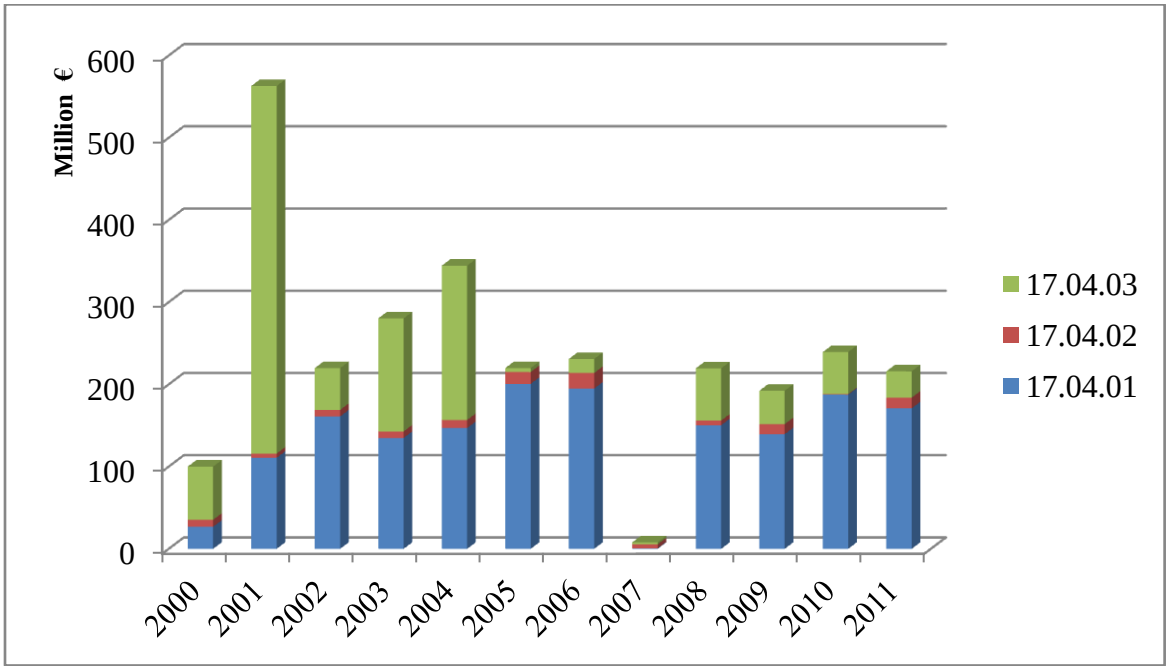
On the other hand, the high costs involved are also an indicator of the potential level of the control costs if action had not been taken early enough and the disease had spread (then e.g. mass culling and trade impact of movement restrictions would have been even higher). The potential wider economic implications of disease outbreaks leading to a crisis are discussed further in section 8.2.5.

Evolution of total EU funding over time

Financial data on the evolution of the overall EU animal health co-financing are available from 2000 to 2011[93]. **Figure 12** presents the evolution of the EU animal health co-financing being broken down into the three different budget lines. The figure clearly shows a downward trend in the amount of EU co-funding for emergency veterinary measures from some € 65 million in 2000 to € 30 million in 2011. The exceptionally large EU financial contribution in 2001 can be attributed to the 2001 FMD crisis in the UK. While the EU animal health co-financing for veterinary emergency measures has decreased over the years, the eradication, monitoring, and control programmes have increased their shares, accounting since 2005 the majority of the EU animal health expenditure; this points to the more efficient use of funds to achieve longer term objectives such as the reinstating of disease free status for major diseases in the EU[94].

[93] Based on COM financial decisions during 1999-2011.
[94] See conclusions of Report on the outcome of the EU co-financed animal disease eradication and monitoring programmes in the MS and the EU as a whole, FCEC for DG SANCO, July 2011. **http://ec.europa.eu/food/animal/diseases/eradication/docs/fcec_report_ah_eradication_and_monitoring_programmes.pdf**

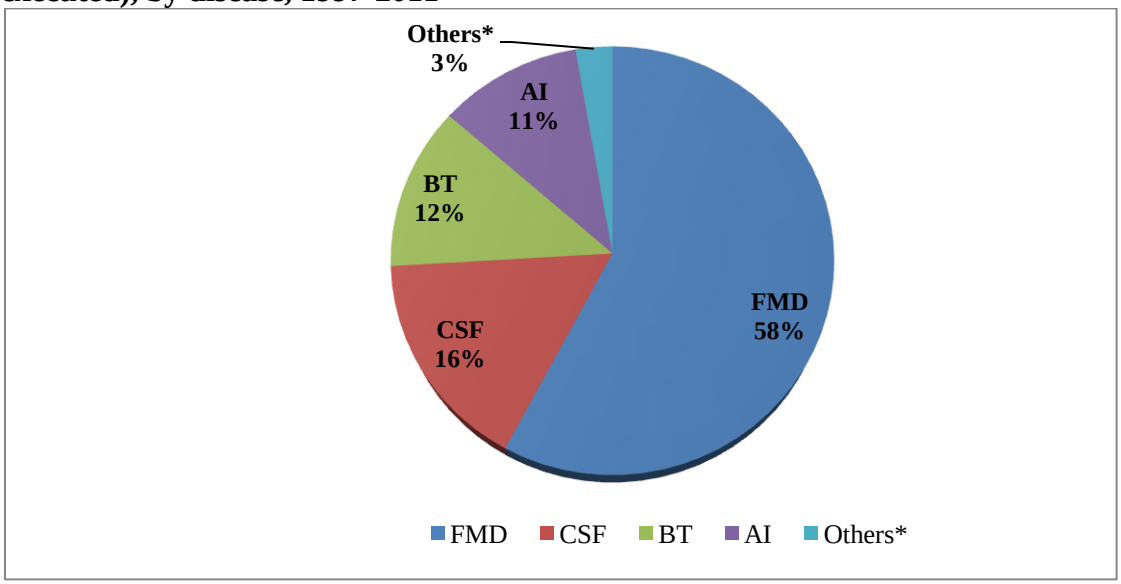
Figure 12: Evolution of overall EU funding for animal health (outturn payments), 2000-2011



Note: Outturn payments are the sum of credits generated in a specific year.
Source: DG SANCO, based on financial decisions 1999-2011

A more disease-focus analysis shows that, between 1997 and 2011, eight diseases were covered by the EU financing for veterinary emergency measures namely: AI, bluetongue, CSF, FMD, Newcastle disease, rabies, sheep pox, and SVD. The total amount of funding has varied greatly between diseases from sheep pox disease which has received approximately €570,000, to FMD which has received more than €669 million, thus accounting for nearly 60% of total EU emergency budgetary line (**Figure 13**).

Figure 13: Total EU funding for veterinary emergency measures (payments executed), by disease, 1997-2011

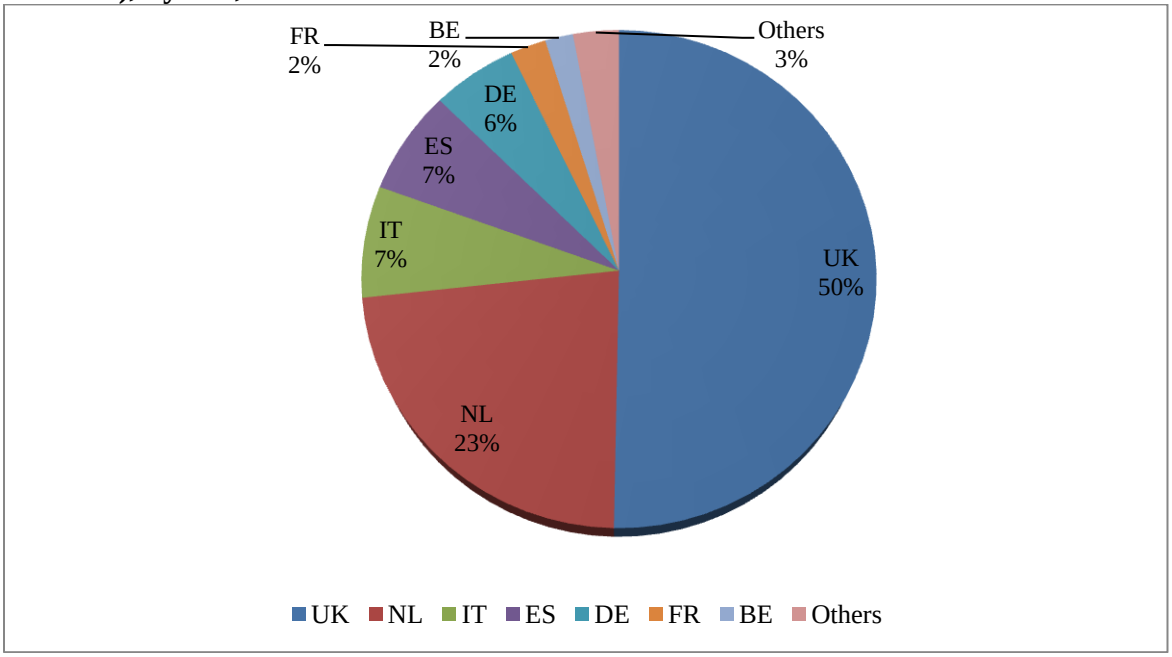


Note Payments executed are the actual payments made to the beneficiaries, i.e. MS, for specific animal health emergencies. E.g. the payments for the 2001 allocation to the heading *'Emergency fund for veterinary complaints and other animal contaminations which are a risk to public health'* were executed over the years, but refer to a cost generated in a specific year (e.g. in the case of FMD in the UK, €355 million were credited in 2001, but they were actually executed (paid) in 2002.

Source: DG SANCO, based on financial decisions 1997- 2011 (line 17040301)

With regard to recipients, over the 1997-2011 period the total amount of funding has varied greatly between MS (**Figure 14**). The UK (€583,218,594) is the largest recipient of funding for veterinary emergency measures followed by the Netherlands (€266.2 million), Italy (€84.2 million), Spain (€ 79.2 million) Germany (€64.2 million), France (€26.9 million), and Belgium (€21.0 million). Two MS, the UK and the Netherlands, account for almost 75% of the total EU emergency veterinary expenditure for the period 1997-2011.

Figure 14: Total EU funding for veterinary emergency measures (payments executed), by MS, 1997-2011



Source: DG SANCO, based on financial decisions 2008- 2011

It is noted that in case of non compliance with the EU legislation[95], the COM has effectively taken corrective action or imposed penalties. This corrective action has been applied mainly in the case of the monitoring and eradication programmes, and only one case where it has been applied with regards to emergency measures is known[96].

Animal health emergencies and their costs on a case by case basis

Based on the MS case studies, this section reviews key outbreaks experienced in the case study MS and the emergency funding for addressing these outbreaks.

The United Kingdom

Since 1998 the UK has reported several animal health emergencies. In 2006-2007 outbreaks were reported for HPAI in domestic poultry and wild birds. There were also several cases of bluetongue in the UK, in the context of the large epizootic that occurred in northern Europe from 2006-2009.

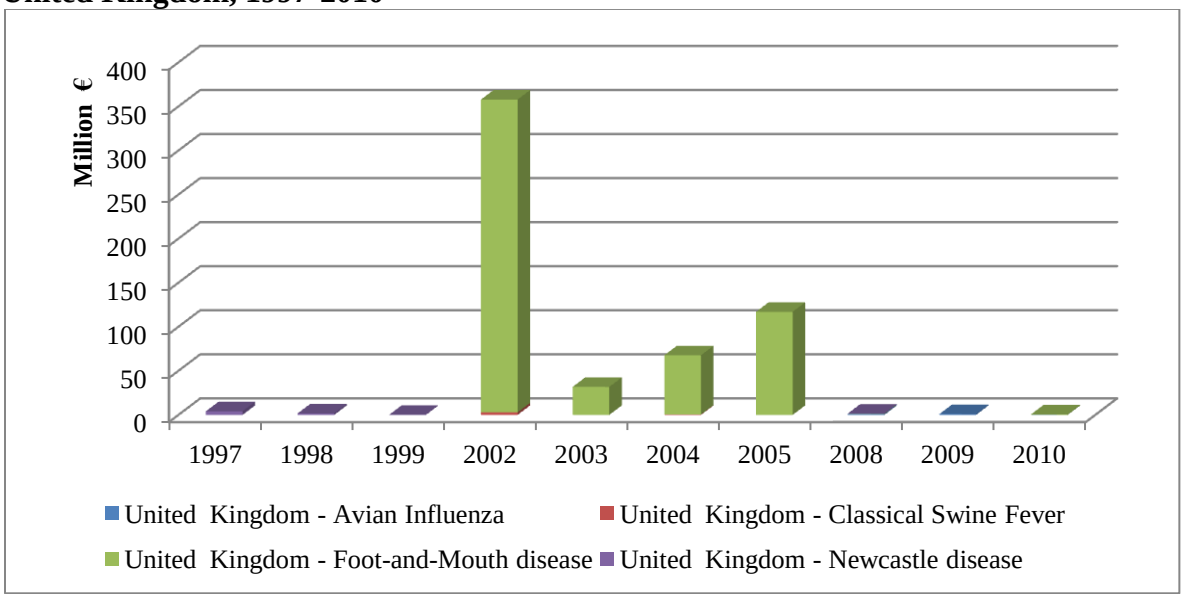
The UK faced a major animal disease crisis in 2001 with the widespread outbreak of FMD. The first outbreak was detected on 21 February at an abattoir and adjacent farm in Essex, England and at the end of the year over 2000 cases were confirmed throughout the

[95] Art. 3 of Council Directive 2009/470
[96] For the period covered under this evaluation it was reported that only in the case of the UK a 100% penalty was applied and no payments were made for financing veterinary emergency measures for CSF in 2000/2001.

UK. The economic impact of the FMD crisis was significant: the cost of the slaughter of 4 million susceptible animals alone was estimated at over £5.8-6.3 billion (**Table 14**). More background on the 2001 FMD crisis in the UK, and the lessons learnt, is provided below.

The UK is the biggest recipient of the EU emergency funding with a total amount of €583 million. The majority of the funding (nearly €572 million) was provided following the 2001 FMD crisis. In 2002 alone, the country received an amount of funding accounting for 60% of the overall budget received since 1997. The Contingency Plans (CPs) for FMD, Avian Influenza, Newcastle Disease and all other exotic diseases of animals were revised by DEFRA in 2009.

Figure 15: EU funding for veterinary emergency measures (payments executed), the United Kingdom, 1997-2010



Source: DG SANCO, based on financial decisions from 1997- 2010 (line 17040301)

The FMD crisis

The FMD crisis in 2001 was one of the biggest in UK history: the overall costs of the outbreak amounted to over £8 billion. Millions of animals were slaughtered and several sectors of the economy were affected in very different ways). An independent inquiry into the Government's handling of the outbreak of FMD in Great Britain during 2001 was conducted in order to draw out lessons and make recommendations (Anderson CBE, 2002)[97]. This inquiry into the lessons to be learned from FMD, reported that '*a contingency plan was in place, and agreed by the European Union, it had gaps and had not been shared widely or vigorously rehearsed outside the State Veterinary Service'*.

[97]. This is one of the three independent inquiries carried out following the 2001 FMD crisis: The other two are: the Policy Commission on the Future Farming and Food and the Royal Society Inquiry into Infectious Diseases in Livestock.

The 2001 FMD crisis also brought to light the weaknesses of what was a strongly centrally driven process in that it ended up with too much 'micromanagement' at central level as what were essentially local decisions had to be taken at the centre and thus ended up paralysing the centre. The outbreak was so large it fragmented the organisational capacity of the country. Unlike other regions, Scotland experienced a less severe spread of the disease due to a different management structure, closer relations between central and local governments and the farming industry and more systematic contingency planning. The Anderson CBE, 2002 inquiry highlighted a number of other shortcomings:

- The early response system was not fast enough or effectively co-ordinated: it was not giving enough priority to the importance of speed - in particular the rapid slaughter of infected animals.
- Government knowledge of farming and farm practices was limited – e.g. sheep movement contributing to the spread of the disease.
- Information systems were incomplete and had to be developed during the outbreak.
- There was a scarcity of resources which concerned veterinary reserves as well as important gaps in managerial and logistical skills.
- The quality of communication was mixed.

Drawing on this experience, a number of lessons to be learned were identified by the inquiry. **Table 13** compares the lessons to be learned identified in 2001 to the progresses made in handling the FMD emergency in 2007. Major improvements have been made in terms of data management, local decision making, local engagement and communications and scalability (Nigel Gibbens, 2011).

Table 13: Lessons to be learned and lessons learned 2001 and 2007 FMD outbreaks in the UK

2001 Lessons to be learned	2007 Lessons learned
Maintain vigilance through international, national and local surveillance and reconnaissance.	Compared to 2001 the nation is far **more vigilant and awar**e of the threat posed by FMD but the risk is real and likely to increase. **Better controls** are in place to reduce the risk of an exotic animal disease entering the country
Be prepared with comprehensive contingency plans, building mutual trust and confidence through training and practice.	Contingency planning in DEFRA and government has undergone a **step change in quality** since 2001. **Many improvements** have been made in levels of preparedness and DEFRA was much better prepared in 2007 than six years ago. Emergency preparedness is taken seriously by Animal Health and is fully understood to be a core function. Nevertheless there is still work to be done.
React with speed and certainty to an emergency or escalating crisis by applying well-rehearsed crisis management procedures.	Ministers, officials and stakeholders at all levels were seized by the **critical importance of speed**. **There was a certainty and clarity in the DEFRA response that was absent six years ago**. The preparations for vaccination are a good example. In only five days teams, equipment and supplies were in place, ready to vaccinate, should the Secretary of State have decided to do so. However, as the disease continued, some aspects of the policy response were uncertain and, at times, confused. The shortcomings in the data and information systems did not help.
Explain policies, plans and practices by communicating with all interested parties comprehensively, clearly and consistently in a transparent and open way.	**Communications were much better handled in 2007.** Nevertheless the overall consistency of DEFRA's communication with stakeholders and the wider farming community could be improved. The challenge in 2007 was much less than in 2001. **Communication technologies** are changing rapidly, bringing **new opportunities and new challen**ges.
Respect local knowledge and delegate decisions wherever possible, without losing sight of the national strategy.	The Government was **more sensitive to the local and regional dimension** of the disease in 2007. However, even with only one Local Disease Control Centre (LDCC), some local stakeholders did not feel fully integrated into the response, although relationships did improve over time. The Core Group of industry experts set up one week after disease broke out involved industry more in decision making. Specific concerns were felt in Scotland and Wales, especially during Phase 2 of the disease. The animal health concordats were out of date as were some of the working arrangements with the devolved administrations
Risk assessment and cost benefit analysis within an appropriate economic model	In 2007 DEFRA and Animal Health showed a far greater appreciation of risk and its importance in effective disease management. DEFRA recognises that its growing function as an emergency response department places risk at centre stage. **Decisions are now far more routinely based on risk assessment** – although the quality of some of these was hampered by poor data and evidence. The decision to lift the restrictions after Phase 1 was based on a risk assessment that took into account all available epidemiological and veterinary knowledge and was in line with EU Directives. It is still important to record that this decision was wrong: it extended the timescale needed to stamp out the disease, and it added extra costs.

2001 Lessons to be learned	2007 Lessons learned
	DEFRA, in co-operation with EU colleagues, needs to ensure that all the learning points taken from this experience are built into future EU FMD control policies and contingency plans, and are widely shared
Use data and information management systems that conform to recognised good practice in support of intelligence gathering and decision making.	The 2002 Report could not have been clearer in its criticism of DEFRA's information systems, and made several recommendations to tackle the shortcomings. It was disappointing to discover how **little progress** had been made over the last six years. During the outbreak, at those points where data were assembled and used to guide policy decisions and support operational practice, the systems in use were little different from those in operation six years ago. This lost time, caused mistakes and added to frustration. The reasons for this failing were explained to us and are described later in the report. The Business Reform Programme now being rolled out in Animal Health is planned to deliver a fully enhanced capability by 2011. In the meantime DEFRA remains in a vulnerable position in the event of a disease outbreak.
Have a legislative framework that gives Government the powers needed to respond effectively to the emerging needs of a crisis.	Government took seriously the recommendations in the 2002 Report and acted quickly to tackle the shortcomings in legislation. Government has made good progress since then in setting **a robust legal framework for managing animal disease** founded as it must be on the basis of EU law. In addition, the **Civil Contingencies Act** provides the legal powers for the wider framework for government management of emergencies. The legislative changes made since 2001 were critical in responding effectively to the 2007 outbreak but could be tested further in a larger outbreak.
Base policy decisions on best available science and ensure that the processes for providing scientific advice are widely understood and trusted	Government positioned science at the centre of its control strategies – **a major lesson learned from 2001**. Scientific advice and capabilities supported policy decisions and operations throughout the outbreak with good examples **in risk modelling,** vaccination decisions, epidemiology, nucleotide sequencing, rapid testing and diagnosis. Many of these techniques were pioneered by the **Institute for Animal Health (IAH) at Pirbright**. Although vaccination was not used in 2007, DEFRA had developed a methodology for its use. Most of the submissions we received, but not all, supported the Government's decision not to vaccinate

Source: Anderson CBE inquiry, 2002 and 2008

The Netherlands

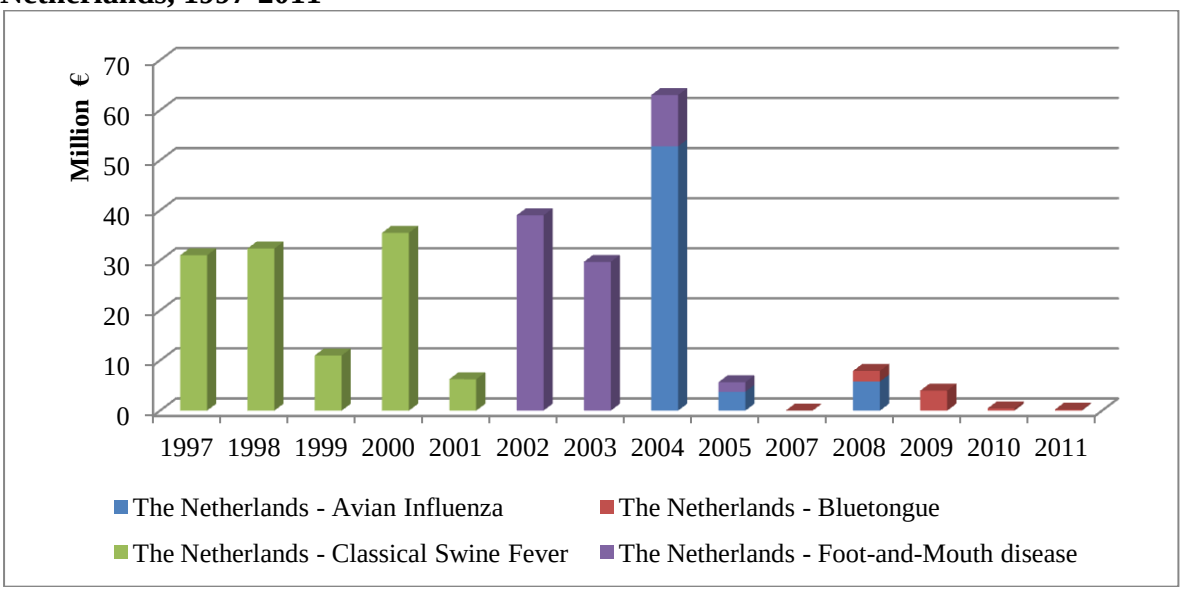
Since 1997, the Netherlands has eradicated several animal diseases. In 1997-98 the country faced a severe CSF-epidemic, causing significant economic losses, but no CSF outbreak has been detected since then. Similarly, following an outbreak of FMD in 2001, no further cases have been reported since then[98].

The country also experienced a severe animal health crisis caused by epizootic of avian influenza. In 2003 several outbreaks of influenza A (H7N7) were confirmed in poultry on several farms. Later, infections were also spread to both pigs and humans. The crisis led to the destruction of some 30 million birds, with direct economic costs estimated at more than €150 million (**Table 14**).

Over the last five years, over 6000 bases of bluetongue, mainly caused by serotype BT-V8N, have been reported.

The NL is the second largest recipient of the EU emergency funding. For the years 1997-2001 funding (€ 116 million) was provided for the CSF emergency. After 2001, the majority of the funding mainly targeted the 2003 AI crisis (nearly €53 million received in 2004) and to contain an FMD outbreak in 2001 (more than €75 million during 2002-2004). In 2005, the NL submitted the CP for FMD to the COM.

Figure 16: EU funding for veterinary emergency measures (payments executed), the Netherlands, 1997-2011



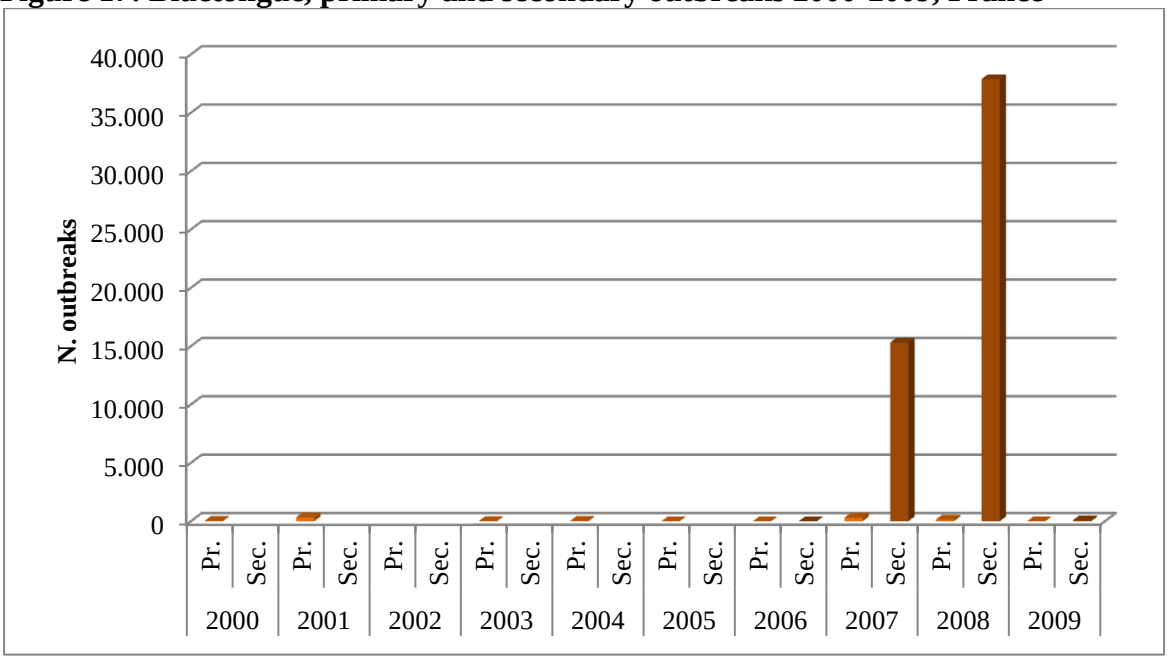
Source: DG SANCO, based on financial decisions from 1997- 2011 (line 17040301)

[98] An overview of FMD outbreaks in the Netherlands in 2001 can be found at *Dutch Ministry of Economic Affairs, Agriculture and Innovation (**http://english.minlnv.nl/**)*

France

In recent years, France experienced a severe BT crisis. In 2007 and 2008, the country reported an escalating number of outbreaks mainly caused by BTV-8 and BTV-1. The spread of the disease was very significant: although in the summer of 2006 the country was only slightly touched by the BT epidemic that was spreading in several EU MS, by the end of 2007 four quarters of the country were affected by the disease, as indicated in the figure below.

Figure 17: Bluetongue, primary and secondary outbreaks 2000-2009, France

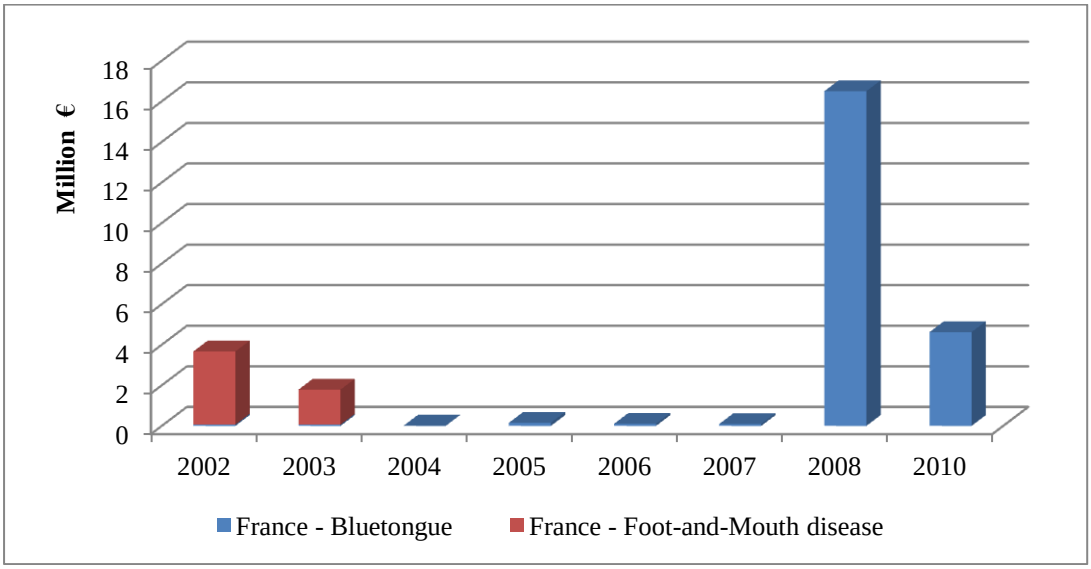


Source: Animal Disease Notification System

The noticeable increase in 2008-2009 EU emergency funding reflects the specific measures (vaccination and surveillance) taken to handle the BT crisis. In terms of economic impact, a national study (Mounaix et al 2008) estimates that the bluetongue outbreak in France caused the loss of 7,000 to 40,000 calves.

France also received over €5.3 million to handle the emergency caused by FMD outbreaks in 2001. The FMD CP was submitted to the COM in 2003.

Figure 18: EU funding for veterinary emergency measures (payments executed), France, 2002-2010

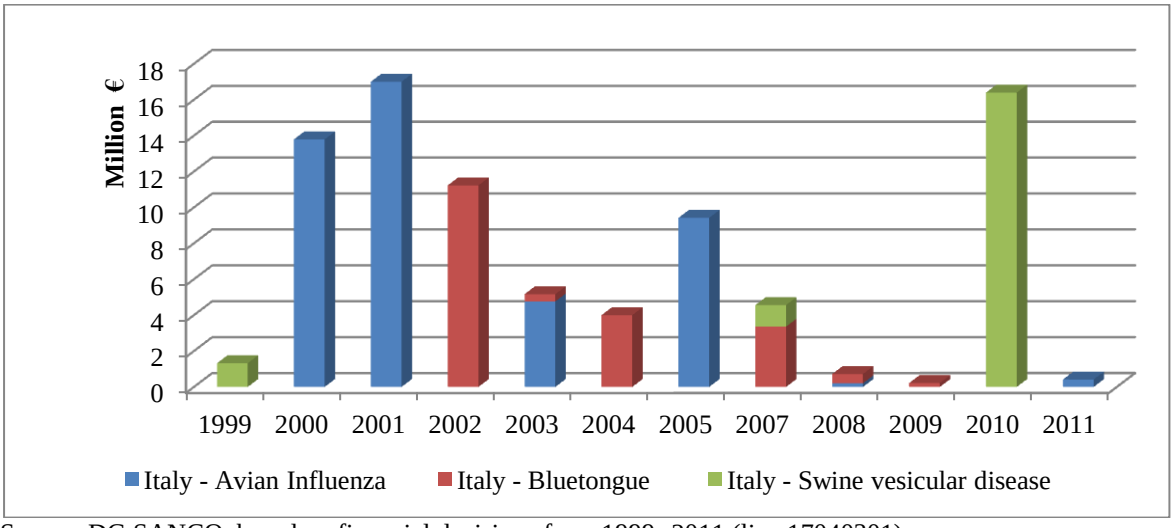


Source: DG SANCO, based on financial decisions from 2002- 2010 (line 17040301)

Italy

The figure below presents the evolution of the funding received from the EU emergency fund. Since 1997, the country has received from the EU emergency funding a total amount of €84 million. More than 50% of the funding was provided for AI (€ 45.6 million) followed by BT vaccination programme (€ 19.7 million) and for SVD (€18.9 million).

Figure 19: EU funding for veterinary emergency measures (payments executed), Italy, 1999-2011



Source: DG SANCO, based on financial decisions from 1999- 2011 (line 17040301)

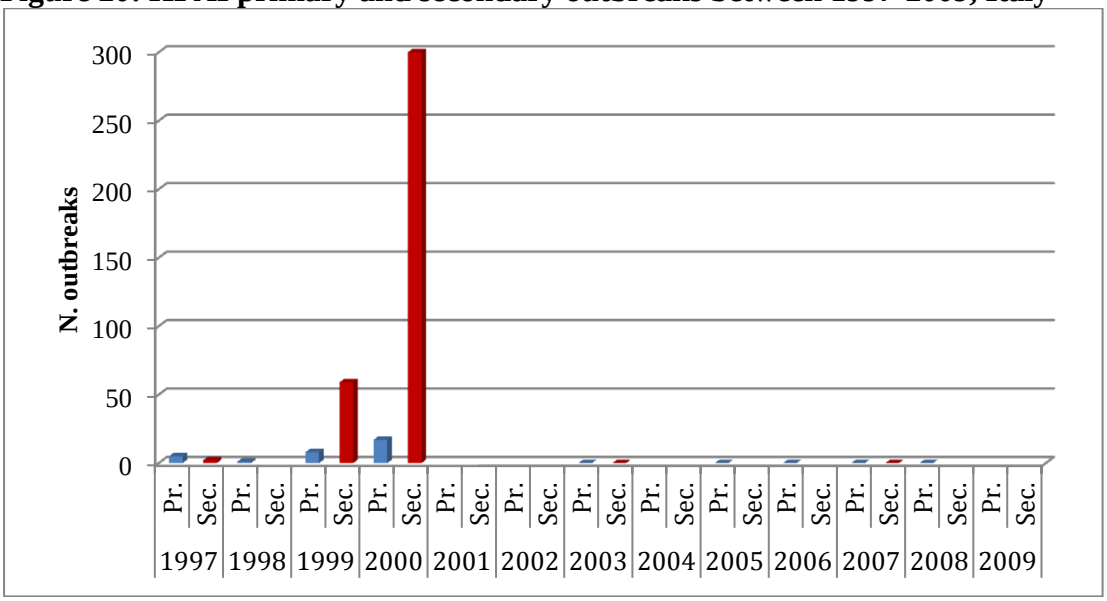
From emergency to crisis: AI outbreaks 1999-2000.

According to both the Italian CA and the main stakeholder organisation (UNA), there are two main triggering factors explaining this crisis. Firstly, in those years EU rules did not cover LPAI strains, as the risk of LPAI mutating to highly pathogenic was underestimated and LPAI control

was not deemed cost effective. Although Italy was conducting surveillance, it could not adopt restrictive measures as there was no compensation. Secondly, the disease emerged in the Regions of Veneto and Lombardy, areas with high density of poultry and extensive vertical integration in poultry production. As a result, the virus rapidly spread (from feed mills to distribution) and mutated to HPAI. The lack of awareness on bio-security risks facilitated the spread of the disease. In the light of the Italian experience, EU legislation on AI was amended, including the monitoring of LPAI strains. In addition, bio-security and preventive measures have been strengthened (e.g. stocking poultry manure is not allowed anymore).

Both the Italian CA and UNA have emphasised that these improvements prevented the 2005 emergency from becoming a crisis. The collapse caused in the market was in fact due exclusively to a communication crisis.

Figure 20: HPAI primary and secondary outbreaks between 1997-2009, Italy



Source: Animal Disease Notification System

In terms of the cost of emergency, the Italian Law n. 218 of 2 June 1998 foresees a budget for compensation which may be increased if not sufficient. It is estimated that the 1999 AI crisis caused the death of approximately 17 million of birds with a cost of around lire 700 million (approximately €360,000) (more detailed data on this may be provided by the IT CA, if available).

The UNA estimated that this crisis caused losses of ca. lire 1.025 billion (approximately €500 million) to the poultry industry. Only in the Region of Veneto, the destruction of infected or suspicious flocks has been estimated to have caused direct costs of €55 million and indirect costs of €257 million (Sabrina Sartore et al).

African swine fever (ASF) in Sardinia

The disease has remained endemic in the Region of Sardinia since it appeared in 1978. The Italian CA has reported that the disease has only ever been detected in non-intensive and traditional farming, without a direct involvement of commercial holdings which trade pig meat and products outside the region. The Ministry of Health is currently closely monitoring the epidemiological situation concerning the ASF as a reoccurrence of the disease was reported in 2011. From

06.12.2011 to 03.01.2012, 4 outbreaks of ASF in domestic swine and 1 in the wild boar occurred in the Province of Nuoro (high-risk zone). Epidemiological information presented to the SCOFCAH in January 2012 indicated that the area subject to restrictions has been greatly reduced and the Provinces of Cagliari, Carbonia-Iglesias, Olbia-Tempioand Oristano are currently free of the disease.

Due to the current evolution of the disease in Sardinia, which could endanger pig herds in other regions of Italy and in other MS in view of trade in pig meat and any products containing pig meat, the COM has therefore considered it necessary to extend the risk areas in Annex I of Decision 2005/363/EC to the whole region of Sardinia (Commission Decision 2011/852/EU). Consequently, since the conditions laid down in Article 5(2) (b) of Decision 2005/363/EC could no longer be met, the derogation granted to Italy to authorise the dispatch of pig meat from Sardinia to areas outside Sardinia has been suspended. The same applies to the derogation granted under Article 6 of that Decision, to authorise the dispatch of pig meat products and other products containing pig meat from Sardinia to areas outside Sardinia.

The pig husbandry system in Sardinia is mainly characterised by 'family' businesses and based on piglet production for consumption. In the remaining part of the system, mainly situated in the internal territories of the region, there are free ranging herds that share a habitat with the wild boar population. Moreover, vast communal unfarmed lands are used as agri-zootechnical areas. Furthermore, old traditional practices of pig farmers, which allow free-range pasture without adequate fences as well as the lack of official animal registration, have hampered correct implementation of bio-security measures.

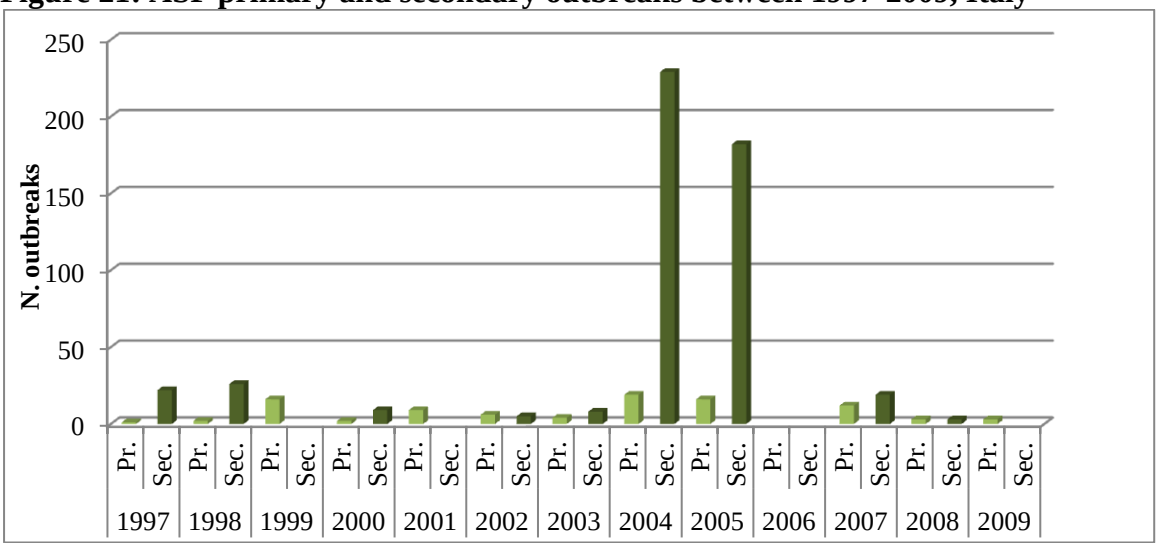
These factors encourage the uncontrolled movement of pigs that are not registered and subject to veterinary controls, and thus make the situation difficult to be controlled. Finally, along with these factors, the main issue is related to the inaccuracy of information flow and inadequacy of outbreak notification, sometimes generic and contradictory. Some problems in communication were highlighted during the FVO mission carried out in June 2008 to evaluate the situation concerning ASF and SVD.

Based on these considerations, the Italian CA has indicated that the lack of ASF eradication should not be attributed to gaps in EU and national legislation, but rather to heterogeneous and inadequate implementation of the rules, which are excessively adjusted according to the regional zootechnical context of the region[99].

[99] In response to the situation, the IT MoH is encouraging the implementation of specific actions to guarantee correct implementation of the existing legislation and thus reduce the risk factors of the disease. These actions include:

- fighting against illegal grazing,
- improving registration of animals,
- adopting sanctions, and
- efficient control of the use of communal lands.

Figure 21: ASF primary and secondary outbreaks between 1997-2009, Italy



Source: Animal Disease Notification System

Swine vesicular disease (SVD)

The IT CA has indicated that the national surveillance and eradication plan for SVD, approved annually by the COM, has allowed the central and northern parts of Italy to become SVD free since 1997 and the Regions of Abruzzo and Sicily to have recently been granted "accreditation" status.
With the introduction of Order of 12 April 2008 and following national plans, approved by the COM, surveillance and eradication measures have been improved in affected areas - e.g. the introduction of a targeted serological control of the holdings, identification of specific bio-security parameters based on different categories of pig holdings and description of activities in housing barns.
Despite improvements, some southern regions are still affected by the presence of SVD. However the IT CA has pointed out that these new measures have proven very effective in reducing the disease presence. The number of outbreaks has declined from 65 to 4 over the last two years (2009-2010). In the Region of Campania, some issues have been highlighted by the IT CA:

- Incomplete database of pig holdings ,
- Inaccurate method of sampling,
- Incomplete national database for the registration of movement of animals.

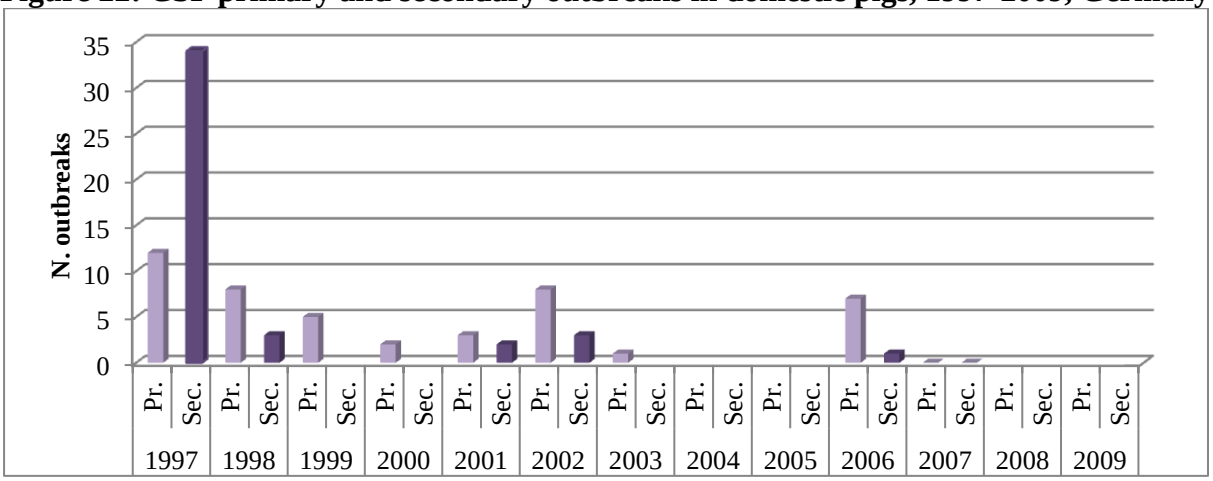
In addition to the existing legislation, a protocol was concluded in 2011 between MoH and CERVES (*Centro di referenza per le malattie vescicolari presso l'Istituto Zooprofilattico Sperimentale di Brescia*) to introduce a plan for granting 'free' status in the Regions of Calabria and Campania. This plan was subsequently developed by a task force of MoH and CERVES in collaboration with the two regions and NAS (Carabinieri Health Protection Unit.

Germany

Germany has experienced several animal health emergencies over the last two decades. However, noticeable progress has been made in the eradication of these animal diseases. CSF was eradicated in DE since 2006, but in certain areas of the country, the wild boar (mainly located

across the borders with DE, FR and LUX) still poses a risk for the transmission of CSF to domestic pigs.

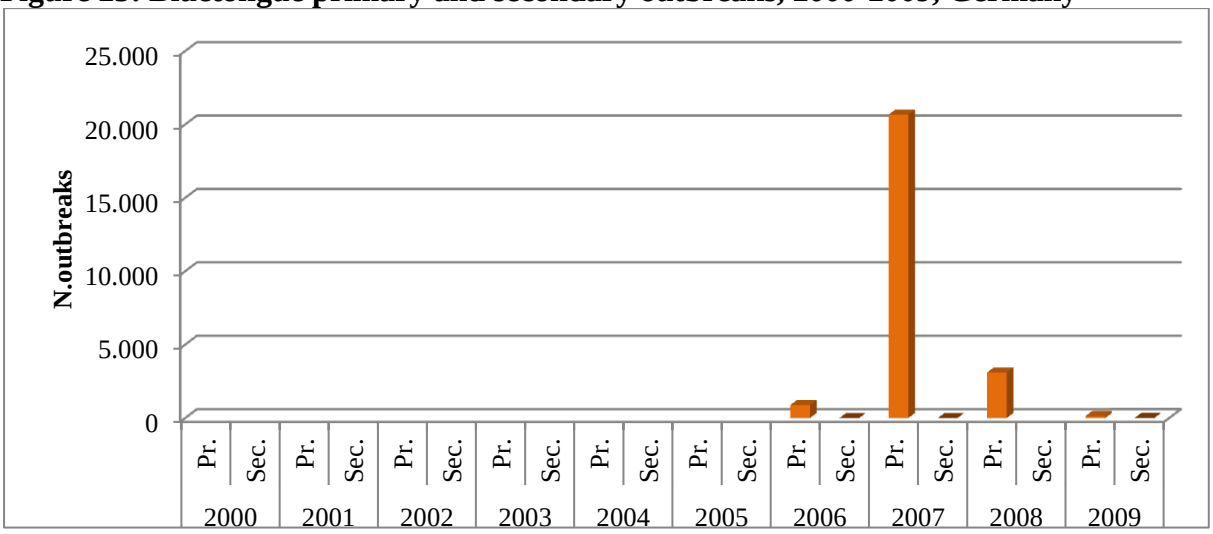
Figure 22: CSF primary and secondary outbreaks in domestic pigs, 1997-2009, Germany



Source: Animal Disease Notification System

In the case of bluetongue (BT) a high number of outbreaks occurred between 2006-2009 caused by serotype BTV-8:

Figure 23: Bluetongue primary and secondary outbreaks, 2000-2009, Germany

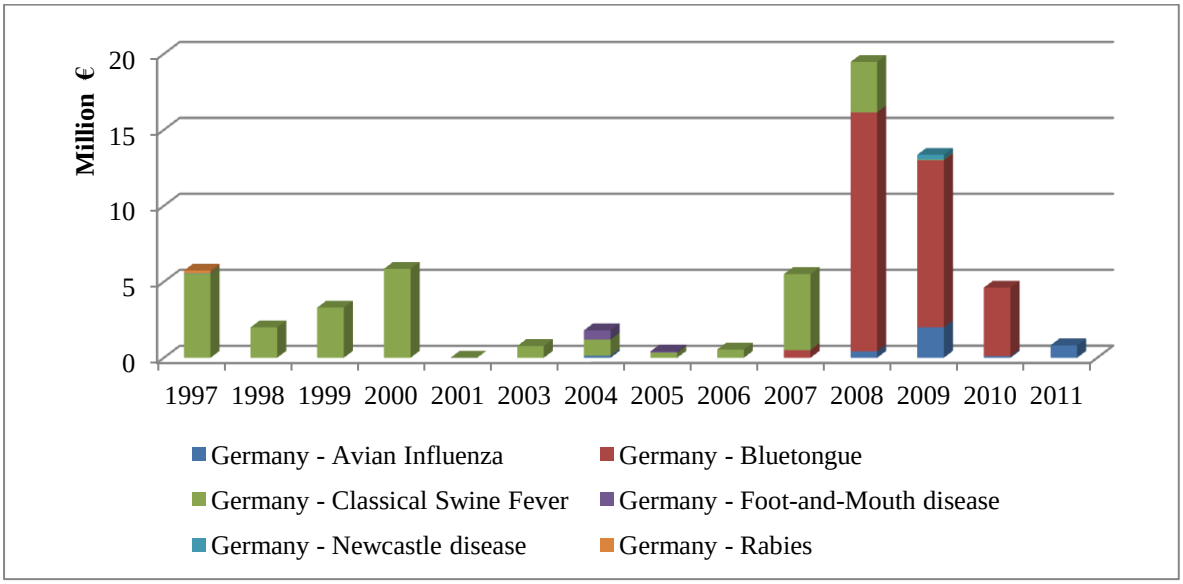


Source: Animal Disease Notification System

Over 400 HPAI outbreaks occurred in wild birds in Rugen Island between 2006-2007, while a few outbreaks in domestic poultry have been reported between 2003 and 2007.

Since 1997, DE has received a total of €64 million from the EU emergency funding. Over the period 1997-2011 the total amount has varied greatly between different animal diseases. The BT crisis has absorbed the largest share of the overall budget (nearly 5°% of the total, i.e. €32 million), followed by CSF (€28 million), AI (€3.5 million) and the other diseases:

Figure 24: EU funding for veterinary emergency measures (payments executed), Germany, 1997-2011



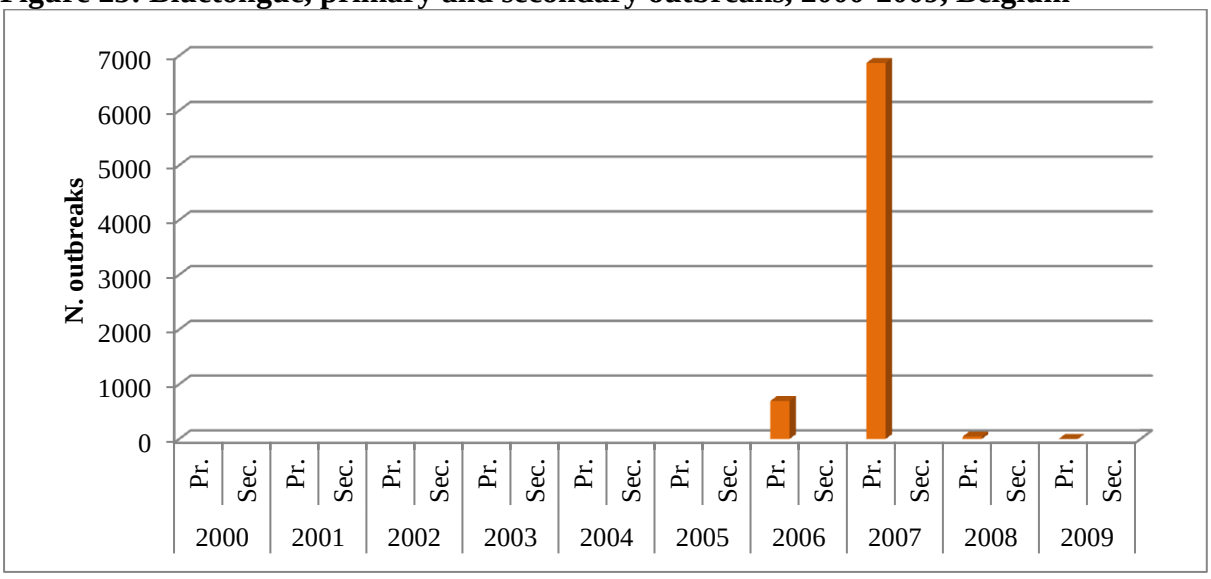
Source: DG SANCO, based on financial decisions from 1997- 2011 (line 17040301)

Contingency Plans have been drafted for AI, FMD, and CSF. In the case of the CSF CP, DE has created a web application which guides users through the document.

Belgium

Although Belgium generally has relatively low risk factors in terms of animal health emergencies, between 2006 and 2009 the country experienced several BT outbreaks, mainly caused by BTV-8 a new serotype never occurred before in Europe. In 2007, BE submitted a CP for BT.

Figure 25: Bluetongue, primary and secondary outbreaks, 2000-2009, Belgium

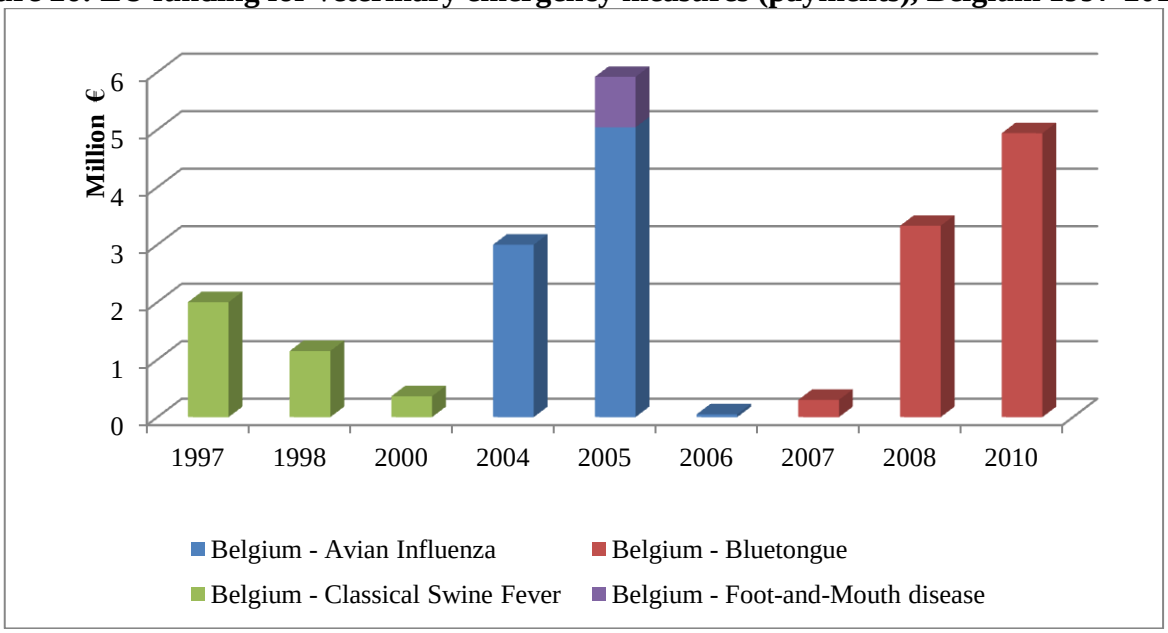


Source: Animal Disease Notification System (ADNS)

Belgium has also reported 8 HPAI outbreaks in domestic poultry in 2003, one outbreak of CSF in wild animals in 2002, and 37 ND outbreaks between 1997and 2000. The figure below presents the

evolution of the funding received from the EU emergency fund since 1997. Belgium has received some € 21 million for avian influenza, classical swine fever, FMD and bluetongue.

Figure 26: EU funding for veterinary emergency measures (payments), Belgium 1997-2010



Source: DG SANCO, based on financial decisions from 1997- 2010 (budget line 17040301)

Poland

There were ten outbreaks of Avian Influenza (AI) in Poland in 2007[100], as follows:

- There was one outbreak among birds kept in captivity. This was confirmed on 11 December in the animal shelter in Krzykały in the Municipality of Orneta, the Warmińsko-Mazurskie Voiovodship. The outbreak encompassed 18 animals including two storks, two cranes, one mute swan, four pheasants, one goose, six dwarf hens and two buzzards; of these, two buzzards and one stork died. The Minister of Environment granted permission to spare birds of protected species from killing.
- There were nine outbreaks in poultry holdings. According to the CA, in each case the outbreaks were secured immediately after detection by establishing and marking protection zones with a 3km radius, and surveillance zones with a 10km radius. A further large buffer zone was established to separate this area from the zone free from disease. Farms and their equipment were cleaned and disinfected.

Since the last outbreak, no further instances of H5N1 HPAI have been detected among domestic or wild birds in Poland.

In 2007 the MS received €854,000 from the EU emergency funding to handle the AI emergency.

[100] According to ADNS data there were 5 primary and 4 secondary HPAI outbreaks in Poland in 2007.

Denmark

Denmark has never experienced severe animal disease outbreaks it is a useful case for examining cross border co-operation, particularly for FMD and BT.

Denmark has seen good developments over the last few years in animal health in terms of the diseases under study in this evaluation. As reported in the latest DK CA (DVFA) report[101]:

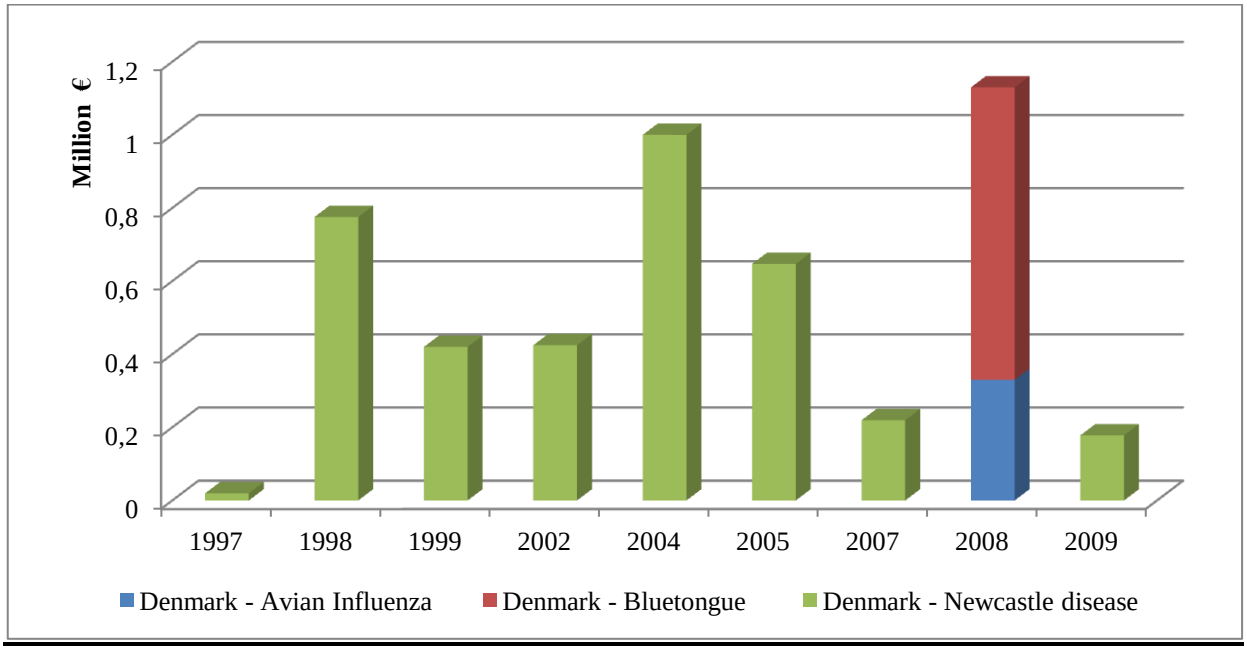
- Bluetongue has not occurred in Denmark since 2008 when bluetongue virus serotype 8 (BTV-8) was detected in 15 herds. Since September 2008, a BTV-8 restriction zone has covered the whole country. However, since November 2010 Denmark is recognised as a BTV-8 lower risk zone by the European Commission based on the absence of outbreaks.
- FMD has not occurred in Denmark since 1983, and Denmark is recognised by the OIE as an FMD-free country where vaccination is not practised.
- HPAI has not been reported in Denmark since 2006. However, in March 2010, LPAI of H7 subtype was detected in two flocks of mallards.
- The last outbreak of Newcastle disease (ND) in Denmark occurred in October 2005.In the summer of 2002, 135 ND outbreaks have also been reported

The budget for animal health emergencies has remained at a fairly stable level since 2007. In principle, there is no limit in the national budget for funding for animal emergencies. In practice, 10 million Danish Crown are spent per year on average (spending has been considerably higher in years with major outbreaks, e.g. 100 million Danish Crown for ND in 2002, 35 million Danish Crown for HPAI in 2006).

Denmark is one of the smallest recipients of the EU emergency funding, the majority (over 75%) of this funding was provided for ND (€3.7 million). Following the first occurrence of serotype BTV-8, the MS has benefitted from EU funding for BT emergency vaccination programme (€800,000). Funding has also been provided for the AI emergency in 2006. The CP for AI has been updated and submitted to the COM in 2007.

[101] Animal Health in Denmark, 2010.

Figure 27: EU funding for veterinary emergency measures (payments executed), Denmark, 1997-2009



Source: DG SANCO, based on financial decisions from 1997- 2009 (line 17040301)

Czech Republic

The Czech Republic is a country that has experienced a relatively few number of animal disease emergencies. Since its accession to the EU (2004) the country has reported 4 HPAI outbreaks in domestic poultry and 15 in wild birds (2006/2007), and 14 bluetongue (BT) cases between 2007-2009 (all primary outbreaks)[102].

In total, 4 outbreaks of HPAI (H5NI) in poultry occurred in 2007, of which 1 primary and 3 secondary[103]. In response, contingency measures were implemented directly after the confirmation of the disease outbreak. The SVA explained that the rapid diagnosis of HPAI worked in a very

[102] The CZ CA (SVA) also reported 30 cases of outbreaks of BSE, and a Newcastle disease outbreak during the evaluation period.

[103] According to the SVA, an HPAI primary outbreak was detected in a commercial poultry flock in the municipality of Tisová on 21 June 2007. As a safeguard measure, 4,586 animals in total were killed using CO_2 in gas-tight containers on the day of confirmation and killing of animals on the holding finished on 22 June 2007. After that, 1,120 head of poultry kept on non-commercial holdings were killed in a contact municipality of Tisová using T61 injections. Killing in non-commercial flocks was finished on 22 June 2007 and all killed poultry was safely disposed of at a rendering plant. A HPAI secondary outbreak was confirmed on 27 June 2007 in a broiler holding in municipality of Nořín. Killing of animals in the outbreak started on the same day and finished on 28 June 2007 in the morning. Animals were again killed using CO2 in gas-tight containers which was followed by killing of poultry in non-commercial flocks in a contact municipality of Nořín; 222 animals were killed using T61 injections and all killed poultry was safely disposed of at a rendering plant. The second and the third outbreaks were confirmed on 11 July 2007 on two holdings owned by the same farmer in municipalities of Netřeby and Choceň. Killing started on 12 July 2007 and finished on the same day on the holding Netřeby and on 13 July on the holding Choceň. Preventive killing of poultry in non-commercial flocks in contact municipalities Netřeby, Kosořín and Choceň was performed on the same days (526 animals were killed using T61 injections). Birds in commercial flocks were killed using CO2 – in gas-tight containers on the first holding (Netřeby) or by gassing the halls on the second holding (Choceň). Preventive killing of poultry in contact commercial holdings in municipalities of Zářecká Lhota and Loučky was performed on 14 July 2007.

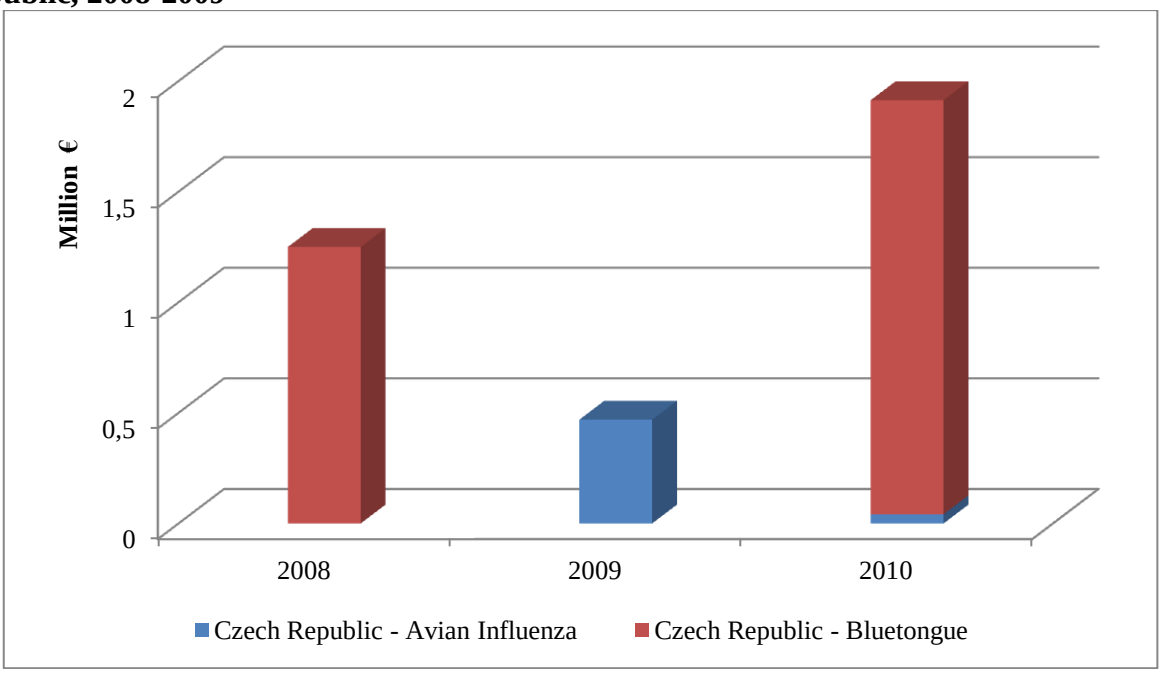
effective manner to contain the outbreaks. Following suspicion of the disease, samples were transported immediately for laboratory testing.

The SVA reported that it has conducted debriefings to assess the strengths and weaknesses of the crisis management once the HPAI emergency was over. For example, it was noted that the number of containers to collect the killed poultry was insufficient. As a result, the number of containers was increased from 9 to 20.

As for BT, the first case was detected in 2007. Emergency vaccination was conducted in the country in 2008 and preventive vaccination was carried out in 2009-2011. The last outbreak of the disease occurred in 2009. Since 25 November 2011 the whole territory of the Czech Republic is declared free from BTV 8.

Between 2007 and 2009 the Czech Republic received financial support from the EU emergency fund for Bluetongue vaccination 2007-2008 and for 2007 avian influenza outbreaks, as follows.

Figure 28: EU funding for veterinary emergency measures (payments executed), Czech Republic, 2008-2009



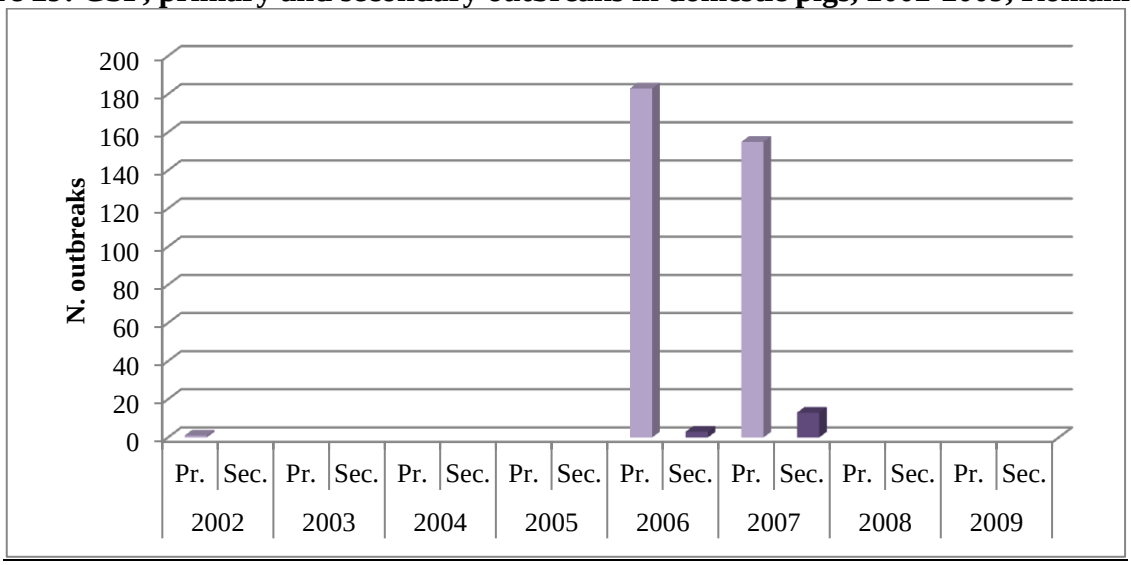
Source: DG SANCO, based on financial decisions from 2008-2010 (budget line 17040301)

Romania

Romania has a large domestic pig population of over 5 million pigs, and a large number of wild boars, estimated at some 60,000 animals. The way pigs are kept in Romania poses a specific risk for the spread of CSF, due to the large number of back-yard holdings (1.3 million in 2010) that rear about 3 million pigs in rural areas, where wild boars also occur. About 2 million pigs are reared in about 300 commercial holdings that can be compared to other industrialised pig holdings present in the EU.

Outbreaks of CSF were recorded in ADNS since 2001. In 2002, one outbreak was recorded in domestic pigs, and in 2006 and 2007 a large number of outbreaks were recorded, mostly in small backyard holdings, except for a very extensive outbreak that occurred on a large commercial holding in western Romania. Since October 2007, no CSF outbreak has been reported.

Figure 29: CSF, primary and secondary outbreaks in domestic pigs, 2002-2009, Romania



Source: Animal Disease Notification System

In the case of AI, Romania reported that a high number of outbreaks occurred in 2005 and 2006 in the area of Brasov [104] in commercial farms, and outbreaks among wild birds occurred in 2006 in the Danube Delta. This spread of H5N1 among domestic and wild birds in Romania has been estimated to have caused losses of around €200 million (USDA, 2006).

8.2.4 Additional costs of SCOFCAH meetings and improving the frequency of FVO CP verification missions

FVO missions and SCoFCAH meetings are two of the key components of the EU rapid response system examined in this evaluation. The focus of this indicator is on the additional costs of the functions performed by the FVO in relation to CP verification, and by the SCoFCAH in relation to information exchange and the adoption of containment measures. The envisaged in the legislation SCoFCAH process for the approval of initial CPs and updates (Theme B) is not covered here, as this process is not followed in practice. However, the analysis of Theme B concludes that if it were to be followed, it would not constitute an effective or efficient mechanism, and that FVO verification missions and certain other additional tools would be more relevant and effective for this purpose

i. Additional cost of SCoFCAH meetings

As discussed in Themes C and D, the costs associated to SCoFCAH meetings include, per meeting: the total cost of reimbursement of travel for one representative of the MS to attend, which ranges from €10,000 to €15,000: travel costs for MS to send additional representatives, which is often considered essential in view of the range of topics covered; and, administrative costs for the COM and the MS (in particular interpretation costs), which can amount to over €20,000. The total costs could therefore reach from €30,000 to €50,000 per meeting. There are at

[104] Although Romania was not an EU MS prior to 2007, the country was already reporting AI outbreaks to the EU through ADNS.

least 12 meetings per year (or about one per month) covering animal health issues, but in years of significant emergencies this can at least double due to emergency SCoFCAH meeting being convened (e.g. in 2006 some 30 SCoFCAH meetings took place, due also to emergency sessions to cover the AI crisis). The total cost of SCoFCAH meetings for animal health issues can therefore range from €360,000 to €600,000 per year, but at times of crisis in can reach double these figures.

Theme C concludes that the information exchange at SCoFCAH, despite the additional time and costs involved, is considered to be an essential element of the decision-making process and is therefore justified. Although it is not possible to isolate the information exchange activity from the decision-making function of SCoFCAH, it is noted that the monthly meetings of SCoFCAH are in any case taking place and therefore the additional time involved is the potential extension of a meeting to cover all the issues raised (e.g. from & to 1.5 days), which could add up to 50% to certain costs of a meeting (i.e. it can be roughly estimated to a potential increase of up to + ca. €10,000 per meeting, for certain meetings[105], for the COM and MS). Certain improvements can be made to provide cost savings, including video-linking to AH experts who are not attending the SCoFCAH meetings which is a cost-effective answer to the need for multiple participants from each MS to be present at the meetings, and the use of CIRCA by MS to facilitate the timely pre- and post-meeting circulation of relevant documents. The use of a technical group as an additional tool to information exchange at SCoFCAH to provide further detail and resolve technical problems, and of a template for epidemiological reports to standardise and improve the information provided are further ways to improve the cost-effectiveness of information exchange during the meetings.

Theme D concludes that the legislative obligation for adopting emergency containment measures at SCoFCAH is considered efficient by MS, while in general there are no unnecessary additional administrative costs for the procedures currently followed for the adoption of such measures. There may nonetheless be savings to be gained in cases where the endorsement of MS containment measures does not need to be voted on, if information provided by the affected MS is sufficient. Most MS also agree that there is significant and real added value in the approval of containment measures at SCoFCAH as opposed to other means, and that the current procedure for adopting emergency containment measures most relevant and effective, primarily for protecting animal and human health, but also for ensuring free movement (trade) of animals and goods from the non-affected areas. Although it has not been possible to obtain specific evidence of monetary values of the benefits of containment measures approved at SCoFCAH (e.g. in terms of trade value gained from regionalisation measures that enabled trade to continue from the rest of the EU), both the MS CAs and stakeholders have stressed the benefits of these measures.

ii. **Improving the frequency of FVO inspection missions to MS to verify CP compliance with the relevant legislation**

As discussed in Themes B and E, FVO missions to MS to verify compliance with the EU legislation (i.e. the CP requirements stipulated in the Annexes to the disease specific Control Directives) are considered the most effective and cost-efficient approach for ensuring that the appropriate and up to date CPs are in place.

[105] I.e. this will not be relevant to every meeting, but only where the sharing of important epidemiological information is necessary, mostly in the context of the adoption emergency measures.

The current number and frequency of FVO inspection missions to MS to verify CP compliance is indicated in EQ E/3. It is concluded that if an increased involvement of the FVO to achieve a cycle of inspection missions every 5 years to verify sufficiently MS CPs was to result in an additional 5/6 missions per year, and all other FVO work (e.g. missions on the monitoring and eradication programmes etc.) was to continue as currently, it would result in an additional requirement for 2 more inspectors in the FVO AH unit.

8.2.5 Economic impact of an animal health crisis

The economic implications of animal diseases and animal disease control have been analysed in some existing studies which have estimated costs and impacts of infectious diseases focusing on specific countries, commodities and cases of outbreaks. The table below presents an overview of the economic impacts of some notable animal health emergency/crises in EU MS

Impacts can extend from several million € in direct losses, such as those incurred from animal culling and the destruction of materials (e.g. HPAI, 2003, Netherlands: > €150 million;) to hundreds of millions € or even several billion € if the indirect losses to the affected sector and the wider economy are also included (e.g. HPAI, 1999-2000, Italy: €650 million; FMD, 2001, UK £5.8-6.3 billion). It is noted that the methodology used in these studies varies considerably, particularly for the estimation of the wider impacts, which depend on the underlying models and assumptions made for the spill-over impact to the economy.

Table 14: Economic impact of animal diseases in certain MS

Country	Impact
Netherlands	A model applied to the 1997/1998 **CSF** outbreak in the Netherlands (in which over ten million pigs were slaughtered), estimates the total financial consequences of the outbreak at US $2.3 billion. Consequential losses for farmers are US $423 million (18% of the total) and losses for related industries are US $596 million (26% of the total) (Meuwissen et al., 1999). The 2003 outbreak of **HPAI** (H7N7 virus) in the Netherlands was particularly severe, leading to the destruction of some 30 million birds, with direct economic costs estimated at more than €150 million (European Commission, 2006).
Italy	In 1999–2000, the outbreak of H7N1 **HPAI** in domestic poultry resulted in US$122 million in compensation for destroyed birds, and it was estimated that indirect costs exceeded US$400 million, bringing the total cost to over US$512 million. (Halvorson, D et al 2003). The Italian poultry association estimated direct and indirect losses at about €650 million, divided as follows: €165 million for dead and culled animal and destroyed materials; €190 million for reduction of egg and poultrymeat production; €165 million for fixed costs (holdings, hatcheries, slaughterhouses etc during the provisional suspension of production); €130 million for loss of farmers' income and worker allowances. In Veneto, the Italian Region with the highest poultry density, the destruction of infected or suspicious flocks has been estimated to have caused indirect cost of € 257 million and direct costs of € 54.5 million (Sabrina Sartore et al). The more recent 2006 AI outbreak had a negative impact on the Italian poultry sector leading to a significant loss in consumer confidence: although estimates vary, the consensus of livestock and farming unions is that consumption fell between 60% and 70% (AVEC 2006, Help Consumatori 2006a and 2006b, Repubblica 2006, Corriere 2006, Guida Sicillia 2006a and 2006b, Il Sole 24 Ore 2006, USDA 2006a). Communication costs of the Italian poultry association to deal with the 2005 AI emergency were estimated at €3.5 million (UNA 2012).

Country	Impact
United Kingdom	In Britain, as a result of the 2001 **FMD** epidemic, four million susceptible animals on 10,157 premises were slaughtered (of which only 2,026 premises were actually declared infected) and a further 2.5 million animals were slaughtered for reasons of welfare. The financial cost of the FMD epidemic, based on the slaughter of 4 million susceptible animals alone, was estimated at over £5.8-6.3 billion (depending on the assumption made for the spill-over impact to the economy). This includes £3.1 billion losses for the agriculture and food chain and £2.7-3.2 billion in losses sustained by the leisure and tourist industry. (Thompson at al. 2001, Ramsay and Riethmuller, 1999). By comparison, the total economic loss for the UK resulting from BSE in the year after the 1996/7 crisis was estimated at between £740 million and £980 million (Atkinson, 2000).
Belgium	**Bluetongue** outbreaks were estimated to have resulted in the loss of one-sixth of the national sheep flock and an overall economic impact of between €35.3 and €104.8 million in 2006-2007 (Hannon at al 2008)
France	According to the estimates of Mounaix et al (2008), the **bluetongue** outbreak in France caused the loss of 7,000 to 40,000 calves, resulting in the following decrease in gross margins: • between 4% and 143% for suckler sheep; • between 6.1% and 43% for suckler cows; • between 1.1% and 12% for dairy cows.
Romania	The spread of **H5N1** among domestic and wild birds in Romania during 2005 and 2006, i.e. prior to EU accession, has been estimated to have caused losses of around €200 million according to Romanian authorities (USDA, 2006b).

Source: compiled by Agra CEAS Consulting

8.3 Conclusions and recommendations (Theme G)

Key findings

Based on the FCEC analysis of the collected evidence base, the following overall conclusions can be drawn on the effectiveness and efficiency of the EU rapid response network (**EQ G/1**):

- Over the evaluation period, out of a significant number of outbreaks, relatively few have developed into a crisis situation. In particular (**indicator 1**):
    - On the basis of the criteria financial cost and economic impact, the following crisis situations were identified: CSF (1997 DE); AI (1999/2000 IT); AI (2003 NL); H5N1 (2005-06); FMD (2001, UK); BT (2007/08, DE/FR/NL/BE). In the last 4 years the EU has not experienced an animal health crisis, while the potential of an ASF crisis due to the risk of re-introduction of this disease from the Caucasus region was avoided.
    - The conclusions reached by the analysis suggest that the availability of a CP, as an indicator of preparedness, can prevent an emergency from becoming a crisis. Nonetheless, the overall effectiveness of the EU rapid response system in preventing an emergency from becoming a crisis extends beyond the availability of CPs as such, to the cooperation and coordination within the overall rapid response network, including cooperation between the COM and MS, between laboratories and with stakeholders.

      The evolution of the EU animal health co-financing indicates a downward trend in the amount of EU co-funding for emergency veterinary measures from some € 65 million in 2001 to € 30 million in 2011 (**indicator 3**). The exceptionally large EU financial contribution in 2001 can be attributed to the 2001 FMD crisis in the UK. This points to the more efficient use of funds to achieve longer term objectives

such as the reinstating of disease free status for major diseases in the EU, as was also concluded by the recent report on the outcome of the EU co-financed animal disease eradication and monitoring programmes, which highlights notable achievements in this area, such as the effective control of CSF, bluetongue and avian influenza in the EU over the last decade (FCEC, 2011). The comprehensive set of legislation now in place (including CPs and the EU emergency network in all its components) can be considered as a valuable shield against traditional contagious animal diseases and appears to be quite effective in terms of triggering the relevant steps and control measures to fight against emerging diseases or new "profiles" of known diseases (e.g. AI with public health risks).

- FVO missions and SCOFCAH meetings are two of the key components of the EU rapid response system examined in this evaluation; the focus (indicator 4) is on the additional costs of the functions performed by the FVO in relation to CP verification, and by the SCoFCAH in relation to information exchange and the adoption of containment measures106, which have already been covered by other Themes. In particular:
    - As indicated in themes C and D, the cost of SCoFCAH meetings cannot, strictly speaking, be broken down between the various activities performed as the information exchange feeds into the adoption of containment measures. Theme C concludes that the information exchange at SCoFCAH, despite the additional time and costs involved (which are relatively marginal and only for certain meetings, as necessary), is considered to be an essential element of the decision-making process and is therefore justified. Similarly, Theme D concludes that the legislative obligation for adopting emergency containment measures at SCoFCAH is considered efficient by MS, while in general there are no unnecessary additional administrative costs for the procedures currently followed for the adoption of such measures. Nonetheless, certain cost savings could be considered (see recommended improvements below).
    - In terms of the FVO missions to MS to verify compliance with the EU legislation, as discussed in Themes B and E, these are considered the most effective and cost-efficient approach for ensuring that the appropriate and up to date CPs are in place.
- The extent of the economic and social impacts (for the affected sectors and the wider economy) of major animal health emergencies/crises that have occurred in the EU27 during the last two decades is so significant (as evidenced from the figures presented in this Theme - **indicator 5**), that it justifies the relatively limited costs of investing on an improved preparedness. This is in line with the approach of the new Animal Health Strategy (2007-2013) "*Prevention is better than cure*" aiming to reduce the likelihood of animal diseases occurrence and spread, and to minimise the impact of outbreaks, and with the COM Action Plan to deliver the strategy's vision for the years 2007-2013 and beyond.

Recommendations

From our review of the evidence base, the following conclusions can be reached on potential improvements to the current system:

[106] The envisaged in the legislation SCoFCAH process for the approval of initial CPs and updates (Theme B) is not covered here, as this process is not followed in practice. However, the analysis of Theme B concludes that if it were to be followed, it would not constitute an effective or efficient mechanism, and that FVO verification missions and certain other additional tools would be more relevant and effective for this purpose.

1. It needs to be considered further whether the ratio of primary to secondary outbreaks would be appropriate for MS to use as a more objective indicator of their performance in the management of certain diseases, and what the target ratio should be set at (**indicator 2**).
2. In terms of the additional costs of SCoFCAH meetings **(indicator 4.i**), certain improvements could be considered to provide cost savings. For the information exchange, these include: video-linking to AH experts who are not attending the SCoFCAH meetings which is a cost-effective answer to the need for multiple participants from each MS to be present at the meetings; the use of CIRCA by MS to facilitate the timely pre- and post-meeting circulation of relevant documents; the use of a technical group as an additional tool to information exchange at SCoFCAH to provide further detail and resolve technical problems; and, of a template for epidemiological reports to standardise and improve the information provided. For the approval of containment measures, savings could be gained in cases where the endorsement of MS containment measures does not need to be voted on, if information provided by the affected MS is sufficient.
3. In terms of the FVO missions to MS to verify compliance with the EU legislation (**indicator 4.ii**), recommendation 1 of Theme E is also relevant here (i.e. to consider an additional requirement for 2 more inspectors in the FVO AH unit, for the FVO to achieve a complete cycle of inspection missions every 5 years to verify sufficiently MS CPs).

9 Overall conclusions and recommendations

During the last two decades the EU has experienced a number of animal health crises, the shockwaves of which have been felt economically, socially and politically. These crises have caused serious damage to the EU livestock sector leading to significant disruptions to markets and the wider economy. Several factors have compounded the risk of such crises – globalization and the resulting increase in trade, the intensification and concentration of production structures within the livestock producing sectors, changes in the structure and operation of the food chain downstream from the livestock production sector, the expansion of EU borders eastwards and the associated increase in the animal populations and diversity of production systems within the EU livestock sector.

Recent outbreaks of epizootic diseases such as avian influenza (AI), foot and mouth disease (FMD) and bluetongue in previously unaffected territories of the EU have highlighted the threat posed by the sudden and unexpected emergence of infectious agents, and further emphasise the need for well-developed and adequately resourced counter-measures to improve the predictability of the EU response system and to ensure rapid containment**.**

Effectively preventing and containing animal health emergencies, so as to avoid a potential crisis, is the main objective of the EU legislation in place requiring MS to have in place contingency planning so as to be prepared to prevent and/or control emergencies. In this context a crisis refers to a situation that could have been avoided if the appropriate preparedness level and measures had been in place. On this basis, the evolution over time of the number of outbreaks and of those that developed into a crisis is an indicator of the overall performance of the EU animal response system.

Based on the FCEC analysis, the following overall conclusions can be drawn on the effectiveness and efficiency of the EU rapid response network.

The availability of well developed, tested and up to date CPs, as an indicator of preparedness, can help prevent an emergency from becoming a crisis. Nonetheless, the overall effectiveness of the EU rapid response system extends to factors well beyond simply having effective CPs in place. The effectiveness of the response also relies on good cooperation and coordination within the overall rapid response network, including between the COM and MS, regular and timely exchange of information (including scientific knowledge and advice) between laboratories and with stakeholders, and the building and maintenance of confidence and trust between all parties.

The evolution of the EU animal health co-financing indicates a downward trend in the amount of EU co-funding for emergency veterinary measures from some €65 million in 2000 to €30 million in 2011. Over the last five years EU co-financing has averaged €37 million, far below the average over the whole period (€91 million, 2000-2011[107]). This points to the more efficient use of funds to achieve longer term objectives such as the reinstating of disease free status for major diseases in the EU, as was also concluded by the recent report on the outcome of the EU co-financed animal disease eradication and monitoring programmes, which highlights notable achievements in this area, such as the effective control of CSF, bluetongue and avian influenza in the EU over the last decade (FCEC, 2011).

[107] In terms of outturn payments, i.e. the sum of credits generated by a MS in a specific year.

The comprehensive set of legislation now in place (including CPs and the EU emergency network in all its components) can be considered as a valuable shield against traditional contagious animal diseases and appears to be quite effective in terms of triggering the relevant steps and control measures to fight against emerging diseases or new "profiles" of known diseases (e.g. AI with public health risks).

As a result of this, over the evaluation period, out of a significant number of outbreaks, relatively few have developed into a crisis. On the basis of the criteria of financial cost and economic impact, the following crises were identified: CSF (1997 DE); AI (1999/2000 IT); AI (2003 NL); H5N1 (2005-06); FMD (2001, UK); BT (2007/08, DE/FR/NL/BE). In the last 4 years the EU has not experienced an animal health crisis, and in particular the potential of an ASF crisis due to the risk of re-introduction of this disease from the Caucasus region was avoided.

FVO missions and SCOFCAH meetings are two of the key components of the EU rapid response system examined in this evaluation. The evaluation has found that the information exchange at SCoFCAH is considered to be an essential element of the decision-making process and is therefore justified and that the legislative obligation for adopting emergency containment measures at SCoFCAH is seen as efficient by MS. Nonetheless, certain cost savings could be considered. FVO missions to MS to verify compliance with EU legislation, are considered to be the most effective and cost-efficient approach for ensuring that the appropriate and up to date CPs are in place.

The extent of the economic and social impacts, for the affected sectors and the wider economy, of major animal health emergencies/crises that have occurred in the EU27 during the last two decades is very significant. On the basis of existing studies, impacts can extend from several million € in direct losses, to hundreds of millions € or even several billion € if the indirect losses to the affected sector and the wider economy are also included. In recent years, due to improved preparedness, effective use of the lessons learnt from the management of outbreaks and development of networks of the actors involved in the EU rapid response system the EU 27 has no longer suffered from such extensive levels of losses.

Nevertheless the size of the potential damage to the livestock sector, the wider EU economy and consumer confidence, all point to the need to remain prepared and vigilant, by continuing to build and improve on the progress achieved so far. This is in line with the approach of the new Animal Health Strategy (2007-2013) "*Prevention is better than cure*" aiming to reduce the likelihood of animal diseases occurrence and spread, and to minimise the impact of outbreaks, and with the COM Action Plan to deliver the strategy's vision for the years 2007-2013 and beyond.

Although the potential adverse impacts of animal disease crises greatly outweigh the relatively limited costs of investing in improved preparedness it remains a key challenge to address needs satisfactorily within increasing budgetary constraints, particularly in the current adverse financial climate. To overcome these constraints, it is crucial to achieve cost savings by improving the EU rapid response structures and the processes involved in order to optimise effectiveness and efficiency. To this end, the evaluation provides detailed conclusions for each of the key components of the EU rapid response system in Themes A to G, on the basis of which recommendations are made.

Annex 1: Judgement criteria, indicators and data sources per EQ

Attached as a separate file

Annex 2: Overview of consultation process

In-depth interviews were carried out in several rounds, with the following organisations:

1. **Commission Services**

   - Further interviews with the relevant units of DG SANCO, including the Food and Veterinary office (FVO), Enforcement unit (E5) and the COM Legal Services.

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2. **Stakeholders at EU level:**

   - Copa-Cogeca
   - AVEC
   - UECBV
   - Federation of Veterinarians of Europe (FVE)
   - European Federation for Animal Health and Sanitary Security (FESASS)

The national counterparts of the stakeholder organisations were in some cases (UECBV, FVE and FESASS) already present in these interviews, as the meetings of these stakeholders are typically organised on a working group basis with extensive participation of national members.

The interviews were conducted on the basis of a consultation guide distributed to the EU organisations in December 2011 and widely disseminated via their EU head offices to the MS, including both those visited in the context of case studies and those not visited.

Further interviews with the national members of key relevant organisations amongst the above list were conducted in 10 MS in the context of case studies.

The case studies of 10 selected MS were conducted in February to March 2012. The field visits in the MS involved interviews with the MS CAs and relevant stakeholders, incorporating also the response of the MS CA to the FCEC survey and the review of the key MS CPs, relevant FVO reports and other relevant documentation.

The purpose of the case studies in 10 MS has been to conduct a more in-depth investigation into the issues explored in this evaluation by finding more evidence for answering the EQs. The case studies have enabled the FCEC to identify the notable characteristics of CP practice and, more generally, to assess the functioning of the Rapid Response Network, to identify what are good or best practices and thus assess the potential and requirements for applying these across the EU. The detailed interviews with the CAs and stakeholders in the 10 MS have also allowed the FCEC to collect further data sources at a national level, to capture – as extensively as possible – the range of viewpoints and positions of the various MS and their stakeholders. This will provide the basis for recommendations for potential areas of improvement in the final phase of the evaluation.

The 10 MS of particular interest were: Belgium (BE), Czech Republic (CZ), Denmark (DK), France (FR), Germany (DE), Italy (IT), the Netherlands (NL), Poland (PL), Romania (RO) and

the United Kingdom (UK). This selection ensures a balance taking into account the appropriate coverage in terms of geographical location (south-north countries), EU accession (new/old MS), actors involved, and epidemiological situation (animal disease outbreaks). During the inception phase it was also decided that the best approach to focus the field visits is to concentrate on the most relevant diseases per MS, although not limited to these focus diseases exclusively**.**

Table 15 presents the selected MS, the focus animal diseases, and the stakeholders consulted. In each MS, the field visit has included interviews with the CAs and with a selection amongst key relevant stakeholders, primarily national members of COPA-COGECA, UECBV, AVEC FESASS, and FVE, as well as any other relevant bodies/structures set up at some MS to provide the capacity for the management of crises.

The selection of MS was confirmed with the SG at the inception phase of the evaluation:

- The decisive criterion for the selection of MS covered by the case studies has been the presence of a key animal disease of EU relevance in the MS. In some MS disease outbreaks became a crisis, such as in Italy (1999) and the Netherlands (2003) for HPAI-P, and FMD in the UK (2001), and therefore the case studies in these MS concentrate on these animal diseases. In other cases, MS have experienced animal disease emergencies which could potentially have become crises (e.g. ASF in Italy, CSF in Germany).

- The Czech Republic and Belgium are used as 'control cases' to compare with the other MS. Indeed, these two MS present relatively lower risk factors, particularly in the case of CZ, but they are still obliged to be prepared by having in place effective, operational CPs.

- Romania is a good case due to its dualistic farming structure (large holdings and backyard holdings). For our analysis it has been relevant to see how Romania has developed its contingency plan in these two different contexts.

- Poland is a relevant case overall for examining the issues of extensive land borders with TCs and smallholdings (the same issues as RO backyard farming).

- Germany, Belgium, the Netherlands, France and Denmark are relevant for examining cross-border cooperation issues between neighbouring MS (i.e. extent to which they cooperate in conducting real time alert exercises).

Table 15: List of stakeholders consulted in the case study MS

MS	Disease Focus[108]	Farmer's association	Association poultry sector	Association red meat sector	FESASS (a)	FVE	Other (b)
BE	All diseases, with particular focus on BT	Boerenbond -BB	VEPEK	FEVEB;	ARSIA		
CZ	All diseases	AA CZ	Czech Poultry Processors Association	Czech Meat Processor Association Pig Breeders Association			
DE	CSF, FMD, HPAI, BT	DBV	?	DVFB and VDF	ADT,		
DK	FMD, HPAI, BT	DAFC	?			DVA	
FR	FMD, BT	FNSEA and APCA:	FIA	FNICGV and FNP	FNGDS		
IT	HPAI, ASF, SVD	Confagricoltura	UNA	UNICEB	AIA		
NL	HPAI, CSF, BT, FMD	NOP/LTO	NEPLUVI	NBHV			PVE (b)
PL	All diseases	FBZPR		Polish Meat Association		KILW	
RO	HPAI, CSF	F.N.P.A.R.	UCPR	RMA			
UK	FMD	NFU	BPC(c)	BMPA and SAMW		BVA	

(a) FESASS has members in some MS only: Belgium; France; Germany; Italy; the Netherlands; Luxembourg; Spain; and, Portugal.
(b) Associations which do not fall into any of the five categories presented – e.g. the PVE which constitutes the joint secretariat of the Productschap Vee en Vlees (PVV; Product Board for Livestock and Meat) and the Productschap Pluimvee en Eieren (PPE; Product Board for Poultry and Eggs).
(c) The consultation with these stakeholders is still ongoing.

[108] Note: the other diseases covered by the Control Directives, including emerging diseases (e.g. RVF), will also be taken into account to the extent relevant in each MS.

Annex 3: Data on disease outbreaks (for the key diseases) in the MS covered by the field visits

Belgium

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
BT																			695		6870		45		2	
CSF	1	7																								

Czech Republic

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
BT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	9	0	4	0
HPAI-P	0	0	0	0	0	0	0	0									0	0	0	0	1	3	0			

Denmark

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
BT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	5	10	0	**0**
HPAI-P																			1							

Germany

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
BT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	883	2	20669	0	3102	0	134	8
CSF	12	34	8	3	5	0	2	0	3	2	8	3	1						7	1	0	0				
HPAI-P													1	0					1		6	0	1			

France

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
BT							31		323	0		0	17	0	34	0	6		6	0	304	15308	137	37885	7	79
CSF	**0**	0	0	0	0	0	0	0	0	0	1	0	0						0	0	0	0				
FMD									2	0												0				
HPAI-P	**0**	0	0		0	0	0	0					0	0			0	0	1		0	0				

Italy

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
ASF	1	22	2	26	16		2	9	9		6	5	4	8	19	229	16	182			12	19	3	3	3	
BT							6857		0	6370	0	430	0	2070	0	136	0		2	234	15	2	1	4	7	60
CSF	10	45	4	14	2	6	2	1	5	0	0	0	1						0	0	0	0				
HPAI-P	5	2	1		8	59	17	334					0	0			0		0		0	0	0			
SVD*	16		25		14		5		11		171		31		125		13		51		89		65		18	

Netherlands

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
BT							0		0	0		0	0	0	0	0	0		456	0	633	5165	66	0	12	0
CSF	4	420	0	5	0	0	0	0	0	0	0	0	0						0	0	0	0				
FMD									1	25											0	0				
HPAI-P	0	0	0		0	0	0	0					2	239			0		0		0	0	0			

Poland

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
HPAI-P	0	0	0		0	0	0	0					0	0			0		0		5	4	0			

Romania

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
CSF	0	0	0	0	0	0	0	0	0	0	1	0	0						183	3	155	13				
HPAI-P	0	0	0		0	0	0	0					0	0			25		172		1	0	0			

United Kingdom

	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	
	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.	Pr.	Sec.
BT							0		0	0		0	0	0	0	0	0		0	0	3	62	0	70	0	0
CSF	0	0	0	0	0	0	3	12	0	0	0	0	0						0	0	0	0				
FMD									10	2020											3	5				
HPAI-P	0	0	0		0	0	0	0					0	0			0		0		2	1	1			

*For SVD data available from ADNS http://ec.europa.eu/food/animal/diseases/adns/index_en.htm
Source: ADNS (data provided by DG SANCO).

Annex 4: EU-27 MS CA survey results

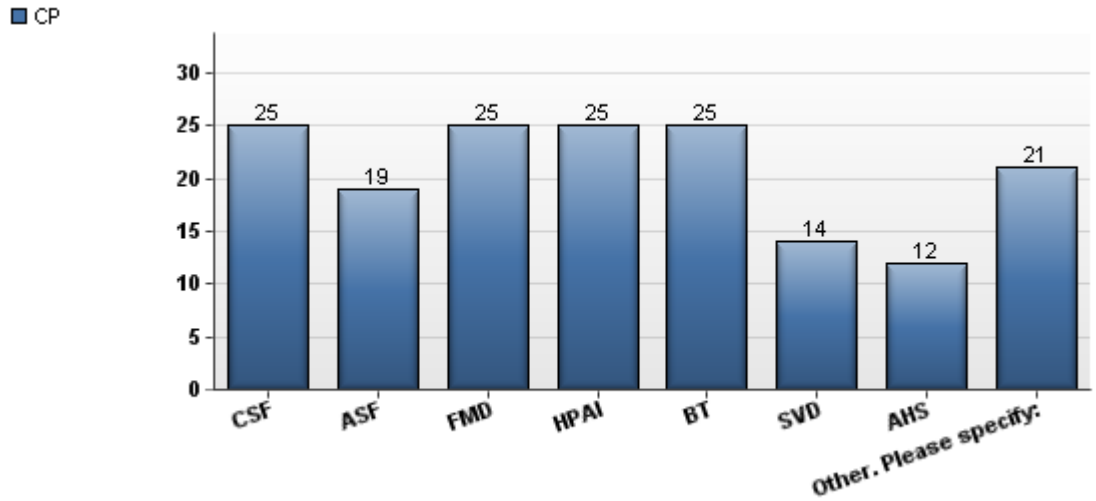
Note: only the quantitative results are reported in this Annex; the qualitative results are currently being processed for incorporation into the analysis of the Themes in the last phase of the evaluation.

Statistic	Value
Total Responses	27

I. EU LEGISLATION RELATED TO CONTINGENCY PLANNING

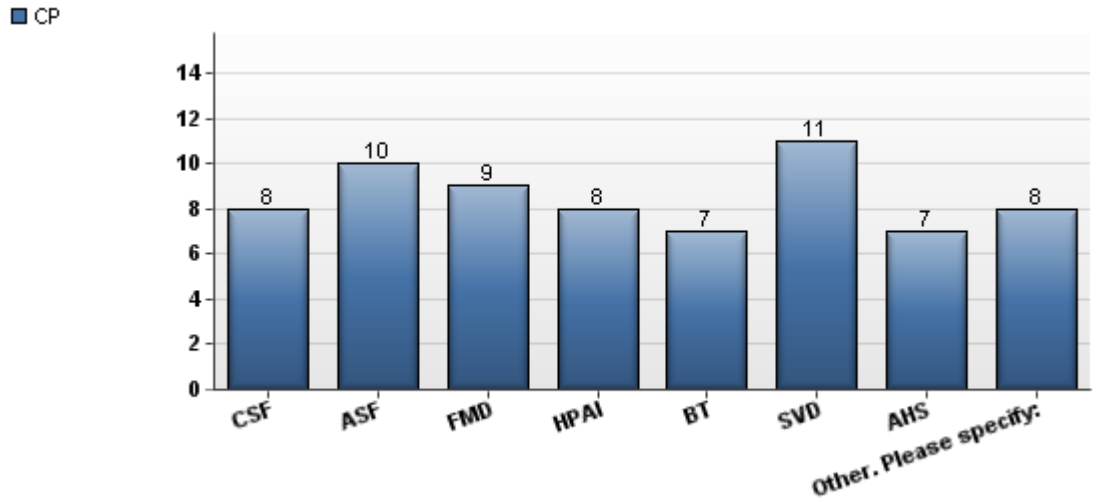
1. For which of the following animal diseases is there a contingency plan (CP) currently in place in your country and since when?

Number of MS having in place disease specific CPs for the main diseases:



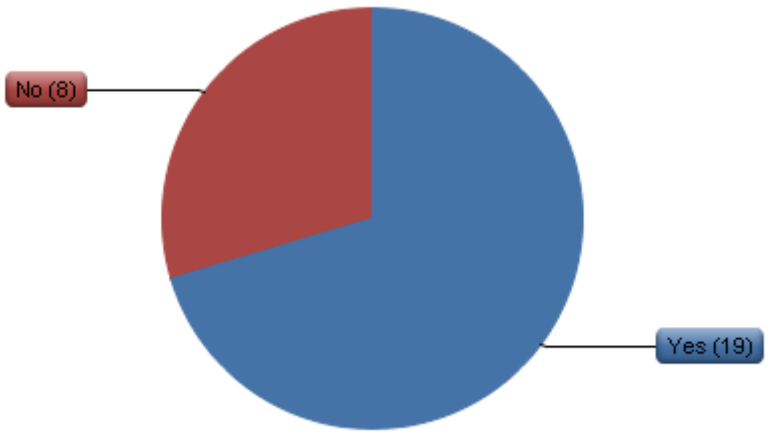
#	Question	CP	Responses
1	CSF	25	25
2	ASF	19	19
3	FMD	25	25
4	HPAI	25	25
5	BT	25	25
6	SVD	14	14
7	AHS	12	12
8	Other:	21	21

Number of MS having in place CPs that are part of a general CP, for the main diseases:



#	Question	CP	Responses
1	CSF	8	8
2	ASF	10	10
3	FMD	9	9
4	HPAI	8	8
5	BT	7	7
6	SVD	11	11
7	AHS	7	7
8	Other. Please specify:	8	8

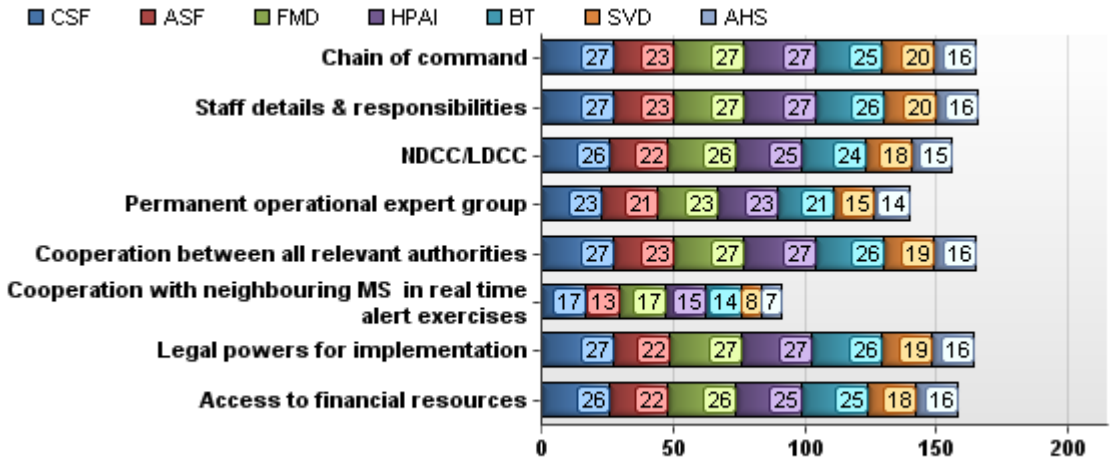
2. In your view, can a generic CP which defines a broad set of criteria with specific CPs per disease as chapters, achieve the same objectives as several disease-specific CPs? Please tick:



#	Answer		Response	%
1	Yes		19	70%
2	No		8	30%
	Total		27	100%

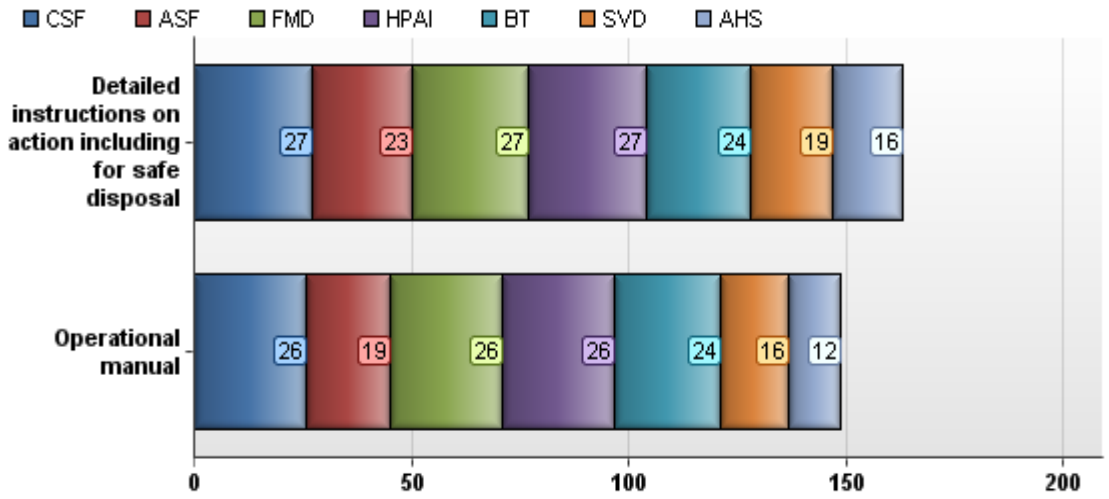
3. a) Which of the following criteria currently laid down in EU legislation do the CPs in your country currently comply with?
Number of MS having in place CPs complying with the following criteria:

Organisation:



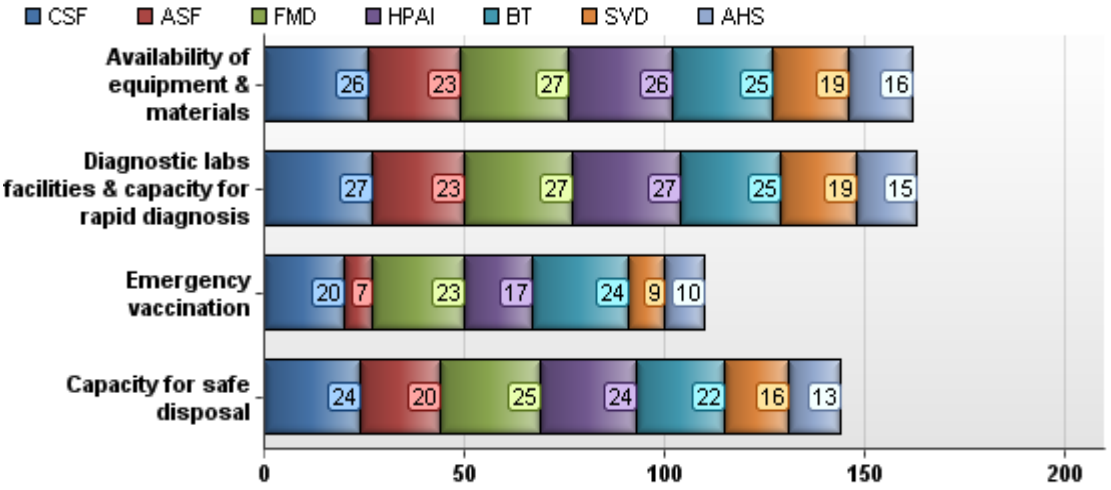
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Chain of command	27	23	27	27	25	20	16	165
2	Staff details & responsibilities	27	23	27	27	26	20	16	166
3	NDCC/LDCC	26	22	26	25	24	18	15	156
4	Permanent operational expert group	23	21	23	23	21	15	14	140
5	Cooperation between all relevant authorities	27	23	27	27	26	19	16	165
6	Cooperation with neighbouring MS in real time alert exercises	17	13	17	15	14	8	7	91
7	Legal powers for implementation	27	22	27	27	26	19	16	164
8	Access to financial resources	26	22	26	25	25	18	16	158

Practical implementation:



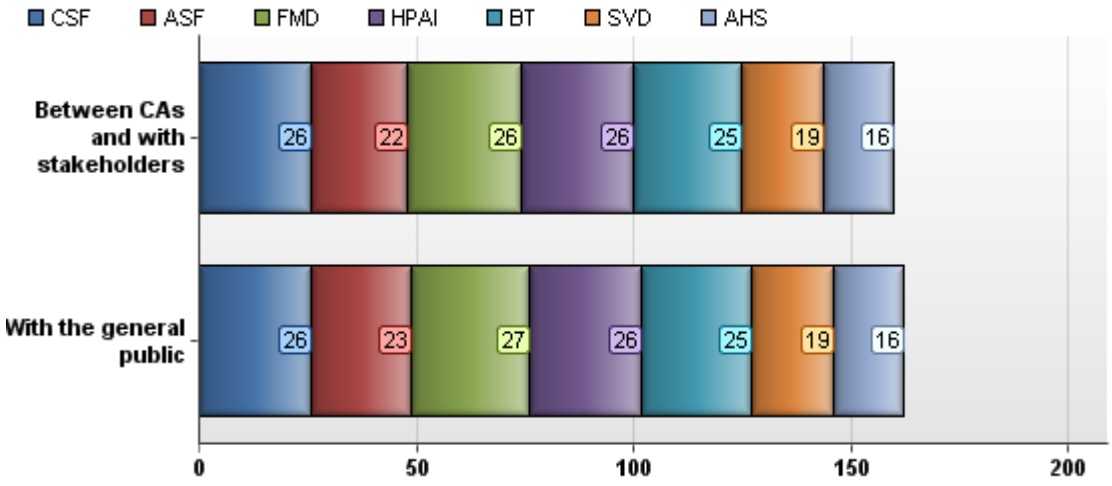
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Detailed instructions on action including for safe disposal	27	23	27	27	24	19	16	163
2	Operational manual	26	19	26	26	24	16	12	149

Tools:



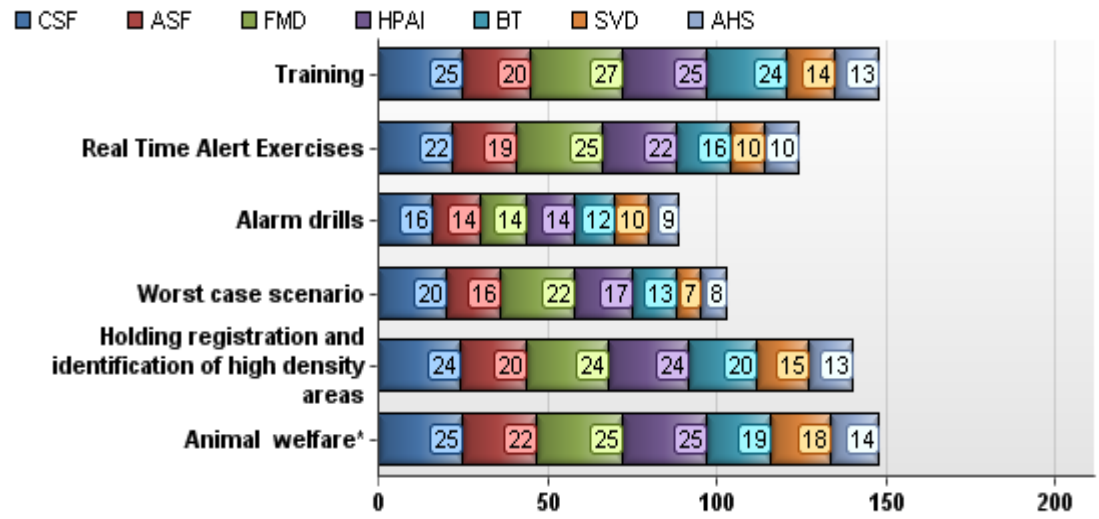
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Availability of equipment & materials	26	23	27	26	25	19	16	162
2	Diagnostic labs facilities & capacity for rapid diagnosis	27	23	27	27	25	19	15	163
3	Emergency vaccination	20	7	23	17	24	9	10	110
4	Capacity for safe disposal	24	20	25	24	22	16	13	144

Capacity for rapid communication:



#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Between CAs and with stakeholders	26	22	26	26	25	19	16	160
2	With the general public	26	23	27	26	25	19	16	162

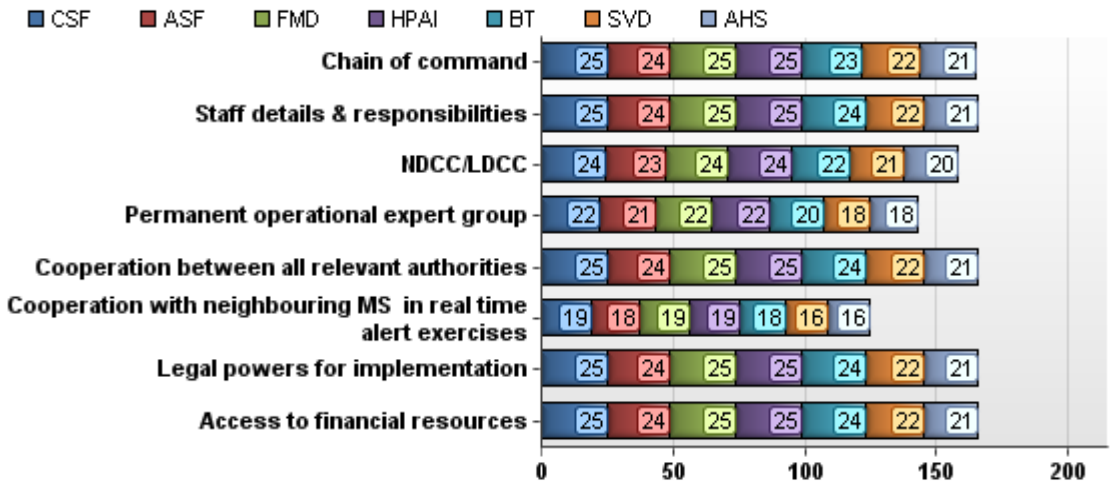
Other criteria:



#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Training	25	20	27	25	24	14	13	148
2	Real Time Alert Exercises	22	19	25	22	16	10	10	124
3	Alarm drills	16	14	14	14	12	10	9	89
4	Worst case scenario	20	16	22	17	13	7	8	103
5	Holding registration and identification of high density areas	24	20	24	24	20	15	13	140
6	Animal welfare*	25	22	25	25	19	18	14	148

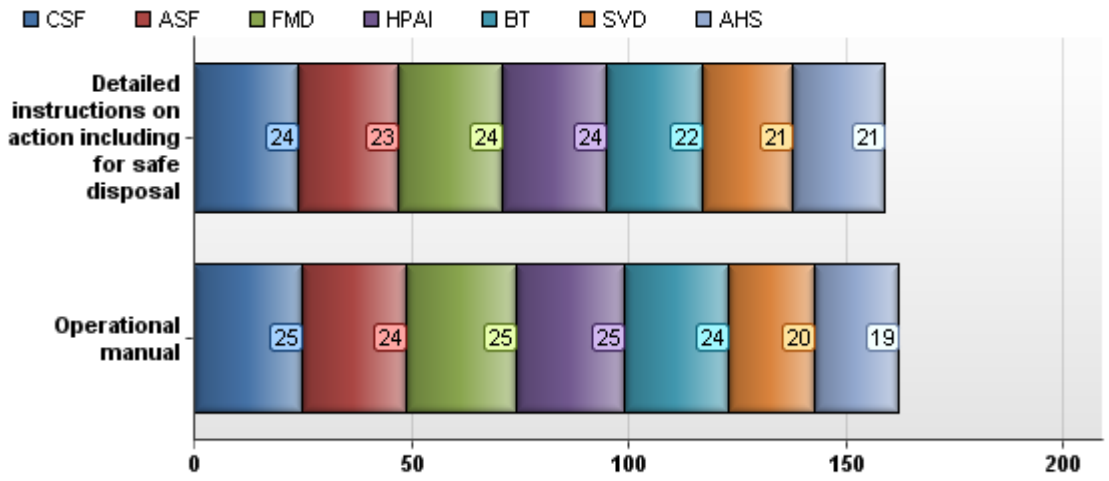
3.b) In your view, which of the following criteria currently laid down in EU legislation are necessary for ensuring an effective CP?
Number of MS considering necessary for ensuring an effective CP the following criteria:

Organisation:



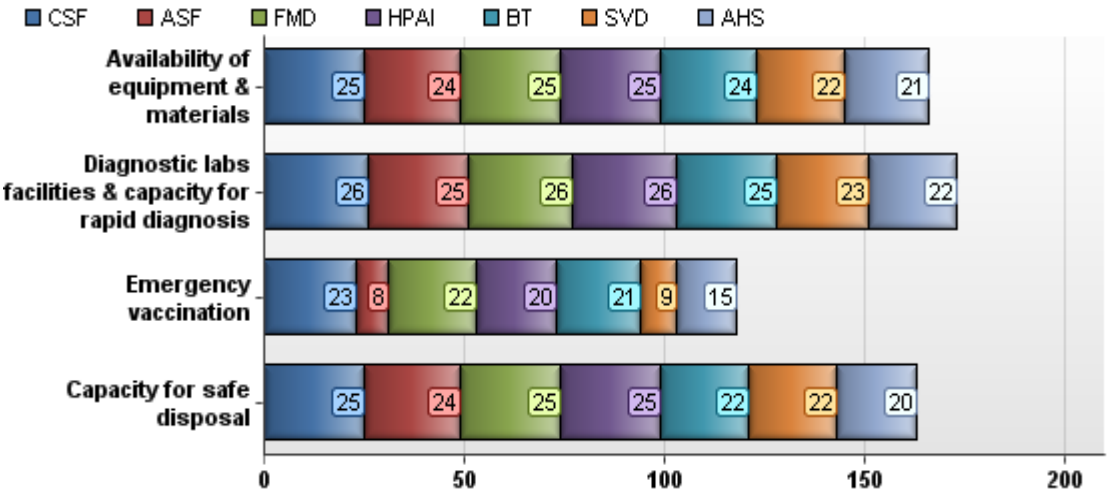
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Chain of command	25	24	25	25	23	22	21	165
2	Staff details & responsibilities	25	24	25	25	24	22	21	166
3	NDCC/LDCC	24	23	24	24	22	21	20	158
4	Permanent operational expert group	22	21	22	22	20	18	18	143
5	Cooperation between all relevant authorities	25	24	25	25	24	22	21	166
6	Cooperation with neighbouring MS in real time alert exercises	19	18	19	19	18	16	16	125
7	Legal powers for implementation	25	24	25	25	24	22	21	166
8	Access to financial resources	25	24	25	25	24	22	21	166

Practical implementation:



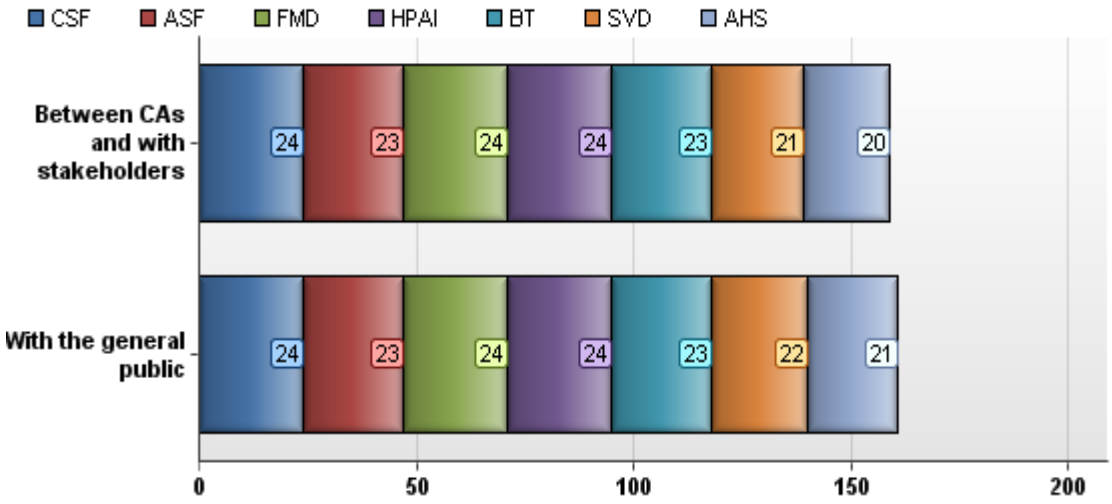
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Detailed instructions on action including for safe disposal	24	23	24	24	22	21	21	159
2	Operational manual	25	24	25	25	24	20	19	162

Tools:



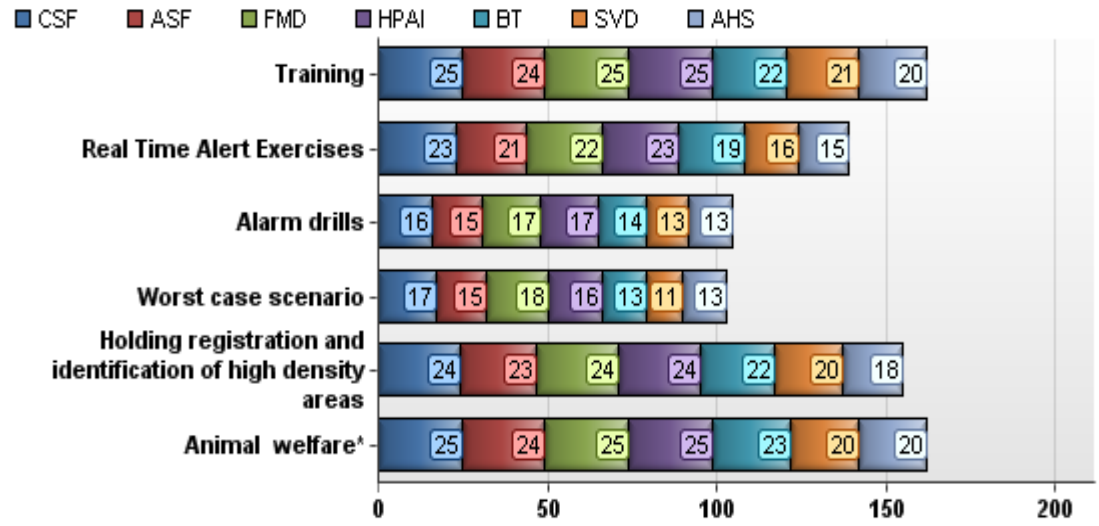
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Availability of equipment & materials	25	24	25	25	24	22	21	166
2	Diagnostic labs facilities & capacity for rapid diagnosis	26	25	26	26	25	23	22	173
3	Emergency vaccination	23	8	22	20	21	9	15	118
4	Capacity for safe disposal	25	24	25	25	22	22	20	163

Capacity for rapid communication:



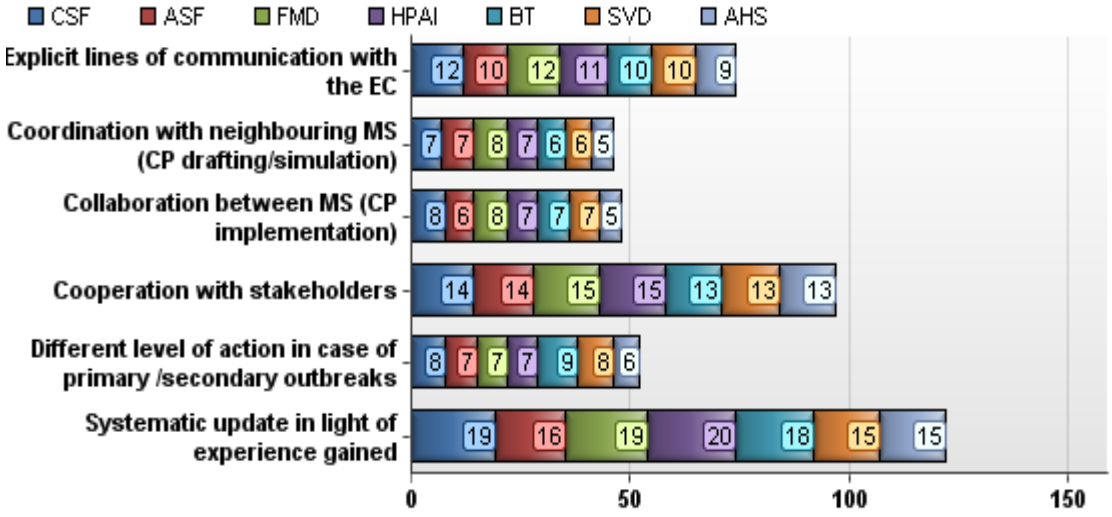
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Between CAs and with stakeholders	24	23	24	24	23	21	20	159
2	With the general public	24	23	24	24	23	22	21	161

Other criteria:



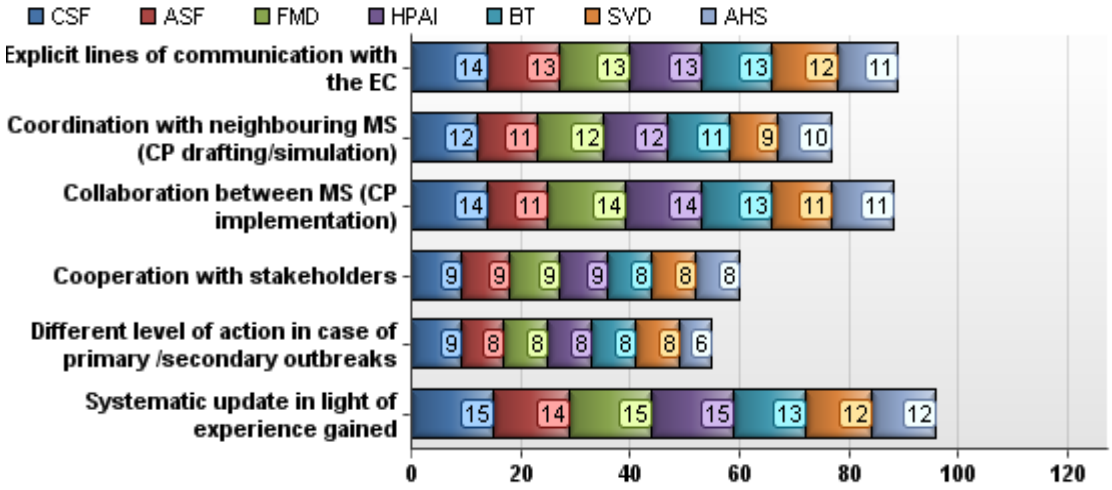
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Training	25	24	25	25	22	21	20	162
2	Real Time Alert Exercises	23	21	22	23	19	16	15	139
3	Alarm drills	16	15	17	17	14	13	13	105
4	Worst case scenario	17	15	18	16	13	11	13	103
5	Holding registration and identification of high density areas	24	23	24	24	22	20	18	155
6	Animal welfare*	25	24	25	25	23	20	20	162

3.c) Do the CPs in your country include additional criteria which are currently not laid down in the EU legislation:
Number of MS including in their CP the following additional criteria:



#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Explicit lines of communication with the EC	12	10	12	11	10	10	9	74
2	Coordination with neighbouring MS (CP drafting/simulation)	7	7	8	7	6	6	5	46
3	Collaboration between MS (CP implementation)	8	6	8	7	7	7	5	48
4	Cooperation with stakeholders	14	14	15	15	13	13	13	97
5	Different level of action in case of primary /secondary outbreaks	8	7	7	7	9	8	6	52
6	Systematic update in light of experience gained	19	16	19	20	18	15	15	122
7	Other. Please specify:	2	2	2	2	2	2	2	14

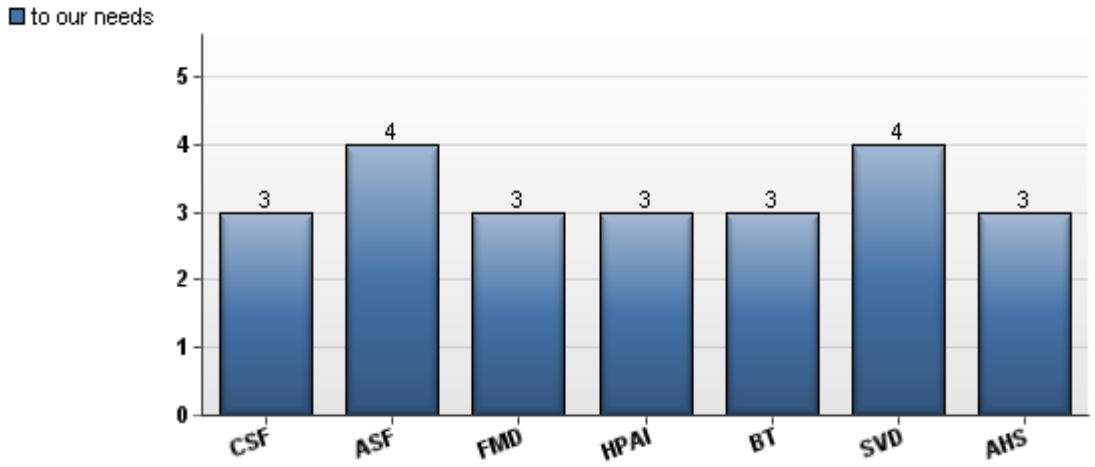
3.d) In your view, which of the following additional criteria need to be laid down in the EU legislation?
Additional criteria considered necessary to be laid down in the EU legislation:



#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Explicit lines of communication with the EC	14	13	13	13	13	12	11	89
2	Coordination with neighbouring MS (CP drafting/simulation)	12	11	12	12	11	9	10	77
3	Collaboration between MS (CP implementation)	14	11	14	14	13	11	11	88
4	Cooperation with stakeholders	9	9	9	9	8	8	8	60
5	Different level of action in case of primary /secondary outbreaks	9	8	8	8	8	8	6	55
6	Systematic update in light of experience gained	15	14	15	15	13	12	12	96
7	Other. Please specify:	1	1	1	1	1	2	1	8

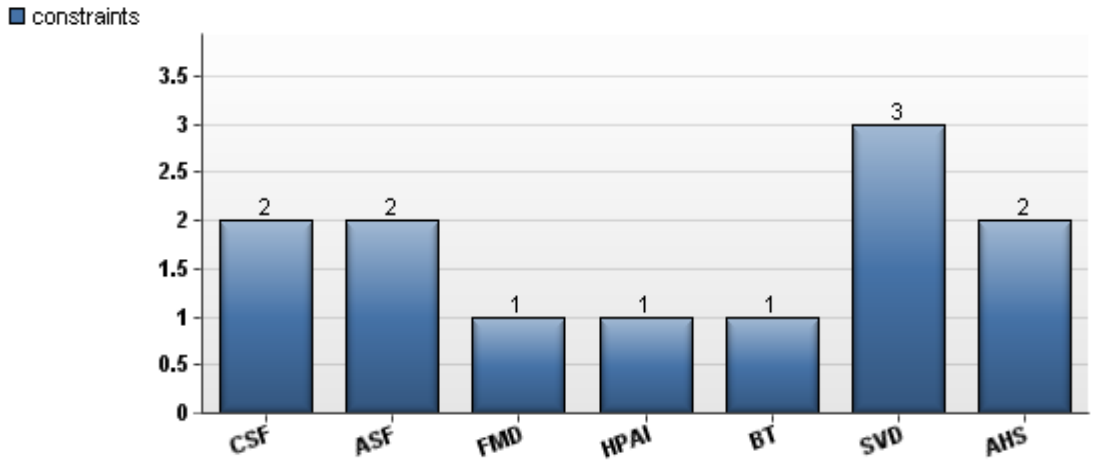
3.e) In case the CPs in your country do not comply with the above mentioned criteria currently laid down in the EU legislation, please indicate the reasons why:

Number of MS indicating as reason: Not relevant to our needs



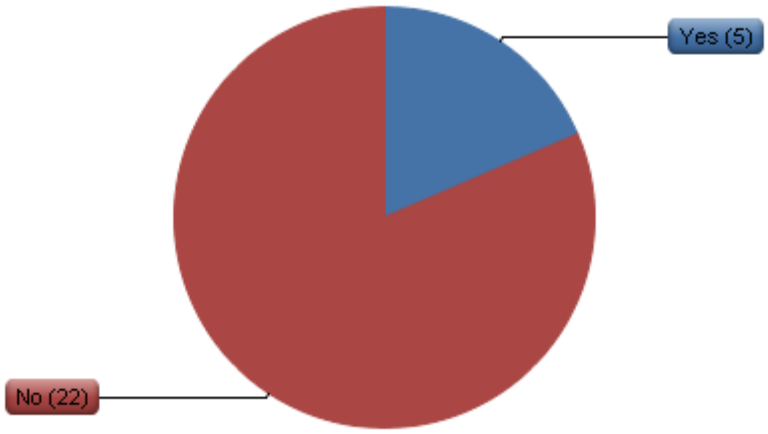
#	Question	to our needs	Responses
1	CSF	3	3
2	ASF	4	4
3	FMD	3	3
4	HPAI	3	3
5	BT	3	3
6	SVD	4	4
7	AHS	3	3

Number of MS indicating as reason: Budgetary/administrative constraints



#	Question	constraints	Responses
1	CSF	2	2
2	ASF	2	2
3	FMD	1	1
4	HPAI	1	1
5	BT	1	1
6	SVD	3	3
7	AHS	2	2

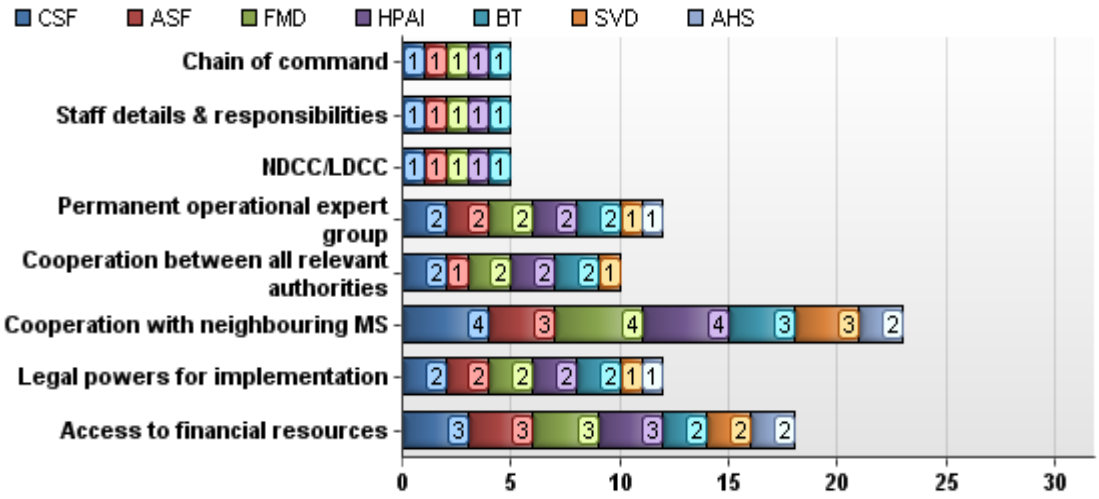
4. In your view, is it necessary to lay down at EU level more detailed/prescriptive implementing rules on criteria for CPs?



#	Answer		Response	%
1	Yes		5	19%
2	No		22	81%
	Total		27	100%

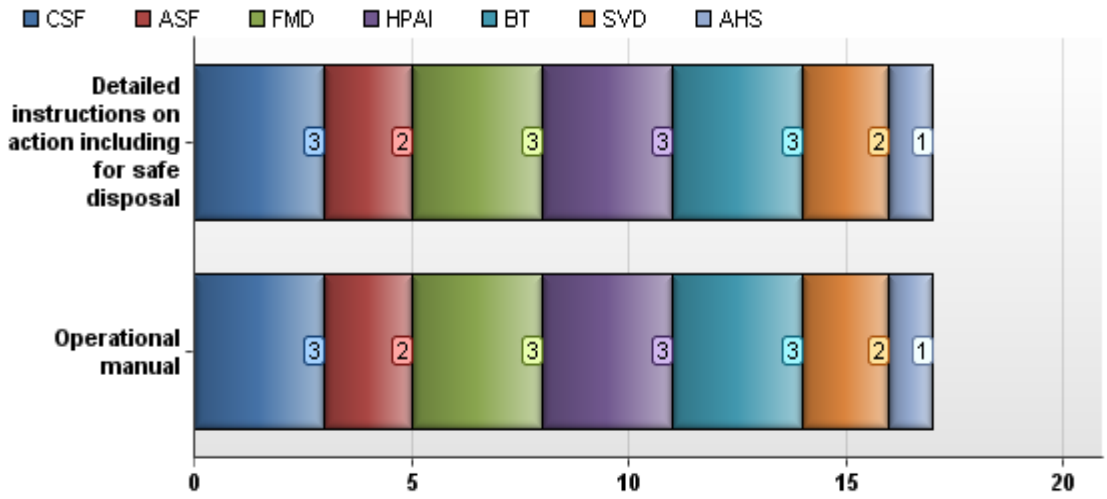
If the answer is 'yes', please indicate for which criteria and for which disease. Criteria currently laid down in EU legislation:

Organisation:



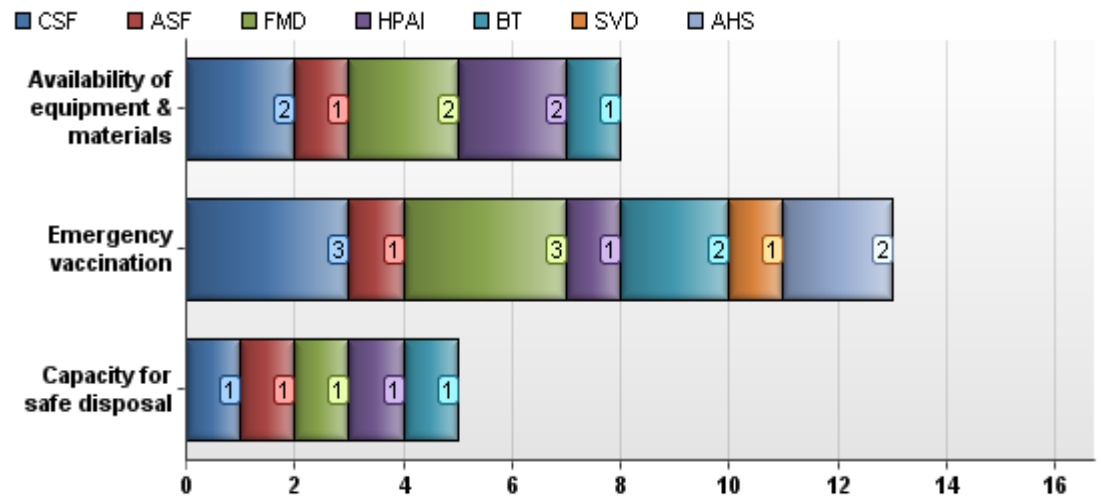
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Chain of command	1	1	1	1	1	0	0	5
2	Staff details & responsibilities	1	1	1	1	1	0	0	5
3	NDCC/LDCC	1	1	1	1	1	0	0	5
4	Permanent operational expert group	2	2	2	2	2	1	1	12
5	Cooperation between all relevant authorities	2	1	2	2	2	1	0	10
6	Cooperation with neighbouring MS	4	3	4	4	3	3	2	23
7	Legal powers for implementation	2	2	2	2	2	1	1	12
8	Access to financial resources	3	3	3	3	2	2	2	18

Practical implementation:



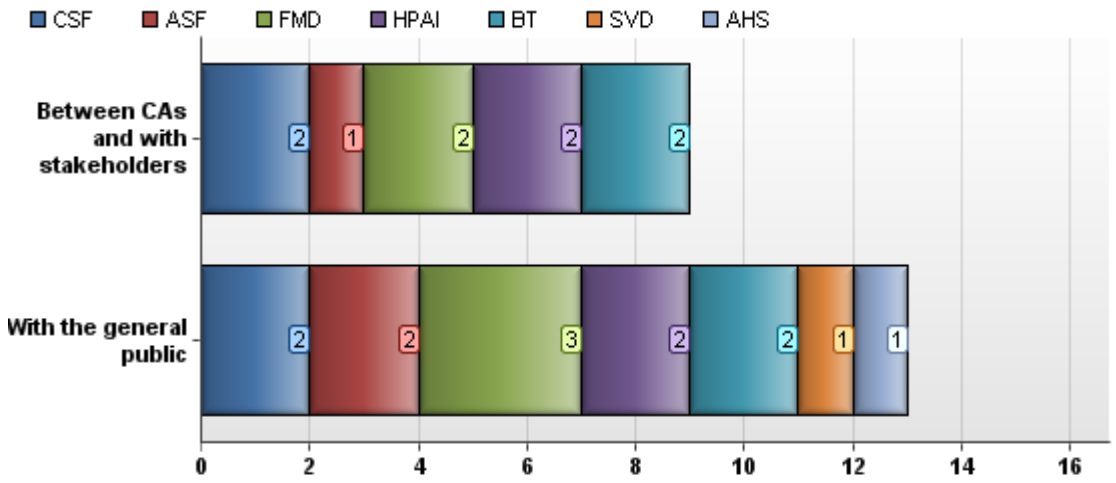
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Detailed instructions on action including for safe disposal	3	2	3	3	3	2	1	17
2	Operational manual	3	2	3	3	3	2	1	17

Tools:



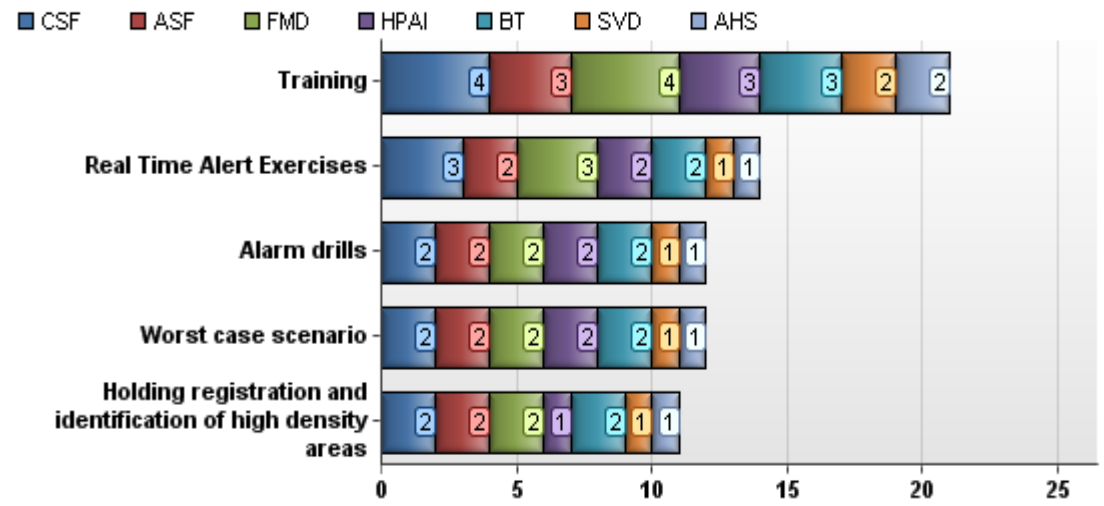
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Availability of equipment & materials	2	1	2	2	1	0	0	8
2	Diagnostic labs facilities & capacity for rapid diagnosis	0	0	0	0	0	0	0	0
3	Emergency vaccination	3	1	3	1	2	1	2	13
4	Capacity for safe disposal	1	1	1	1	1	0	0	5

Capacity for rapid communication:



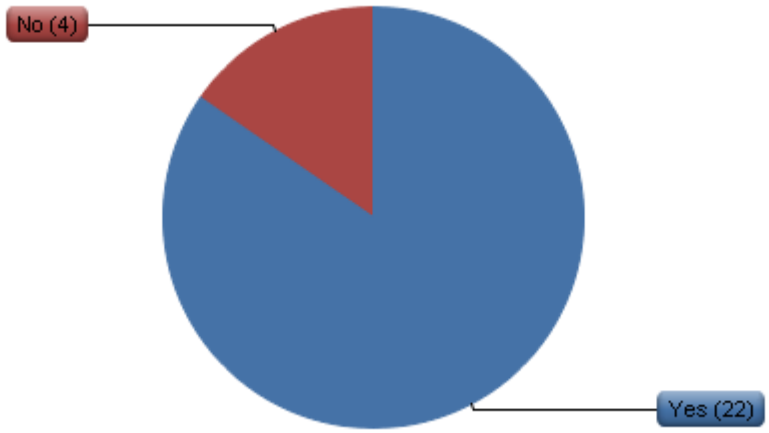
#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Between CAs and with stakeholders	2	1	2	2	2	0	0	9
2	With the general public	2	2	3	2	2	1	1	13

Other criteria:



#	Question	CSF	ASF	FMD	HPAI	BT	SVD	AHS	Responses
1	Training	4	3	4	3	3	2	2	21
2	Real Time Alert Exercises	3	2	3	2	2	1	1	14
3	Alarm drills	2	2	2	2	2	1	1	12
4	Worst case scenario	2	2	2	2	2	1	1	12
5	Holding registration and identification of high density areas	2	2	2	1	2	1	1	11

Have the EU guidelines produced in 2000 been used when drafting the CPs in your country?

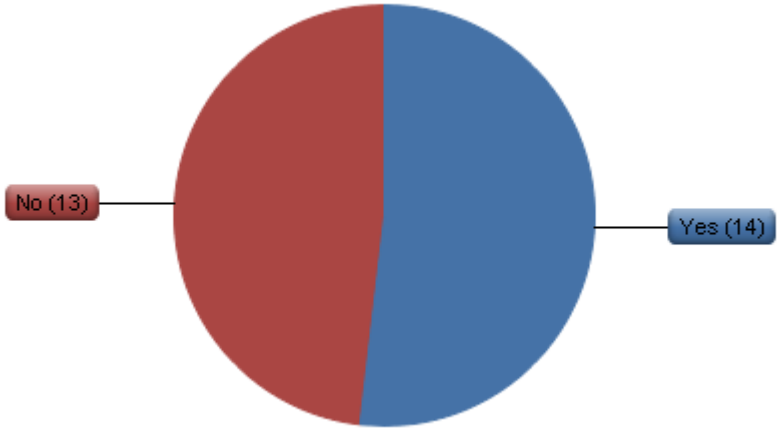


#	Answer		Response	%
1	Yes		22	85%
2	No		4	15%
	Total		26	100%

If 'no', please specify reasons why:

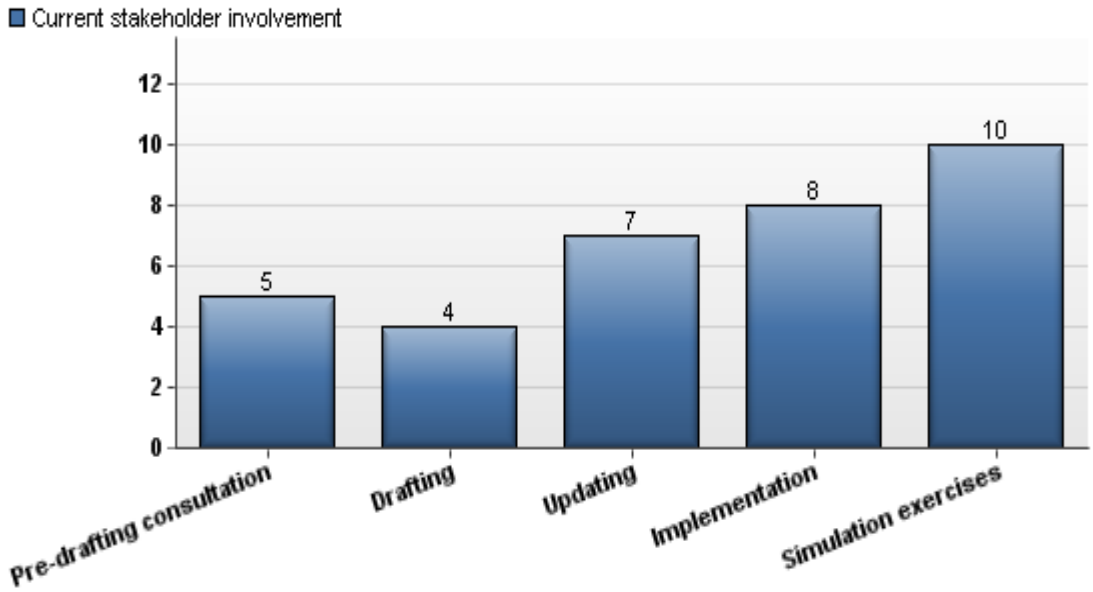
Text Response
Detailed prescriptions of the vertical EU law are the basis for the CPs.
Before accession, we have not been aware of their existence.

6. In the context of CP development:
a) Are relevant stakeholders (i.e. those representing farmers and agri-food industries) currently involved in the different phases of CP development in your country?



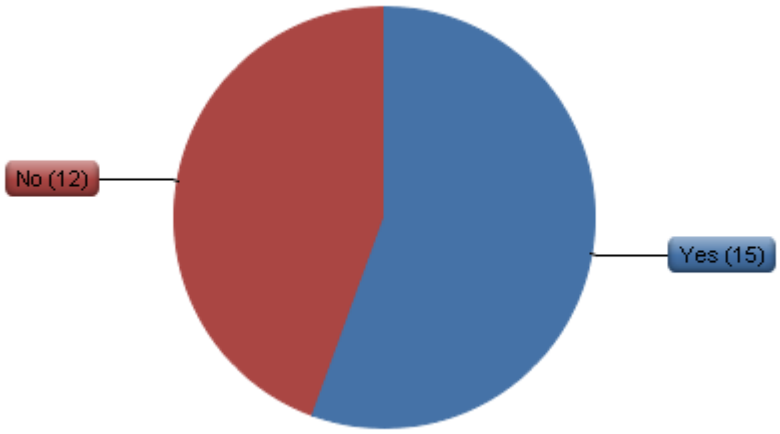
#	Answer		Response	%
1	Yes		14	52%
2	No		13	48%
	Total		27	100%

If 'yes', please specify in which phase/s of CP development stakeholders are currently involved:
Number of MS:



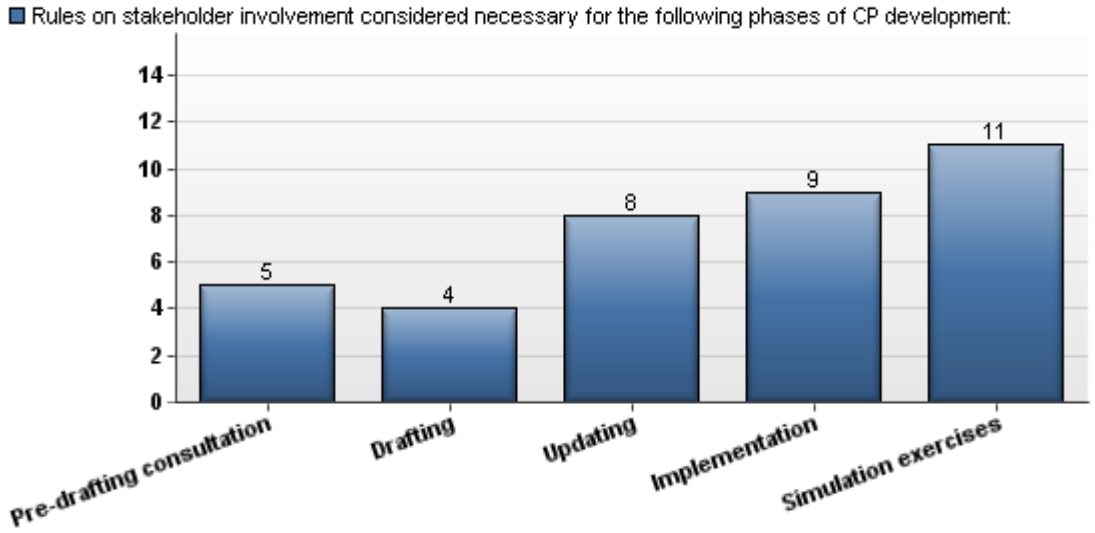
#	Question	Current stakeholder involvement	Responses
1	Pre-drafting consultation	5	5
2	Drafting	4	4
3	Updating	7	7
4	Implementation	8	8
5	Simulation exercises	10	10

6. b) In your view, is it necessary to have clearly defined rules laid down in the EU legislation for the involvement of relevant stakeholders (i.e. those representing farmers and agri-food industries)?



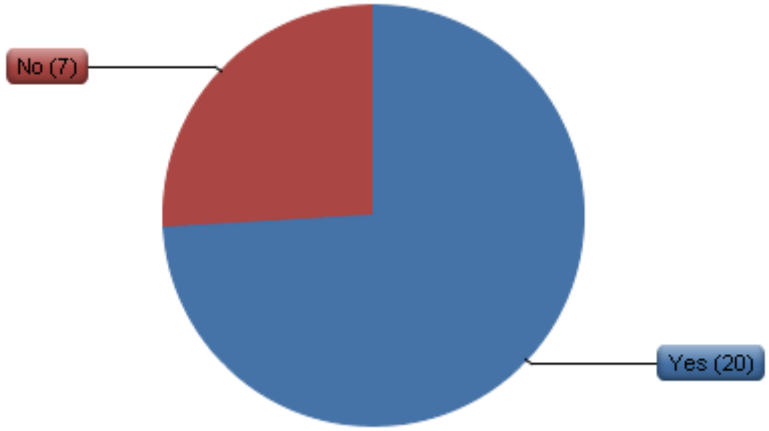
#	Answer		Response	%
1	Yes		15	56%
2	No		12	44%
	Total		27	100%

If 'yes', please specify for which phase/s of CP development it is considered necessary to lay down rules in the EU legislation on stakeholder involvement. Number of MS:



#	Question	Rules on stakeholder involvement considered necessary for the following phases of CP development:	Responses
1	Pre-drafting consultation	5	5
2	Drafting	4	4
3	Updating	8	8
4	Implementation	9	9
5	Simulation exercises	11	11

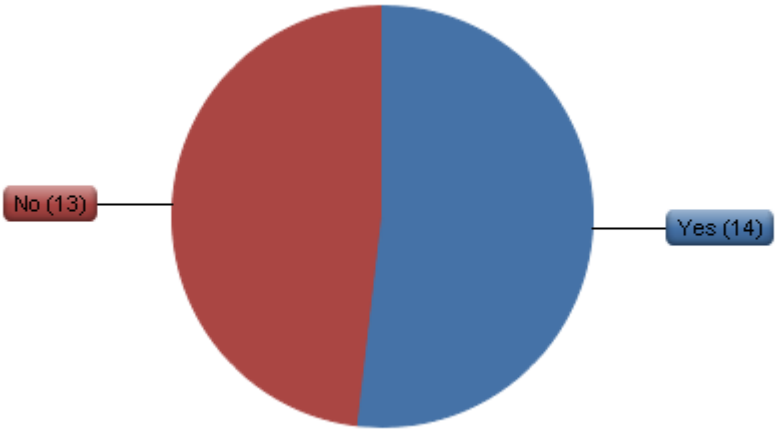
7. In assessing crisis preparedness and management capacity in your country:
a) Are objective performance indicators (e.g. disease prevalence, cost benefit analysis) currently being used?



#	Answer		Response	%
1	Yes		20	74%
2	No		7	26%
	Total		27	100%

7. b) In your view, is it relevant and possible to lay down such indicators in the EU legislation?

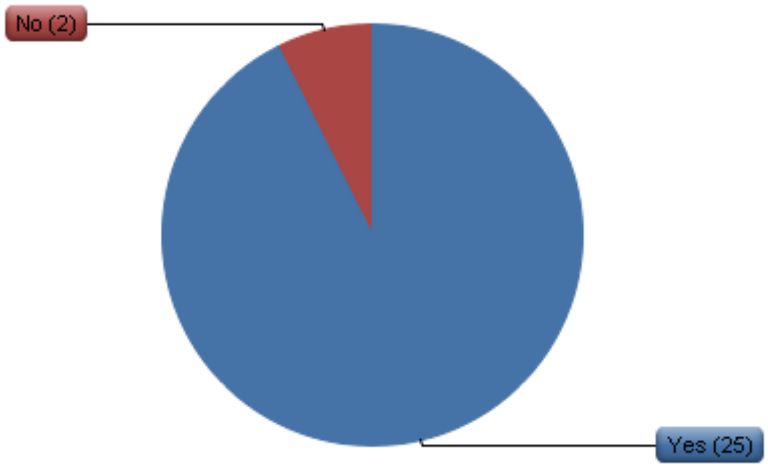
Number of MS indicating it is **relevant and possible**:



#	Answer		Response	%
1	Yes		14	52%
2	No		13	48%
	Total		27	100%

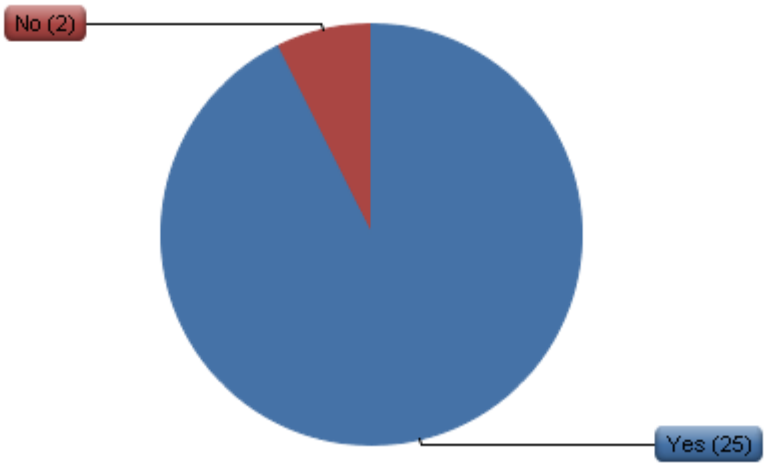
8. Overall, in your view, is the scope of CPs in the EU legislation broad enough to make these an effective tool in achieving the following goals:

Disease containment:



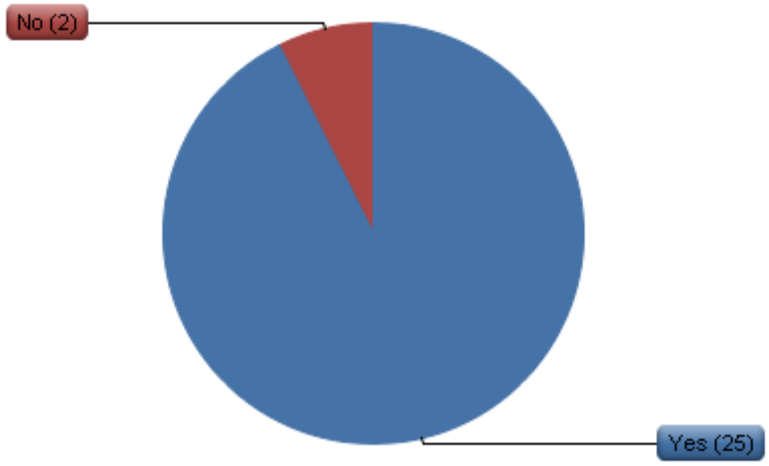
#	Answer		Response	%
1	Yes		25	93%
2	No		2	7%
	Total		27	100%

Control:



#	Answer		Response	%
1	Yes		25	93%
2	No		2	7%
	Total		27	100%

Eradication:



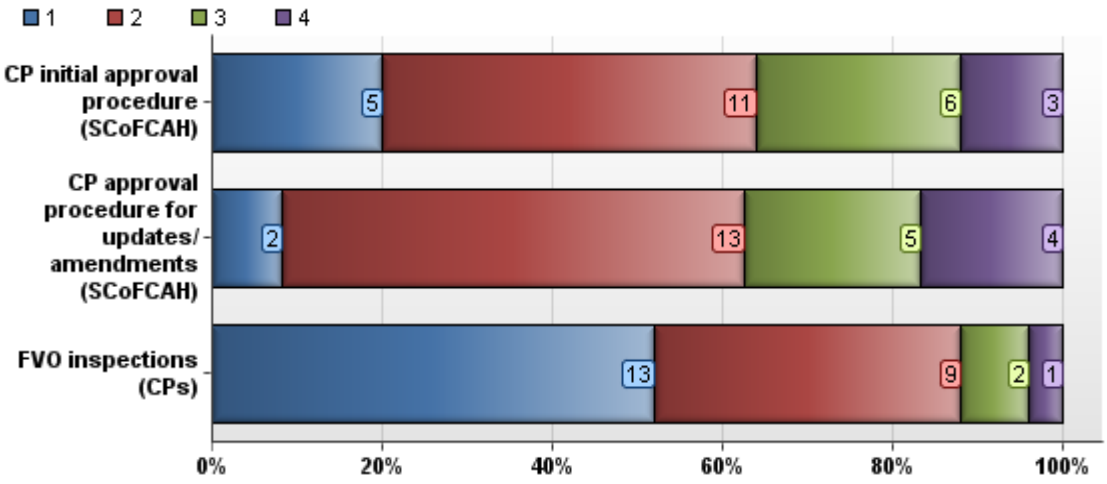
#	Answer		Response	%
1	Yes		25	93%
2	No		2	7%
	Total		27	100%

II. THE EVALUATION, APPROVAL AND FOLLOW-UP OF THE CPs

9. In your view, taking into account the experience gained from the evolution over the last 20 years of contingency planning in the MS, and the administrative/budgetary constraints:
a) To what extent are the current procedures/mechanisms for CP evaluation/approval and follow-up relevant, effective and efficient?

Relevant:

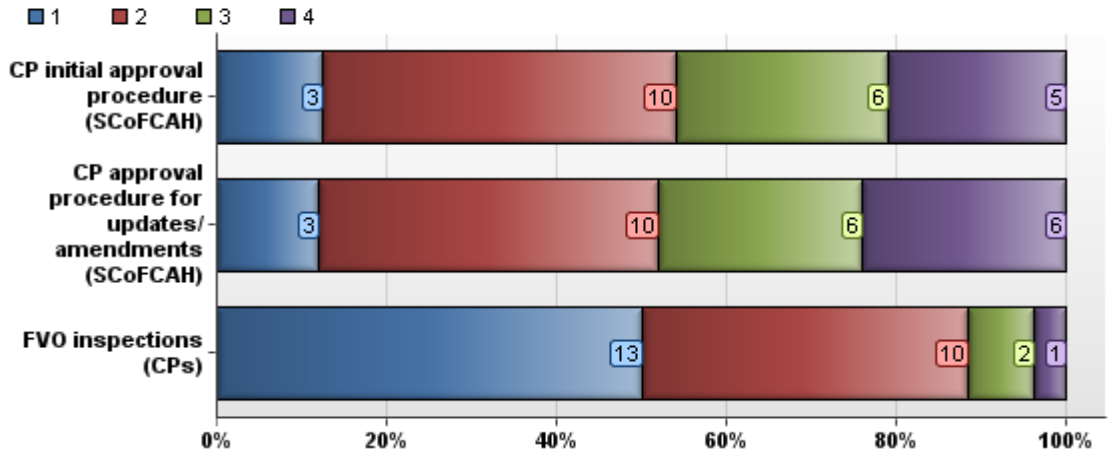
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	CP initial approval procedure (SCoFCAH)	5	11	6	3	25	2.28
2	CP approval procedure for updates/ amendments (SCoFCAH)	2	13	5	4	24	2.46
3	FVO inspections (CPs)	13	9	2	1	25	1.64

Effective:

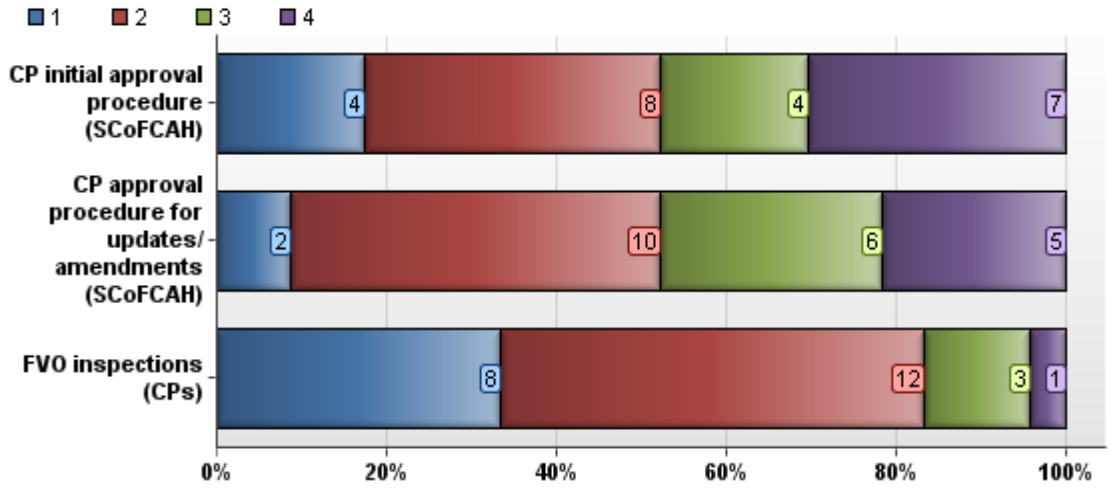
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	CP initial approval procedure (SCoFCAH)	3	10	6	5	24	2.54
2	CP approval procedure for updates/ amendments (SCoFCAH)	3	10	6	6	25	2.60
3	FVO inspections (CPs)	13	10	2	1	26	1.65

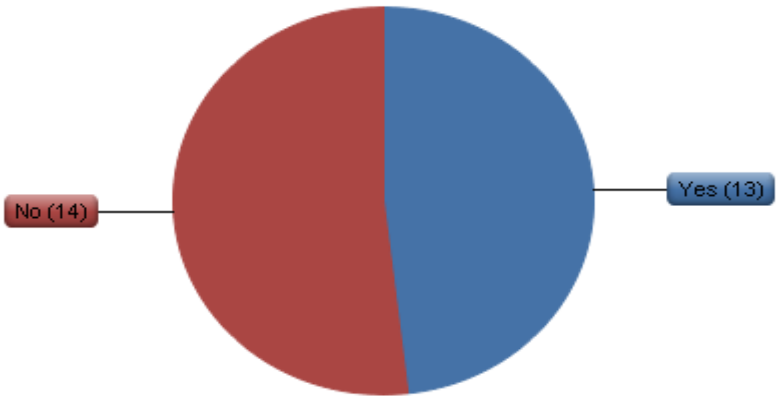
Efficient:

1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	CP initial approval procedure (SCoFCAH)	4	8	4	7	23	2.61
2	CP approval procedure for updates/ amendments (SCoFCAH)	2	10	6	5	23	2.61
3	FVO inspections (CPs)	8	12	3	1	24	1.88

9.b) Is there a need to improve current procedures/mechanisms?



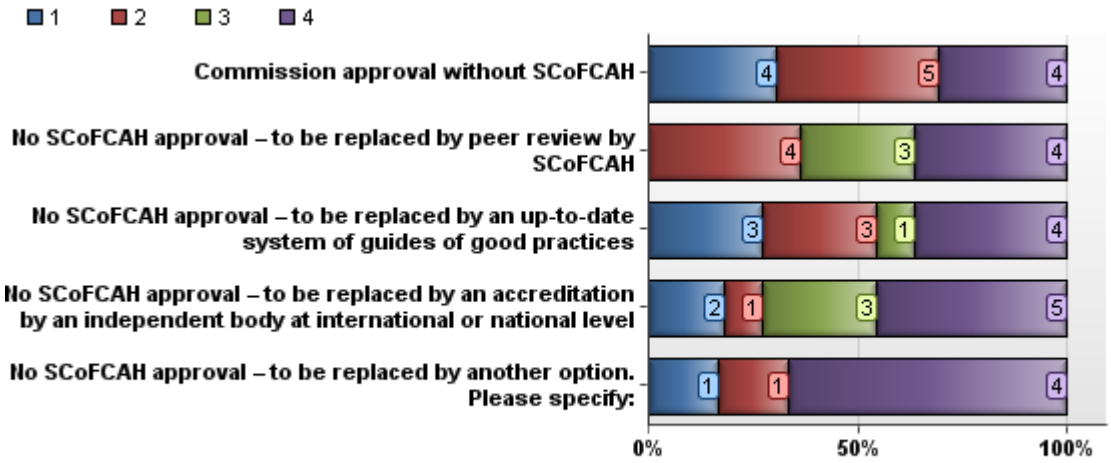
#	Answer		Response	%
1	Yes		13	48%
2	No		14	52%
	Total		27	100%

9.c) If the answer is 'yes', to what extent could the following potential alternative options and/or additional tools be relevant, effective and efficient in ensuring that effective CPs are in place?

Potential alternative options:

Relevant:

1=very, 2=fairly, 3=not very, 4=not at all

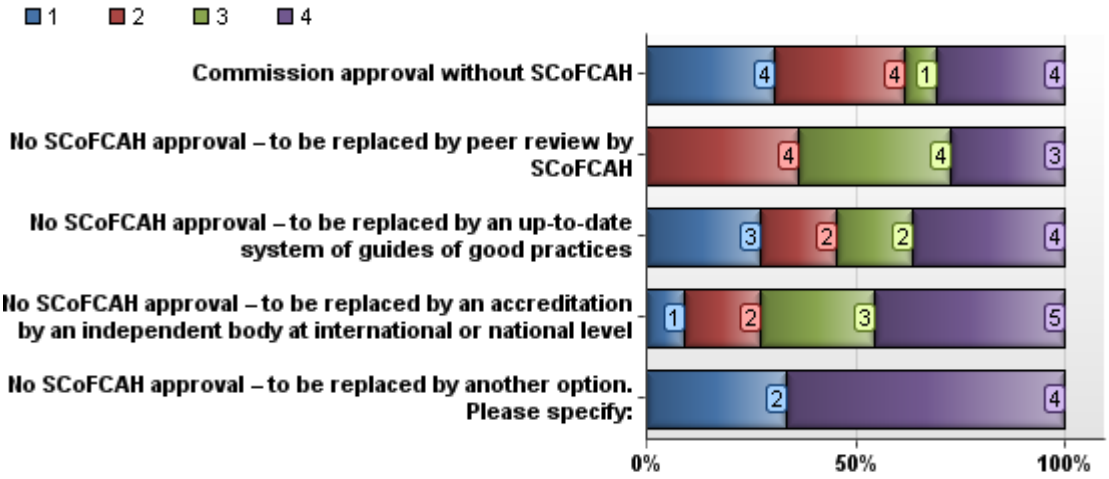


#	Question	1	2	3	4	Responses	Mean
1	Commission approval without SCoFCAH	4	5	0	4	13	2.31
2	No SCoFCAH approval – to be replaced by peer review by SCoFCAH	0	4	3	4	11	3.00
3	No SCoFCAH approval – to be replaced by an up-to-date system of guides of good practices	3	3	1	4	11	2.55
4	No SCoFCAH approval – to be replaced by an accreditation by an independent body at international or national level	2	1	3	5	11	3.00
5	No SCoFCAH approval – to be replaced by another option. Please specify:	1	1	0	4	6	3.17

No SCoFCAH approval – to be replaced by another option. Please specify:
FVO inspections/ FVO reporting to SCoFCAH
FVO missions for evaluation

Effective:

1=very, 2=fairly, 3=not very, 4=not at all

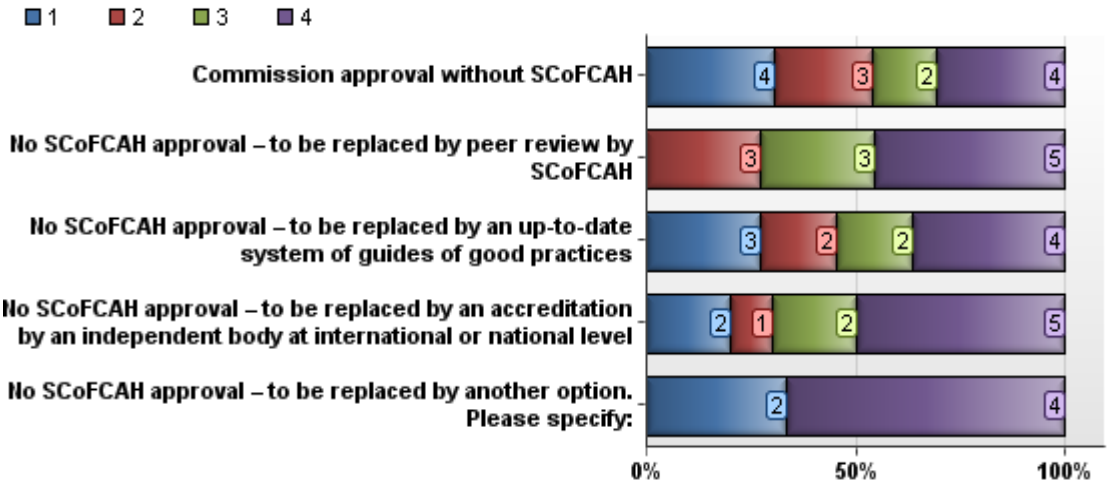


#	Question	1	2	3	4	Responses	Mean
1	Commission approval without SCoFCAH	4	4	1	4	13	2.38
2	No SCoFCAH approval – to be replaced by peer review by SCoFCAH	0	4	4	3	11	2.91
3	No SCoFCAH approval – to be replaced by an up-to-date system of guides of good practices	3	2	2	4	11	2.64
4	No SCoFCAH approval – to be replaced by an accreditation by an independent body at international or national level	1	2	3	5	11	3.09
5	No SCoFCAH approval – to be replaced by another option. Please specify:	2	0	0	4	6	3.00

No SCoFCAH approval – to be replaced by another option. Please specify:
FVO inspections/ FVO reporting to SCoFCAH
FVO missions for evaluation

Efficient

1=very, 2=fairly, 3=not very, 4=not at all



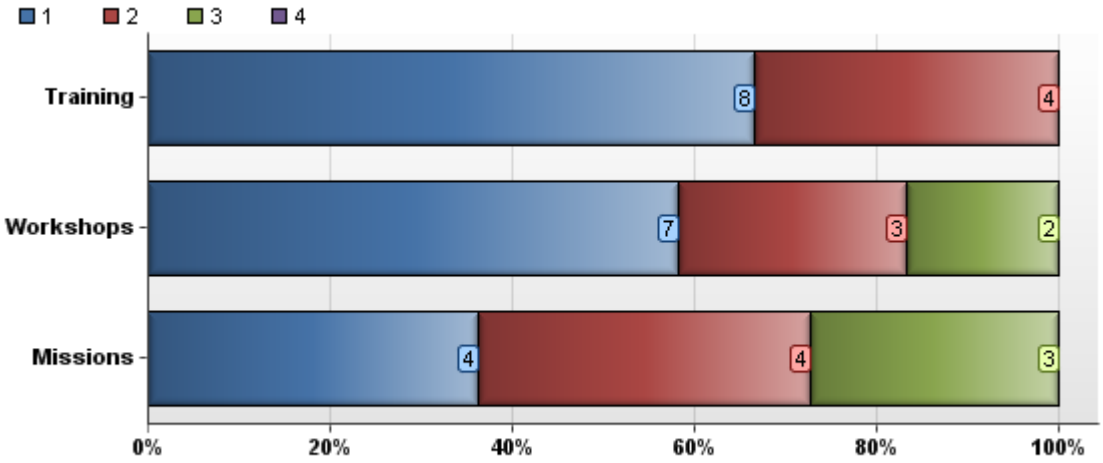
#	Question	1	2	3	4	Responses	Mean
1	Commission approval without SCoFCAH	4	3	2	4	13	2.46
2	No SCoFCAH approval – to be replaced by peer review by SCoFCAH	0	3	3	5	11	3.18
3	No SCoFCAH approval – to be replaced by an up-to-date system of guides of good practices	3	2	2	4	11	2.64
4	No SCoFCAH approval – to be replaced by an accreditation by an independent body at international or national level	2	1	2	5	10	3.00
5	No SCoFCAH approval – to be replaced by another option. Please specify:	2	0	0	4	6	3.00

No SCoFCAH approval – to be replaced by another option. Please specify:
FVO inspections/ FVO reporting to SCoFCAH
FVO missions for evaluation

Additional tools:

Relevant:

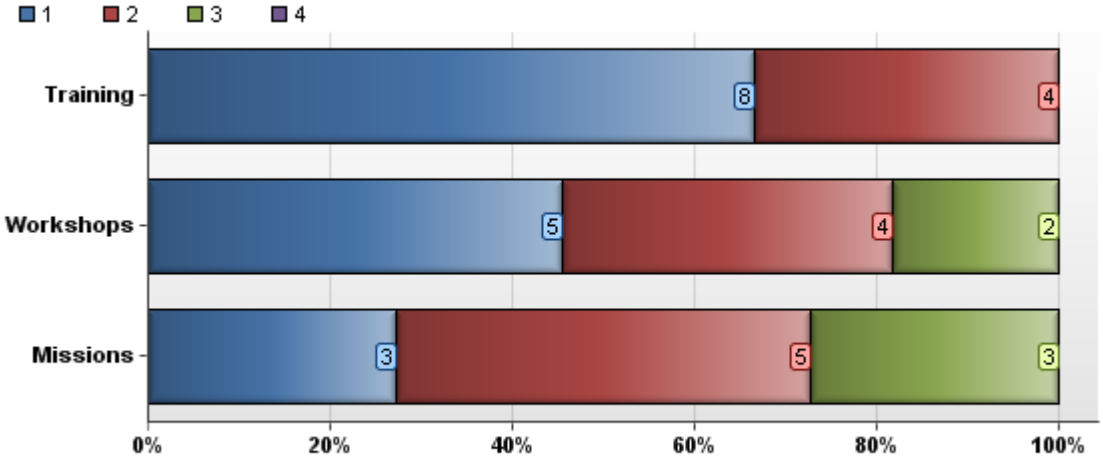
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	Training	8	4	0	0	12	1.33
2	Workshops	7	3	2	0	12	1.58
3	Missions	4	4	3	0	11	1.91
4	Other. Please specify:	0	0	0	0	0	0.00

Effective:

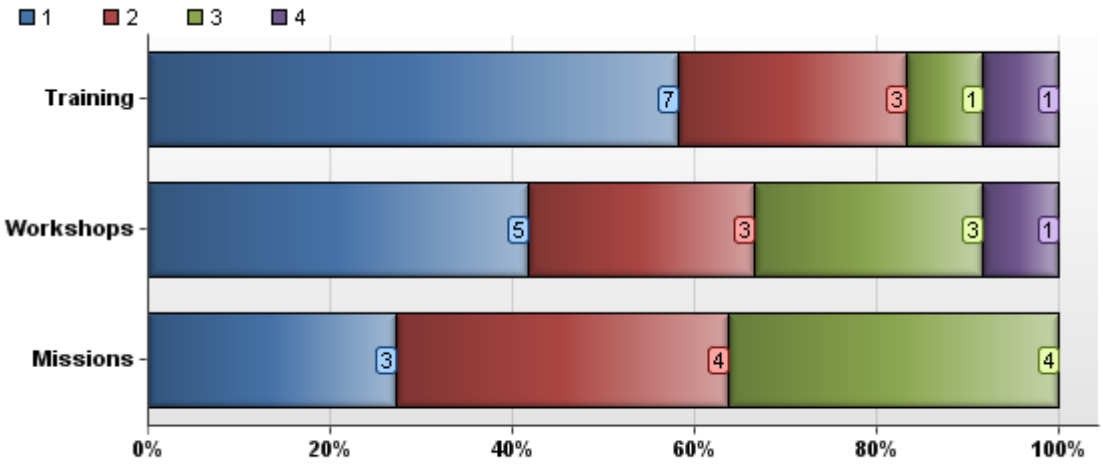
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	Training	8	4	0	0	12	1.33
2	Workshops	5	4	2	0	11	1.73
3	Missions	3	5	3	0	11	2.00
4	Other. Please specify:	0	0	0	0	0	0.00

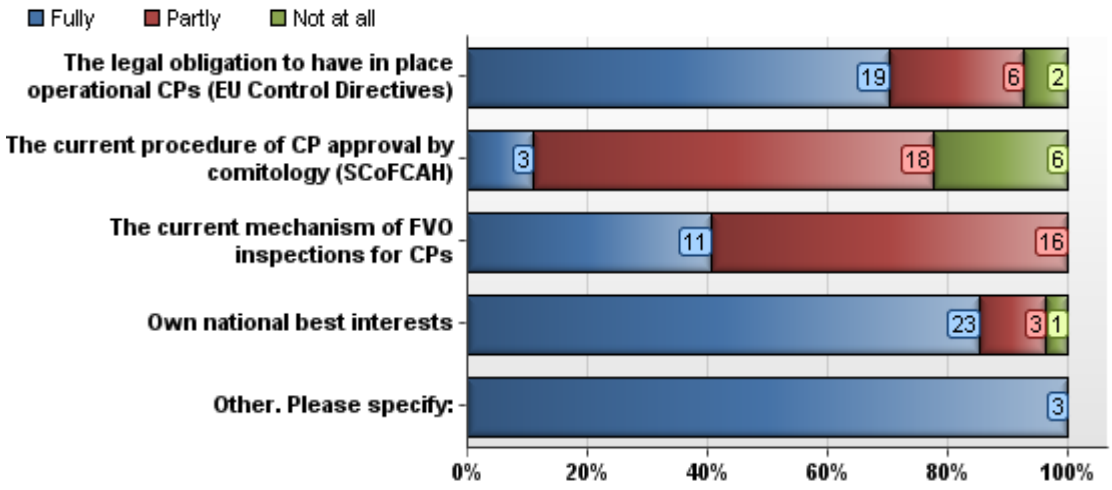
Efficient:

1=very, 2=fairly, 3=not very, 4=not at all



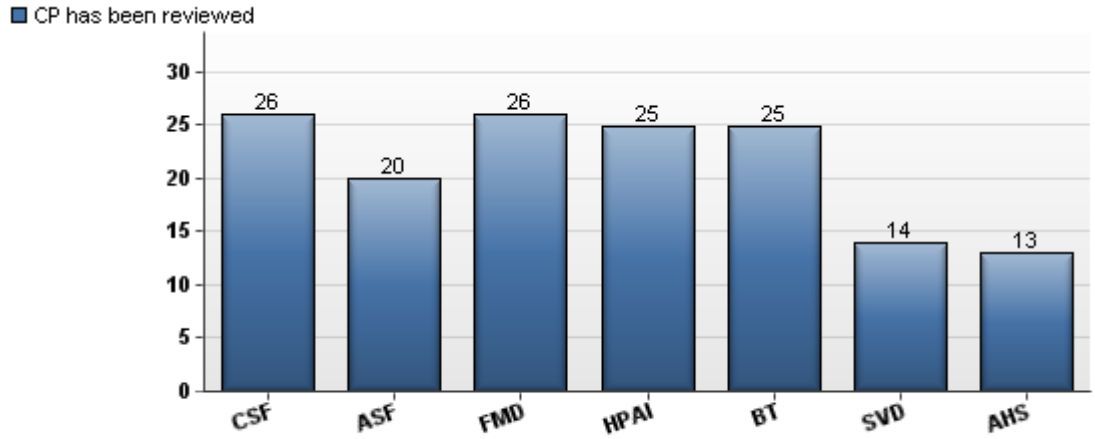
#	Question	1	2	3	4	Responses	Mean
1	Training	7	3	1	1	12	1.67
2	Workshops	5	3	3	1	12	2.00
3	Missions	3	4	4	0	11	2.09
4	Other. Please specify:	0	0	0	0	0	0.00

10. To what extent do the following factors contribute to ensuring the objectives of contingency planning (i.e. achieve animal disease preparedness and rapid reaction) in your country?



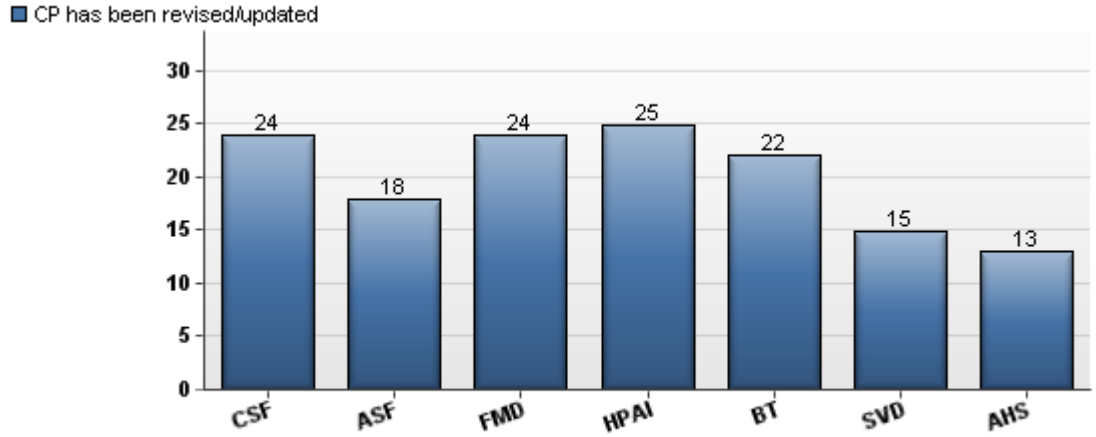
#	Question	Fully	Partly	Not at all	Responses	Mean
1	The legal obligation to have in place operational CPs (EU Control Directives)	19	6	2	27	1.37
2	The current procedure of CP approval by comitology (SCoFCAH)	3	18	6	27	2.11
3	The current mechanism of FVO inspections for CPs	11	16	0	27	1.59
4	Own national best interests	23	3	1	27	1.19
5	Other. Please specify:	3	0	0	3	1.00

11. Have the CPs in place in your country been reviewed in line with the provisions foreseen in the EU legislation (disease specific Control Directives)?



#	Question	CP has been reviewed	Responses
1	CSF	26	26
2	ASF	20	20
3	FMD	26	26
4	HPAI	25	25
5	BT	25	25
6	SVD	14	14
7	AHS	13	13

12. Have the CPs in place in your country been revised/updated in line with the provisions foreseen in the EU legislation (disease specific Control Directives)?



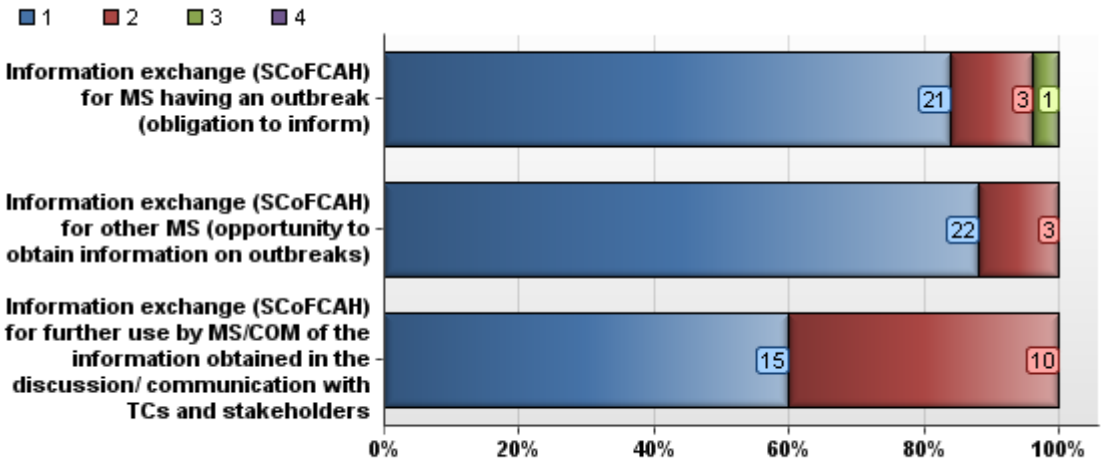
#	Question	CP has been revised/updated	Responses
1	CSF	24	24
2	ASF	18	18
3	FMD	24	24
4	HPAI	25	25
5	BT	22	22
6	SVD	15	15
7	AHS	13	13

III. EXCHANGE OF INFORMATION ON OUTBREAK EVOLUTION AT SCOFCAH

13. In your view, taking into account technological progress, regarding communication tools in particular, and the administrative/budgetary constraints:
a) To what extent is information exchange as currently taking place at SCoFCAH meetings relevant, effective and efficient?

Relevant:

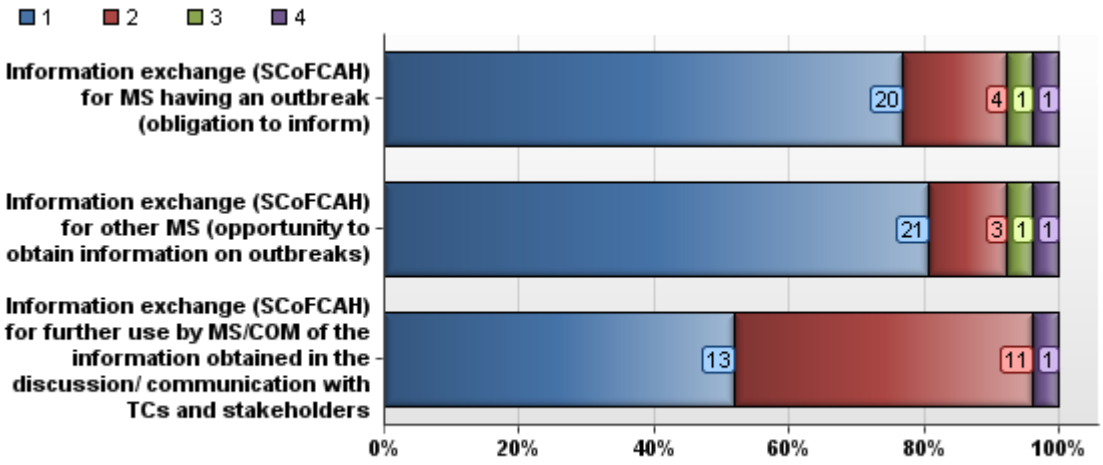
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	Information exchange (SCoFCAH) for MS having an outbreak (obligation to inform)	21	3	1	0	25	1.20
2	Information exchange (SCoFCAH) for other MS (opportunity to obtain information on outbreaks)	22	3	0	0	25	1.12
3	Information exchange (SCoFCAH) for further use by MS/COM of the information obtained in the discussion/ communication with TCs and stakeholders	15	10	0	0	25	1.40

Effective:

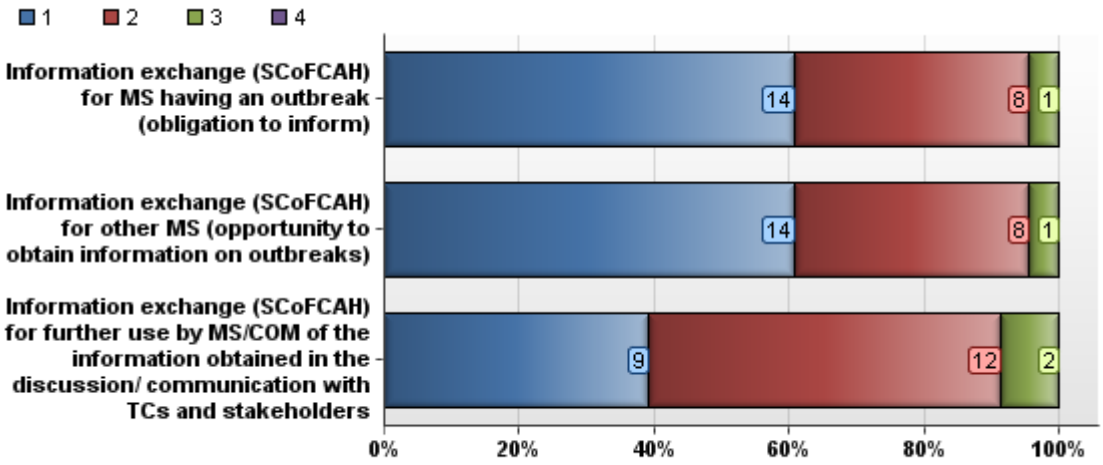
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	Information exchange (SCoFCAH) for MS having an outbreak (obligation to inform)	20	4	1	1	26	1.35
2	Information exchange (SCoFCAH) for other MS (opportunity to obtain information on outbreaks)	21	3	1	1	26	1.31
3	Information exchange (SCoFCAH) for further use by MS/COM of the information obtained in the discussion/ communication with TCs and stakeholders	13	11	0	1	25	1.56

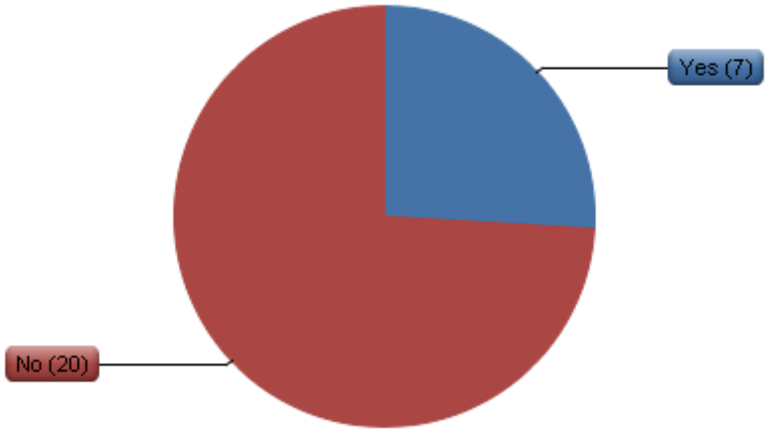
Efficient:

1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	Information exchange (SCoFCAH) for MS having an outbreak (obligation to inform)	14	8	1	0	23	1.43
2	Information exchange (SCoFCAH) for other MS (opportunity to obtain information on outbreaks)	14	8	1	0	23	1.43
3	Information exchange (SCoFCAH) for further use by MS/COM of the information obtained in the discussion/ communication with TCs and stakeholders	9	12	2	0	23	1.70

13.b) Is there a need to improve current procedures?

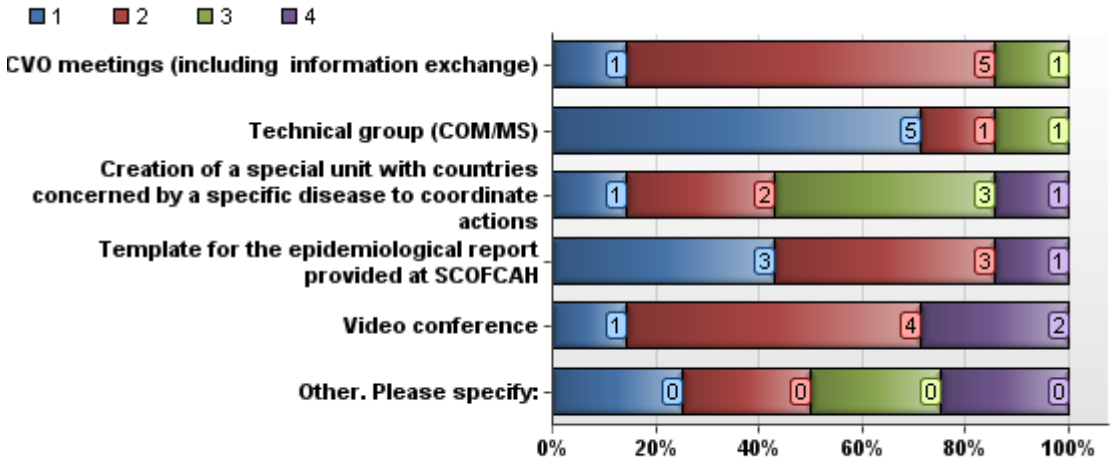


#	Answer		Response	%
1	Yes		7	26%
2	No		20	74%
	Total		27	100%

13.c.1) To what extent could the following potential alternative options be relevant, effective and efficient in providing the required background to the decision-making process?

Relevant:

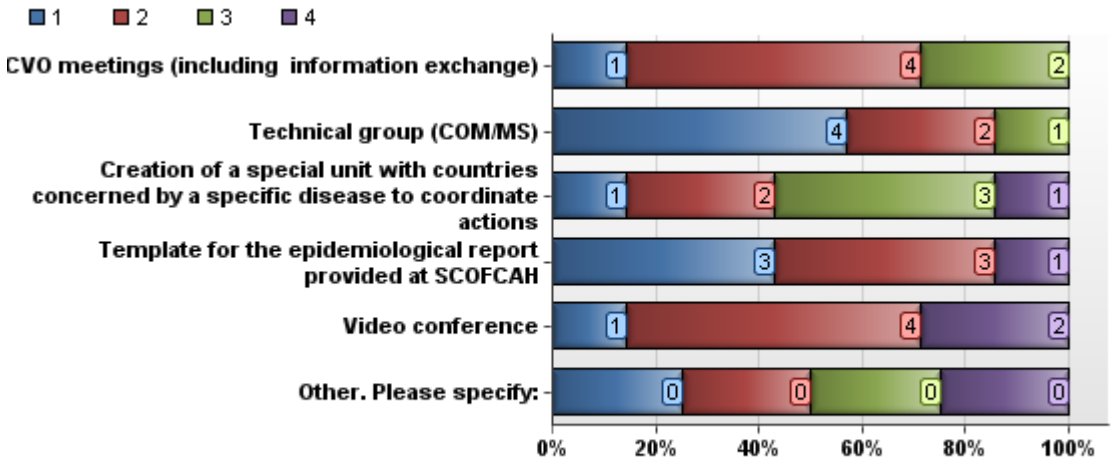
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	CVO meetings (including information exchange)	1	5	1	0	7	2.00
2	Technical group (COM/MS)	5	1	1	0	7	1.43
3	Creation of a special unit with countries concerned by a specific disease to coordinate actions	1	2	3	1	7	2.57
4	Template for the epidemiological report provided at SCOFCAH	3	3	0	1	7	1.86
5	Video conference	1	4	0	2	7	2.43
6	Other. Please specify:	0	0	0	0	0	0.00

Effective:

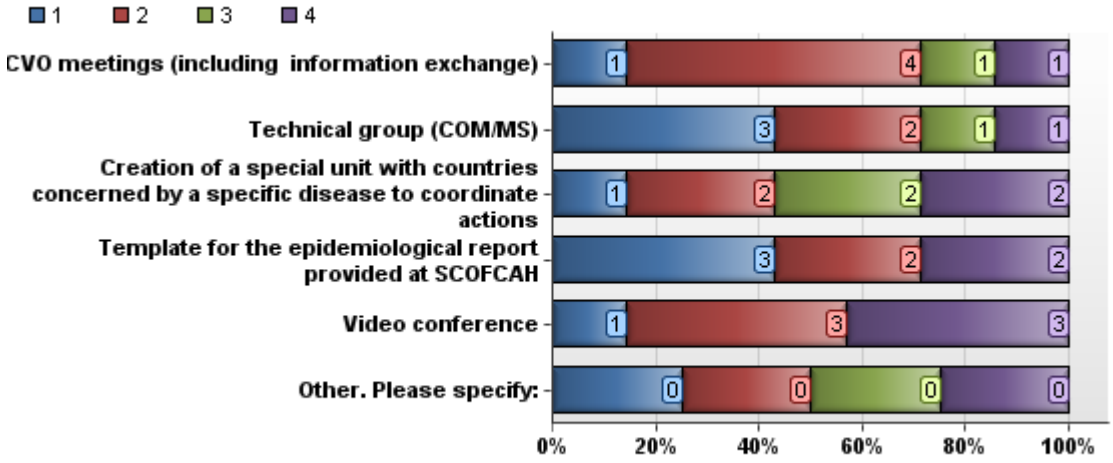
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	CVO meetings (including information exchange)	1	4	2	0	7	2.14
2	Technical group (COM/MS)	4	2	1	0	7	1.57
3	Creation of a special unit with countries concerned by a specific disease to coordinate actions	1	2	3	1	7	2.57
4	Template for the epidemiological report provided at SCOFCAH	3	3	0	1	7	1.86
5	Video conference	1	4	0	2	7	2.43
6	Other. Please specify:	0	0	0	0	0	0.00

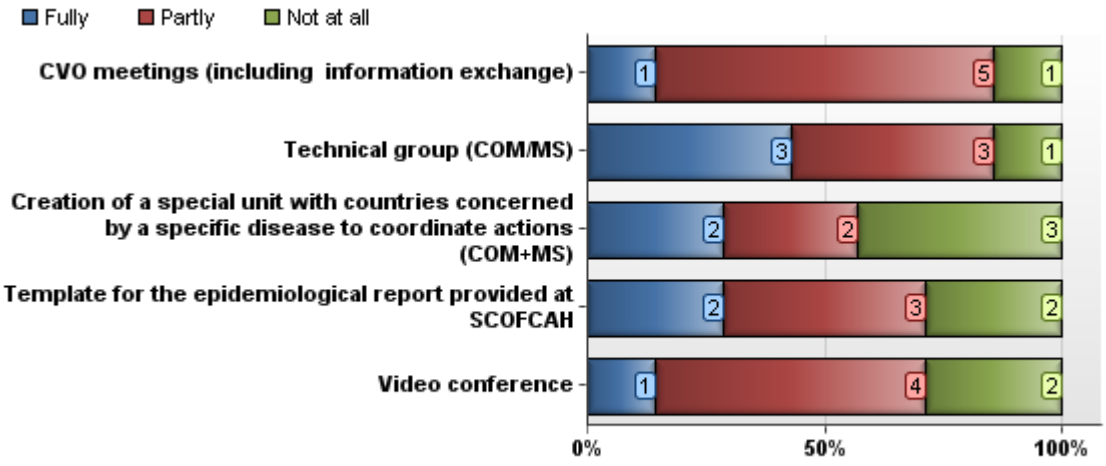
Efficient:

1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	CVO meetings (including information exchange)	1	4	1	1	7	2.29
2	Technical group (COM/MS)	3	2	1	1	7	2.00
3	Creation of a special unit with countries concerned by a specific disease to coordinate actions	1	2	2	2	7	2.71
4	Template for the epidemiological report provided at SCOFCAH	3	2	0	2	7	2.14
5	Video conference	1	3	0	3	7	2.71
6	Other. Please specify:	0	0	0	0	0	0.00

13.c.2) To what extent could the following options replace the current information exchange procedure at SCoFCAH?

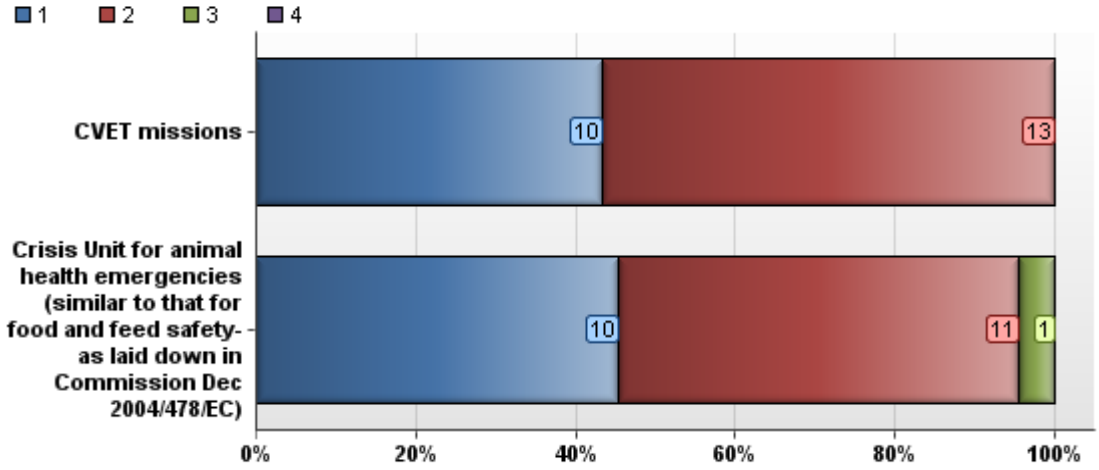


#	Question	Fully	Partly	Not at all	Responses	Mean
1	CVO meetings (including information exchange)	1	5	1	7	2.00
2	Technical group (COM/MS)	3	3	1	7	1.71
3	Creation of a special unit with countries concerned by a specific disease to coordinate actions (COM+MS)	2	2	3	7	2.14
4	Template for the epidemiological report provided at SCOFCAH	2	3	2	7	2.00
5	Video conference	1	4	2	7	2.14
6	Other. Please specify:	0	0	0	0	0.00

14. To what extent, in your view, are the following mechanisms and/or structures relevant, effective and efficient in providing additional support to the information exchange currently provided at SCoFCAH?

Relevant:

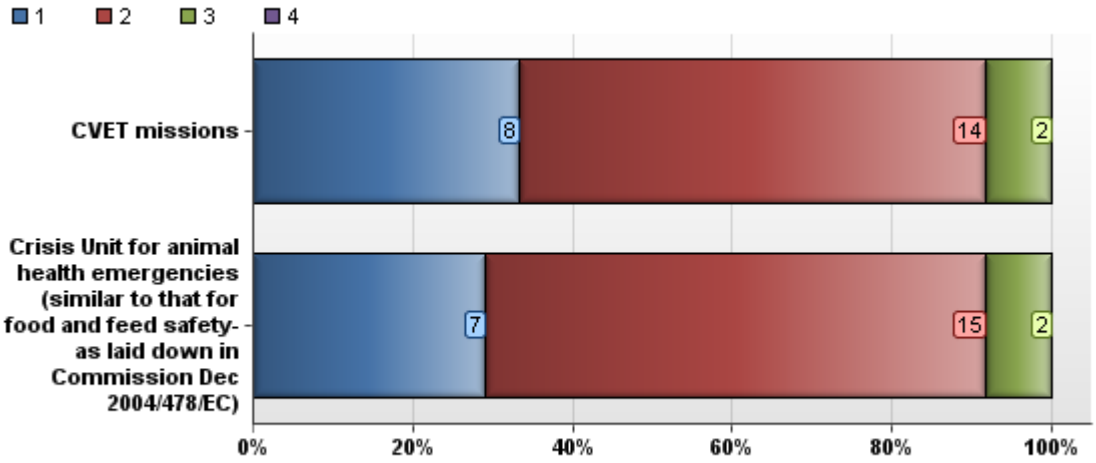
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	CVET missions	10	13	0	0	23	1.57
2	Crisis Unit for animal health emergencies (similar to that for food and feed safety- as laid down in Commission Dec 2004/478/EC)	10	11	1	0	22	1.59

Effective:

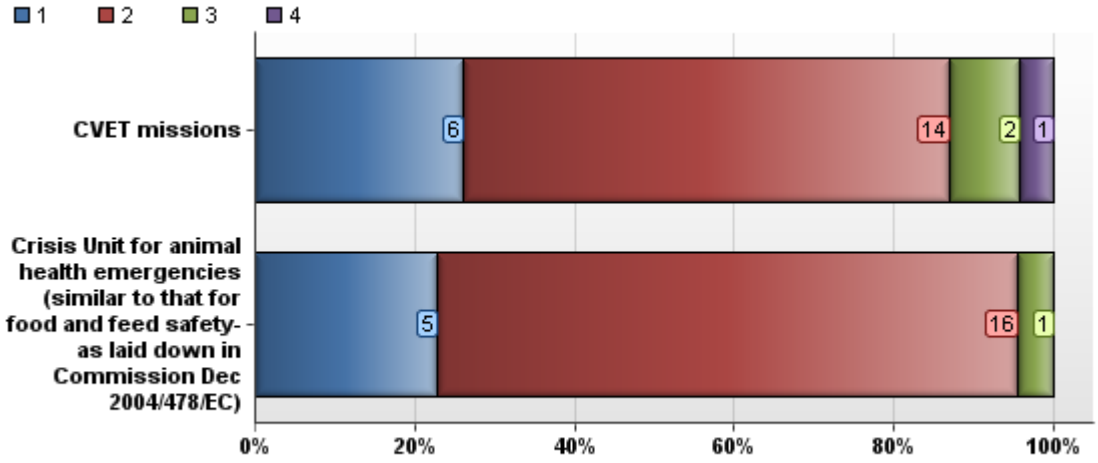
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	CVET missions	8	14	2	0	24	1.75
2	Crisis Unit for animal health emergencies (similar to that for food and feed safety- as laid down in Commission Dec 2004/478/EC)	7	15	2	0	24	1.79

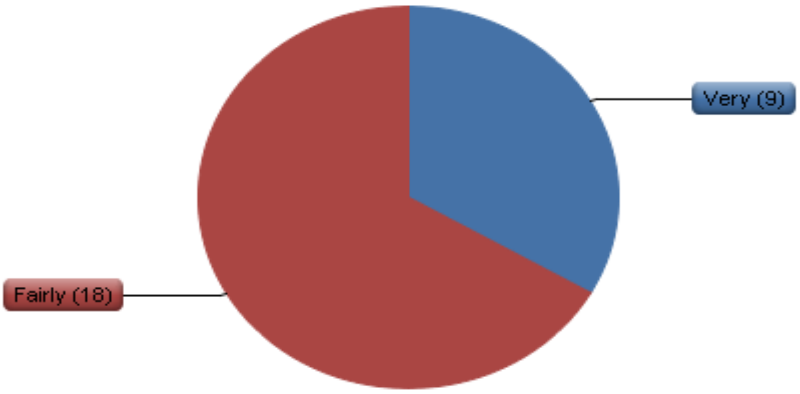
Efficient:

1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	CVET missions	6	14	2	1	23	1.91
2	Crisis Unit for animal health emergencies (similar to that for food and feed safety- as laid down in Commission Dec 2004/478/EC)	5	16	1	0	22	1.82

15. In your view, taking into account administrative/budgetary constraints:
a) To what extent is the current procedure for adopting emergency containment measures at SCoFCAH meetings efficient?

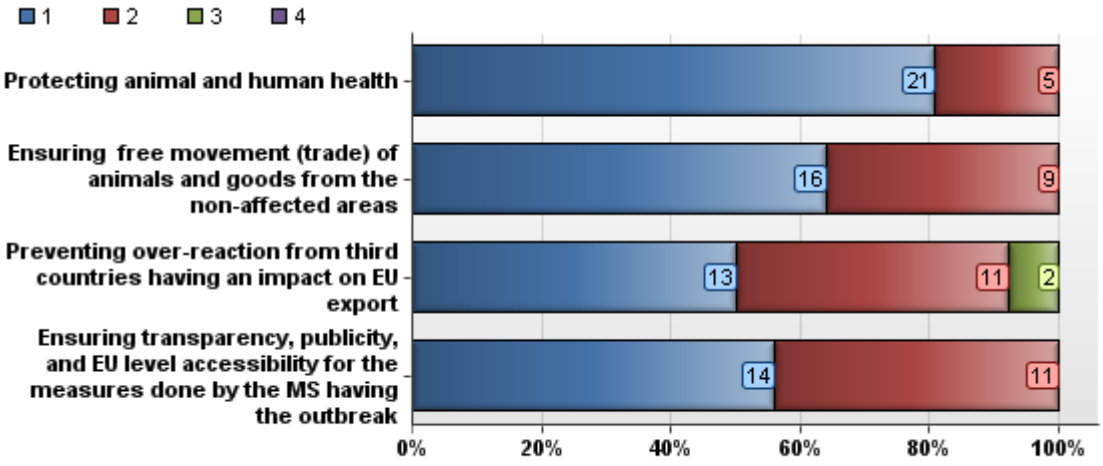


#	Answer		Response	%
1	Very		9	33%
2	Fairly		18	67%
3	Not very		0	0%
4	Not at all		0	0%
	Total		27	100%

15.b) To what extent is the current procedure for adopting emergency containment measures at SCoFCAH meetings relevant and effective in terms of achieving the following objectives?

Relevant:

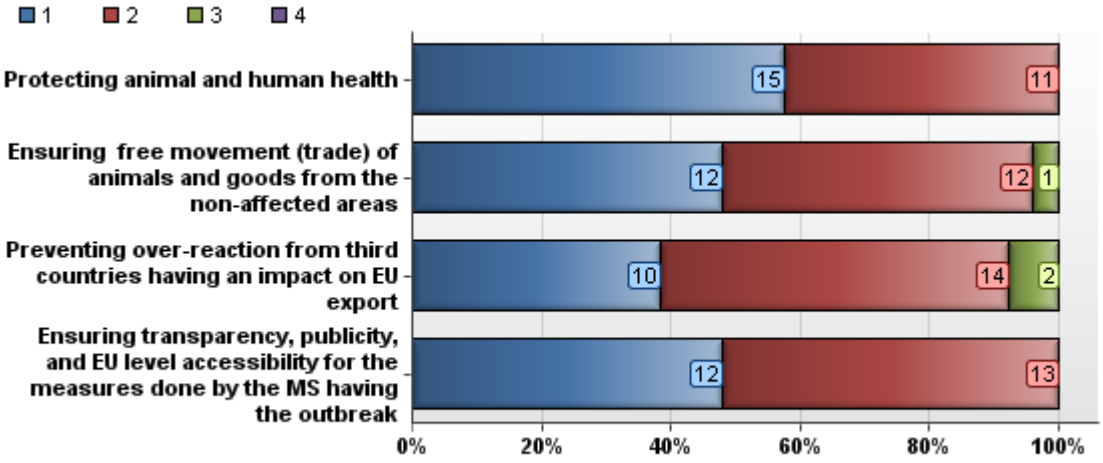
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	Protecting animal and human health	21	5	0	0	26	1.19
2	Ensuring free movement (trade) of animals and goods from the non-affected areas	16	9	0	0	25	1.36
3	Preventing over-reaction from third countries having an impact on EU export	13	11	2	0	26	1.58
4	Ensuring transparency, publicity, and EU level accessibility for the measures done by the MS having the outbreak	14	11	0	0	25	1.44

Effective:

1=very, 2=fairly, 3=not very, 4=not at all



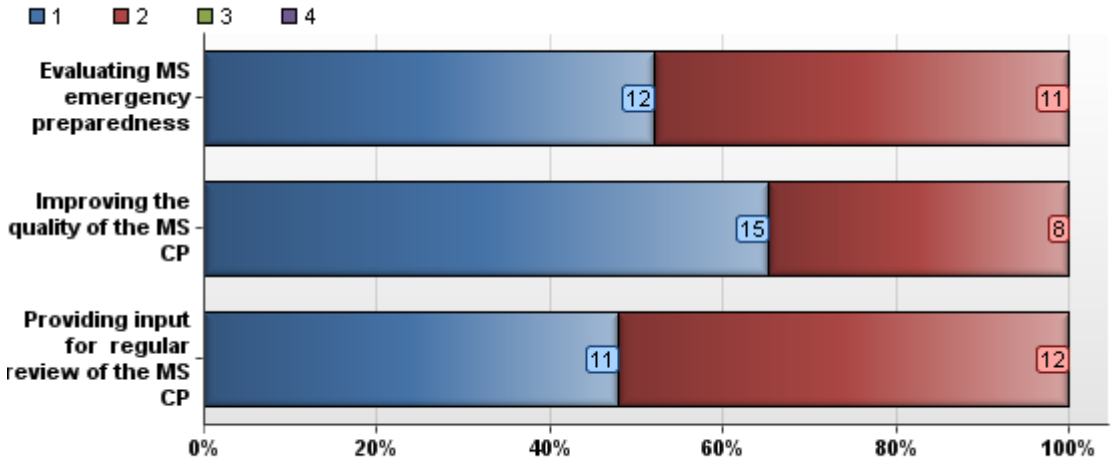
#	Question	1	2	3	4	Responses	Mean
1	Protecting animal and human health	15	11	0	0	26	1.42
2	Ensuring free movement (trade) of animals and goods from the non-affected areas	12	12	1	0	25	1.56
3	Preventing over-reaction from third countries having an impact on EU export	10	14	2	0	26	1.69
4	Ensuring transparency, publicity, and EU level accessibility for the measures done by the MS having the outbreak	12	13	0	0	25	1.52

V. FVO VERIFICATION MISSIONS REGARDING CPs AND DURING/AFTER OUTBREAKS OF EPIZOOTICS

16. In terms of the FVO verification missions regarding CPs in peace time (including simulation exercises) and during/after outbreaks of epizootics:
a) To what extent is the way of conducting FVO verification missions relevant and effective in terms of achieving the following objectives?

Relevant:

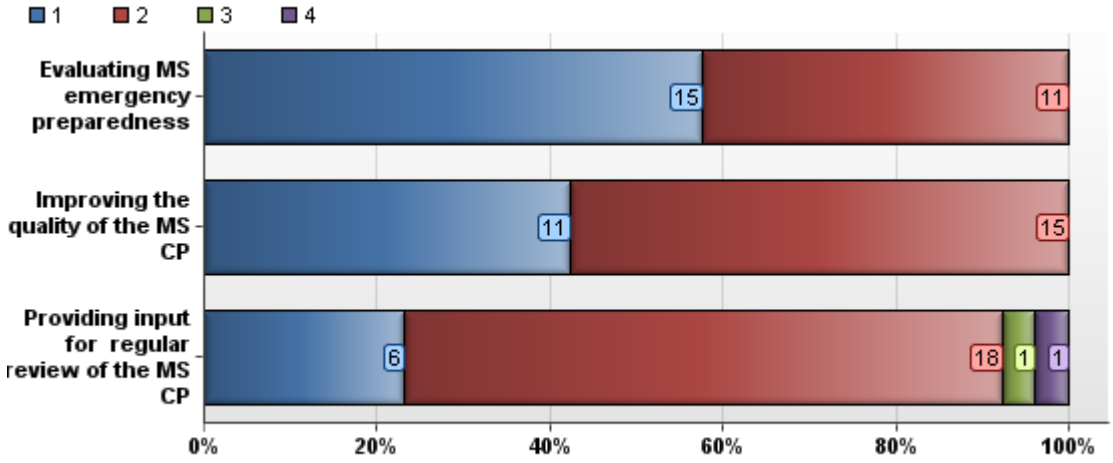
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	Evaluating MS emergency preparedness	12	11	0	0	23	1.48
2	Improving the quality of the MS CP	15	8	0	0	23	1.35
3	Providing input for regular review of the MS CP	11	12	0	0	23	1.52

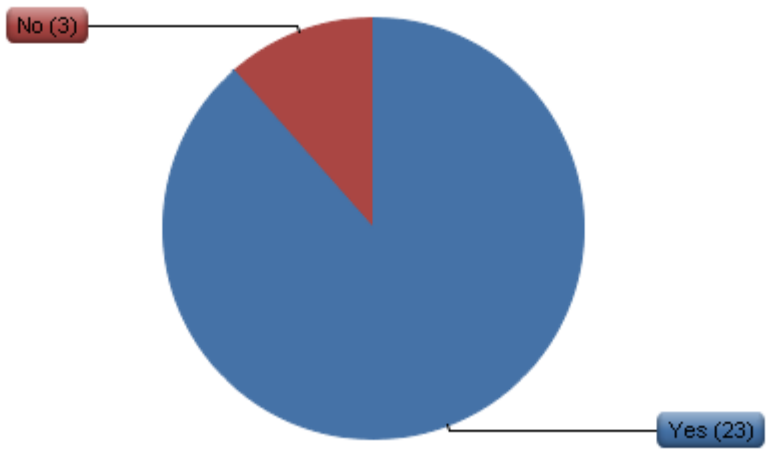
Effective:

1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	Evaluating MS emergency preparedness	15	11	0	0	26	1.42
2	Improving the quality of the MS CP	11	15	0	0	26	1.58
3	Providing input for regular review of the MS CP	6	18	1	1	26	1.88

16.b) Is the current frequency of FVO missions in your country sufficient for achieving the above objectives?



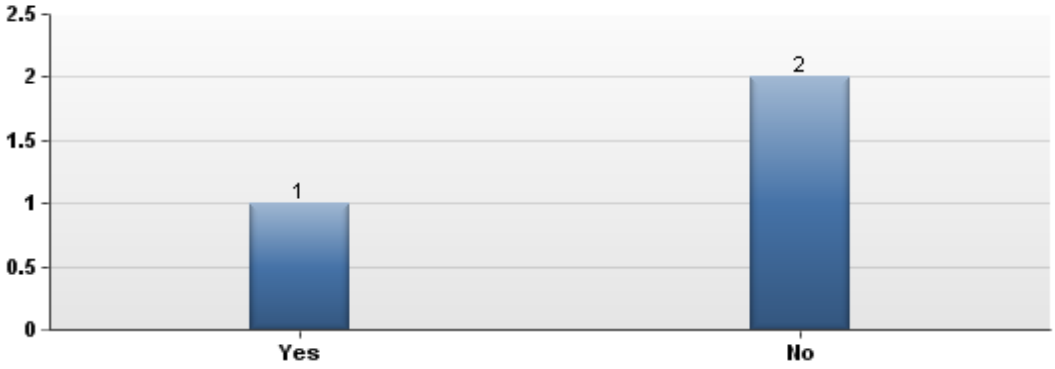
#	Answer		Response	%
1	Yes		23	88%
2	No		3	12%
	Total		26	100%

16. c) If the answer is 'no', what would you consider a sufficient frequency?

CP verification missions every 5 years:

#	Answer		Response	%
1	Yes		3	100%
2	No		0	0%
	Total		3	100%

CP verification missions more frequently:

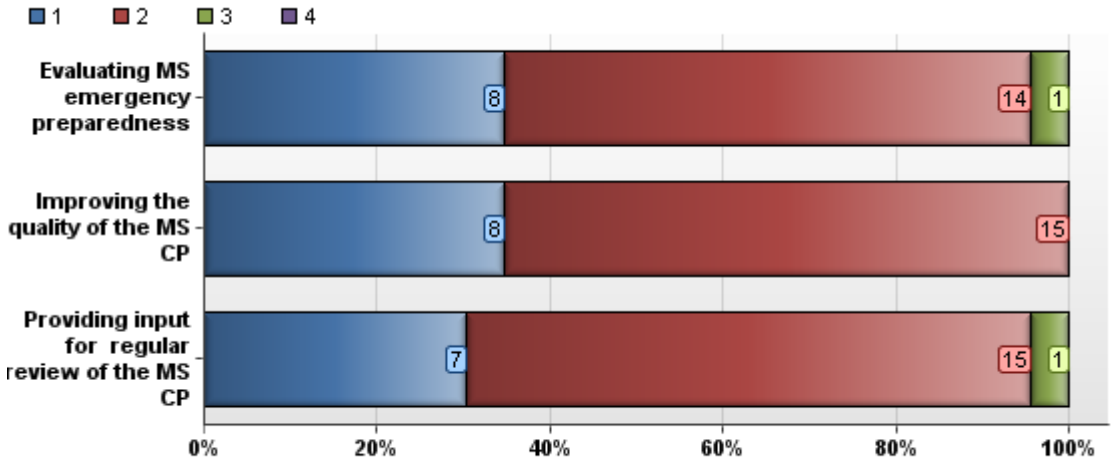


#	Answer		Response	%
1	Yes		1	33%
2	No		2	67%
	Total		3	100%

16.d) To what extent is the way of drafting of FVO reports on the outcome of the verification missions relevant and effective in terms of achieving the following objectives?

Relevant:

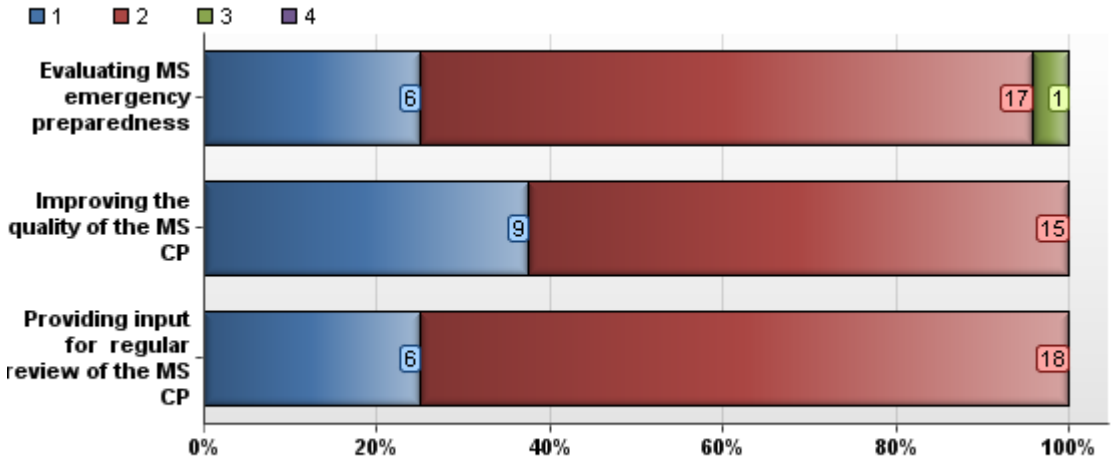
1=very, 2=fairly, 3=not very, 4=not at all



#	Question	1	2	3	4	Responses	Mean
1	Evaluating MS emergency preparedness	8	14	1	0	23	1.70
2	Improving the quality of the MS CP	8	15	0	0	23	1.65
3	Providing input for regular review of the MS CP	7	15	1	0	23	1.74

Effective:

1=very, 2=fairly, 3=not very, 4=not at all

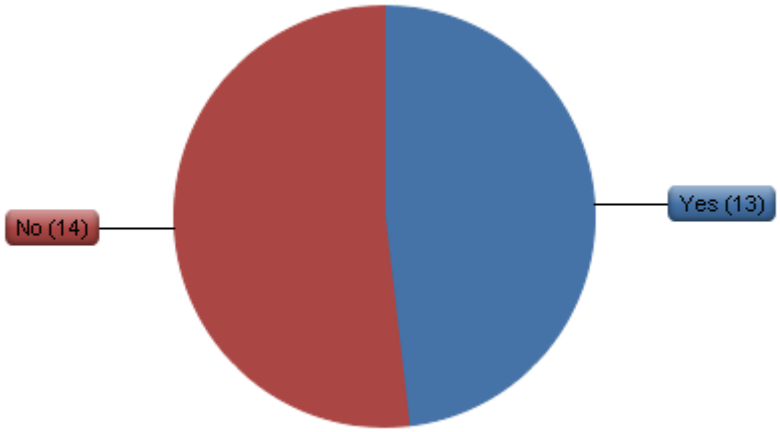


#	Question	1	2	3	4	Responses	Mean
1	Evaluating MS emergency preparedness	6	17	1	0	24	1.79
2	Improving the quality of the MS CP	9	15	0	0	24	1.63
3	Providing input for regular review of the MS CP	6	18	0	0	24	1.75

VI. THE INFORMARTION FLOW BETWEEN NEIGHBOURING MS AND STAKEHOLDERS IN CASE OF EPIZOOTICS; COOPERATION AND COORDINATION BETWEEN CAs AND POs BOTH DURING CP ELABORATION AND IMPLEMENTATION (INCLUDING SIMULATION EXERCISES)

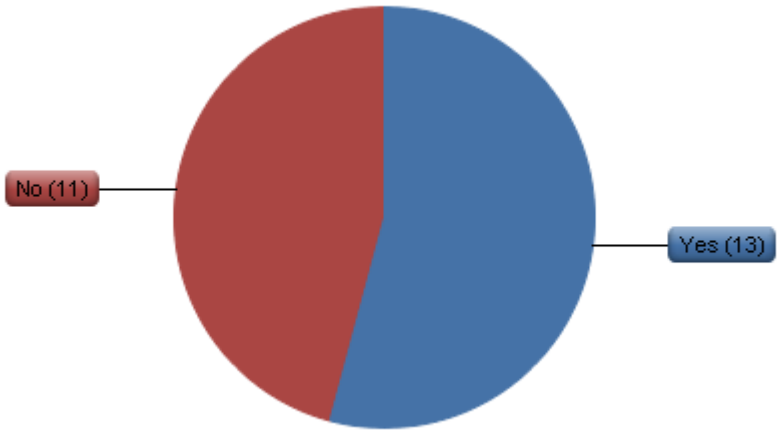
18. In your view, should CPs be made available to the wider public?

Publicly available in their entirety (e.g. online publication):



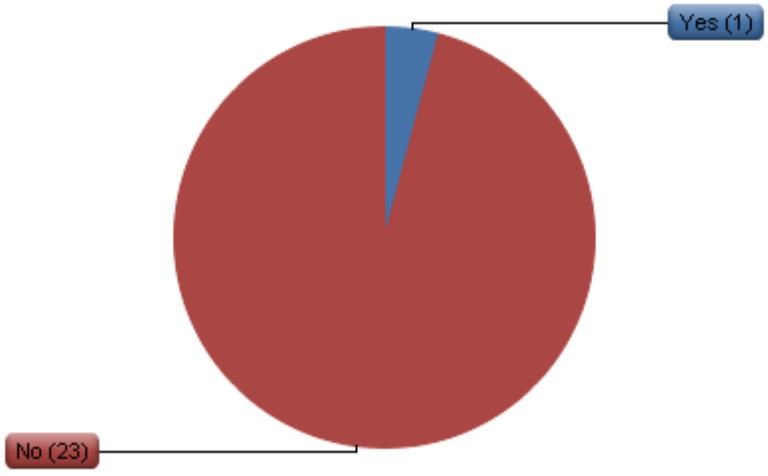
#	Answer		Response	%
1	Yes		13	48%
2	No		14	52%
	Total		27	100%

Only summaries publicly available (e.g. online publication):



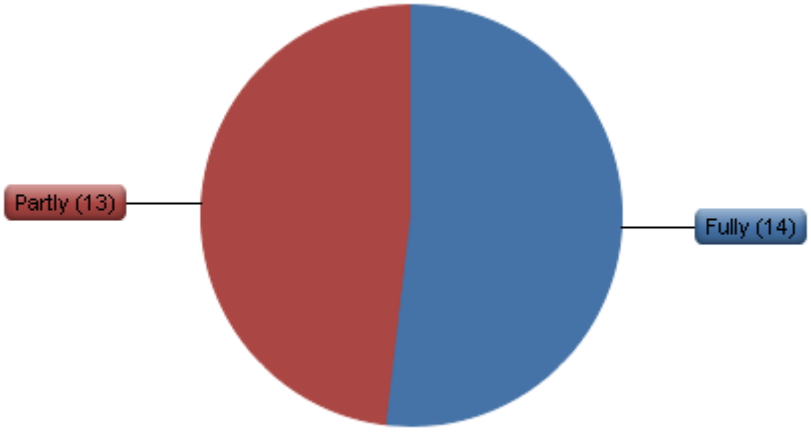
#	Answer		Response	%
1	Yes		13	54%
2	No		11	46%
	Total		24	100%

Not available at all:



#	Answer		Response	%
1	Yes		1	4%
2	No		23	96%
	Total		24	100%

19. In your view, to what extent is the current communication flow from the relevant CAs to citizens/consumers in emergency cases sufficient?



#	Answer		Response	%
1	Fully		14	52%
2	Partly		13	48%
3	Not at all		0	0%
	Total		27	100%

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