EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Relations with agencies and advisory groups

PLENARY MEETING OF THE ADVISORY GROUP ON THE FOOD CHAIN AND ANIMAL AND PLANT HEALTH

27 NOVEMBER 2015

Summary Record

1. WELCOME BY MR PRATS MONNÉ, DIRECTOR-GENERAL OF THE DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

SANTE Director-General (DG) opened the meeting and welcomed participants. He outlined the food safety context (strong demand on health and safety, anxiety on globalisation, climate change) and the need to focus on areas where SANTE's actions can make a difference. He indicated that people nowadays are very conscious about health as well as food safety issues and that gives a clear input to managers and policy makers where to focus the effort, what are the most important issues and challenges.

He highlighted the importance of building a strong partnership between stakeholders and SANTE in an area that is one of the most harmonised sectors, the leading EU employer and of vital importance for all EU citizens. He underlined that transparent and improved consultation of stakeholders, is one of the main priorities of the Juncker Commission. It is a fundamental part of better regulation.

DG further acknowledged the good functioning of this forum as a diverse group of members with different interests representing the whole food and feed supply chain, its sound architecture (plenaries focussed on general issues and technical working groups), and its role in DG SANTE work.

2. COMMISSION'S PRIORITIES, KEY INITIATIVES, AND SANTE STRATEGIC OBJECTIVES

Regarding SANTE strategic objectives SANTE Director-General (DG) stressed the importance of prevention and the management of crises and the need of our systems to become more alert, preventive and reactive.

He stated that one of the key tasks is to propose an improved EU response and coordination system on Plant Health threats based on the New Plant Health law and on the experience gained in the food and animal health sector.

He further underlined the key threats with serious socio-economic implications the focus of SANTE work must be on, namely antimicrobial resistance (AMR) that kills 25 000 people per year in the EU due to infections caused by antimicrobial resistant bacteria with extra healthcare costs and productivity losses of at least 1.5 billion.

Endocrine disruptors is a highly sensitive and mediatised file. An impact assessment is currently performed. SANTE is presently focusing on the methodological criteria. This should guide the EU action in 2017.

DG stressed that nutrition is a key health determinant as scientific evidence demonstrates. The report on transfats that is due by end of this year is a priority and whatever action takes place after, it must follow the rules of better regulation (impact assessment, consultations).

DG pointed at close collaboration of SANTE with regulatory agencies – European Food Safety Authority (EFSA), the food chain risk assessor, with European Centre for Disease Prevention and Control (ECDC) on food borne diseases, AMR and European Medicines Agency (EMA) on AMR and veterinary medicinal products.

DG expressed his appreciation of Advisory Group contributions to the recent initiative of SANTE on the implementation by MS of Hazard analysis and critical control points (HACCP) - a major tool for a well-functioning food safety chain and encouraged the Advisory group members to continue to provide important input to SANTE work.

3. BETTER REGULATION PACKAGE

COM presented main aspects/documents of Better Regulation Package adopted by the European Commission in May 2015.

COM stressed that Better Regulation (BR) is a collection of tools to support decision making – not a substitute for it. The process covers the whole policy cycle to ensure initiatives are evidence-based, transparent participation of all stakeholders is present, to avoid unnecessary burdens for business/public authorities, to ensure high-quality initiatives and to ensure that policies actually deliver as foreseen and remain fit for purpose.

COM stressed that apart from compulsory public consultation in the context of all impact assessments and evaluations, all roadmaps, adopted legislative proposals, and important draft delegated and implementing acts[1] are published and open for feedback from stakeholders.

To involve stakeholders more in the whole policy cycle for each initiative a consultation strategy must be elaborated at the beginning of the process, which sets out the consultation objectives, the targeted stakeholders and the identified consultation activities. Each initiative will be also accompanied by explanatory memorandum in order to better explain why the given legislation is proposed.

COM further outlined the main new elements regarding the impact assessment (IA). More guidance on different types of impacts and methodologies will be provided and sharper focus will be on subsidiarity, proportionality, SMEs and competitiveness as well as on assessment who will be affected by a proposed legislation and how.

[1] See BR guidelines, chapter VII, para 4.1 for exceptions: http://ec.europa.eu/smart-regulation/guidelines/ug_chap7_en.htm

In order to ensure that legislation remains fit for purpose COM will annually review selected legislation by the means of Regulatory Fitness and Performance Programme. COM will communicate REFIT actions selected in its work programme.

Stakeholders will be able to provide input via new REFIT Stakeholder Platform consisting of experts from Member States and stakeholder experts plus experts from Committee of Regions and Economic and Social Committee.

Strengthen scrutiny will be provided by independent Regulatory Scrutiny Board (6 full time members) that will examine impact assessments and major evaluations and fitness checks in order to check that the legislation meets high quality standards.

COM concluded with outlining the main elements of Inter Institutional agreement that is still under negotiation.


3 BR-ppt.pdf

Comments and questions raised

BEUC asked about implementing and delegated acts consultation. Since COM will consult only on important implementing acts how it will be decided what is important; can stakeholders signal to COM about the interest in specific act and where all the acts can be found once published for consultation.

COM replied that the intention is to subject more implementing and delegated acts to feedback. The list of exceptions when and under which conditions no feedback is required is under preparation[2]. The modalities are still subject to negotiation. Once the IT system is set up the implementation will start in the course of next year. The feedback tool will be integrated under the new Better Regulation portal (single access point), to be launched by June 2016.

FoEE commented on cost-benefit approach in which COM assume that less burden for companies present a benefit for citizens. According to some studies mainly in the area of food safety this assumption is not correct. FoEE expressed concern such a prominent role is given to cost-benefit approach in forming the legislation. FoEE asked which body would provide the additional impact assessment in case that European Parliament or Council have substantial amendments to COM proposal.

Regarding the definition of cost benefit/effectiveness COM stated that the idea is to better quantify burden and it depends on specific policy.

COM replied that in case of substantial amendments to the COM proposal COM experts or independent experts can be used. It will be defined in the IIA, still subject to negotiation.

[2] Based on the criteria for exceptions set out in the better regulation guideline (see former footnote)

EUROPABIO asked whether a new guidance will be put in place on how to decide if IA is needed. It also raised a question how the principle of internal market will be taken into consideration when drafting the IA.

COM stressed that if there is no IA to accompany the initiative, it must be justified in a roadmap, which is published and open to feedback. Stakeholders can provide their opinion, arguments if they think the IA is needed. Regarding the internal market COM explained that concerns can be raised by stakeholders once a roadmap of a new initiative is published. These concerns will be considered by the Commission in the further preparatory work of the initiative.

EUROGROUP for ANIMALS stated that animal welfare should be taken into consideration when preparing the IA where relevant. It also expressed concern on the lack of animal welfare in the COM work programme.

EUROGROUP for ANIMALS would like in the course of the meeting to get information about changes in DG SANTE. Chair confirmed the available information will be given under AOB.

FOODDRINK EUROPE asked about the stakeholder group, about the timeframe for establishing it. FOODDRINK EUROPE would also like to know whether there is already some knowledge on impact of feedback to existing roadmaps.

ESA asked what would in case of substantial amendments from EP trigger the new, additional IA.

INDEPENDENT RETAIL EUROPE stated that REFIT Stakeholder Platform should not be limited to usual suspects, should be of greater diversity in order to make original contribution.

EHPM stressed the importance of transparency. Commented that comitology register should be improved to make it user friendlier and asked about a specific online tool where to follow delegated acts development.

FESASS supported the BR initiative as a step in the right direction but stated it is too early to conclude. It pointed at the fact that although quantitative figures are important at the end it is a political decision that counts. FESASS asked about the independency of IA, how the expertise from COM and EP will be brought together.

COM confirmed that vacant places for stakeholders' representatives in REFIT Stakeholder Platform have been published and a new setting should start working in early 2016. COM stressed the importance of balanced representation.

With regards to roadmaps published, the number of responses depends on policy and a specific initiative. It is still an early phase of a process so no updated roadmaps based on feedback are yet published.

COM informed participants that a central place for publishing all delegated acts will be available within the context of BR portal and should become operational in summer 2016.

COM explained that all the modalities on a new reassessment of the IA following significant changes to the COM proposal will be concluded in IIA.

4. EU CRISIS PREPAREDNESS IN PLANT HEALTH

COM briefly presented the main concerns in the area of plant health, namely introduction of pests in non-native environment due to globalisation of trade and effects of climate change and gave a few examples, e.g. pine wood nematode, red palm weevil, *Xylella fastidiosa*.

A proposal for the future EU plant health regime was adopted by the Commission in 2013 and at the moment goes through co-decision. It has two pillars, Plant Health Regulation and Official Controls Regulation which is more horizontal. The ambition is to have Plant Health Regulation agreed by the end of 2015 with entry into force three years after adoption.

The main elements of a new legislation are: intensified surveillance of the territory, contingency plans in MS, updated stricter import regime, more integrated IT system for imports/interceptions/outbreaks – notifications similar to system existing in animal health, establishing of diagnostic reference laboratories, principles of outbreak management will become a part of the legislation.

In the area of crisis prevention and preparedness COM stressed the importance of intensified surveillance programs, therefore MS are encouraged to do more, COM will develop guidelines and committed itself to prepare annual analysis of the results. This must be combined with awareness raising campaigns to inform stakeholders and broad public. COM stressed the more horizontal screening is needed and early warning systems must be built up. This will be done with the help of European Food Safety Authority (EFSA) and European and Mediterranean Plant Protection Organization (EPPO). COM highlighted the need of regular monitoring and follow-up of notifications of pest outbreaks in the EU, regular monitoring and follow-up of import interceptions. Regarding contingency plans COM pointed at the need to develop these in MS with involvement of stakeholders. COM stressed also the importance of pest risk analysis document with updated information on new but also older regulated pests.

In crisis management it is essential to learn lessons from animal health and food safety on how to assist MS in an efficient way. The main elements to consider are: criteria for triggering a plant health crisis, when to call on EFSA opinion, when and how to perform an audit, how to use national emergency measures, the use of technical experts teams, resources available.

4 crisis preparedness in PH - STakeholders ı

Comments and questions raised

COPA-COGECA highlighted that on the farm level there are not enough tools to fight against new pests and diseases arriving in Europe, broader spectre of active substances is missing.

COM confirmed that during the meeting of chief plant health officers the point on farm level was raised and it will be included in the global discussion.

On ESA question on the approach to third countries regarding imports interceptions, and whether DG TRADE is involved COM confirmed that DG SANTE collaborates closely with DG TRADE when trade with third countries is involved.

5. FINAL OVERVIEW REPORT ON THE STATE OF IMPLEMENTATION OF HACCP IN THE EU AND AREAS FOR IMPROVEMENT

COM stressed that the project was done with cooperation and thanks to the contribution of colleague in DG SANTE, Member States (MS) and stakeholders.

COM (FVO) briefly summed up the objectives of a Hazard analysis and critical control points (HACCP) project to obtain overview of the situation on implementation of hazards in the EU, to identify main difficulties and good practice examples, to receive suggestions for improvement. COM presented three strands of a project, 1) series of fact-finding missions to eight Member States, questionnaire to the non-visited MS, stakeholder consultation, 2) roadmap for better HACCP implementation and 3) publication of overview report.

Regarding stakeholder consultation the project was introduced to the Advisory group in its plenary meeting of April 2014, dedicated working group took place in May 2014 and a questionnaire was distributed with a deadline in June. The main issue raised by stakeholders was a very strong demand for clearer guidance with examples. Stakeholders expressed concerns with regard to a crucial importance of prerequisites, implementation of certain HACCP principles and on difficulties to analyse hazards. The main issues with regard to flexibility were the crucial importance of flexibility for small food business operators. All stakeholders agreed that flexibility cannot compromise safety. On official control stakeholders criticized lack of common understanding between competent authorities and operators as well as lack of sector-specific training for competent authorities' inspectors or inconsistent approaches/interpretation of requirements between inspectors.

COM further informed participants on the positive results of the project but stressed also the need for improvements, in particular the variety of national frameworks for implementation of HACCP-based systems between and within MS leading to inconsistency of interpretation and implementation, some of the core concepts are not understood, flexibility as the least understood one.

Overview Report includes a roadmap for better HACCP implementation listing actions at the level of EU, Member States as well as the level of industry/federations.

5 HACCP-FEEDBACK to ADVGRP2.pdf

Comments and questions raised:

FEFAC stated that a certain level of attention should be paid also to food products intended for feed, these should be properly handed and stored.

COM confirmed this is taken into account.

FOODDRINK EUROPE wanted to know whether the guidance on hygiene took this report into consideration. FOODDRINK EUROPE pointed at need to deal also with chemicals – contaminants even if the focus is on microbiological aspects. It also stressed the importance of training in this respect.

COM confirmed that they cooperated closely and that all hazards should be taken into consideration.

UEAPME welcomed the presentation of the report and agreed that the main issues were well identified and SMEs are happy with it as it stands. Nevertheless, SMEs would benefit from a new article 8 bis in the general food regulation to include systematically an impact assessment for SMEs.

COM stressed that it is a dynamic document constantly improving but if revised stakeholders will have opportunity to comment.

6. QUESTIONNAIRE/SURVEY TO MEMBER STATES' COMPETENT AUTHORITIES CONCERNING THE PRUDENT USE OF ANTIMICROBIALS IN ANIMALS (A TASK FORESEEN UNDER THE COMMISSION'S ROAD MAP AND ACTION PLAN CONCERNING ANTIMICROBIAL RESISTANCE)

COM briefly introduced the aims of the project, mainly to examine how Member States (MS) ensure that the relevant legal requirements on the availability, distribution and use of antimicrobials are respected, to assess the implementation of national and new EU guidance on prudent use of antimicrobials in animals, especially for critically important antimicrobials, and to identify and disseminate best practices implemented by MS.

For the purpose of collecting information, the questionnaire was sent to MS competent authorities as well as to Iceland, Norway and Switzerland. EU stakeholders were consulted via the Advisory Group and Federation of Veterinarians of Europe (FVE) national members were also consulted.

Food and Veterinary Office (FVO), SANTE Directorate F, also expect to receive an official request to share the responses with the European Medicines Agency (EMA) and European Food Safety Authority (EFSA) to help in their task to prepare advice on AMR.

After receiving the responses the subsequent steps will be a series of FVO fact-finding missions to be performed in nine MS during 2016.

COM concluded that the outcome of the overall project will be individual reports of the fact-finding missions published on the FVO website (individual reports will not contain any recommendations since these are fact-finding missions rather than audits).

A final overview report will be published on the FVO website summarising key findings of the questionnaire responses, desk study and fact-finding missions.

COM concluded by thanking all of the organisations that already provided their responses and encouraging the members of the Advisory Group that did not respond yet to do so.

6 Prudent use
Advisory Group preser

Comments and questions raised

IFAH-EU confirmed that it will respond shortly with a general position and that it will also send a common document on prudent use of AMR prepared jointly with other partners (including EPRUMA, European Platform for the Responsible Use of Medicines in Animals). It confirmed this issue is of great interest to IFAH-EU, even more so now when the article on AMR has been added to the chapter on Sanitary and Phytosanitary Standards (SPS) in Transatlantic Trade and Investment Partnership (TTIP) negotiations.

FVE supports this project to have better insights on what is being done in different countries on this topic and how to learn from each other. National members of FVE were encouraged to respond and will be again reminded. FVE asked about the deadline and whether some flexibility on this was possible.

COPA-COGECA confirmed that the input of EPRUMA mentioned by IFAH-EU has already been included in COPA-COGECA's response to the questionnaire.

AVEC will remind their national members about the questionnaire since there are many initiatives ongoing on monitoring and reporting in the poultry sector, both in the public and private domains.

COM thanked for the support and encouraged all stakeholders to send either their specific input on responding to the questionnaire or their general position on the topic (prudent use of antimicrobials in animals), and/or associated policy documents by mid-January. COM also committed to attend a future meeting of the Advisory Group in order to update members on the outcome of the project.

7. CAMPYLOBACTER CONTROL WITHIN THE REVISION OF POULTRY MEAT INSPECTION

COM briefly outlined the conclusions from the workshop on Campylobacter in 2014 stressing the biosecurity at farm level and hygiene in the slaughter process play a vital role with additional measures such washing the carcases or decontamination are seen as supplements.

COM then presented a comprehensive approach for control of *Campylobacter* in poultry consisting of:

- establishment of a process hygiene criterion (PHC) to ensure that corrective actions are taken when contamination exceeds a certain limit,
- enhanced supervision of the implementation of the new *Campylobacter* PHC and the existing *Salmonella* PHC within poultry meat inspection,
- authorisation of peroxyacetic acid (PAA) for decontamination following the positive EFSA opinion. This treatment would supplement good hygiene practices not replace them.

With regards to the use of PAA for decontamination COM highlighted the importance of a well-prepared communication strategy in order to explain advantages of its use, EFSA opinion, etc. to consumers.

COM concluded informing participants on next steps and highlighted the intention to proceed with the three acts as a package.


7 Campy 2015.pdf

Comments and questions raised

AVEC considered the proposed of PHC too ambitious, can lead to discouragement of business operators if they are not able to comply with the given set of criteria. It stressed that source of contamination is coming from the farm level so should be tackled there not only in slaughterhouses. AVEC expressed a negative opinion on introducing treatment by PAA for decontamination. Furthermore, it thinks that the use of PAA is not well argumented and that EFSA's opinion is not firm and it is based on limited data coming from US.

BEUC supported the setting of PHC but opposed the PAA decontamination. BEUC stated that increased biosecurity and good hygiene or new techniques give enough tools to avoid the use of chemicals; according to survey consumers strongly oppose the use of chemicals for meat decontamination. It stressed that risk of AMR cannot be excluded and workers' safety was not considered. BEUC asked whether the draft proposal will be consulted with stakeholders.

FoEE asked about the decision process and shared BEUC concern on impact of PAA on health of workers in slaughterhouses.

COM highlighted that the discussion on criteria is still ongoing and pointed at difficulties of control on farm level.

COM stressed that indeed there are new technologies developed; decontamination with chemicals provides an additional possibility to reduce *Campylobacter*. COM agreed that data on PAA decontamination are limited and coming from US since without authorisation cannot be used in Europe.

With regards the procedure COM confirmed the adoption will go through commitology Committee on Plants, Animals, Food and Feed.

Concerning the workers' health safety COM stated that if it is of a concern it would be addressed in EFSA opinion.

8. IMPACT ASSESSMENT ON CRITERIA TO IDENTIFY ENDOCRINE DISRUPTORS – SHORT UPDATE

COM gave a short update on latest developments regarding the impact assessment (IA) on criteria to identify endocrine disruptors since the last plenary meeting in April 2015.

COM informed participants that the Report on public consultation was published before summer. A number of events took place to dialogue with stakeholders, i.a. three round tables between March and May, a conference on 1 June on the impact assessment on criteria to identify endocrine disruptors in the context of the Plant Protection Products Regulation (EC) 1107/2009 and the Biocidal Products

Regulation (EU) 528/2012, and a technical meeting on the methodology developed by the Joint Research Centre (JRC) for evidence screening of chemicals developed in the context of the Impact Assessment the 6 November.

COM confirmed that all presentations and documents of these events are available on SANTE website.

Regarding the IA itself, there supportive work is progressing well. First step is to screen the chemicals to estimate which may fall under the different options for criteria to identify endocrine disruptors as outlined in the roadmap. This is done by a contractor based on a method developed by JRC. The results are expected to be available in 2016. The second phase is expected to start in 2016 once the first results of the evidence screening are available.

Comments and questions raised

EUROGROUP for ANIMALS asked about the Workshop on endocrine disruptors to be organised in 2016 by DG ENV and JRC stressing that animal welfare should be involved there.

COM explained that the mentioned workshop is not directly connected with IA, but the comment is noted and will be passed to relevant colleagues.

9. PRESENTATION OF THE FINAL DRAFT OF THE BEST PRACTICE DOCUMENT ON COEXISTENCE OF GENETICALLY MODIFIED COTTON WITH CONVENTIONAL AND ORGANIC FARMING

COM (JRC) briefly presented the mission of the European Coexistence Bureau (ECB) and its execution approach – through trigger of crop-specific technical working groups. COM (JRC) summed up the scope of the work of Technical Working Group on cotton and underlined its work done so far.

COM (JRC) presented in details the structure and main topics of the report, starting with the major features of cotton biology, relevant for coexistence. In the EU cotton currently is produced in three EU Member States with Greece being the main cotton grower, followed by Spain and Bulgaria. The farms for cotton production are characterised by their small size and large number.

COM (JRC) further explained the existing segregation systems in cotton production, namely in cotton seed production, schemes for identity-preserved cotton production, organic cotton and *ex ante* modelling scenarios for coexistence between GM and non-GM cotton in Spain. That analysis identified eight potential points for admixture: seeds/crop from the previous year's harvest; seeds for sowing; seed storage; sowing; cross-pollination; harvesting; transport; and intermediate storage.

COM (JRC) listed the best practice for coexistence in cotton production as follows: best practice for ensuring seed purity is the use of certified cotton seeds (EU legislation); best practice for reducing pollen-mediated gene flow is establishment of buffer zones of 5m to achieve admixture below 0.9% and 10m buffer zone for below of 0.1%. The respective isolation distances are: 30 m for 0.9% threshold and 100 m for 0.1%. Best practices during sowing, harvesting and storage in farm are to avoid intersection between GM and non-GM crop processing. The handling of non-GM crops prior to GM crops eliminates the risk of admixture. Cleaning thoroughly

the equipment used for processing of GM cotton before it can be used for processing of non-GM crops or the use of dedicated equipment for different production systems (GM and non-GM) are other alternatives.

Regarding the coexistence with honey production, the current practices in honey production and marketing in Europe are sufficient to ensure that adventitious presence of GM cotton pollen in honey is far below the legal labelling thresholds and even below 0.1%.

COM (JRC) concluded the presentation with information about economic analyses of proposed best practices.

9 BPD.pdf

Comments and questions raised

FoEE asked about the economic value of cotton production for food/feed and the best practice for equipment maintenance during harvesting.

COM (JRC) replied that the use of cotton seed products for food or feed purposes is setback by gossypol toxin presence but with proper technological steps for its preclusion or with the blending in recommended proportion in compound feed it is efficient protein source mainly for animal husbandry.

Regarding the efficient machinery management, for limitation of cross contamination to 0.1% it is better to use separate machines and for 0.9% cleaning is sufficient. Alternatively first processing of non-GM and only after GM cotton is economically founded. In general, the utilization and maintenance of equipment should be done in a sound economic manner.

EUROPABIO stated that since no GM cotton is cultivated in the EU this is a theoretical work, but without downplaying its value.

COM (JRC) agreed and highlighted that elaborated documents are universal, containing current state of art knowledge.

10. REPORT ON VOLUNTARY GM-FREE FOOD LABELLING SCHEMES IN THE EU

COM presented the findings of the study performed by an external contractor for COM, on the state of play in the EU of GM- free food labelling. The study was published in July 2015 on the website of DG SANTE (http://ec.europa.eu/dgs/health_food-safety/dyna/enews/enews.cfm?al_id=1621)

The study gives a snapshot of GM-free labels in place or in development in the Member States, and describes their respective technical characteristics. The study also aimed to identify whether, and to what extent the existence of these different GM-free labelling schemes impact the access of European consumers to food information and the functioning of the internal market.

The study concludes that variations across GM-free labelling schemes suggest potential underlying internal market and consumer protection/information issues. However, the assessment of the current evidence, including the fact that GM-free labels markets are predominantly national with limited intra-EU exchanges, does not indicate a clear need for harmonization at the present time.

In view of the conclusions of the study, COM does not consider appropriate to engage at this point in time in a harmonization process.

COM concluded informing the stakeholders that the study is open to public for information and feedback.

Comments and questions raised

On SLOW FOOD question what the deadline is for feedback and what the further steps are COM replied that at the moment there is no further action foreseen.

11. SHORT INFORMATION ON POINTS RAISED BY STAKEHOLDERS:

Update on the Official Controls file

COM briefly outlined the state of play of the negotiations on the official control proposal.

On 6 May 2013 the Commission adopted the official control proposal which aims at simplifying and modernising the existing legal framework (Regulation (EC) 882/2004). The European Parliament (EP) adopted its position at first reading on 15 April 2014.

The Permanent Representatives Committee agreed on a general approach with regard to the proposed Regulation in October 2015 and the Luxembourg Presidency received the mandate to engage in trilogue negotiations.

The first trilogue took place on 9 November 2015; this was followed by three technical meetings. Technical drafting meetings are being held to find compromise wording on any outstanding issue.

The Commission is fully engaged in the discussions to actively contribute to rapid and balanced trilogue negotiations. It is envisaged that a political agreement could be reached at early second reading during the Dutch Presidency.

COM confirmed that both, the EP report and the general approach of the Council are available on the respective websites.

Update on the Veterinary Medicines file

COM gave a short update on the proposal for a regulation on veterinary medicinal products developed with the needs and characteristics of the veterinary sector in mind. COM explained the major problems, namely overall lack of availability of authorised veterinary medicines in the EU as well as antimicrobial resistance.

COM stressed the main objectives of the veterinary medicines legislation revision as follows: increase the availability of veterinary medicinal products, reduce administrative burden, stimulate competitiveness and innovation, improve the

functioning of the internal market, and address the public health risk of antimicrobial resistance.

COM further informed participants on the state of play of discussions in the European Parliament (EP), Council of the European Union and European Economic and Social Committee.

11 Vet Update New VPMs Reg_19112015.

Comments and questions raised

IFAH-EU expressed its support to this key piece of legislation and asked about a procedure in case EP makes many substantial amendments, whether in that case there will be a new impact assessment provided?

COM replied that it is too early to know the extent of amendments and if there will be a need for a new impact assessment. It will have to be discussed at a later stage when the situation is clearer.

Update on the study on the labelling products from cloned animals and their offspring

COM informed participants that the final report was received from contractor and it will go through quality assessment. It is expected to be publicly available on DG AGRI website in January 2016.

Comments and questions raised

EUROGROUP FOR ANIMALS asked about more details how the report was put together.

COM briefly explained the process, starting with the call for tender with specifications and requirements. The selected contractor studied literature, consulted stakeholders, interviewed experts, made a cost analysis.

BEUC stressed that it was not consulted and asked on the state of play of discussion on the report in the Council.

COM replied that the working group in the Council should meet the following week and the COM will inform about the state of the study. After its publication the report of the external study can contribute to a more factual discussion of the subject.

12. ANY OTHER BUSINESS

On a question from EUROGROUP for Animals Chair shortly informed participants on proposed changes in SANTE organigram including the changes concerning the unit dealing with the Advisory Group.

Chair reminded members that in cooperation with the European Commission's Directorate General for Health and Food Safety (DG SANTE) the U.S. Food and Drug

Administration (FDA) will hold a public meeting for EU Stakeholders on 9 December on new rules recently published under the U.S. Food Safety Modernization Act (FSMA).

Chair informed participants about preliminary dates for plenary meetings in 2016: 29 April and 25 November. Chair thanked all the participants for their constructive contributions and closed the meeting.