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COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING DOCUMENT

**Lessons learned from the 2011 outbreak of Shiga toxin-producing *Escherichia coli*
(STEC) O104:H4 in sprouted seeds**

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1. INTRODUCTION

From May to July 2011, a major outbreak occurred in the EU due the contamination of sprouted seeds by Shiga toxin-producing *Escherichia coli* (STEC) O104:H4 with clusters in the North of Germany and in the Bordeaux region in France. Based on the date of onset, the outbreak started in Germany at the beginning of May and reached a peak on 22 May 2011. On 22 June 2012, an increase of haemolytic-uremic syndrome (HUS) and bloody diarrhoea cases was also reported in the Bordeaux region of France. A few days later the strain was identified as the same as in German outbreak.

As soon as the outbreak was notified, the German and *Länder* health services were mobilised, launching of alert systems at all levels (local, national, EU and international) and all parties involved collaborated intensively. The German Robert Koch Instituted reported 855 cases of HUS and 2987 cases of bloody diarrhoea (without HUS), including 53 fatalities in Germany in its final presentation and evaluation on the outbreak¹. An additional 54 HUS (incl. 2 deaths) and 83 diarrhoea cases were reported through the European Centre for Disease Prevention and Control (ECDC) as linked to the German cluster in other countries of Europe, Canada and the United States. The Bordeaux cluster counted for 24 cases, including 7 HUS².

As soon as first cases were notified by Germany, the Commission launched its emergency procedures and organised daily meetings with the national public health and food safety authorities of all the Member States and with the relevant European risk assessment agencies to discuss the evolution of the outbreak and the measures to control it. In addition, the response to the outbreak and related measures was further discussed with the Member States through the Health Security Committee.

The European Commission coordinated the response to the outbreak at EU level and was assisted by the ECDC, the European Food Safety Authority (EFSA) and the EU reference laboratory (EURL) for *Escherichia coli* (*E. coli*) providing:

- scientific risk assessments,
- advice on preventive measures addressed to the public,
- a platform to exchange best practice on treatment,
- advice on possible sources of contamination of fresh vegetables and possible risk mitigation measures including best possible hygiene throughout the food chain,

¹ Final presentation and evaluation of epidemiological findings in the EHEC O104:H4 Outbreak, Germany 2011 (http://www.rki.de/cln_153/nn_217400/EN/Home/EHEC_final_report,templateId=raw,property=publicationFile.pdf/EHEC_final_report.pdf). Reporting of epidemiological data based on the German national case definition.

² Information provided by the French authorities at a meeting of Chief Veterinary and Public Health Officers, Brussels 18 November 2011, available at: http://ec.europa.eu/food/food/docs/ehec_181111_CVO_France.pdf

- on the spot assistance in the epidemiological investigation of Germany, which has played a crucial role in identifying sprouted seeds as the source of the outbreak, and
- the development of a method that reduces the time needed to detect the *E. coli* bacterium in food, from about six days to 48 hours.

In order to inform the public and the press, the Commission drew up daily "updates" of the situation, which were shared with the Health Security Committee Communicators' network and food safety authorities. In addition, the Commission kept its website dedicated to this outbreak up-to-date.

The **losses for farmers in the fruit & vegetable sector** were estimated at least 812 Million (Mio) € in the first 2 weeks: (source: Copa-Cogeca). In addition a temporary **export ban** of vegetables to Russia occurred, constituting an annual value of 600 Mio €.

The Commission supported the sector with exceptional measures on **market intervention** for a total value of 227 Mio Euro. Such measures concerned the products most directly affected by the crisis, i.e. tomatoes, cucumbers, lettuces and certain endives, courgettes and sweet peppers. Consumers had massively refrain from buying these vegetables in the beginning of the outbreak because of uncertainty on the source and recommendations not to consume these products raw.

In follow-up of the outbreak, several **promotion activities** were also launched in order to win back consumer trust in fruits and vegetables.

Finally, the Commission launched on 19 July a **media campaign** in all EU Member States.

A detailed analysis on the impact of these actions, carried out by the Commission, is in Annex 2.

Despite the actions taken, the tremendous public health impact, the losses in the fruit and vegetable sector and the interventions highlight the need to take lessons from the crisis and to investigate where improvements are possible to avoid similar losses in future.

The objective of this document is to indicate **possible actions from the EU** to prevent similar outbreaks or to limit their scale and to be better prepared for food-borne outbreaks in general. Actions are also needed to strengthen coordination between the health and food safety authorities in line with the "**One Health**" principle.

2. CURRENT RELEVANT EU LEGISLATION

The legal framework to prevent, monitor and manage food-borne outbreaks is multidisciplinary. It contains requirements for public health and food safety managers, risk assessors and risk communicators. The need for coordination between these actors and between different levels (local, national, EU and international) is laid down in these EU rules. An overview is provided in Annex 3.

3. RISK ASSESSMENT

EFSA and ECDC have worked jointly to deliver a number of rapid assessments during the STEC outbreak. These agencies are drawing conclusions on the outbreak within their field of competence. In this section, the focus is on the support/input from these agencies needed by the Commission for introducing measures as follow-up of the crisis.

- The Commission has asked EFSA to assess and prioritise **the risk of pathogens in food of non-animal (plants, mushrooms) origin** in cooperation with ECDC. In particular, EFSA should identify specific food/pathogen combinations most often linked to food of non-animal origin, identify the main risk factors linked to these specific food/pathogen combinations, and recommend mitigating options to reduce the risk posed by these food/pathogen combinations, as well as microbiological criteria, if relevant. Based on such opinion the need for additional specific measures for certain food of non-animal origin will be evaluated to supplement the enforcement of existing rules. The opinion will supplement the specific opinion on the risks posed by pathogenic bacteria in seeds and sprouted seeds which was adopted by EFSA in October 2011³.
- The Commission will ask EFSA for technical support to evaluate in cooperation with ECDC the need **to update the way of reporting results from monitoring of pathogens in food of non-animal origin** in order to ensure that such monitoring provides the most appropriate information for risk managers and risk assessors and ensures linking with human data. In addition further standardisation of outbreak reporting must be considered to better allow trend analysis of outbreaks and involved food commodities.
- EFSA and ECDC will be asked to elaborate a Standard Operational Procedure (SOP) for **joint risk assessment in the event of outbreaks**.

4. RISK MANAGEMENT

4.1. Prevention

As a first step, discussions have already started on **preventive measures** on seeds for sprouting and for direct human consumption and on the **production of sprouted seeds** based on the recommendation of the October 2011 EFSA opinion. However, a number of actions are relevant for all food of non-animal origin and therefore a broader preventive approach is anticipated:

- The Commission insists on the responsibility of the Member States to **enforce** the application of the existing rules in Regulations (EC) No 852/2004 and 2073/2005.
- Dedicated **missions of the Commissions' Food and Veterinary Office** will gather information on best practices in sprout production and primary production of food of non-animal origin in Member States as well as audit the enforcement of the existing

³ EFSA Journal 2011;9(11):2424 [101 pp.].

provisions in the Member States and in the most important exporters of seeds and food of non-animal origin to the EU.

- The relevant European stakeholders' organisations will be encouraged to develop **EU guides for good hygiene practice**.
- The Commission will propose specific rules to improve availability of information on **traceability** for seeds intended for sprouting and for direct human consumption.
- The Commission intends to organise dedicated sessions under the programme **Better training for Safer Food** on hygiene in primary production for major trade partners.
- The Commission will submit **specific legal rules on seeds and sprout production** based on the October 2011 EFSA opinion for an opinion at the Standing Committee on the Food Chain and Animal Health. These measures may include the approval of establishments producing sprouted seeds, the mandatory washing of seeds before sprouting, as well as the introduction of microbiological criteria, including process hygiene criteria, for sprout production and microbiological criteria for seeds for sprouting or for human consumption.

4.2. Preparedness

The Commission and Member States should constantly review existing practices and arrangements to ensure and improve preparedness in case of a new outbreak. The Commission is fully committed to seeking out the lessons which can be derived from past experiences, including the very recent one of the EHEC outbreak. Several issues should be considered while looking for continuous improvement

- Testing existing arrangements during normal times is essential to ensure that they respond and perform efficiently when a crisis is present. Inter-sectoral **preparedness exercises** on outbreak coordination and response involving public health and food safety authorities should be scheduled addressing lessons learnt during the outbreak such as cooperation between the local, national and EU competent authorities, interaction with international partners concerned and coordination of risk communication at local, national and EU level. The experience in a number of Member States, already carrying out such exercises, can be used for this purpose.
- The feasibility of creating a **database for molecular testing** of major food-borne pathogens should be reflected upon to facilitate a quick link between human isolates and food or animal isolates. This would be developed in close collaboration with EFSA, ECDC and the EU reference laboratories for these pathogens.
- **Dedicated trainings** within Better Training for Better Food on food-borne investigations and outbreak management will be organised with the involvement and technical support of EFSA and ECDC. The target audience will be a mix of public health and food safety authorities.

- Additional efforts are required on **laboratory analyses** for pathogens in food of non-animal origin. This includes the need for specific proficiency tests, validation of analytical methods and validation of pooling techniques, coordinated by the EURLs.
- Depending on the scale and particular circumstances of the crisis, the establishment of a network of Member State officials responsible for communication in the event of an outbreak.

4.3. Outbreak management

4.3.1. *Reviewing existing processes (General Plan, Standard Operating Procedures)*

During the recent STEC crisis, some of the existing mechanisms for crisis management were put to test even though not all were formally activated. The Commission is currently reviewing the direct experience gained during the crisis to consider any adjustment that might be necessary to the General Plan established by Decision 2004/478/EC and/or to other more operational guidance for action which is being compiled into a set of comprehensive Standard Operating Procedures. Particular attention is being paid to the issues already mentioned in this paper, to the principles enshrined in the General Plan, and to other relevant issues, among which are the following:

- the need to ensure effective and smooth **coordination** between the EWRS and the RASFF including a proposal for a Decision on serious **cross border health threats** providing specifically for better linkages between existing EU alert and notification systems;
- the need to ensure that the system is not burdened by unnecessary procedural steps and allows sufficient **flexibility** to address all possible situations;
- the need to provide for appropriate coordinated mechanisms to carry out **tracing back and tracing forward** exercises at EU level with the technical support of the scientific agencies when required;
- the need to give adequate attention to **communication issues** as an integral part of the response to a crisis, including the development of a communication strategy at the outset of a crisis, and to specific logistic issues;
- the need to provide for the necessary interaction and coordination with **international partners and third countries** in case of a crisis of international significance.

The Commission is committed to share the result of the review which is ongoing with the Member States (and notably with the crisis coordinators who are the designated interlocutors in the context of the General Plan), and with other concerned interlocutors as appropriate.

4.3.2. *Other crisis management tools*

The following tools, currently in place, will be strengthened and further developed as needed, notably:

- iRASFF, the online platform of RASFF, will be further developed and extended to all Member States. It will help to inform faster and in a more structured way while ensuring that the information remains reliable, transparent, sound, robust and verified. Members of the system will be able to interact on each other's data.
- EWRS will be upgraded taking into account all the serious cross border threats to health and the management needs arising from the notified events. The current EWRS links online the Commission and the competent public health authorities in each Member State responsible for planning and implementing measures, the ECDC, EMA and WHO. EWRS is currently used to notify threats and help to coordinate the response to serious events caused by communicable diseases. It will be further developed in line with the legal proposal on serious cross border threats to health. Synergies between RASFF and EWRS will be enhanced in order to reach a consistent EU response.

4.3.3. *Management of clinical cases*

Support for the **management of clinical cases** in future outbreaks will be prepared.

- The STEC outbreak has shown that clinical management issues could benefit from better coordination, exchange of information on treatment options and best practices, etc. at EU level. The fact that the German authorities made available information in English on clinical management was appreciated by the other MS. The necessity to undertake clinical support at EU level in future outbreaks should be considered on an ad hoc basis, as was done during the *E. coli* outbreak with the setting up by the ECDC of a platform for exchange of best practice, teleconferences with clinicians and development of clinical reference materials.
- The mechanism of consultation of available expertise during the *E. coli* outbreak proved very useful to rapidly establish an EU expert group which quickly provided answers and guidelines to be used to treat patients during the event. This mechanism should be re-assessed and if needed improved. Once this step has been completed the mechanism should be tested and a more formal procedure (Modus of understanding or SOPs for response) should be put in place and regularly assessed. The mechanism could be triggered in case of possible future needs.

4.4. **Evaluation and review**

Directive 2003/99/EC (food and animals) and Decision 2119/98 (human data) provide a sound basis to follow trends on prevalence of pathogens in food, animals and humans and to evaluate the effect of measures taken to combat these pathogens. Decision 2119/98 will be reinforced by the proposal for a Decision of the European Parliament and of the Council on serious cross-border threats to health. Analyses on trends will be further improved by standardisation of outbreak reporting.

5. RISK COMMUNICATION

A communication strategy is already foreseen by Sections 7 and 8 of the Annex to Decision 2004/478/EC. It will thus be part of the review mentioned above (see point 4.3.1). In that context, recent experience will also be used for the purpose of improving the way communication takes place in times of crisis.

It should be stressed that standard practices of communication should be maintained even (and especially) under the high pressure of an outbreak situation to ensure efficient and coordinated risk communication and communication towards the public at all levels – local, national, EU and international.

This means that information must be timely, **sound and robust**, and that all involved partners should coordinate their communication activities in a faithful and transparent fashion so as to avoid the transmission of contrasting messages to the public. Appropriate consideration will be given to the need:

- to ensure that coordination with all relevant partners, including with other international organisations (World Health Organisation (WHO), Food and Agriculture Organisation of the United Nations (FAO), the World Organisation for Animal Health (OIE) etc.) also extends to the handling of communication to the public
- to fully involve national actors involved in communication activities in times of crisis;
- to put to optimal use existing communication networks (such as the one active within the context of the EU Health security Committee) and other tools for the exchange of crisis related information (including RASFF and EWRS).

In addition to efficient coordination between Member States at the European level, these efforts and exercises should address the need for communication coordination with competent sub-national and international authorities. The European Commission and the Health Security Roadmap of the WHO Regional Office for Europe will notably contribute in strengthening cooperation on health security matters and risk communication on cross border health threats.

As regards communication to the public, **the involvement of communication specialists** at EU and national level in the crisis management teams needs to be considered in order to find a correct balance between three potentially conflicting objectives: be transparent, to reassure and avoid an adverse reaction from the general public.

Based on the experience during the STEC O104:H4 outbreak, the development of a dedicated and regularly updated website should be considered for each major outbreak to provide information on the crisis management to the general public. This should, however, form part of a broader strategy which identifies the most appropriate and effective communication channels given the particularities of the outbreak.

6. CONCLUSION

A number of actions have been indentified and launched that will improve the safety of sprouts and, more broadly, food of non-animal origin. More generally, the actions will improve the management of food-borne outbreaks. This requires however an effective cooperation within and between Member States, between Member States and the EU institutions, between the EU and international organisations, and between risk assessors, risk managers and risk communicators. Most important issues to reach our goals are:

- Strengthen EU capacities to ensure protection of citizens against cross border health threats;
- Awareness of the need for improvement of hygiene in food of non-animal origin including primary production and import by better enforcement of existing hygiene provisions;
- Enhanced preparedness through regular practical exercises involving all key players in an outbreak;
- Respect of responsibilities and involvement of all partners in outbreak management;
- Better coordinated and clear communication;
- Improve tools of market intervention and product promotion to reduce reaction time to crises outbreak and thereby limit the negative economic impact on the EU sector;
- Strengthen public-private initiatives linking producers (incl. processing, retail and trade) and citizen/consumers to increase awareness and enhance communication and knowledge.

Annex 1

TIME TABLE

Initiative	Time line
Sharing views and experiences with public health and food safety authorities	1° semester 2012
Risk assessment pathogens in food of non-animal origin (see point 4.2, first bullet point)	2013
Preventive legal measures on sprout production (see point 4.1, last bullet point)	1° semester 2012
SOPs outbreak management (See point 4.3)	1° semester 2012
iRASFF (see point 4.3)	1° semester 2012
EWRS to be upgraded and extended to cover further threats (see point 4.3)	From 2012 onwards
Communication network food safety (See point 5)	1° semester 2012
FVO missions (See point 4.1, second bullet point)	2° semester 2012 onwards
Preparedness and response exercise (See point 4.2, first bullet point)	From 2012 on
Database molecular tests (See point 3, second bullet point)	2012
Decision of the European Parliament and of the Council on serious cross-border threats to health (see point 4.4)	Adoption expected in 2012
BTSF food-borne outbreak investigations and outbreak management (See point 4.1, seventh bullet point)	Selection contractor: 2012, trainings: 2013

Annex 2

ECONOMIC ANALYSIS STEC OUTBREAK 2011

1. MARKET IMPACT

1.1. Overall sector production

Fruit and vegetables are high-value crops with a wide diversity in species grown in relatively small production areas. Fruit and vegetables represent 3% of the EU's cultivated area but account for 17% of the value of the EU's agricultural production. The total production value is estimated to be more than **47 billion €**. The fruit and vegetables supply chain has an estimated turnover of more than **120 billion €** with approximately 550.000 employees and 3.4 million farm holdings.

Out of a total production of 101 million T, **72%** is marketed or processed on the local market of the Member State where the product has been grown. The intra-EU trade of fruit and vegetables represents around 24 million T of produce being exchanged every year between Member States. **Germany** is the single largest receiver of intra-EU produce with more than 6.6 million T⁴ per year.

1.2. Operators' losses

Table 1: Estimated losses of Member States as declared by farmers associations, classified by amount.

Country	Total losses 30 May - 12 June (Million euros)
Spain	350
Italy	150
Poland	90
Netherlands	83
Germany	65
Greece	30
France	15
Belgium	12
Other MS	17.6
Total of available estimations	812.6

For the weeks 22 and 23 (30 May - 12 June), Table 1 summarises the losses that COPA-COGECA and member states farming organisations claimed.

⁴ Eurostat and DG AGRI C2 elaboration.

This global estimation refers of the **first two weeks of the crisis only** show that the threshold of **1 billion €** in total damage could have been surpassed.⁵

2. TRADE IMPLICATIONS

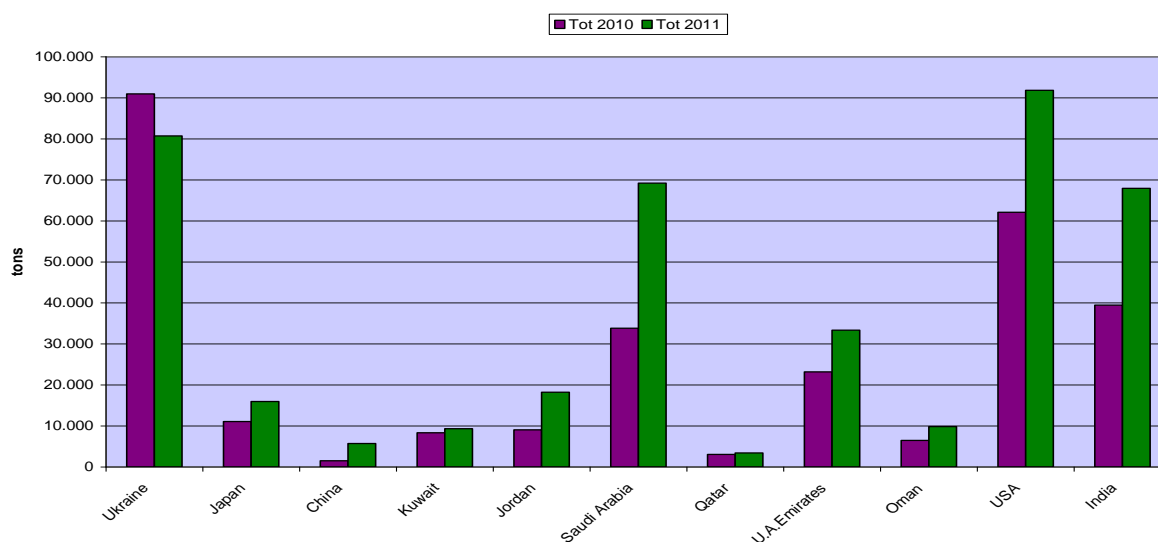
2.1. Trade in general

The EU imports more than **12 million T** of fresh produce from third countries, making the EU the world’s largest importing region, while exporting more than **5 million T** to third countries.

In 2010, the EU exported 0.6 million tons of vegetables to the **Russian Federation**, which amounted to 35% of all EU vegetable exports in that year. The value of these exports was about €600 million. In 2011 the amount of exports was 0.6 million tons.

Beside the Russian Federation, other main trading partners are Ukraine, USA, India, Japan, China, and Arab countries, (Kuwait, UAE, Saudi-Arabia, Qatar, Jordan, and Oman)⁶.

Graph 1: Fruit & Vegetables Export 2010-2011



2.2. Restrictions

The *E. Coli* crisis led to several trade restrictions, which caused economic losses in the agricultural and trade sector.

⁵ An up-date will be available after the next COPA-COEGA working group (fruit & vegetables meeting) on 28 April 2012.

⁶ Source: DG Trade data processing (potatoes included)

Table 2: Measures put in place by the most important trade partners

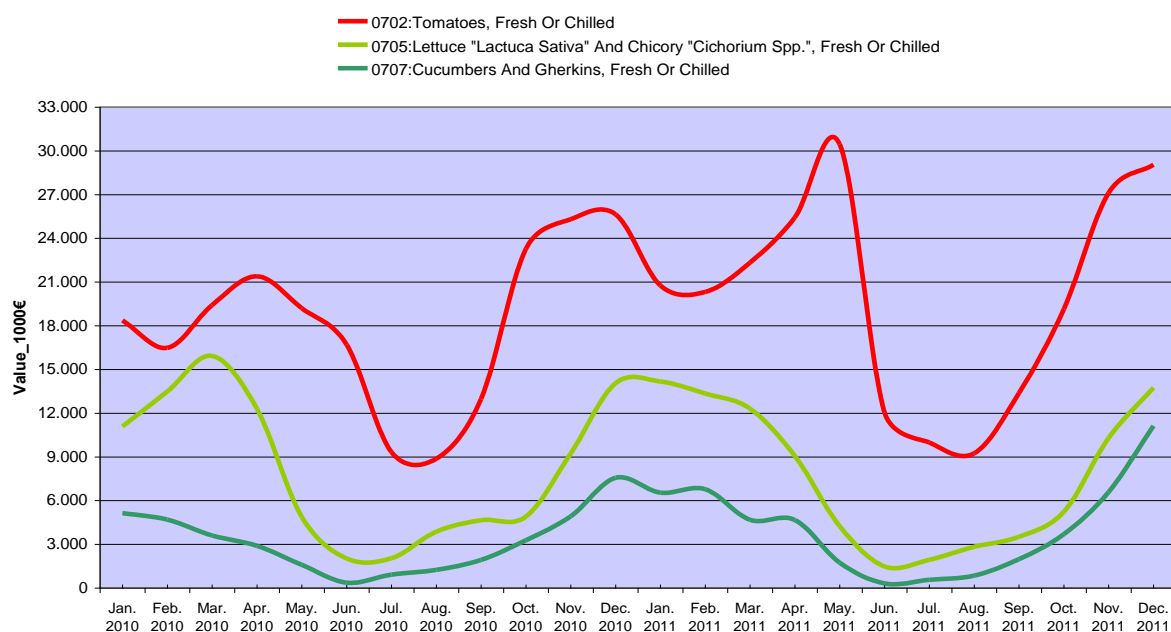
Country	2010 Imports (tons)	Restrictions
Russian Federation	<u>TOT = 952 489</u> Potatoes = 335 720 Tomatoes = 81 302 Onions = 166 720 Lettuce = 15 146 Carrots = 63 218 Cucumbers = 6 766	Ban on EU vegetables entered on force on 2 June 2011; on 22 June it was replaced by a temporary certification system, based on a monitoring by Member States and transmission of a list of laboratories involved in this monitoring for each Member State to the RF. On 9 August 2011 all restrictive measures were entirely lifted.
USA	<u>TOT = 62 068</u> Tomatoes = 1 127 Onions = 6 320 Lettuce = 939 Cucumbers = 742	Increased surveillance for bean sprouts and seeds from bean sprouts from Germany .
Ukraine	<u>TOT = 90 968</u> Tomatoes = 8 326 Onions = 25 155 Carrots = 21 003 Cucumbers = 114	Ban on EU vegetables , specific form to be filled in (or sampling and test will be conducted in Ukraine). Transitional measure for vegetables shipped before 10 June 2011.
India	<u>TOT = 39 450</u> Dried Leg. Veg. = 39 038	None
Saudi Arabia	<u>TOT = 33 831</u> Potatoes = 23 311	All fresh (not frozen) vegetables from Germany .
UAE	<u>TOT = 23 172</u>	Vegetables from Spain, Germany, Denmark and the Netherlands should be accompanied with a health certificate stating that the vegetables are free from E. coli pathogens, issued by administration in exporting country.
Jordan	<u>TOT = 9 042</u>	EU vegetables .
Japan	<u>TOT = 11 091</u>	None

2.3. Trade impact

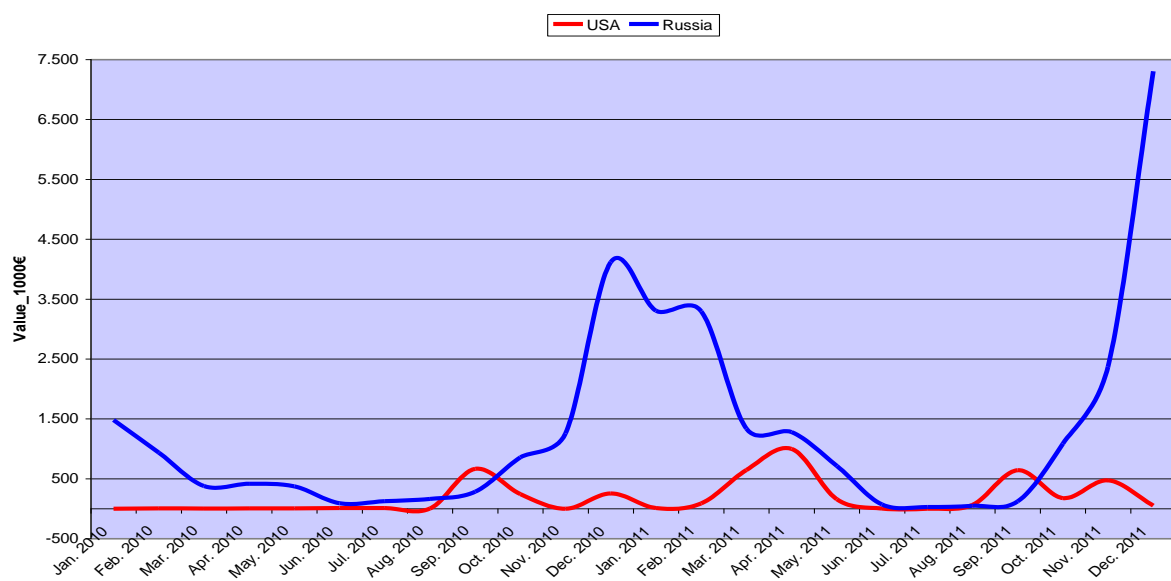
The graph below shows the different trends of EU27 trade with the main importers countries cited above, considering the **three main "unjustly guilty" vegetables**. It is noticeable that the 2011 trends are similar to the ones of 2010; especially in summer, the most difficult period in 2011 for fruit and vegetables exports, the graph demonstrates that the decrease was quite similar in the same period the previous year⁷.

⁷ Source: DG Trade data base

Graph 2: Comparison among different products



Graph 3: Cucumbers and Gherkins, Fresh or Chilled



Graph 3 shows only the trends in **cucumbers export to Russia and USA**, main cucumbers exporters from EU27. Although imports from USA remain stable, with a little decrease during the E. coli crisis between May and August 2011, the Russian trend is quite irregular, with a deep decrease during 2011 summer. However, like in the previous graph, this does not seem to be an exception, as is similar to the tendency of 2010 summer⁸.

⁸ Source: DG Trade data processing

3. THE EU RESPONSE

3.1. Emergency aid

On 14 June EU Member States voted on a **210 million euro emergency aid package** for fresh vegetables producers. Commission Implementing Regulation 585/2011 for laying down temporary exceptional support measures for the fruit and vegetable sector was published on the OJ on 18 June. This amount was increased to 227 million euro by the Commission Implementing Regulation (EU) No 768/2011 published on 3 August 2011 to allow the Commission to pay 100% of the demands for compensation received from the different Member States.

Finally, the total amount of payments has been 79% of the total amount notified to the Commission.

Considering the eight major claimants reported in Table 1, Table 3 shows that Spain and Italy did not pay the total amount initially requested in the notifications to the Commission (Spain paid 47 M€, which represents 66% of the amount notified and IT 15,3 which is only 44% of what was notified). On the contrary, Poland, Netherlands, Germany, Greece, Portugal and Romania carried out payments amounting to 94-100% of the budget initially requested to the Commission.

Table 3: *E. coli* crisis support measures (Million €)⁹

A Member State	FY2011			FY2012 ^{***}
	B Amount notified to the Commission ^{**}	C Payments in FY2011	D=C/B % Paid in FY2011 of the total notified to the Commission ^{**}	E Payments from 16th October to 31th December 2011
BE	3,606	3,590	100%	0,000
BG	2,563	1,962	77%	0,008
CZ	0,262	0,223	85%	0,000
DK	0,858	0,858	100%	0,000
DE	16,004	15,430	96%	0,000
EE	0,001	0,001	100%	0,000
IE	0,013	0,013	100%	0,000
EL	7,788	7,345	94%	0,000
ES	70,971	47,038	66%	0,000
FR	1,655	1,578	95%	0,000
IT	34,625	15,321	44%	0,042
CY ^{***}				
LV	0,057	0,057	100%	0,000
LT ^{***}				
LU ^{***}				
HU	1,516	1,464	97%	0,000
MT ^{***}				
NL	27,181	25,550	94%	0,000
AT	2,234	2,224	100%	0,000
PL	46,395	45,143	97%	0,000
PT	5,244	5,244	100%	0,000
RO	3,745	3,733	100%	0,000
SI	0,193	0,193	100%	0,000
SK	0,536	0,529	99%	0,000
FI ^{***}				
SE	0,113	0,113	100%	0,000
UK	0,649	0,649	100%	0,000
EU	226,210	178,257	79%	0,049

⁹ * Commission implementing regulation (EU) No 585/2011, No 768/2011 and No 769/2011.

** Notification from the MS to the CE following the article 7.2 of the Commission Implementing Regulation (EU) 585/2011.

*** Negative declarations after FY2011 are not taken into account for the calculations of late payments.

In the Declaration of November 2011, Spain declared -175.713,06 € and in December -432.441,88 €

Table 4: Comparison of initial declared damage with officially notified and actually paid compensation per Member State (Million €)¹⁰

Ranking	Country	Notified (M€)	Paid (M€)	Declared (M€)*	
				(first 2 weeks)	(final results)
1	Spain	71.0	47.0	350	-
2	Poland	46.4	45.1	90	-
3	Italy	34.6	15.3	150	-
4	Netherlands	27.2	25,6	83	315
5	Germany	16.0	15.4	65	-
6	Greece	7.8	7..3	30	-
7	Portugal	5.2	5.2	NK	-
8	Romania	3.7	3.7	9	-
9	Belgium	3.6	.4.0	12	30
10	Bulgaria	2.6	2.0	NK	-
11	Austria	2.2	2.2	3.7	3.7
12	France	1.7	1.6	15	-
13	Hungaria	1.5	1.5	NK	-
14	Denmark	0.9	0.9	2	2
15	UK	0.6	0.6	NK	-
16	Slovakia	0.5	0.5	NK	-
17	Czech Republic	0.3	0.2	NK	-
18	Slovenia	0.2	0.2	NK	-
19	Sweden	0.1	0.1	NK	-
20	Latvia	0.1	0.1	NK	0.9
21	Ireland	0.0	0.0	NK	-
22	Estonia	0.0	0.0	NK	-
Total	EU 27	226.2	178.2	812.6	-

* According to COPA-COGECA Working group "fruit and vegetables"

Special reference has to be made to the report from the Dutch Producer organizations, one of the main producers and notably traders in fruit & vegetable. They claim that for the whole year the estimated the loss is 230 Million € for producers and an additional 85 Million € for the traders, which adds up to a total loss of 315 Million €.

3.2. Communication

A media package launched by DG Agriculture of the European Commission on the occasion of the EU Agricultural Council on 19 July consisting of a **press advert** (one, mainly free distribution newspaper per country) and a **video news package distributed freely to all**

¹⁰ * Commission implementing regulation (EU) No 585/2011, No 768/2011 and No 769/2011.

** Notification from the MS to the CE following the article 7.2 of the Commission Implementing Regulation (EU) 585/2011.

*** Negative declarations after FY2011 are not taken into account for the calculations of late payments. In the Declaration of November 2011, Spain declared -175.713,06 € and in December -432.441,88 €

televisions, reaching an estimated number of 37 million people in the EU.. The total budget for this media campaign was €601.785.

In addition to the information and promotion programmes adopted each year and in light of the *E. coli* crisis, Commissioner Dacian Cioloş has proposed a regulatory change which enabled professional organisations to submit additional promotional programmes for fresh fruit and vegetables in the single market and in third countries by 15 August with an **additional budget** for this initiative¹¹. In this framework the European Commission has approved, on 15 November 2011, 14 programmes for co financing, out of which 11 targeted the internal market and 3 targeted third countries. The total budget of the programmes was € 34,1 million, of which the EU contributed € 17,0 million (50%).

4. CONCLUSIONS AND OUTLOOK

Producers

Form the point of view of the economic operators, this crisis created damages to the supply chain (direct losses, produce withdrawals) in excess of **1 billion €** due to lost sales, low prices, overcapacity. Despite the EU compensation, full recovery will take years.

Trade

Arguably the biggest damage was on the **image of fresh produce**. EU consumers and in Third countries do associate fruit & vegetables with healthy nutrition, not with food poisoning. Reputation damage to specific produce (cucumbers) and Member States (Spain) was especially high. Restoring confidence takes much longer than the few seconds it took to destroy it, even if mistakenly.

Consumer

It became apparent that consumer information should be strengthened when it comes to good hygiene practices while preparing food and, in particular, when handling fruit and vegetables, such as in washing produce thoroughly as well as hands and kitchen utensils used to prepare fruit or vegetables which helps to avoid the risk of cross-contamination.

European Commission

The European Commission is working on the possibility to amend current implementing rules on crisis prevention and management after discussion in the Management Committee (over the course of the coming weeks) to reflect some of the lessons learnt during the *E.coli* crisis, e.g. with green/non- harvesting operations for greenhouses.

¹¹ Source: European Commission Press Release.

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/829&format=HTML&aged=0&language=FR&guiLanguage=en>.

The Commission report on the 2008 Fruit & Vegetables Reform is set to be published by May / June 2013 which is some 7 months ahead of schedule and legislative proposals are expected to accompany the report.

The formal launch of the Impact Assessment (IA) to accompany this legislative proposal has been launched in end March 2012 with the final IA report expected for May 2013.

Annex 3

RELEVANT EU LEGISLATION

1. General requirements

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹² ensures a high level of protection of human health and consumers' interest with regards to food. This Regulation lays down the general principles including the risk analysis concept, the precautionary principle and the protection of consumers' interest. It is required to ensure that food is safe, to ensure traceability and indicates the primary responsibility of food business operators.

2. Prevention by hygiene requirements

General rules for the hygiene of foodstuffs are laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs¹³ introducing principles such as the farm to fork approach and procedures based on the Hazard Analysis and Critical Control Points (HACCP) principles where relevant. Based on this Regulation, a *Salmonella* criterion for sprouted seeds and an *E. coli* criterion for ready-to eat pre-cut fruit and vegetables have also been established since 2006 (Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs¹⁴)

3. Preparedness and monitoring

Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC¹⁵ ensures that monitoring of food-borne pathogens is carried out at the most relevant stage of the production chain, and that results from the Member States are reported and submitted to EFSA for trend analysis. The Directive also sets out the legal base for investigating food-borne outbreaks and requires Member States to ensure communication at the national level with all involved sectors (public health, food safety, feed, etc.) and to keep the Commission updated on the respective national contact points.

The human health Community network under Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the

¹² OJ L 31, 1.2.2002, p.1.

¹³ OJ L 139, 30.4.2004, p. 1 as corrected in OJ L 226 25.6.2004, p.3.

¹⁴ OJ L 338, 22.12.2005, p. 1.

¹⁵ OJ L 325, 12.12.2003, p. 31.

epidemiological surveillance and control of communicable diseases in the Community¹⁶ covers epidemiological surveillance and early alert and response coordination to serious events caused by communicable diseases. Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control¹⁷ provides the ECDC with a mandate covering surveillance and risk assessment of threats to human health from communicable diseases and illnesses of unknown origin. The Early Warning and Response System application (EWRS) allows sharing of information which is essential for the notification of outbreaks, and coordination of measures between the Member States and the Commission to respond to serious cross-border events caused by communicable diseases.

A number of implementing measures have been adopted and further amended under Decision 2119/98/EC, including:

- A list of diseases to be progressively covered by the Community network in accordance with Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council¹⁸;
- Case definitions for the diseases included in the previous list in order to guarantee a consistent EU reporting in accordance with Commission Decision 2002/253/EC of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council¹⁹;
- Criteria for reporting to the Community Network through the EWRS for the prevention and control of communicable diseases events of Community relevance in accordance with Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council²⁰.

A proposal for a Decision on serious cross-border threats to health²¹ has been submitted to the European Parliament and the Council. It aims to better protect European citizens from health threats which can be of biological, chemical or environmental nature. Building on existing systems and structures, the proposal covers comprehensively preparedness, early warning and notification, monitoring, surveillance, risk assessment and finally, crisis

¹⁶ OJ L 268, 3.10.1998, p. 1.

¹⁷ OL L 142, 30.4.2004, p. 1.

¹⁸ OJ L 28, 3.2.2000, p. 50.

¹⁹ OJ L 86, 3.4.2002, p. 44.

²⁰ OJ L 21, 26.1.2000, p. 32.

²¹ http://ec.europa.eu/health/preparedness_response/policy/hsi/index_en.htm

response management of such threats. Also, the Health Security Committee will be formalized to ensure an effective EU wide coordinated response in a public health crisis.

4. Outbreak management

Chapter IV of Regulation (EC) No 178/2002 provides the rules for the management of food crisis, for the adoption of emergency measures and for the operation of the Rapid Alert System for Food and Feed (RASFF). In particular, Articles 55 to 57 of the Regulation require the establishment of a comprehensive plan (the "general plan") for the coordinated handling of situations involving direct or indirect risks to human health deriving from food and feed which are not likely to be eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of the emergency mechanisms laid down in Articles 53 and 54 (the s-called "safeguard measures"). The general plan referred to in Article 55 above was established in the Annex to Commission Decision 2004/478/EC of 29 April 2004 concerning the adoption of a general plan for food/feed crisis management²², and includes principles and practical procedures for the management of a crisis involving a serious direct or indirect risk to human health, including the principles of transparency to be applied and a communication strategy.

At national level, for the implementation of the general plan in question, Article 13 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules²³ requires Member States to draw up operational contingency plans setting out the measures to be implemented in cases of risks posed by feed or food.

5. Coordination

With the entry into force of the Lisbon Treaty, the Union has been empowered to support, coordinate or complement the action of Member States in the area of the protection and improvement of human health, directed towards improving public health, preventing illness and diseases, and obviating sources of danger to health. It covers 'monitoring, early warning of and combating serious cross-border threats to health', respecting the responsibility of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. Furthermore, the treaty provides that the Union should take into account requirements linked to a high level of protection of human health while defining and implementing its policies and activities. The principle of 'health in all policies' is particularly relevant in the multi-sectorial context due to the transnational dimension of serious cross-border threats to health. At international level, a comprehensive framework on health security exists in the form of the International Health Regulations.

²² OJ L 212, 12.6.2004, p. 60.

²³ OJ L 165, 30.4.2004, p. 1.