EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 10 MARCH 2015

(Section Toxicological Safety of the Food Chain)

CIRCABC Link: *https://circabc.europa.eu/w/browse/3548b628-fe6f-4ef2-9bf0-922f2dcfa676*

A.01 Follow-up to the scientific opinion from EFSA on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables. - endorsement of provisional levels of reference for intra-Union trade

Following the discussions and conclusions at the previous meeting of the Committee on 11 February 2015 and the detailed discussions in the Expert Committee "Industrial and Environmental Contaminants" on 2 March 2015, the proposed revised levels as reference for intra-Union trade were presented. These levels were based upon available occurrence data obtained after September 2013. These levels are provisional awaiting the availability of more data on the occurrence of perchlorate in food.

A comment was made as regards the proposed levels for tea and herbal and fruit infusions, indicating that the proposed levels as reference of respectively 0.75 mg/kg and 1.0 mg/kg are based on a limited number of occurrence data and are too high to provide a high level of human health protection. On the other hand, other delegations indicated that they could not agree on significant changes after the discussions at the Expert Committee meeting on 2 March 2015.
Therefore it has been agreed that the European stakeholder organisation, Tea and Herbal Infusions Europe, has to provide significantly more occurrence data on perchlorate in tea and herbal and fruit infusions and to provide a rationale/explanation on the reasons of the presence of perchlorate in tea and herbal and fruit infusions. This information shall be considered by the Committee at its meeting scheduled on 23 June 2015 in view of a possible review of the levels as reference for intra-Union trade for tea and herbal and fruit infusions.
This information needs to be made available sufficiently in advance of the meeting of the Committee (at least two weeks in advance and preferably also in advance of the meeting of the Expert Committee Industrial and Environmental Contaminants provisionally scheduled on 28 may 2015). In the absence of sufficient data and /or explanation giving the reasons for the presence of perchlorate in tea and herbal and fruit infusions, the levels as reference for intra-Union trade will be proposed to be set at 0.5 mg/kg at the meeting of the Committee on 23 June 2015.

These revised levels as reference for intra-Union trade are of application as from 16 March 2015 and the levels agreed at the Committee on 16 July 2013 are no longer valid.

The competent authorities of the Member States agreed not to take action below these levels. Upon request it was clarified that for taking action, measurement uncertainty has to be taken into account and the level as reference has to be beyond reasonable doubt exceeded, taking into account the correction for recovery and measurement uncertainty.

The statement, including the revised levels as reference for intra-Union trade, in annex to this point of the summary report was endorsed by a large majority of Committee.

The Committee was also informed that the statement shall be published on the website of DG Health and Food Safety [1] before 16 March 2015.

The UK made following declaration :

"The UK acknowledges the original requirement for levels of reference for intra-Union trade for perchlorate in food and has been supportive of this. As perchlorate can be present as a contaminant it is reasonable to take action to encourage good agricultural practice (GAP). The UK is also mindful of the recently adopted EFSA tolerable intake.

The UK notes the level of support for the new revised reference levels from the expert committee discussions, the desire to implement them quickly, that the Commission has taken account to some extent stakeholder concerns and that some member states consider the proposed levels not strict enough. Therefore, on that basis the UK will accept the current proposed levels.

Nevertheless, the UK has serious reservations that what was initially intended primarily to harmonise intra union trade and to promote GAP is, in light of the highly conservative EFSA TDI, developing into food safety risk management but without the necessary due process and assessment that this entails. We also consider that this is being done with unnecessary haste and without a substantial data set.

The UK notes that the levels are stated as provisional; Member States may choose how to implement them; Member States can decide what action should be taken for exceedances and that the Commission has stated that if the levels are too challenging in light of new data that they can be changed quickly. However, in all but name these are likely to be seen as de facto maximum limits throughout the EU.

During technical discussion at expert committee it has been acknowledged by all that we don't yet have sufficient data to set maximum limits and that the monitoring process is not complete (indeed the Recommendation on monitoring has not yet been established), therefore it must also be considered that the same is true for the proposed reference levels.

While stakeholder feedback has been taken account of to some extent in the new reference levels and the UK strongly supports this, UK stakeholders have made clear that they don't yet have the data to be sure of their position in regard to the proposals.

Significantly it has also not been made clear that the proposed revisions will have any tangible health benefit for the specific consumers at risk. The principal risk is due to sub optimal iodine nutrition and where iodine nutrition is adequate then the risk to consumers from perchlorate is negligible. Furthermore, perchlorate is only one of a number of goitrogens that inhibit iodine uptake by interfering with thyroid function that are present in the diet, many of which are natural components of foods. It is not clear how the provisional levels for perchlorate or any potential future maximum limits will impact this broader situation.

For the reasons stated above the UK urges that we proceed with caution and care when considering further risk management action in regard to perchlorate.

UK is fully supportive of draft Commission Recommendation on the monitoring of the presence of perchlorate in food. (SANTE/0001/2015).

The UK considers that a limit for the level of perchlorate in fertilizers should be discussed at the relevant expert committee as part of a GAP package."

- endorsement of a draft Commission Recommendation on the monitoring of the presence of perchlorate in food. (SANTE/0001/2015)

The European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain (CONTAM Panel) recommended that there is a need for more data on the occurrence of perchlorate in food in Europe, especially for vegetables, infant formula, milk and dairy products, to further reduce the uncertainty in the risk assessment. High levels have been found in Cucurbitaceae and leaf vegetables especially those grown in glasshouse / under cover. The analysis of perchlorate in drinking water should include, if possible, also drinking water not falling under the definition of food as provided for in Regulation (EC) 178/2002 [2] .

There are not sufficient occurrence data on the presence of perchlorate in food in particular from food sampled after 1 September 2013. Mitigation measures have been put in place since and the data on perchlorate from samples taken thereafter reflect better the principle "as low as reasonable achievable" following good practices and the current presence of perchlorate in food.

Therefore Member States, with the active involvement of food business operators, are recommended to perform monitoring for the presence of perchlorate in food, particularly in :

a. fruits, vegetables and processed products thereof, including juices.
b. foods for particular nutritional uses intended for infants and young children
c. dried herbs and spices; tea; herbal and fruit infusions.
d. beverages, including drinking water.

Furthermore, investigations should be performed to identify the factors resulting in the presence of perchlorate in food. In particular, the analysis of the presence of perchlorate in fertilizer, soil, irrigation and processing water is appropriate in situations where these factors are relevant.
The analytical results are to be provided on a regular basis and at the latest by February 2016 to EFSA in view of the consideration of setting possible maximum levels of perchlorate in certain foods.

The draft Recommendation was endorsed by the Committee.

[1] http://ec.europa.eu/food/food/chemicalsafety/contaminants/docs/statement_perchlorate_in_food_en.pdf

[2] 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 safety (OJ L 31, 1.2.2002, p. 1)

Annex :

The following statement, including the revised levels as reference for intra-Union trade, was endorsed by a large majority of Committee. The Committee was also informed that the statement shall be published on the website of DG Health and Food Safety before 16 March 2015.

“Statement as regards the presence of perchlorate in food endorsed by the Standing Committee on Plants, Animals, Food and Feed on 10 March 2015

Background information

The perchlorate ion (ClO4 -) is very stable in water, and its salts are highly soluble in water. Perchlorate occurs naturally in the environment, in deposits of nitrate and potash, and can be formed in the atmosphere and precipitate into soil and groundwater. It also occurs as an environmental contaminant arising from the use of nitrate fertilizers and from the manufacture, use and disposal of ammonium perchlorate used in rocket propellants, explosives, fireworks, flares and air-bag inflators and in other industrial processes. Perchlorate can also be formed during the degradation of sodium hypochlorite used to disinfect water and can contaminate the water supply. Water, soil and fertilizers are considered to be potential sources of perchlorate contamination in food.
Need for more monitoring data
There is a need for having more data on the presence of perchlorate in food. In particular, there are not sufficient occurrence data on the presence of perchlorate in food sampled after 1 September 2013 as it is considered that then mitigation measures were from then onwards put in place and these data might reflect the principle “as low as reasonable achievable” following good practices. More occurrence data on the presence of perchlorate are also needed to enable a more accurate exposure assessment.

So therefore Member States, with the active involvement of food business operators, are requested to monitor the presence of perchlorate in food. A Commission Recommendation on the monitoring of the presence of perchlorate shall be adopted in April 2015.
The following method of analysis has been identified to provide reliable results:
"Quick Method for the Analysis of Residues of numerous Highly Polar Pesticides in Foods of Plant Origin involving Simultaneous Extraction with Methanol and LC-MS/MS Determination (QuPPe-Method) - Version 7.1" The method can be downloaded from: http://www.crl-pesticides.eu/library/docs/srm/meth_QuPPe.pdf
In addition the article "Analysis of Perchlorate in Food Samples of Plant Origin Applying the QuPPe-Method and LC-MS/MS" has to be consulted in which it is reported how to integrate the environmental contaminant perchlorate into the abovementioned QuPPe multiresidue method. The article can be downloaded from http://www.analytik-news.de/Fachartikel/Volltext/cvuase2.pdf

The Limit of Quantification (LOQ) should be targeted not be higher than 2 µg/kg for the analysis of perchlorate in foods for infants and young children, 10 µg/kg in other foods and 20 µg/kg in dried herbs and spices and dried herbs and tea for infusion.
Sampling is to be performed in accordance with current sampling procedures in place to control the level of nitrates in leafy vegetables and pesticide residues in food.
Investigations on the sources of contamination and related mitigation measures
Member States, with the active involvement of the food business operators, should perform investigations to identify the factors resulting in the presence of perchlorate in food. In particular, the analysis of the presence of perchlorate in fertilizer, soil, irrigation and processing water is appropriate in situations where these factors are relevant.
A harmonised provisional enforcement approach for intra-Union trade
Divergent approaches as regards the issue of perchlorate in fruits and vegetables have resulted in problems/tensions in intra-Union trade and therefore a harmonised enforcement approach was appropriate. This harmonised enforcement approach should take into account the consumer health protection and what is feasible and achievable taking also into account good practices and regional differences.
The provisional enforcement approach is to address problems and possible tensions in intra-Union trade. Competent authorities of Member States can determine to which extent they enforce the levels of perchlorate as reference for intra-Union trade for their domestic production / products placed on their domestic market. The competent authorities of the Member States agreed not to take action below these levels. For taking action, measurement uncertainty has to be taken into account and the level as reference has to be beyond reasonable doubt exceeded, taking into account the correction for recovery and measurement uncertainty.
The revised levels as reference for intra-Union trade, provided in the table hereafter, are based upon available occurrence data obtained after September 2013. The provisional enforcement approach is provisional awaiting the availability of more data on the occurrence of perchlorate in food.
These revised levels as reference for intra-Union trade are of application as from 16 March 2015 and the levels agreed at the Committee on 16 July 2013 are no longer valid.

Levels of perchlorate as reference for intra-Union trade
FOOD (*) level (mg/kg)

(*)
Fruits and vegetables 0,1
with the exception of
- Cucurbitaceae and leafy vegetables except 0.2
- - celery and spinach grown in glasshouse/undercover 0.5
- - herbs, lettuce and salad plants, including rucola, grown in glasshouse/under cover 1.0

Dried spices (except dried herbs and paprika), dried hops 0,5
Tea (Camellia sinensis), dried 0,75
Herbal and fruit infusions, dried 1.0

Foods for infants and young children - ready-to-eat 0,02

Other food 0,05
(*) The levels as reference values for intra-Union trade applies, insofar not specified, to the unprocessed food. For dried, diluted, processed and compound foodstuffs, Article 2 of Regulation (EC) 1881/2006 is of application."

A.02 Endorsement of a guidance document for competent authorities on the application of Article 9(4) of Regulation (EU) 884/2014.

Following the comments made at the Committee on 11 February 2015, the guidance document was modified and presented.

Some further editorial amendments were suggested and accepted.

The Committee endorsed the guidance document for competent authorities on the application of Article 9(4) of Regulation (EU) 884/2014.

The Commission representative indicated that the guidance document would be published on the website of DG Health and Food Safety [3] shortly after the meeting. He stressed the importance of a correct application of the guidance to ensure a good functioning of the control provisions provided for in Regulation (EC) 884/2014.

[3] http://ec.europa.eu/food/food/chemicalsafety/contaminants/docs/guidance_art-9-4.pdf

A.03 Exchange of views and discussion on possible ways forward as regards the Fusarium toxin contamination situation in the European maize harvest 2014.

The weather conditions that preceded and accompanied the 2014 maize crop have been characterized by an unprecedented warm winter followed by an exceptionally wet spring and abundant rain in summer.
The level of Fusarium toxins (deoxynivalenol, fumonisins and zearalenone) found in the raw maize crop is significantly high and very often above the maximum regulatory limits prescribed for mycotoxins presence in raw materials and food products. The occurrence of

mycotoxins is extended to a large portion of the European territory (EU and non-EU countries).

As a consequence, up to 60 % of the maize that was initially destined for the milling industry exceeds the regulatory levels for at least one mycotoxin.

Maize millers use maize varieties that have particular and essential quality characteristics. For these reasons, milling maize varieties are produced under supply chain contracts to respond to the needs of the maize milling industries. The reduced availability of milling maize in the EU related to exceeding regulatory limits for mycotoxins causes a supply problem.

Therefore a request for a temporary derogation was introduced by a major EU stakeholder organisation.

As in previous meetings, divergent views were expressed as regards this request for derogation. Several delegations supported explicitly the request for derogation while a few other delegations indicated not to support the request for derogation. The reasons for not supporting the requested derogation were related to the risk for public health in particular for persons suffering from coeliac disease, despite the conclusions of the scientific statement from EFSA delivered on the 22 May 2014 [4] indicating that a temporary (slight) increase of the maximum levels for deoxynivalenol, zearalenone and fumonisins would not increase significantly the risk for public health, whilst recognising that the human exposure to these mycotoxins is high.

Other delegations indicated to support the request for derogation to a certain extent but were of the opinion that it would be appropriate to limit the derogation. Several options were put forward for consideration :

- derogation for deoxynivalenol, being the main problem, and not for zearalenone and fumonisins;
- derogation only for unprocessed maize and intermediate cereal products but no derogation for finished products;
- the derogation for finished products should be limited to a few well described products (e.g; cornflakes) and not cover large food groups (e.g. maize based foods).

Furthermore if the derogation is granted, guidance is needed on the enforcement.

The Commission indicated to consider the different viewpoints and to work out a proposal for consideration and conclusion at the next meeting of the Committee on 14 April 2015. Also the stakeholder organisations shall be kept informed and their views on possible options for derogation will be requested.

[4] EFSA (European Food Safety Authority), 2014. Evaluation of the increase of risk for public health related to a possible temporary derogation from the maximum level of deoxynivalenol, zearalenone and fumonisins for maize and maize products. EFSA Journal 2014;12(5):3699, 61 pp. doi:10.2903/j.efsa.2014.3699
Available at: http://www.efsa.europa.eu/en/efsajournal/doc/3699.pdf

A.04 Exchange of views on the envisaged review of Commission Implementing Regulation (EU) 322/2014 imposing special conditions on the import of feed and

food originating in or consigned from Japan following the accident at the Fukushima nuclear power station.

The Commission representative presented the envisaged review of the measures currently under consultation within the Commission, based upon the more than 81 000 occurrence data on radioactivity in feed and food other than beef provided by the Japanese authorities concerning the fourth growing season after the accident.

In view of ensuring consistency and predictability in policy as regards measures on feed and food from Japan, it is proposed to base the review on the same principles as for 2014 applied to prefectures other than Fukushima.

These principles are :

A list of feed and food products from the zone of prefectures with restrictions has to be pretested before export to the European Union.
* A prefecture was listed in case a non-compliance has been found by the Japanese authorities in a product originating from that prefecture during the growing season preceding the review.
* A feed or food product was listed in case a non-compliance has been found by Japanese authorities during the growing season preceding the review in that product originating from the zone with restrictions (except Fukushima).

- In a few prefectures the only non-compliance found was related to mushrooms, known to accumulate radioactivity. For these prefectures, only mushrooms have to be pretested before export to the European Union. In a few other prefectures only mushrooms and a few wild edible plants were found to be non-compliant, and only for these products pretesting is required before export to the EU.

Applying these principles the following changes to Implementing Regulation (EU) 322/2015 are proposed:

a. Delisting of the two prefectures Aomori and Saitama because no non-compliance has been found.
b. For the prefectures within the "zone with restrictions" (Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Iwate and Chiba), lifting of the pretesting requirement for rice, soybeans, Uwabamisou and buckwheat is proposed The pretesting requirement for mushrooms , fish and fishery products, and some listed edible wild plants and the processed and derived products thereof are proposed to be maintained.
c. For the prefectures Akita, Yamagata and Nagano, lifting of the pretesting requirement for bracken is proposed. The pretesting requirement for mushrooms and some listed edible wild plants and the processed and derived products thereof are proposed to be maintained and it is also proposed to add Japanese royal fern bracken.
d. For the prefectures Shizuoka, Yamanashi and Niigata, it is proposed to maintain the pretesting requirement for mushrooms and to add Koshiabura.

For Fukushima a more cautious approach is proposed compared to the other prefectures and therefore non-compliances in 2 consecutive years (2013 and 2014) is

required to delist a product from the pre-testing requirement. Following this approach, pretesting is needed for: mushrooms, fish and fishery products, rice, soybeans, (Japanese) persimmon, Japanese and giant butterbur (fuki), Aralia spp., bamboo shoot, bracken, Japanese royal fern, Ostrich fern and Koshiabura compared to the current situation whereby it is required that all feed and food (except alcoholic beverages) from the prefecture Fukushima continued to have to be pretested before export to the EU .

To reduce the administrative burden, it would be no longer required to report three monthly all analytical results of the control at import to the Commission (in case of finding of non-compliance, notification to the RASFF).

An exchange of views took place. A few delegations were in favour of a further alleviation of the measures than proposed given that the controls at import performed until now provide evidence that the Japanese authorities have the situation under control. On the other hand, a few delegations were of the opinion that it would be appropriate to be more cautious as regards feed and food from the prefecture Fukushima. Most delegations supported to a very large extent the measures as proposed.

Also the need to keep the specific recommendation provided for in RASFF notification 11-653-add 30 of 3 January 2012 on the monitoring on an at random basis for the presence of Caesium-134 and Caesium-137 migratory pelagic fish in FAO Major Fishing Area 61 and derived/processed products thereof was discussed. The migratory pelagic fish species of relevance are the tuna (albacore, bluefin, bigeye and skipjack) and billfishes (swordfish and marlin).
After some discussion, it was concluded that it was appropriate to keep the recommendation but it is up to the competent authorities of the Member States to decide to which extent this recommendation is implemented in their country.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs.

Katsuobushi is a traditional Japanese food product made from bonito. Recent evidence has been provided that the lower MLs for polycyclic aromatic hydrocarbons (PAHs) applicable as from September 2014 are not achievable. Therefore the draft Regulation foresees that the maximum levels, applicable before 1 September 2014, continue to apply to *Katsuobushi*.
The product name "*Sprotid*" is a general traditional name in Estonia for a product which traditionally can contain both sprat and Baltic herring depending on the season and availability. The smoking procedure for this small Baltic herring is the same as the one applied to sprats and consequently levels of PAHs are similar. Therefore the draft Regulation provides to establish the same maximum level for both fish species.
One delegation could not agree on the draft Regulation as PAHs are genotoxic carcinogen and in any increase of the level in any product is not acceptable.

Vote taken: favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards the maximum level of OTA in Capsicum sp.

To enable the spices producing countries to put prevention measures in place and in order to avoid disruptions of trade to an unacceptable extent, it was foreseen that for a limited period of time a higher maximum level was applicable. Although there is a significant improvement in the application of good practices in the different producing regions in the world, the projected lower maximum level for OTA is not achievable in paprika. It is therefore proposed to establish a somewhat higher maximum level for OTA in paprika which is achievable by applying good practices and which ensures a high level of human health protection.

One delegation could not support the draft Regulation as they are not in favour of the increase of the maximum level for OTA given that OTA is carcinogenic substance but acknowledged that *Capsicum* spp are only a minor contributor of the human exposure to OTA.

Vote taken: favourable opinion.

M.01

No points were raised under any other business.