EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH HELD IN BRUSSELS ON 20 FEBRUARY 2014

(Section Toxicological Safety of the Food Chain)

A.01 Monitoring of the presence of 2 and 3-monochloropropane-1,2-diol (2 and 3-MCPD), 2- and 3-MCPD fatty acid esters and glycidyl fatty acid esters in food.

Monochloropropane-1,2-diol (3-MCPD) is a food processing contaminant classified as a possible human carcinogen for which a tolerable daily intake (TDI) of 2 µg/kg b.w. has been established. A maximum level of 20 ug/kg for hydrolysed vegetable protein (HVP) and soy sauce has been established for liquid products containing 40 % dry matter, corresponding to a maximum of 50 µg/kg in the dry matter by Commission Regulation (EC) 1881/2006.

Esters of 2 - and 3-monochloropropane-1,2-diol (MCPD) and glycidyl esters are important contaminants of processed edible oils used as foods or food ingredients. EFSA has published on 20 September 2013 a scientific report on the analysis of occurrence of 3-monochloropropane-1,2-diol (3-MCPD) in food in Europe in the years 2009-2011 and preliminary exposure assessment.

More occurrence data on the presence of the MCPD fatty acid esters and glycidyl fatty acid esters are necessary to enable a more accurate exposure assessment.

Therefore in this draft Recommendation, the monitoring of the presence of MCPD, MCPD-esters and glycidyl esters in vegetable oils and fats, derived foods and foods containing vegetable oils and fats is recommended.

Certain delegations indicated that national consultations on this draft Recommendation are still ongoing and therefore a possible endorsement of this draft recommendation was postponed to the next meeting of the Committee.

A.02 Outcome of the acrylamide workshop on 13-14 January 2014. Issues for attention and conclusions.

The Committee was informed on the outcome of the acrylamide workshop, organised by the European Commission and which was held on 13-14 January 2014.

It was expected that every sector presented in detail at the workshop how the FoodDrinkEurope (FDE) toolbox is implemented in practice in the production process. In addition each sector was invited to give concrete information on how the hazard acrylamide is managed within the HACCP system and to provide information on the critical control points, critical limits at critical control points, monitoring procedures at critical control points, corrective actions when monitoring indicates that a critical control point is not under control (Article 5 of Regulation (EC) No 852/2004.

Also for the tools in the toolbox identified as commercially applicable, it was mentioned that it would be appropriate to provide an estimate to which extent the tools were implemented in the sector.

Also consumer organisations were invited to present their initiatives/campaigns towards consumers to make them aware of the good cooking practices to keep acrylamide levels in home prepared foods as low as possible.

At the workshop the major importance of the breeding and agricultural sector was highlighted to control the presence of acrylamide in potato and cereal-based foods.

For potatoes, the following points were highlighted :

- The need to develop potato varieties with in particular low reducing sugar content and low free asparagine content
- Good storage conditions to avoid formation of high quantities of reducing sugars
- Difference in existing varieties as regards formation of reducing sugars
- Influence of fertilisation on acrylamide forming potential of potatoes.

For cereals, the following points were highlighted :

- Need to develop cereal varieties with low free asparagine content.
- Environmental factors have significant effects on free asparagine content
- Sulphur deficiency results in massive accumulation of free asparagine in wheat grain
- Nitrogen fertilisation increases free asparagine and total free amino acid concentration in cereals.

The milling sector has an important role and responsibility as intermediate sector between the agricultural sector and the food processing to raise the awareness of the importance of low free asparagine containing cereal varieties and to continuously highlight the need for availability of low free asparagine containing cereals in order to enable the milling sector to provide the food processing industry with low free asparagine containing cereal flours.

For the sector of coffee and coffee substitutes, there are for the time being no commercially applicable tools for reducing acrylamide available. The control of acrylamide is done to the extent possible through prerequisite programs.

The potato crisp and French fries industry provided concrete information on how the hazard acrylamide is managed within their production process by :

- Managing incoming potatoes for reducing sugar content
- Process control through higher moisture in finished product and reducing fryer temperature (potato crisps)
- Process control through blanching, using disodium diphosphate, dextrose and control of temperature and moisture (French fries)
- Removing dark coloured crisps
- Guidance on optimal frying (French fries).

As regards the sector of breakfast cereals, the efforts and tools to reduce acrylamide content used by the sector were not presented in detail at the workshop. After the workshop, information was provided by the sector that the efforts to reduce acrylamide content are related to the control of temperature/pressure/time /moisture/colour and flavour during the cooking and toasting process.

The plant bakery sector and the fine bakery sector presented the tools but no concrete information was provided how and to which extent the tools are applied by the sector to reduce acrylamide content.

The baby food sector presented the tools for several baby food products but each tool was presented with limitations in application and therefore no concrete information was provided how and to which extent the tools are applied by the sector to reduce acrylamide content.

Results of recent surveys were presented by the consumer organisation, highlighting that in certain products still high levels of acrylamide are found, concluding that more efforts are needed to reduce the acrylamide content. Information was provided on raising consumer awareness as regards the acrylamide issue but more efforts to raise awareness will be necessary in the future.

Finally a presentation was made by the UK competent authority on possible way forward from a regulatory point of view to reduce the acrylamide content in food. The competent authority from Poland presented the findings on acrylamide in their country.

A.03 Report for 2012 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products.

During the 2012 monitoring campaign on residues of veterinary medicinal products in food of animal origin in accordance with Directive 96/23/EC, over 770.000 samples were analysed. The non-compliance rate was 0,25%. Non-compliances related to

hormones are influenced by the natural presence of certain substances in certain plants and new information on natural formation of some hormones.

In authorised veterinary medicinal products, the non-compliance rate is highest for the animal species for which little veterinary medicinal products are available (rabbit, farmed game and honey). The high non-compliance rate (> 4 %) in horses demonstrates that it is justified to apply a strict enforcement of existing EU legislation in this sector.

A.04 Guidance document on criteria for categorisation of food enzymes.

The guidance document on criteria for categorisation of food enzymes was presented. The purpose of this guidance document is to provide food business operators and competent authorities with criteria for determining the status of a food enzyme either as an ingredient or as a processing aid.

A decision tree and the principles for using it have been established where the absence/presence of the food enzyme in the final food after processing and the absence/presence of a technological function of the food enzyme in the food as marketed or as prepared by consumer are the two issues that are considered for differentiating food enzymes used as processing aids and as ingredients.

Only one Member State was not in favour of the guidance document due to some discrepancies in relation to the classification of food enzymes as processing aids.

The Commission explained that the guidance document was the best compromise taking into account the different views of some Member States. The guidance document can be updated to incorporate further concrete examples on the basis of the experience gained during the assessment of the food enzyme dossiers.

A.05 Union Guidelines on Regulation (EU) N° 10/2011 related to general requirements.

The Guidelines were welcomed by the Member States. Comments received from some Member States were discussed. On the request for availability of the guidelines in all EU languages the Commission services acknowledged the importance of different language versions and will make translations available provided available resources allow for this. Outcome of the discussion : the Guideline was endorsed by the Committee.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station.

The measures, contained in Implementing Regulation (EU) 996/2012 which were taken following the accident at the nuclear power station in Fukushima as regards food and feed imported from Japan are up for revision by 31 March 2014. Several revisions have already taken place since the accident in March 2011. This review is based on the occurrence data on radioactivity in feed and food provided by the Japanese authorities of the 3rd growing season (period January 2013 – December 2013) after the accident.

The Japanese authorities have provided about 85.000 data on the presence of radioactivity in a wide range of foodstuffs (except beef) and 232.000 data on beef from the 3rd growing season and mainly originating from the prefectures from the zone with restrictions.

The review continues to apply the following principles :

- All feed and food (except alcoholic beverages) from the prefecture Fukushima continue to have to be pretested before export to the European Union, independently of the analytical results for certain feed and food products.

- 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 is listed in case a non-compliance has been found by the Japanese authorities in a product originating from that prefecture during the 3rd growing season. A feed or food product is listed in case a non-compliance has been found by Japanese authorities during the 3rd growing season 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 or to mushrooms and a few wild edible plants. For these prefectures, only mushrooms and these wild edible plants have to be pretested before export to the European Union.

The examination of the occurrence data and the application of the principles results in the following measures proposed for consideration for this review :

The restrictive measures in place have been lifted for 2 prefectures (Tokyo and Kanagawa) and have been eased for 7 other prefectures (Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Iwate and Chiba). For 4 other prefectures (Shizuoka, Yamanashi, Niigata and Aomori), restrictive measures remain in place for mushrooms and for 3 other prefectures (Nagano and two newly included prefectures Akita and Yamagata) restrictive measures have been put in place for a few products (mushrooms and a few edible wild plants). For the control at import, a further reduction of the frequency of controls will apply.

For tea, no non-compliance has been found in the 3rd growing season and for that reason no pretesting is required for tea originating from the zone with restrictions.

Also no non-compliance has been found in tea originating from the prefecture Fukushima, where it is only grown to a very limited extent and according to the Japanese authorities not exported to the EU. It is proposed to no longer require a declaration of origin for tea originating from prefectures other than Fukushima, and this shall result in a significant reduction in administrative burden.

Based on the monitoring results from the 2014 growing season, it is foreseen to undertake a review of these measures shortly before 31 March 2015.

Several delegations indicated that it would have been appropriate to discuss the review of the measures in detail in a specific dedicated meeting of experts, enabling to examine the data, as this possibility was mentioned at the last meeting of the Committee. The Commission indicated that this was indeed mentioned but there was not enough time for such an expert consultation to ensure a timely adoption and entry into force of the measure before the expiry of the current measure on 31 March 2014. However the Commission representative committed to organise such an expert consultation for the next review before 31 March 2015.

One delegation mentioned that different formats of the declaration are used depending on the prefecture in which they are issued and that it not always easy for the inspector to identify the signature on the list of authorised signatures corresponding with the signature on the declaration. The Commission representative indicated to raise these issues with the Japanese authorities in order facilitate the control.

One delegation was of the opinion that although it is acknowledged that no non-compliances were identified as regards tea from Japan, the delegation was of the opinion that it would be appropriate to maintain the requirement of the declaration of origin for tea originating from prefectures other than Fukushima.

Finally a clarification was requested as regards “random controls”. The Commission representative indicated that with random controls it is meant that controls at import should take place at a low frequency of controls i.e. less than 5 % of imported consignments should be controlled.

Vote taken: Qualified majority (323 votes in favour, 29 votes abstained).

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) N° 1152/2009.

The point was not discussed as the internal Commission consultation procedure was not yet finalised.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) laying down specific conditions applicable to the import of okra and curry leaves from India repealing Commission Implementing Regulation (EU) N° 91/2013.

The point was not discussed as the internal Commission consultation procedure was not yet finalised.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EC) N° 1881/2006 as regards erucic acid.

As a consequence of the entry into force of the Lisbon Treaty, the powers conferred on the Commission by Council Directive 76/621/EEC in order to implement some of their provisions need to be aligned to Article 290 of the Treaty on the Functioning of the European Union.

Council Directive 76/621/EEC establishes a maximum level for erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils and fats. Erucic acid is a natural plant toxin which is a contaminant according to the definition of the contaminant provided in Council Regulation (EEC) No 315/93 as the presence of erucic acid in food is the result of the agricultural production, more in particular the choice of the variety. To simplify legislation it is appropriate to establish the maximum level for erucic acid in Regulation (EC) 1881/2006. Furthermore it is appropriate to harmonise the provisions for foodstuffs with a fat content equal or less than 5 %. Council Directive 76/621/EEC shall then be repealed subsequently.

A stricter maximum level for erucic acid in infant formulae and follow-on formulae has been established by Commission Directive 2006/141/EC, and it is appropriate to indicate this maximum level also in Regulation (EC) No 1881/2006.

The measures have been taken over in the draft Regulation as provided for in Directive 76/621/EEC. A more in depth examination of the measures itself will take place once the EFSA scientific opinion on the risk assessment of the presence of erucic acid in feed and food is available. A request for such a scientific opinion will be addressed to EFSA within short notice.

Vote taken: unanimous in favour.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision amending Decision 98/536/EC as regards the list of national reference laboratories.

The amendment of the list of national reference laboratories active in monitoring of residues of veterinary medicinal products in food of animal origin under Directive 96/23/EC was voted.

Vote taken: unanimous in favour.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) N° 1333/2008 of the European Parliament and of the Council as regards the food categories of meat and the use of several additives in meat preparations as defined by Regulation (EC) N° 853/2004.

The new Union list of food additives (applicable since June 2013), provides much more transparency and clarity about the authorisation status of additives. In addition the guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004, endorsed by all Member States on 17 June 2013, clarified how to distinguish between meat preparations and meat products.

Following this, the industry and certain Member States, realised that additives are used in the meat area that are not (and were never) authorised and have introduced requests to authorise some of these uses in certain traditional as well as more general uses in non-traditional meat preparations.

The requests have been presented and discussed with the relevant Member States' experts. Following these discussions the Commission prepared a draft measure in which it extends the use of certain additives in traditional meat preparations was presented.

During the discussion some Member States, in particular those that do not have traditional meat preparations, expressed concerns that their products are discriminated. Other Member States raised concern that the traditional products are insufficiently described and that the extension of the use of nitrites in these products may create additional risk for the consumer.

Vote postponed

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) N° 1333/2008 of the European Parliament and of the Council as regards the use of polyvinyl alcohol-polyethylene glycol-graft-co-polymer in solid food supplements and the Annex to Commission Regulation (EU) N° 231/2012 as regards its specifications.

The Commission received an application for authorisation of the use of polyvinyl alcohol-polyethylene glycol-graft-co-polymer (PVA-PEG graft co-polymer) in aqueous instant-release film coatings for food supplements.

The European Food Safety Authority evaluated the safety of PVA-PEG graft co-polymer when used as a food additive and concluded that its use in food supplements as film coating is of no safety concern for the proposed uses.

PVA-PEG graft co-polymer is intended for use in aqueous instant-release film coatings for food supplements. It protects against unpleasant tastes or odours, improves appearance, makes tablets easier to swallow, gives a distinctive appearance, and protects sensitive active ingredients. A specific property of the substance is that it is extremely flexible, has low viscosity, and dissolves rapidly in acidic, neutral, and

alkaline aqueous media. It is therefore appropriate to authorise the use of PVA-PEG graft co-polymer as a glazing agent in solid food supplements and to assign E 1209 as E-number to that additive.

The specifications for PVA-PEG graft co-polymer should be included in Regulation (EU) No 231/2012 when it is included in the Union lists of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.

Vote taken: Qualified Majority (340 votes in favour, 12 votes abstained).

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) N° 1333/2008 of the European Parliament and of the Council as regards the use of caramel colours (E 150a-d) in beer and malt based drinks.

The European Food Safety Authority issued an opinion on 3 February 2011 as regards the re-evaluation of the safety of caramel colours as food additives. In that opinion the Authority established a group ADI of 300 mg/kg bw/day. Within this group ADI an individual ADI of 100 mg/kg bw/day was established for E 150c ammonia caramel. In December 2012, the Authority issued a statement providing a refined exposure assessment for the caramel colour E 150c the ADI be exceeded.

After considering more detailed national information about the real uses of ammonia caramel (E 150c), the Member States concerned demonstrated that the actual intake is significantly lower. However, taking into account that beer is the main contributor to the exposure in adults, it is appropriate to amend the conditions of use and to establish maximum use levels for ammonia caramel (E 150c) in food subcategory 14.2.1 'Beer and malt beverages' to guarantee a high level of protection of human health.

In addition, an application for authorisation of the use of caramel colours (E 150a-d) in malt beverages was submitted on 4 June 2013 and was made available to the Member States.

Beer is not defined in the Union legislation and the national definitions vary among the Member States. Consequently a particular product classified as beer in one Member State could be classified as malt beverage in another. Since there is a technological need for caramel colours (E 150a-d) in malt beverages and the use of caramel colours is authorised in beer only, the current situation has a negative impact on the internal market and hinders the free movement of those products. Therefore it is appropriate to rectify this situation.

The common characteristic of malt beverages is the absence of malt as such in the final product and similarities in the technology and in the need for food additives with beers. There is a need for caramel colours to restore a consistent colour which has been affected by the production processes and/or to make malt beverages made from pale malts visually more appealing. Roasted malts cannot be used to provide the dark colour since they impart strong flavour which is not appropriate for those products.

Malt beverages are niche products providing an alternative to products in which the use of caramel colours is currently authorised (i.e. flavoured drinks and beers). Therefore, it is not expected that the authorisation of use of caramel colours in malt beverages would have a significant impact on total exposure to caramel colours.

Vote taken: unanimous in favour.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) N° 1333/2008 of the European Parliament and of the Council as regards the use of Advantame as a sweetener and the Annex to Commission Regulation (EU) N° 231/2012 as regards its specifications.

The Commission received an application for authorisation of the use of advantame as a sweetener in several food categories.

There is a technological need for the use of advantame as a food additive in various food and table-top products in order to replace caloric sugars thus allowing for a reduction of the caloric content of those foodstuffs.

The addition of advantame as a sweetener to the categories of foods in which high-intensity sweeteners are authorised according to Annex II to Regulation (EC) No 1333/2008 will provide manufacturers with greater flexibility in formulating energy-reduced foods, meaning that advantame provides an alternative to already approved high-intensity sweeteners, offering consumers and the food industry the option to choose from a wider selection of sweeteners, thus reducing the intake of each individual sweetener.

The European Food Safety Authority evaluated the safety of advantame when used as a food additive and expressed its opinion in 2013. It established an ADI for advantame of 5 mg/kg bw/day and concluded that the proposed uses and use levels of advantame as a sweetener would not be of safety concern. Therefore, it is appropriate to authorise the use of advantame as a sweetener and to assign E 969 as an E-number to that food additive.

The specifications for advantame should be included in Regulation (EU) No 231/2012 when it is included in the Union lists of food additives laid down in Annexes II and III to Regulation (EC) No 1333/2008 for the first time.

Therefore, Regulations (EC) No 1333/2008 and (EU) No 231/2012 should be amended accordingly.

One Member State abstained as in its opinion the draft should reflect that advantame is a source of phenylalanine. Commission referred to EFSA's opinion on advantame where it is considered that the maximum possible exposure (estimated based on weight basis) to phenylalanine expected from ingestion of advantame as a general purpose sweetener was much lower than the dietary exposure to that compound, and therefore, of no safety concern for healthy consumers (adults and children). For a phenylketonuric child, the additional phenylalanine intake expected from ingestion of

advantame-containing foods and beverages would represent a small increment (less than 1%) in the exposure to phenylalanine.

Vote taken: qualified majority (342 votes in favour, 10 votes abstained).

M.01 A.O.B.

Exchange of views on recent RASFF notifications regarding the presence of chloramphenicol in papain :

Chloramphenicol (CAP) is an antibiotic which use is prohibited in food producing animals. For control purposes, a Minimum Required Performance Limit (MRPL) of 0.3 µg/kg is established by Commission Decision 2002/657/EC for CAP in food of animal origin.

Following detection of CAP in quantifiable amounts with methods of analysis capable of detecting at least 0.3 µg/kg of CAP in enzymes, enzyme preparations, premixtures and food ingredients (semi-finished food products), the SCFCAH at its meeting held in Brussels on 21 October 2013 confirmed the use of the MPRL for the management of the contamination incident relating to the presence of CAP in concerned commodities. Such commodities cannot be used for feed and food production. They cannot be placed on the market and have to be withdrawn from the market.

In November 2013, levels of CAP higher than the MRPL were detected in papain obtained from papaya. Further investigations including sampling and analysis have been carried out by the papain producing companies concerned. Some samples of latex (raw material) contained levels of CAP up to 10 ppb, while some samples of enzyme preparations (concentrated powder or liquid form) contained up to 20 ppb CAP (in the concentrated powder). The companies concluded that the only possible source of CAP is the uptake by the papaya plant. Uptake by plants of CAP present in the soil is supported by a number of scientific publications. The company has further provided data indicating that the levels of CAP in the final food are much lower than the MRPL due to the very low quantities of papain used in food applications.

The above measures agreed at the Standing Committee of 21 October 2013 for the management of the contamination incident are also applicable for intermediate products and products destined for the final consumer in which papain is used. However, these measures should not apply to the papain preparation as such provided that levels of CAP in papain are related to natural presence and that it is restricted to business to business market.

All above mentioned risk management measures are transitional measures until the EFSA's risk assessment on the presence of CAP in food is available and subsequently the Commission together with the Member States re-assess the situation.

Chlorates :

A delegation raised the issue of the presence of chlorates in fruits and vegetables and made reference to the draft guidelines as regards targeted monitoring to be undertaken

as regards the presence of chlorates in feed and food, which are foreseen to be discussed at the section Pesticide residues the Standing Committee of the Food Chain and Animal Health on 24 and 25 February 2014. Although chlorates were previously used as pesticides (herbicides), their use in the EU is no longer authorised since 2008. The presence of residues of chlorates is therefore very probably not related to the use of chlorates as pesticides but probably other sources. Therefore, the delegation was of the opinion that the presence of chlorates in fruits and vegetables should be regulated as a contaminant rather than as a pesticide residue, as is the case for perchlorate.

The Commission representative replied that there is a difference between perchlorate and chlorates. Perchlorate has never been authorised as pesticide or biocide, while chlorates were in the past authorised as pesticides. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin provides for the possibility to establish a temporary MRL where pesticide residues may arise as a result of environmental or other contamination and therefore regulating the presence of chlorates in feed and food falls within the scope of Regulation (EC) 396/2005.