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 25 NOVEMBER 2015

(Section Toxicological Safety of the Food Chain)

CIRCABC Link: *https://circabc.europa.eu/w/browse/03e6d750-28b6-41b8-9397-75abdab4f950*

A.01 Approval of the national residue monitoring plans for residues of veterinary medicinal products in food of animal origin.

Following evaluation by the European Commission Directorate General for Health and Food Safety (DG SANTE) and a review by the European Union Reference Laboratories, the 28 Member States' residue monitoring plans for animals and animal products for 2015 are considered to be in conformance with Council Directive 96/23/EC.

As stipulated in Article 8(2) of this Directive, each Member State has ten working days in which to provide comments on the plans. If no comments are received by 11 December 2015, the plans shall be deemed to be approved which will be reflected accordingly in the residues application.

A.02 Note of the French Authorities to the European Commission concerning the use of E 450 in canned crustaceans under Regulation (EC) No 1333/2008 on food additives.

In the note the French authorities request clarification as regards the use of the term canned, which they consider as products that are "food biologically stable in airtight containers". Certain Member States interpret canned referring to products in containers regardless of whether these types of food are sterilised to maintain them stable at ambient temperature or marketed chilled (semi-preserved product).

As there was divergence in view of the Member States, it was suggested to bring this for further consultation on the agenda of the Meeting of the Working Party of Governmental Experts on Additives.

A.03 Feedback from the Workshop and Conference on Regulatory Challenges on Innovation in food of 8-9 and 10 October 2015.

At the occasion of Expo Milan 2015, DG SANTE organised a workshop and a conference on regulatory challenges on innovation in food. Both events focused on food additives, food enzymes, flavourings, novel foods and food contact materials. For each of these topics EU framework regulations exist and authorisation procedures are in place.

The events aimed at recognising the challenges for the EU legislation, and to receive feed-back from stakeholders on whether the legal framework sufficiently allow the food business operators to bring new, innovative products on the market. At the same time it was an opportunity to exchange views between researchers, regulators, the food industry and consumer organisations on how the legislation can better guarantee that future innovations will meet consumer needs.

The objective of this note is to inform the Committee about the main feed-back received from the stakeholders related to the Food Improvement Agents. A more comprehensive report including conclusions and recommendations on novel foods and food contact materials will be presented at a later stage.

- Overall, stakeholders are happy with the regulatory framework in area of additives, enzymes and flavourings.
- Potential applicants often have difficulties to understand the rules and procedures for new authorisations. This is also illustrated by many incomplete application dossiers.
- A main issue raised by the food industry is the time to get access to the market and consequently the timelines of the procedures. For the industry, regulatory delays reduce the attractiveness of innovation. Shortening of timings allow better and quicker return on investment.
- The USA and Japan have authorisation systems, with well determined deadlines, in place that are based on risk analyses. Both countries have systems to support applicants to efficiently prepare application documents. Furthermore, in the USA, a self-regulating GRAS (Generally Recognised as Safe) system allows immediate access to the market when there is scientific consensus that there is no safety concern. In Japan a specific procedure exist for ordinary food ingredients used as food additive.
- A presentation was made by DG JRC about project “Delivering on EU Food Safety and Nutrition in 2050 - Future challenges and policy preparedness”. A main conclusion is that for the regulators, flexibility and foresight will be required.
- The consumer organisations are open to innovations in food. Benefits for the consumer must be considered and well explained. The opinion of the consumer is not always well understood. Consumers can support innovations such as more efficient production processes or more efficient use of resources, even if they are not of direct benefit to the consumer.

The following recommendations and requests were expressed at the conference :

- Monitoring and correct implementation of the EU rules was considered essential to have trust in the EU food safety system.

- More guidance is needed in particular destined at SME's preferably in the different EU languages. Training session in order to understand better these guidance's are considered to be useful.
- Pre-notification meetings with applicants on information needed in the dossiers and to provide preliminary feed-back on dossiers are considered valuable. This was also requested to EFSA, in order to prepare quality dossiers and to avoid stop the clock procedures.
- Improved collaboration/consultation to timely inform about innovations and to take into account consumers was requested.
- Improved transparency of the authorisation procedure is requested. Consumer organisations asked to be informed and heard at an earlier stage of the procedure.
- The regulator has a role in communication, however he should be neutral. Benefits of the innovations should be clearly explained.

A.04 Exchange of views on the labelling of substances having a technical function in the production of bakery ware.

Regulation (EC) No 1333/2008 authorises the use of several additives as flour treatment agents. These are substances, other than emulsifiers, that are added to the dough to improve its baking quality: phosphoric acid and phosphates (E 338 – 452), ascorbic acid and ascorbates (E 300 – 301) and L-cysteine (E 920). These agents contribute to the stability of the dough, the structure of the crumb and the volume of the bread. Other additives such as emulsifiers and raising agents that are authorised for use in bakery ware will also contribute to the structure and volume.

As these substances are used for a technical purpose in the manufacturing and processing of the bakery ware, in which they remain present as such or as by-product, they are considered to be a food additive. In accordance with Regulation (EU) No 1169/2011 on the provision of food information to consumers, they have to be included in the list of ingredients. Therefore the exemption rules for labelling according to Article 20 of that regulation do not apply.

The Commission clarified that these substance do not have a function in the flour to which they are added, but they serve a function during the manufacturing of the bread. This point of view was agreed during a Meeting of the Working Party of Governmental Experts on Additives.

The UK requested to bring this back to that working group for further discussion.

A.05 Feedback from the Expert Committees on contaminant issues in particular as regards the foreseen recast of Commission Regulation (EC) No 1881/2006 (details to follow).

As no meetings of the Expert Committees have taken place since the previous meeting of the Committee, a short feedback was provided on a number of files under discussion :

- as regards the recast of Regulation (EC) 1881/2006: a dedicated ad hoc meeting is taking place on 26 November (the day after the meeting of the Committee) and it is foreseen to have an additional discussion on the recast in

the specific Expert Committees (i.e. Agricultural Contaminants, Industrial and Environmental Contaminants and POPs in Food) before finalisation. It is the intention to submit the draft Regulation for opinion at the next meeting of the Committee, scheduled on 4 February 2016.

- as regards acrylamide, delegations were informed that an options paper was submitted for discussion at meeting of the Expert Committee Industrial and Environmental Contaminants on 21 and 22 September 2015. Divergent views as regards the appropriate regulatory approach were expressed. Based on the outcome of the discussions at that meeting and taking into account new information provided by stakeholder organisations (which is regularly uploaded on CIRCABC for information to the competent authorities of the member States) the Commission services intends to present a concrete proposal on the way forward for discussion at the meeting of the Expert Committee "Industrial and Environmental Contaminants" scheduled for 16 December 2015.

- as regards the topics pyrrolizidine alkaloids in honey, tea, herbal infusions, herbs, spices and food supplements, opium alkaloids in poppy seeds and tetrahydrocannabinol in hemp derived foods and monitoring in food of animal origin, no specific progress cold be reported as no meeting of the Expert Committee has taken place since the previous meeting but it was announced that it is foreseen to have a discussion on these topics at the forthcoming meeting of the Expert Committee "Agricultural Contaminants" scheduled on 14 December 2015.

A.06 Exchange of views on the follow-up of the EFSA opinion on FGE.203.

Following the earlier discussions on this issue, the Commission presented an overview of a measure establishing a deadline for submitting additional scientific data on the 20 substances of the group and also amending their conditions of use. This will be further discussed at the working group on flavourings.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the title of the food category 12.3 Vinegars.

The Union list of food additives was established based on food additives permitted for use in foods in accordance with Directives of the European Parliament and of the Council 94/35/EC, 94/36/EC and 95/2/EC and after reviewing their compliance with Articles 6, 7 and 8 of Regulation (EC) No 1333/2008. The Union list includes the food additives on the basis of the categories of food to which they may be added to.
Acetic acid (also used as a food additive E 260), when diluted with water (4-30 % by volume) and used for purposes other than a food additive, is fit for human consumption and could be used as a food or food ingredient in the same manner as vinegars from agricultural origin.

It followed from the discussions with Member States at the Working Party of Governmental Experts on Additives that there is an equivalent technological need for food additives for diluted acetic acid and for vinegars from agricultural origin.
Therefore, it is appropriate to revise the title of food category 12.3 ‘Vinegars’ to specify that it includes diluted acetic acid (diluted with water to 4-30 % by volume) fit for human consumption in order to ensure that there is transparency and legal certainty regarding the use of food additives in that food.

Vote taken: unanimous in favour.

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 groundnuts from Brazil, Capsicum annuum and nutmeg from India and nutmeg from Indonesia and amending Regulations (EC) No 669/2009 and (EU) No 884/2014.

The results of the official controls carried out by the Member States in pursuant to Regulation (EC) No 669/2009 [1] on groundnuts from Brazil, *Capsicum annuum* and nutmeg from India and nutmeg from Indonesia show a continuous high frequency of non-compliance with maximum levels of aflatoxins. Those results provide evidence that the import of those foods and feeds constitute a risk for animal and human health. No improvement of the situation could be observed after several years of increased frequency of controls at Union borders.

In order to protect human and animal health in the Union, it is necessary to provide for additional guarantees in relation to that food and feed from Brazil, India and Indonesia. All consignments of groundnuts from Brazil, *Capsicum annuum* from India and nutmeg from India and Indonesia has to be accompanied by a health certificate stating that the products have been sampled and analysed for the presence of aflatoxins and have been found compliant with Union legislation. The results of the analytical tests should be attached to the health certificate. It is therefore necessary to integrate these commodities in Commission Implementing Regulation (EU) No 884/2014 [2] .

Besides the exemption of consignments destined to a private person for personal consumption and use, also very small consignments of certain feed and food, namely not exceeding 20 kg, e.g. used for commercial exhibitions or sent as commercial samples are excluded from the scope . The requirement of a health certificate accompanied by the analytical result is for such consignments not proportionate to the low risk for public health of such consignments.

The Turkish and Iranian authorities have informed the Commission of a change of the competent authority whose authorised representative is entitled to sign the health certificate. The Brazilian authority is also competent for feed. Therefore, these changes have been introduced accordingly.

In order to reduce unnecessary administrative burden, it is foreseen that in case of a consignment in which packaging is combining several small packages/entities, it is not necessary that the identification number of the consignment is mentioned on every

individual package in the consignment but sufficient on the package combining these small packages/entities.

Following problems experienced, it specified that the entries of the Common Entry Document (CED) related to the favourable completion of the documentary check have to be completed before authorising the transfer of the consignment to a Designated Point of Import.

Finally as there are egusi seeds imported from other *Citrullus* species than *Citrullus lanatus*, it is proposed to replace *Citrullus lanatus* by *Citrullus* spp.
The Commission representative announced that it is the intention to review the current entries to Regulation (EU) 884/2014 early next year and to discuss possible new entries (such as spices from Ethiopia because of frequent findings of high levels of aflatoxins and ochratoxin A).

An exchange of views took place.

An explicit provision requiring that the CED, completed after the documentary check as regards the relevant entries, is presented (physically or electronically) by the feed and food business operator or their representative to the custom authorities before the authorisation of the transport to the Designated Point of Entry(DPI) for possible identify and physical check was not yet inserted, as the insertion was only proposed very shortly before the meeting and it was indicated that a consultation with the custom authorities was needed before being able to accept it.

Furthermore it was mentioned that the guidance document from the Customs project group to co-ordinate activities on the protection of health, cultural heritage, the environment and nature (PARCS) on the special conditions for import due to contamination risk (aflatoxins) (Regulation (EU) 884/2014) needs to be corrected and completed. The Commission representative committed to contact the competent colleagues in DG TAXUD on this.

[1] Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504 (OJ L 194, 25.7.2009, p. 11).

[2] Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 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) No 1152/2009 (OJ L 242, 14.8.2014, p. 4).

Vote taken: unanimous in favour.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) 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 and repealing Implementing Regulation (EU) No 322/2014.

The proposed measures in the draft Commission Implementing Regulation (EU) are a significant alleviation in comparison with the current measures provided for by Commission Implementing Regulation (EU) 322/2014. The next review of the measures is foreseen to take place before 1 July 2016. Furthermore it has been explicitly foreseen that several commodities with a different CN code can be covered by one declaration in order to reduce administrative burden without deteriorating the level of public health protection.

A delegation could not support the proposed measures as the proposed measures are considered not to be proportionate to the risk. Based on the findings and analytical results, a much farther going alleviation or even a repeal of the measures would be proportionate to the risk.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending and correcting Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of certain food additives permitted in all categories of foods.

Due to the difficulties encountered during the transfer of food additives to the new categorisation system provided in Annex II to Regulation (EC) No 1333/2008, foods for infants and young children were not transferred from Article 2(3)(b) of Directive 95/2/EC to table 1 of Part A of Annex II to Regulation (EC) No 1333/2008. Therefore, that table should be corrected to include foods for infants and young children provided in Directive 2009/39/EC, as replaced by Regulation (EU) No 609/2013.
In view of Article 16 on the use of food additives in foods for infants and young children of Regulation (EC) No 1333/2008, it is important to clarify the conditions of use of the food additives listed in food category 0. 'Food additives permitted in all categories of foods' of part E of Annex II of that Regulation and to amend the title of that category.
Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended and corrected accordingly.

Vote taken: unanimous in favour.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Steviol glycosides (E 960) as a sweetener in energy reduced or with no added sugars coffee, tea & herbal infusion beverages, flavoured instant coffee and instant cappuccino products, malt-based and chocolate/cappuccino flavoured drinks.

The Commission received a request for authorisation of the use of steviol glycosides (E 960) as a sweetener in certain energy-reduced or with no added sugars beverages

falling under the food subcategory 14.1.5.2 ‘Other’ of Annex II to Regulation (EC) No 1333/2008.
Steviol glycosides are non-caloric sweet-tasting constituents and may be used to replace caloric sugars in certain beverages, thus reducing the caloric content of those products. Consequently, steviol glycosides provide sweetness to those beverages without delivering additional calories to the final product, offering consumers energy-reduced or with no added sugars products, in accordance with Article 7 of Regulation (EC) No 1333/2008.
In 2010, the European Food Safety Authority (EFSA) issued an opinion on the safety of steviol glycosides as a food additive (E 960) and established an Acceptable Daily Intake (ADI) of 4 mg/kg body weight/day, expressed as steviol equivalents. In view of the proposed extension of uses, EFSA revised the exposure assessment of steviol glycosides and concluded that the exposure estimates are below the ADI for all age groups.
Therefore, it is appropriate to authorise the use of steviol glycosides (E 960) as a sweetener added to the energy-reduced or with no added sugars beverages in food subcategory 14.1.5.2 “Other”: coffee, tea and herbal infusion beverages (at maximum level of 30 mg/l), flavoured instant coffee and instant cappuccino products (at maximum level of 30 mg/l) and malt-based and chocolate/cappuccino flavoured drinks (at maximum level of 20 mg/l).

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) No 1333/2008 of the European Parliament and of the Council as regards the use of Steviol glycosides (E 960) as a sweetener in mustard.

The Commission received a request for authorisation of the use of steviol glycosides (E 960) as a sweetener in mustard falling under the food subcategory 12.4 of Annex II to Regulation (EC) No 1333/2008.
Steviol glycosides are non-caloric sweet-tasting constituents and may be used to replace sucrose in the production of mustard thus allowing for an extension of its shelf life and its microbiological stability (decreasing the content of sugar prevents the process of fermentation for which sugar is a substrate) whilst retaining the demanded organoleptic properties of the product.
In 2010, the European Food Safety Authority (EFSA) issued an opinion on the safety of steviol glycosides as a food additive (E 960) and established an Acceptable Daily Intake (ADI) of 4 mg/kg body weight/day, expressed as steviol equivalents. Authorising this sweetener in mustard at 120 mg/kg (as steviol equivalents) would lead to an increase in the intake of E960 within limits considered to be an additional negligible exposure of the consumer and therefore not of safety concern.
Therefore, it is appropriate to authorise the use of steviol glycosides (E 960) as a sweetener added to mustard (food subcategory 12.4) at maximum level of 120 mg/kg and to amend Annex II to Regulation (EC) No 1333/2008 accordingly.

Vote taken: unanimous in favour.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards amendment of the conditions of use of certain flavouring substances from a group related with an alpha beta unsaturation structure and removal from the Union list of certain other substances of the same group.

The Commission presented the proposal for Regulation split in two parts following the opinion of the Legal Service during the interservice consultation.
The measure relating to the amendment of the conditions of use was discussed.
The measure relating to the withdrawal of the 4 substances was voted.
One delegation indicated not to support the measure as they are of the opinion that a six month transitional period, in line with established practice, should be provided for substances which are no longer supported by industry. Another delegation abstained as they wished to have clear criteria for substances to be removed from the list and substances to remain on the list with restrictions. Furthermore, they wished to have an approach for the 9 substances of FGE 208 at the same time.

Vote taken: Favourable opinion.

M.01 A.O.B.

Chlorates

The delegation of Belgium presented their position as regards the setting of maximum residue levels for chlorates in food in the frame of Regulation (EC) 396/2005 on maximum residue levels in or on food and feed of plant and animal origin. They are of the opinion that Regulation (EC) is not the appropriate legal framework for setting MRLs for chlorates as the MRLs established in Regulation (EC) 396/2005 is set on raw commodities while the contamination with chlorates is occurring during processing. Furthermore they are of the opinion that the default MRL of 0.01 mg/kg for residues of plant protection products in food for infants and young children is not applicable to chlorate, especially not to chlorate that comes from process water. The delegation of Spain supported the views expressed by the delegation of Belgium.
The Commission representative indicated that the Commission services are of the opinion that the maximum residue levels for chlorate are to be established in the frame of Regulation (EC) 396/2005 and confirmed to be aware of the particular issues related to the contamination of food commodities by chlorate during processing as the consequence of the presence of chlorate in the process water. The Committee was informed that an extensive discussion on MRLs of chlorate in food is foreseen to take place at the next meeting of the section Pesticide Residues of the Standing Committee on 30 November/1 December 2015.