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SUMMARY RECORD OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH HELD IN BRUSSELS ON 19th MAY 2010

SECTION "TOXICOLOGICAL SAFETY OF THE FOOD CHAIN"

Chairman : Mr M. FLUEH

All the Member States were present, except Bulgaria and Greece.

1. **Possibly, exchange of views and possible opinion on a draft proposal for Commission Directive amending Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients: use of dimethyl ether as a new extraction solvent and conditions of use of the solvents methanol and propan-2-ol as extraction solvents for flavourings**

   (*Document SANCO/10581/2010*)

   (Legal basis : Article 4a of Directive 2009/32/EC – Regulatory procedure with scrutiny (curtailed delay of 2 months))

   Vote: qualified majority in favour (323 votes in favour, 22 votes absent).

2. **Exchange of views on the decision of Denmark to ban Bisphenol A in food contact materials for children under the age of 3**

   The Danish representative informed the Member States on their decision from end of March to ban Bisphenol A in food contact materials intended to come into contact with food for 0-3 years old. The justification for the ban, the national risk assessment of the Danish food institute was shortly introduced. The Commission services explained the procedure foreseen in case of national safeguard measure in accordance with Article 18 of Regulation (EC) N° 1935/2004. Following this procedure, the Commission has asked the European Food Safety Authority (EFSA) for its advice on the Danish risk assessment. EFSA will provide this advice together with an evaluation of the underlying toxicological study and a comprehensive review and analysis of the most recent scientific literature together in one scientific opinion. Due to the need for the EFSA Panel to consider hundreds of studies in the literature review, EFSA will now deliver a scientific opinion in early July rather than end of May. Member States expressed the need for a risk assessment and risk management decision at EU level as soon as possible. The French representative informed that

the French Parliament has passed a proposal of a law to ban Bisphenol A containing infant feeding bottles. Further steps by the Government are needed before the law becomes effective.

3. Discussion and possible agreement of the Committee on the rules for use of occurrence data collected in the area of contaminants

The rules on use, disclosure and re-use by EFSA, Member States and European Commission of occurrence data in the area of contaminants in food and feed, collected in the frame of the activities of the Standing Committee on the Food Chain and Animal Health and related Expert Committees were presented and discussed.
Some comments on the document were made which was consequently amended to take into account these comments. The document as amended was agreed and is attached as Annex to the report of the meeting.

4. Discussion and possible agreement of the Committee on the status of the in-shell pecan nut coloured with the food additive E 112 (azorubine)

The Member States were asked to consider whether in-shell pecan nuts, where the shell (non edible part) is coloured with a food colour, should fall under the food additive legislation. Article 3(2)(a)(iii) of Regulation (EC) No 1333/2008 excludes from the food additive definition "substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods".
The question is whether a "shell" should be covered by the term "materials" and therefore could be excluded from the legislation on food additives. It was reminded that the term "materials" should be understood in accordance with the definition set by Regulation (EC) No 1935/2004 on food contact materials. This definition made an explicit reference to materials in order to avoid overlapping with provisions contained in the Regulation (EC) No 1935/2004. Therefore, Member States supported the interpretation that the "shell" of pecan nut is part of the food and falls within the scope of the legislation on food additives. The in-shell pecan nut is considered as "unprocessed food" according to Article 15 of Regulation (EC) No 1333/2008 and therefore should not be coloured at all, except if otherwise mentioned in the legislation.

5. Discussion on the use of fermented vegetable broth, enriched with nitrite : outcome of discussion at the additives working group/for endorsement

The Standing Committee on the Food Chain and Animal Health endorsed, in its meeting of 14 December 2006, the outcome of the additive working group that the use of a spinach extract containing high levels of nitrate in sausages with an intended technological purpose of preservation is a deliberate use of a food additive. Such a use of a food additive should comply both with the food additive legislation and also be labelled in compliance with the appropriate food labelling legislation.

The Commission was informed that such extract may also undergo a microbiological fermentation, which transforms the nitrate into nitrite, before it is used in the meat production process. The nitrite present in the fermented broth will have a technological function in the final food such as preservation and colour stabilisation and can be deliberately used as a food additive.

Nitrites are authorised in meat products, in most cases at a maximum amount that may be added during the manufacture of 150 mg/kg. The nitrites used must comply with the purity criteria laid down in Directive 2008/84/EC. Nitrite added to food under the form of fermented vegetable broth does not comply with the criteria laid down in this Directive.

This issue was discussed at a meeting of the Working Party of Governmental Experts on Food Additives of 15 February 2010. The majority of the Member States experts confirmed that such a practice would be a deliberate use of a food additive if used for the intended technological purposes, such as preservation and colouring, in the final food. Consequently this use must comply with the food additive legislation, including the conditions of use in Annex III to Directive 95/2/EC as well as the purity criteria in Annex I to Commission Directive 2008/84/EC.

Therefore an authorisation is required implying an update of the Directive 2008/84/EC laying down purity criteria. Furthermore, clarification is needed in order to assure that the added nitrite complies with the maximum allowed levels laid down in Directive 95/2/EC.

6. Information on the state of play of new additive authorisation requests

The Commission explained the conclusions of the discussion that took place at the working group of Governmental experts on food additives during its meetings in March and April 2010 concerning several new applications for the use of additives in foodstuffs. The working group considered requests for use of 7 new additives and 14 requests for extension of use of already authorised additives.

For most of the additives, the applicants have been informed that additional information related to general conditions of their use is needed :

- technological need and why the expected effects can not be achieved by other economically and technological practical means,
- possible misleading of the consumer,
- advantages and benefits for the consumer.

In some cases the proposed uses may lead to too high exposure which is a safety concern for the consumer. The applicants are requested to revise the proposed uses. EFSA may than be requested to perform a new exposure assessment.

Requests are acceptable in 2 cases and the new use can be included in the EU-lists of food additives. 3 requests were considered not acceptable.

I. Requests accepted

⇒ Basic methacrylate copolymer (new additive)

Basic methacrylate copolymer is intended to be used as a glazing agent / coating agent that provide moisture protection and taste making in solid food supplements.
The working group concluded that the additive is acceptable for use in food supplements at the proposed use level of 30 mg/tablet. The proposed use can be included in the EU list of food additives.

⇒ Acacia Gum modified with Octenyl Succinic Anhydride as an emulsifier (new additive)

A request was introduced to use acacia gum modified with octenyl succinic anhydride, as an emulsifier in different food categories and as an emulsifier for flavourings to be used in a wide range of foodstuffs.
The working group has accepted the application under the use levels included in the EFSA opinion. The proposed use in foodstuffs can be included in the in the EU list of food additives. The proposed use in flavourings can be included the EU list of additives authorised in flavourings, without prejudice to the authorisation of flavourings in the different food categories.

II. Requests not accepted

⇒ Sulphites, E 220 – E 228, in crustacean

Extension of use of sulphites in crustaceans was requested up to levels of 500 mg/kg in the edible part of shrimps, in order to control melanoses.

Most Member States experts are of the opinion that higher levels are not acceptable as there is already concern about too high exposure to sulphites. Furthermore, Directive 2006/52/EC already authorised the use of 4-hexylresorcinol in shrimps in order to control melanoses.

As a consequence the extension of use can not be accepted.

⇒ Calcium lignosulphonate as carrier in vitamins and carotenoids (new additive)

EFSA, in its opinion, stated that the submitted data were not sufficient to propose an Acceptable Daily Intake (ADI).
As safe use can not be guaranteed, the working group has rejected the application.

⇒ Sucrose esters of fatty acid, E 473 in flavour concentrates for use in fruit flavoured beverages.

An authorisation was requested for sucrose monoesters of lauric acid, myristic acid, palmitic acid and stearic acid, produced by an alternative route,

for the applications already authorised by the Directive 95/2/EC and to extend the authorisation in flavour concentrates for use in fruit flavoured beverages.
The working group concluded that the alternative route of manufacturing sucrose esters of fatty acids is acceptable. The proposed new route of manufacturing will be included in the EU list establishing purity criteria for food additives planned to be established by beginning 2011.
However, the working group rejected the request of the petitioner to extend the authorisation of sucrose esters of fatty acids in flavour concentrates for use in fruit flavoured beverages. The working group based its argumentation on the opinion of EFSA which concluded that the current authorisations permitted under the legislation on food additives may lead to an exceedance of the ADI for high consumers.

7. A.O.B.

The Commission services informed the Member States on the current status of a draft measure imposing special conditions on imports of certain food contact materials originating in or consigned from People's Republic of China and Hong Kong. Following extensive comments of Member States, the draft is currently being updated and the update discussed with other Commission services.

Belgium suggested having a summary of the responses on the interpretative decisions taken so far in the area of food additive legislation. COM took note and indicated to consider further.

Michael FLUEH,
Head of Unit (signed)

ANNEX TO REPORT (agenda item 3)

Occurrence data collection in the area of contaminants in food and feed
Collected in the frame of the activities of the Standing Committee on the Food Chain and Animal Health and related Expert Committees
Rules on use, disclosure and re-use of these data

Context

The European Commission (COM), the Member States (MS) and the European Food Safety Authority (EFSA) have interconnected roles and responsibilities in the area of occurrence data collection.
Experience shows that a good cooperation in accordance with a common set of rules between these 3 actors is essential.
EFSA at the request of the members of its Advisory Forum (national bodies undertaking similar tasks as EFSA), would like to publish a document describing for each sector the rules for the use, disclosure and re-use of data.

In practical terms, the scope of the proposed rules concern the data identified in the Expert Committee on contaminants in food and feed as necessary for assessing and managing a risk linked to contaminants. It concerns data on undesirable substances falling within the scope of Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[1] and contaminants falling within the scope of Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[2] but which are not subject of more specific Union rules. This means that it applies to agricultural, industrial, environmental, processing, neo-formed contaminants and inherent plant toxins and **not** to pesticide residues, veterinary drug residues, residues from food contact materials, etc.

On the basis of this common identification, the COM recommends all MS to collect data allowing the assessment of the level of contamination of certain food and/or feed and the level of exposure. EFSA usually makes a call for data linked to this recommendation.

MS collect these data, submit these data to EFSA (or COM in specific cases) but keep ownership of the data they have submitted. EFSA, as the EU risk assessor, analyses these data and uses them for risk assessment. The COM, as the EU risk manager, uses these data for EU risk management purposes.
Given the public health objectives of these different exercises, the rules are based on the fact that MS provide the data and consent to the use of these data for the related EU risk assessment and risk management processes, including their disclosure and publication under the rules mentioned below.
The data and analyses of data published in scientific opinions or in EU reports become public and can be therefore used without altering their content and with a reference to the scientific opinion or the report.

[1] OJ L 140, 30.5.2002, p. 10
[2] OJ L 37, 13.2.1993, p. 1

However, specific cases need to be addressed such as the transmission of data to international bodies or the re-use of the data submitted by individual MSs for an EU purpose not foreseen at the time of the transmission of the data.

Rules applied in the area of contaminants in food and feed

The following rules do not affect the right of MS to disclose, use or re-use the data they have collected and transmitted to EFSA and/or COM

In the above mentioned areas, the following rules for use, disclosure and re-use of occurrence data are already applied in the EU data collection work undertaken by COM, MS and EFSA.

- The data submitted by MS are whenever appropriate and technically feasible subject to plausibility checks performed by EFSA at an early stage of data processing. EFSA ensures the transparency of this mechanism towards MS. In case of significant inconsistencies, the results of these plausibility checks should be made available to MS before further processing or at least before they are incorporated in scientific reports or other documents provided by COM and EFSA and EFSA should get into contact with the data management units of the MS for further clarification.
- MS (provider of data) are individually informed of the outcome of the validation and quality control check of the data submitted by the MS.
- Individual country data are provided and can be used/re-used by Commission (in Standing Committee on the Food Chain and Animal Health (SCOFCAH) and related Expert Committees) and EFSA (Scientific Panels and working groups) within their activities. Individual country data should be accessible to all the MS.
- In published reports, no country specific analyses (e.g. comparing one MS with another) should be done, unless the MS concerned have given their agreement to that. Equally, no information about specific brands or names of producers, should be given. Analyses at EU level or at regional level (e.g. Northern/Southern Europe) should be possible, where appropriate.
- Data submitted by MS should be provided through EFSA to JECFA or to other relevant intergovernmental bodies under the conditions mentioned above. EFSA informs the MS and the COM, if possible sufficiently in advance, of their intention to submit data to JECFA or to other relevant intergovernmental bodies in order to enable MS to submit to EFSA additional available data in view of a complete submission by EFSA of all available data to JECFA or to other relevant intergovernmental bodies. EFSA informs then the MS and COM of the transmission of the data in order to avoid double submission.
- When transmitting the data to JECFA or to EFSA contractants, EFSA mentions that the data may exclusively be used for the objectives of the JECFA call or of the contract.
- For country specific analysis or other purposes (such as EU research projects) MS are consulted in SCOFCAH or in the relevant Expert Committee on that request/intention and are asked to give their agreement within a certain time period. If objections are raised, the request will be reconsidered in SCOFCAH.