Record of the views expressed at the

4th Meeting of the EFSA Stakeholder Discussion Group on Food Chemical Occurrence Data

Held on 04/10/2016, Brussels (Belgium)

Participants

- **Chair:** Doreen Dolores Russell (EFSA)
- **Members of the Discussion Group**

Organisation	Name
AESGP – Association of the European Self-Medication Industry	Maud Perrudin
BEUC - The European Consumer Organisation	Gemma Trigueros
CEFIC – European Chemical Industry Council	Miguel Prieto Arranz
ELC – Federation of European Speciality Food Ingredients Industries	Petr Mensik
ESA – European Snacks Association	Marta de la Cera
FEDIOL - The EU Vegetable Oil and Proteinmeal Industry	Julie Roïz
FoodDrinkEurope	Angeliki Vlachou
Food Supplements Europe	Cynthia Rousselot
ICGA – International Chewing Gum Association	Manon Ombredane
EDA – European Dairy Association	Kinga Adamaszwli Christian Bruun Kastrup
ELC – Federation of European Speciality Food Ingredients Industries	Joy Hardinge
NATCOL – The Natural Food Colours Association	Valerie Rayner
SNE - Specialised Nutrition Europe	Farai Maphosa
UNESDA - Union of European Soft Drinks Association	Helen Benson

- **Apologies**

Beate Kettlitz (FoodDrinkEurope), Chris Bruyninckx (formerly UNESDA), Andreas Varlamos (former Chair EFSA Stakeholder Consultative Platform), Patrick Coppens (Food Supplements Europe), Christophe Leprêtre (ICGA), Aaron O'Sullivan (SNE), Bettina Breuer (SpiritsEuorpe).

- **Observers from the European Commission**

Wim Debeuckelaere (for item 4.5), Frans Verstraete (for item 4.4), Andreia Alvarez-Porto and Guillermo Cardon – European Commission DG Health and Food Safety (SANTE), Unit E2 (Food Processing Technologies and Novel Foods).

- **Other observers**:

David Tennant (Independent scientific adviser), Marc Leclerc (AMFEP for item 4.5), Guglielmo Adinolfi (Starch Europe for item 4.5), Anna-Maria de Smet (Brewers of Europe for item 4.5), Yves Le-Bail Collet (Starch Europe for item 4.5)

- **Representatives of the European Food Safety Authority**

Doreen Dolores Russell (Evidence Management (DATA) Unit), Enikő VARGA (DATA Unit), Jose Angel Gomez Ruiz (DATA Unit), Mary Gilsenan (DATA Unit), Alexandra Tard (FIP Unit), Yi Liu (FIP Unit), Goran Kumric (EXREL Unit).

1. Welcome and round table presentation

The Chair, Doreen Dolores Russell (EFSA DATA Unit), welcomed all the participants and the Commission representatives to the 4th meeting of the EFSA Stakeholder Discussion Group on Food Chemical Occurrence Data. Apologises were received from Chris Bruyninckx, Andreas Varlamos, Patrick Coppens, Christophe Leprêtre, Aaron O'Sullivan, Bettina Breuer and Beate Kettlitz.

A 'tour de table' was conducted enabled the meeting's participants to introduce themselves.

2. Adoption of agenda

The agenda was agreed and the programme for the day outlined together with an overview of the main topics to be discussed.

3. The future of the Discussion Group on Food Chemical Occurrence Data: Contextualising the new approach to stakeholder engagement with the EFSA Strategy 2020

Doreen Dolores Russell presented an overview of the evolution and development of the new approach EFSA will implement to engage with its stakeholders. She described the background to the new exchange platforms that EFSA aims to establish with a wider and more representative group of stakeholders together

with the new stakeholder registration process and associated criteria for selection.

Christian Brunn Kastrup (EDA) asked if there could be a methodology for facilitating dialogue with industry before an opinion is published, in particular with regard to levels of food additives used in Panel opinions. David Tennant (Independent scientific advisor) asked if it would be possible under the new approach to have a mechanism for sharing EFSA opinions prior to publication to enable stakeholders to provide their feedback in view of the uncertainties underpinning exposure methodologies. EFSA replied that prioritising public and stakeholder engagement in the scientific assessment process is the first strategic objective of the EFSA 2020 Strategy. Within this context, EFSA aims to optimise its engagement with registered stakeholders through a greater variety of platforms to enable interaction with a larger range of stakeholder groups and a more balanced representation of views and interests.

4. Topics for discussion

4.1. An introduction to the project 'The Potential Application of Market Research Data in Dietary Exposure Modelling'

David Tennant presented an overview of the project 'The Potential Application of Market Research Data in Dietary Exposure Modelling', a joint research project proposal for food additive producer and user trade associations in Europe.
The project aims to find a methodology to take food additive occurrence into account in a quantitative manner in exposure assessments using market survey data. The progress made to date using MINTEL GNPD (Global New Product Database) to assess the temporal distribution of the occurrence of five groups of food additives was presented as well as initial observations from a food industry questionnaire and the proposed next steps of the project.

Christian Brunn Kastrup (EDA) emphasised that the food categorisation is crucial for the estimation of dietary exposure to food additives in demonstrating that the results are not misleading. Mary Gilsenan (EFSA DATA Unit) asked if other databases are used apart from MINTEL. She also highlighted that the MINTEL GNPD database is used also by EFSA mainly to cross check the occurrence of an additive in a food category; in particular when no usage or analytical occurrence data are available or when the data available is limited.

4.2. The reporting of additive usage representativeness to EFSA - some propositions

Petr Mensik (ELC) gave some background to his organisation, its membership activities, and also described the characteristics of speciality food ingredients the

members of his association produce. He indicated that some EFSA opinions have stated that insufficient or the limited available data have led to some uncertainties in the assessments. He informed the meeting that some ELC members submit data based on the recommended use levels and suggested that these data could be used by EFSA by indicating recommended use levels in the Maximum Permitted Level field of the reporting template.

The speaker asked whether EFSA could use data on recommended use levels in refined exposure scenarios and in particular when food additives are permitted 'quantum satis'. Alexandra Tard (EFSA FIP Unit) confirmed that when additives are permitted for use 'quantum satis' and when no other data are available, EFSA uses the data reported at recommended use levels in the maximum level exposure assessment scenario. In response to a comment from ELC on uncertainty regarding how and whether data sent to EFSA are used, Mary Gilsenan informed participants that data providers are acknowledged in the Panel opinions.

David Tennant stated the considerable effort needed to gather usage data from the industry and that it can be frustrating when the data are disregarded. He noted that use of higher than needed additive usage levels are not cost effective. He further added that EFSA uses Member States' additive occurrence data in place of industry data which often has high reported values above the technical need and as such Member States' samples are probably suspect samples. Mary Gilsenan responded that EFSA also collects food additive analytical occurrence data from Member State competent authorities using the SSD (Standard Sample Description) data model which requires a considerable amount of meta data describing an analytical result to be documented such as details of the sampling method, sampling strategy etc. Scientific experts in the EFSA working groups decide whether the data are used for an opinion. In most cases, suspect samples are not used. She also noted that in the assessment of dietary exposure, a conservative approach is typically used in order to protect consumers. David Tennant expressed his doubts about the reliability of the analytical methods used by Member States for analysing food additives. Andreia Alvarez-Porto (SANTE) highlighted that the analytical occurrence monitoring data are sent to the Member States' competent authorities by accredited laboratories with corresponding accredited analytical methods and that as part of the assessment process, EFSA assesses and deals with potential outliers.

4.3. Update on exposure approach for food additives re-evaluation and on the re-evaluation programme

Alexandra Tard updated the meeting about the FAIM (Food Additive Intake Model[1]) template new version, the use of the MINTEL GNPD database when assessing exposure to food additives, the EFSA working group dedicated to the exposure assessment which was set up at the beginning of this year and its workload (including an update of the approach to be followed for the exposure assessment as part of the safety assessment of food additives under re-evaluation) and the state of play regarding the food additive re-evaluation programme. She indicated that for the MINTEL GNPD database parallel checks for its reliability are made using comparisons with German and Irish databases. A few published EFSA ANS scientific opinions contain in the appendixes, a table summarising foods labelled with the food additive evaluated, per sub-category according to MINTEL classification. This table should now always be included in ANS opinions. One task is also to link food categories/sub-categories as in Mintel GNPD to food categories according to the regulation.

Angeliki Vlachou (FoodDrinkEurope) asked about the planning for future calls for additive usage data. EFSA confirmed that a further call is planned but the date is not yet confirmed. It is tentatively scheduled by the end of the year or early next year. The number of additives foreseen in the call is not yet confirmed. In response to a question from Miguel Prieto Arranz (CEFIC) regarding the duration of the next call for data, EFSA replied that it will be of approximately 9 month duration call for data.

Christian Bruun Kastrup sought clarification on the fact that some additives in the recent call (batch 5) are not used as additives but rather as processing aids and if this is the case how should they be reported. EFSA confirmed that they should not be reported as food additives. Referring to Annex III of Regulation No 1333/2008, Petr Mensik asked if any calls are planned for food additives within food additives. EFSA responded that to date this has not been specified in calls but that it is important to know if an additive is used as a food additive within a food additive. EFSA will check and report back to the Discussion Group. Doreen Dolores Russell informed the group about the tentative plan for a food additive workshop being organised in 2017. David Tennant gave some suggested topics for a possible food additive workshop: use of occurrence data/analytical data in dietary exposure assessments. Gemma Trigueros (BEUC) asked a question about the use as an ingredient of Konjac gum which is often used as an ingredient rather than a food additive and how this distinction was resolved. EFSA advised that this is being discussed at working group level and that exposure to gum as a food ingredient is not taken into account in the food additive re-evaluation process.

[1] http://www.efsa.europa.eu/en/applications/foodingredients/regulationsandguidance

4.4. Dietary exposure to chemical contaminants: The contribution of industry data to EFSA's scientific work

Jose Angel Gomez Ruiz (EFSA DATA Unit) presented an overview of the central role of chemical occurrence data in dietary exposure assessments. He described the main groups of occurrence data collected, the mode of collection and how the data is managed and validated. The specific characteristics of chemical occurrence data from industry were presented, including the percentage of occurrence data from industry in the EFSA contaminant occurrence database. Though often representing specific contaminants such as process contaminants, industry data has made a significant contribution to EFSA's scientific risk assessments.

Christian Bruun Kastrup applauded the sharing of this information adding that it was encouraging to hear that industry provided this data. Frans Verstraete (SANTE) confirmed that the data from industry were related to some specific contaminants adding that he would like to encourage industry to provide more data from their own controls.

Christian Bruun Kastrup expressed his concerns about confidentiality as this can affect the willingness of industry to provide data. Frans Verstraete stated that no confidential information is mandatory when reporting contaminant data such as the brand name of the food and the manufacturer's name. He also confirmed that the commercially sensitive data can be anonymised. He gave an example from mycotoxins whereby 'country of origin', which is considered sensitive, can be dealt with as 'EU data' David Tennant asked about the reliability of analytical data for contaminant exposure assessments, in particular what quality controls are applied compared with food additives. Jose Angel Gomez Ruiz informed the group that decisions regarding the reliability of analytical results are discussed and taken at working group level taking into account judgement from experts in analytical chemistry who attend working groups, literature data, as well as in-house expertise. He also explained that for some contaminants, analytical performance requirements are laid down in European legislation and that every step is documented in a scientific opinion regarding the treatment of analytical data used for a contaminant exposure assessment. Petr Mensik asked about the cooperation between EFSA's ANS and CONTAM Panels in particular within the context of taking into account, where applicable, exposure as a food additive. EFSA replied that there is close cooperation between the EFSA units supporting both Panels (for e.g. data exposure assessors support several EFSA units and corresponding Panels and share information on occurrence/additive data). Also the EFSA Scientific Committee addresses issues that are cross cutting across a number of scientific Panels or scientific areas.

4.5. Data collection/consultation for conducting exposure assessments for food enzymes

Following some opening remarks by Wim Debeuckelaere (SANTE), Yi Liu (EFSA FIP Unit) informed the meeting about the adoption this year of the CEF Panel Statement on the exposure assessment of food enzymes. A food process-based methodology to estimate dietary exposure to food enzymes has been developed.

Additionally, a major challenge encountered in assessing the submitted enzyme dossiers is the lack of a direct link between the enzyme usage data and the food consumption data: enzyme usage data are expressed on a raw material basis (raw agricultural commodity or food ingredient), while food consumption data are reported in foods as consumed. To overcome this challenge, EFSA has made use of a EC working document on food processes in which food enzymes are used to, i) harmonise the description of intended uses that were provided in the dossier but in a harmonised way and ii) draw up a list of process-specific FoodEx categories and technical factors that convert foods-as-consumed to food ingredients or raw agriculture commodities.

A draft call for collecting feedback on technical input data used to estimate exposure was shared with the meeting. The plan is that EFSA will launch a series of calls requesting feedback from industry stakeholders on technical factors used in enzyme exposure assessments. Each call will consist of one Excel file containing separate sheets corresponding to food processes defined by a European Commission working document. The input data provided will be used to calculate dietary intake for a batch of dossiers with the corresponding intended use. The first call is scheduled to be launched after the meeting relating to baking and brewing processes. Regarding the first call, Yi explained that each sheet has been pre-filled by EFSA, and stakeholders are invited to provide feedback concerning i) the food list, ii) technical factors used to disaggregate between food as consumed and food ingredient or raw materials to which food enzymes are added. Given the nature of this targeted call and with the aim of adopting food enzymes opinions before the end of 2016, EFSA plans to give 4 weeks for the call. As such the participants were asked to give their opinion on the proposed launch date and duration.

Christian Bruun Kastrup asked about enzyme risk in relation to allergies and whether this was to do with the amount rather than the presence of an enzyme. Marc Leclerc (AMFEP) replied that several studies have shown that the risk of allergenicity by ingestion of enzymes is not an issue but that the toxicological assessment is related to the biological origin of the food enzyme. He also asked when the dietary exposure application template using aggregated food consumption data would be available for applicants. EFSA replied that no timeline has been set, because EFSA will apply the new methodology to estimate

exposure for the already submitted dossiers, and the template will be an additional output of this effort.

In relation to the call for feedback on technical input factors, EFSA asked who in the Discussion Group could provide the information requested. Angeliki Vlachou commented that this the first time they have seen this request for information and consequently they would need to discuss with their members and also fully understand what kind of data is needed. As such, FoodDrinkEurope is not in the position to send any data within the short timeframe specified. Commenting on the reporting table presented by Yi, Anna-Maria De Smet (Brewers of Europe) added that information on how much grain they are using for making beer is readily available from the brewer industry. In addition they too require time to understand what EFSA wants. Her sector might have relevant data, but it cannot be provided in one month. Other discussion group members added that they are not familiar with enzymes while others expressed concern about the short timescale proposed.

Marc Leclerc informed the group that AMFEP has received a request from EFSA to provide additional information / technical specification for substantiating the possibility of the absence of transfer of 'food enzyme – total organic solids (FE-TOS)' into the distilled alcohol and glucose syrups during the respective food processes. Christian Bruun Kastrup commented that historically dairy products producers had no interest in the amount of food enzymes that remain in the dairy products as there has neither been a legal requirement nor a safety issue to motivate such an interest. AMFEP clarified that the request concerns FE-TOS, not food enzyme as such. Christian confirmed that EDA could contribute to the call, but not within 4 weeks.

Concerning the fate of enzymes in foods, Marc Leclerc mentioned that four weeks is too short given the complexity of the data, and also that this is the first time AMFEP has been requested to this type of information but added that in their view the new methodology as proposed by the EFSA CEF Panel is the right way to go and suggested publishing the new methodology description. EFSA emphasised the importance of the call, as each call will unblock a batch of dossiers, it would be efficient to 'consult' input data first, and then use the same input data to estimating dietary exposure for multiple dossiers consistently.

Post-meeting note:

Based on the comments collected in the meeting, EFSA decided not to launch the call immediately after this meeting. Instead, EFSA will first publish the CEF Panel's adopted Statement in the EFSA Journal. In terms of the duration of the call, EFSA will consider extending it from 4-weeks to a longer period.

4.6. The refined additive usage reporting template for the Batch 5 call for data and the new feature developed for electronic data submission

Enikő Varga (EFSA) provided an update on the enhancements introduced to the additive usage reporting template. More validation checks and automatic filling have been introduced and there is also a new feature to transform the data into coded data for direct upload into EFSA's web interface. She highlighted that online training is available upon request. The Discussion Groups' opinion on the form of feedback they would like on their data following transmission to EFSA was presented.

She also mentioned that data reliability needs to be confirmed by data providers and presented an example of a data reliability statement which EFSA requests data providers to confirm following data transmission.

Many of the Discussion Group members expressed concern about the reliability statement as presented by EFSA and sought clarification on the exact meaning. Some members of the group noted that it would be very difficult to give the assurances requested by EFSA as they would need to go back to all the members of the industry associations who provide the data. EFSA re-iterated that in the interest of transparency and quality of data underpinning our scientific assessments, it very important to receive assurance from data providers on the reliability of the data submitted. EFSA explained that it was requesting assurance to the best of data providers' knowledge and agreed to re-draft the wording and share with the Discussion Group. It was agreed that a revised statement for data reliability would be sent out with the draft minutes from the meeting.

In relation to data feedback from EFSA after data transmission, the preferred option by members of the group was to receive feedback on the cleaned dataset together with a frequency table by food group and food additive.

5. Any other business

The Chair thanked the all the participants for their input and contributions. She advised that the presentations would be sent the discussion group in the coming days while the minutes would be shared with the group for their comments prior to publication on the EFSA website. She also encouraged the meeting participants to register as stakeholders.

6. Closure of the meeting

The meeting was closed at 16:50