European Food Safety Authority

Brussels, 19 November 2013

EFSA/SHP/LdL/2013

Records of the views expressed in the

1ST MEETING OF THE EFSA STAKEHOLDER CONSULTATIVE PLATFORM DISCUSSION GROUP ON FOOD CHEMICAL OCCURRENCE DATA BRUSSELS (BELGIUM) 19 NOVEMBER 2013

MEMBERS OF THE DISCUSSION GROUP

Chair: *Mary Gilsenan*

AESGP – Association of the European Self-Medication Industry	*Kinga Adamaszwili*	FoodDrinkEurope	*Angeliki Vlachou, David Tennant*
BEUC – The European Consumer Organisation	*Camille Perrin*	SNE - Specialised Nutrition Europe	*Aaron O'Sullivan*
CAOBISCO – Association of Chocolate, Biscuit and Confectionery Industries of the European Union	*Ylenia Maitino*	ICGA - International Chewing Gum Association	*Christophe Leprêtre*
CEFIC – European Chemical Industry Council	*Miguel Prieto Arranz*	NATCOL – The Natural Food Colours Association	*Valerie Rayner*
ELC – Federation of European Speciality Food Ingredients Industries	*Joy Hardinge, Petr Menšik, David Tennant*	UNESDA - Union of European Soft Drinks Association	*Chris Bruyninckx*
FEDIOL - The EU Oil and Proteinmeal Industry	*Julie Roïz*	EDA – European Dairy Association	*Hélène Simonin*

APOLOGIES

BEUC – The European Consumer Organisation – *Gemma Trigueros*

FEDIMA – Federation of the EU Manufacturers and Suppliers of Ingredients to the Bakery, Confectionery and Patisserie Industries – *Jean Christophe Kremer*

FoodDrinkEurope – *Beate Kettlitz*

OBSERVERS

Wim Debeuckelaere – DG Health and Consumers (SANCO), Unit E3 (Chemicals, Contaminants and Pesticides)

Kathy Macchia – DG Health and Consumers (SANCO), Unit E3 (Chemicals, Contaminants and Pesticides)

REPRESENTATIVES OF THE EUROPEAN FOOD SAFETY AUTHORITY

Stakeholder Consultative Platform Secretariat: *Lucia de Luca, Muriel Pesci, Judith Ricketts*

Mary Gilsenan	*Claudia Heppner*
Stavroula Tasiopoulou (by teleconference)	*Alexandra Tard (by teleconference)*

1 WELCOME AND ROUND TABLE PRESENTATIONS

Mary Gilsenan, Head of the Dietary & Chemical Monitoring Unit at EFSA, opened the meeting highlighting the importance for EFSA of having the opportunity to hear the contributions of the members of the Discussion Group (DG) and to tackle the challenges regarding the provision of chemical occurrence data in the area of food additives and contaminants to support EFSA's scientific work. Mary welcomed the decision of EFSA's Stakeholder Consultative Platform (Platform)to set up a Discussion Group to engage with stakeholders in this area. Mary gave the floor to Claudia Heppner, Head of the Food Ingredients and Packaging (FIP) Unit and Lucia de Luca, Stakeholder Relations Officer. Mary welcomed Stavroula Tasiopoulou and Alexandra Tard, Scientific Officers in the FIP Unit who were connected by phone from Parma. Mary invited participants to introduce themselves. The Chair noted that apologies were received by Gemma Trigueros (BEUC), Jean Christophe Kremer (FEDIMA), and Beate Kettlitz (FoodDrinkEurope).

Before starting the meeting, Mary asked participants if they had any other points to be added to the draft agenda which was circulated to participants prior to the meeting. With no further points raised for discussions, the Chair adopted the agenda.

2 FOOD ADDITIVES RE-EVALUATION PROGRAMME: LEGAL REQUIREMENTS

The Chair gave the floor to Wim Debeuckelaere, Head of Unit on Chemicals, Contaminants and Pesticides at DG Health and Consumers, who presented the re-evaluation programme for food additives as outlined in Commission Regulation (EU) No 257/2010 of 25 March 2010. Wim clarified the timeframe for the re-evaluation of the various categories of food additives and pointed out how the legal timeline has an impact on the work of EFSA, which in turn also depends on the data the Authority receives from industry. Wim also pointed out that the Regulation foresees that EFSA shall make open calls for data, listing the kind of data EFSA requires stakeholders to provide. He also said that information on human exposure to food additives is a crucial aspect of the evaluation in the risk assessment process, and it therefore has to be as refined as possible. This is a task the Discussion Group on Food Chemical Occurrence Data could certainly contribute to.

3 DISCUSSION GROUP ON FOOD CHEMICAL OCCURRENCE DATA

The Chair took the members through the Terms of Reference of the Group which were circulated prior to the meeting. She highlighted that discussions within the Group and information exchange can focus on practical aspects and challenges regarding provision of occurrence data and usage data from stakeholders with a particular focus on food additives and contaminants, yet will not be exclusively restricted to these two areas. Mary also pointed out that to ensure EFSA is engaging with all interested parties,

membership of the Group is open also to non-members of EFSA Stakeholder Platform and that the Secretariat is open to future expression of interest. Mary also stressed the fact that it is important to define official members of the group for the purpose of openness and transparency, but that representatives of the various organisations can change depending on the topics discussed. Regarding the frequency of the meetings, Mary suggested that there should be approximately one meeting per year, but there could be more, depending on the needs of EFSA or of the members. Records of the meeting will be shared with members to check their accuracy and a report will be published in the first quarter of each year.

Mary then gave the floor to Lucia de Luca who informed participants that this Group should refer back regularly to the Platform and that the Platform will decide on any demand to renew the mandate of the Group.

In response to a request for clarification received from FoodDrinkEurope, Mary answered that this Group is meant to be a forum for discussion and invited members to bring forward suggestions or deliver presentations.

4. Exposure assessment of food additives (FAIM)

Stavroula Tasiopoulou provided an overview of the exposure assessment of food additives using the FAIM template (Food Additive Intake Model)[1], which was developed in 2012 as within the guidance for submission of food additives by the EFSA ANS Panel as a screening tool to estimate chronic dietary exposure to food additives within the framework of the food additive re-evaluation programme (Commission Regulation (EU) No 257/2010), as well as to support applicants calculating preliminary dietary exposure assessments for new food additives or extensions of use of existing food additives. FAIM contains summary food consumption statistics from 26 dietary surveys from the EFSA Comprehensive Food Consumption Database. Stavroula informed members of the group that an update of the FAIM template is envisaged in 2014 when new consumption data will be included in the EFSA Comprehensive Database. She noted that the FAIM model generates conservative exposure estimates and that refined exposure assessments using raw food consumption data are performed by EFSA when necessary.

Angeliki Vlachou (FoodDrinkEurope) noted that guidance from EFSA on how representative data is defined would be welcome. She asked which Member State food consumption data will be included in the update of the FAIM template.

David Tennant (FoodDrinkEurope) asked when stakeholders could expect to receive feedback from EFSA in response to the comments sent on the FAIM template, regarding in particular the data used, and the way the model operates, since it results in very conservative estimates of exposure. Claudia Heppner informed the group that a technical report is in preparation and that it is scheduled to be published by the end of the year.

David Tennant asked whether the new version of FAIM will be available for consultation with stakeholders. Claudia Heppner indicated that this could be arranged and that this Group could be part of the consultation on the revised FAIM template.

[1] http://www.efsa.europa.eu/en/efsajournal/doc/2760.pdf

Camille Perrin (BEUC) noted the importance of collecting analytical data from Member States as a validation check for the food additive usage data sent by industry.

Chris Bruyninckx (UNESDA) noted that some food categories relevant to food additive exposure are not included in the FAIM template (e.g. no entries for juices containing lemon/lime), and asked whether there are plans to further work on FoodEx level 4 food categories. Stavroula Tasiopoulou noted that it is not currently possible to work at such a refined level in FAIM, but reminded the participants that more refined exposure assessments can be carried out using raw food consumption data available to EFSA in the Comprehensive Database.

David Tennant expressed a wish to have further refinements made to the FAIM template; he noted that more refinement in the food categories could extend its use beyond that of a screening tool, into an instrument to better identify key contributors to exposure.

Aaron O' Sullivan (SNE) asked whether it is anticipated that more food consumption data on sensitive consumer groups would be collected by EFSA. Mary informed the group of the ongoing EU Menu project (2011 – 2018) which entails financial support and guidance to Member States to collect more harmonised food consumption data at European level for use in EFSA exposure assessments; within this framework, food consumption data on specific population groups are requested.

Wim Debeuckelaere noted that the European Commission (EC) intends to provide guidance to Member States on the monitoring of food additives. In the course of 2014, the EC will have a clear view of what is needed and what Member States can do to contribute to the data collection process. Within this context, Member States can have further dialogue with various sectors of national local food industry to define specific uses of food additives, a task which would be difficult to carry out at European level. The EC will benchmark with what EFSA is doing in this area.

David Tennant asked whether analytical data collected from individual Member States would be used to estimate exposure at national level, or whether Member State analytical data would be pooled to provide estimates of European exposure (as is currently the case with analytical data on contaminants).

David Tennant asked whether stakeholders would have better access to food consumption data from the EU Menu project. Mary Gilsenan indicated that this would be the case and that unlike the Comprehensive Food Consumption Database, EFSA will have more ownership of the EU menu data.

5. Exchange of views on closed call for data submission on food additives – Batch 1 and 2

Claudia Heppner presented an overview of usage level data and analytical concentration data received by EFSA from interested parties, stakeholders and Member States up to date in response to the public call launched in March 2013. Claudia thanked the members for their timely contributions and indicated that the response rate for data transmission was much better than past calls for data.

Petr Mensik (ELC) said members would benefit from a more specific calendar of the timelines of the re-evaluation programme than the one provided in the European Commission Regulation (EU) No 257/2010. This would help stakeholders in planning their work with their delegates and in being able to provide more sound data and information on time. He asked whether it would be possible to have information on which interested parties had submitted data in response to a specific call and the type of data submitted, since it may facilitate coordination between the different stakeholders. Claudia Heppner clarified that EFSA's ANS Panel will discuss a refined work programme for 2014-2015 during its December 2013 plenary meeting and plans to release, after endorsement by the ANS Panel, a more refined work programme including information on the calls for usage level data and toxicological information on EFSA's webpage. In addition, Claudia mentioned that EFSA can release the names of interested parties having submitted data for a particular food additive if they refer to an industry association; however if data are provided by a single company then EFSA needs their permission in order to release this information.

Camille Perrin (BEUC) raised the issue of poor analytical methods for some food additives (e.g. gums and colours) to which EFSA acknowledged awareness. Mary Gilsenan noted that in the data collection template, information on analytical methods is requested, as is the case when collecting contaminant data. With accompanying information on analytical methods, working group experts may decide not to include analytical data based on a particular method in an exposure assessment, if this method is not considered suitable for the food additive or food matrix in question. Joy Hardinge (ELC) also noted the difficulty in measuring food additive concentrations in some food matrices, and in particular when a food additive is also present as a natural food ingredient. She noted that it is not possible to differentiate an analytical result with respect to a natural food ingredient and an intentionally added food additive. Aaron O' Sullivan (SNE) concurred with this issue within the context of PARNUTS (Foods for Particular Nutritional Uses), which in some cases may contain the same substance as a nutrient and as an intentionally added food additive.

Wim Debeuckelaere (European Commission) noted that analytical data for food additives are collected in Member States for control purposes (e.g. to detect food fraud) and therefore should be used with caution in exposure assessments.

Christophe Leprêtre (ICGA) asked whether EFSA would consolidate methods of analysis used by different national control laboratories to generate data Member States sent to EFSA and share such consolidated list of methods with industry experts. He also noted that most of the usage data provided to EFSA from industry are based on standard recipes and that in practice actual usage levels may be lower than recipe maximum amounts. As a consequence, he added that data provided by industry were conservative from a dietary exposure point of view. Aaron O'Sullivan (SNE) concurred with this practice with respect to the colours industry. Christophe Leprêtre stressed the importance of differentiating the two data sources (i.e. usage data from industry and occurrence data from Member State monitoring programmes) due to (I) the uncertainty linked to the methods of analysis and, (II) the fact that industry data are likely to be more conservative and based on recipes.

Claudia Heppner asked members of the group how difficult it would be to retrieve usage data for refined food categories. Valerie Rayner (NATCOL) explained that typically

industry would have information on maximum levels of use of food additives based on recipes. It is more difficult to retrieve actual usage level data from member companies.

David Tennant (FDE) noted that it is discouraging when usage level data are discarded from ANS Panel Opinions despite efforts by stakeholders to collect the data.

Helene Simonin (EDA) noted that member companies find the task of data collection burdensome and time-consuming, especially when refined data are requested.

It would be feasible to go back to member companies to request refined data only when related to specific uses.

Angeliki Vlachou (FoodDrinkEurope) requested a yearly plan of food additives data collection from EFSA. One call per year with a four to five month deadline would be more feasible given the fact that data collection requires huge efforts for industry.

Wim Debeuckelaere (European Commission) asked whether food industry stakeholders can provide an overview of the food products in which food additives are most likely to be used; Joy Hardinge (ELC) noted that there are different sector groups within the area of food additives and that members of such groups would be in a position to advise on this. Wim Debeuckelaere also asked whether FoodDrinkEurope screens the data prior to sending them to EFSA and how representative the data are. Angeliki Vlachou (FoodDrinkEurope) confirmed that FoodDrinkEurope screens the data prior to their submission. She also noted that the organisation does not provide data for the totality of the food and drink industry and that not all their members provide data. She also noted that in order to interpret data in the correct way, the additional information included in the comment field of the food additive usage template should be taken into consideration. Chris Bruyninckx (UNESDA) noted the importance of taking into account the information included by the data providers in the comments field in exposure assessments – the information in this field should be promoted.

Christophe Leprêtre (ICGA) asked what is the rationale for undertaking a refined exposure assessment for an additive for which no biological effect is observed (e.g. QS additives; example of gums); he asked what the Commission will do with such exposure assessments, and what will be the next steps for QS food additive evaluations.

Claudia Heppner answered that a decision tree is currently being discussed in the ANS Panel on the way exposure assessment should be performed, taking into account different possible scenarios (e.g. food additives with ADI not specified, QS, food additives present in foods not authorised by the legislation, the use of analytical data, also in junction with usage levels).

David Tennant noted that the food additive data collection template is not specifically developed to reflect information for food additives. He asked whether EFSA intends to have a dialogue on this. Online submission would be preferable.

Other improvements/issues to the data submission template include: I) Insertion of a dilution factor column; II) Definitive of food additive usage (e.g. preparation, active principle); III) In which countries a food additive is used.

Comments were also received on the difficulties of food coding in the FoodEx of food items which are part of composite foods (icing vs. iced cake) but distinct authorised uses of food additives apply in the legislation. It was also noted that the use of PARAM code and PARAM text may lead to confusion during the submission of data. Finally, it was suggested to make some simplifications to the data collection template since many fields of the template are not applicable for food additives.

Chris Bruyninckx (UNESDA) requested a work plan from EFSA regarding the ANS opinions on food additives to be discussed and adopted by the ANS Panel in the next few months. Claudia Heppner said that at the beginning of 2014, EFSA should be in a position to provide an overview of the work of the year.

6. ANY OTHER BUSINESS

No other topics were raised under this point.

7. CLOSURE OF THE MEETING

The Chair informed members that records of the meeting will be circulated to members and invited them to comment, should the report contain inaccuracies.

The Chair thanked the members for their participation and active contribution and the Secretariat for its support. As no other points were raised, the Chair closed the meeting.

ANNEX I: COMMENTS FROM NATCOL ON DATA PROTECTION TEMPLATE

NATCOL

EFSA Stakeholder Consultative Platform Discussion Group on Chemical Occurrence Data

Stakeholder feedback on issues surrounding the process for obtaining usage data for the exposure assessments

Introduction

At the EFSA Stakeholder Consultative Platform Discussion Group on Chemical Occurrence Data meeting on 19th November 2013, food industry stakeholders identified a number of concerns associated with the use of reporting templates provided for food additive usage data collection by the EFSA FIP Unit. The reporting templates are available for download from the EFSA web site[1]. Stakeholders agreed to collate their comments and to submit them to the Stakeholder Relations secretariat. The feedback has been divided into two main aspects: firstly the practical problems associated with the linked spread sheets and difficulties associated with downloading and then getting them to work in different operating environments. Secondly the appropriateness of the template design that was intended to gather relevant data on food additive usage.

Technological issues

A number of respondents experience difficulties when opening and using the templates. It was understood that two spread sheets, the first for reporting and the second containing reference data need to be open in MS Excel at the same time. This was to allow automatic form-filling macros to operate from drop-down menus or reference tables. Unfortunately, whether because of differences in operating systems or versions of MS Excel, this operation did not work for some people. There may have also been issues surrounding permissions, firewalls and other security devices that prevented macros from running.

A web-based system for uploading data could be a simple alternative. Data could be entered into a temporary file and then up-loaded into the data entry system after checking. A system of user accounts would ensure adequate control over quality, confidentiality, etc. This would also allow registered users to view data in the system and, if necessary, query apparent conflicts.

Template design

The templates had two main sets of issues associated with them: firstly they include fields that are not relevant to food additives (e.g. three fields on 'Product treatment') and secondly they exclude field of critical importance (e.g. dilution ratios, if linked to certain flavours/colours/varieties, etc.).

[1] http://www.efsa.europa.eu/en/data/call/130327.htm

Furthermore, there is a considerable amount of ambiguity, for example 'Country of reporting' does not necessarily mean the country where the food containing the additive is consumed, 'Market share' is completely undefined and could mean a number of different things. The current template fields have been listed in Table 1 with some stakeholder comments.

Table 1. Current fields included in template with stakeholder comments

Current fields	**Comment**
Product Id S.A0	Unclear what is required
Country of reporting S.04	Does not necessarily correspond to country of consumption
EFSA Product Code (S.12)	See text
EFSA Product code (text preview) (S.12)	See text
Authorised additives and conditions of use (S.A1)	See text
Product full text description (S.14)	
Product treatment (S.17)	Relevance unclear
Product treatment 2 (S.17)	Relevance unclear
Product treatment 3 (S.17)	Relevance unclear
Brand name (S.18)	Brand of additive or food?
Manufacturer (S.19)	Additive or food?
Market share (S.A3)	Ambiguous. Term need clear definition.
Representativeness of the usage (S.A4)	Ambiguous - needs additional field for qualification (e.g. 'orange/brown' varieties only
Year of reporting (S.28)	Ambiguous - does this mean - year of exposure?
Result code (R.01)	Unclear what is required
Parameter code (R.06)	Ambiguous - why not use specific E-numbers?
Parameter text (R.07)	Ambiguous - how different from R.06? Why not link automatically?
Usage unit (R.A0)	
Usage level minimum (R.A1)	Data not used in EFSA/ANS exposure calculations - relevance?
Usage level typical (R.A2)	Data not used in EFSA/ANS exposure calculations - relevance?
Usage level maximum (R.A3)	Ambiguous - needs additional field for qualification (e.g. 'non-sterile packaging only')
Is maximum permitted level defined (R.A4)	Unnecessary – in legislation
Maximum permitted level (R.A5)	Unnecessary – in legislation
Function of food additive (R.A6)	Unnecessary – in legislation
Expression of the result (R.25)	
Comment of the result (R.32)	

The template needs to set up so that it is clear the inter-country differences can be clearly recorded. The specific nature of the usage also needs to be recorded, so that if its use is associated only with certain flavours/colours/varieties, then this can be taken into consideration in exposure estimates. Many products are presented as concentrates (either liquid or powders). The use levels in such products if frequently much higher than in the corresponding non-concentrated product and so it is necessary to indicate whether the product is concentrated or not and if it is, then what the appropriate dilution factor should be. In many cases an additive is used in only part of a food (e.g. coatings or fillings) in which case it is necessary to report this and the ratio of the part to the whole product.

Usage levels are further complicated by including both the Foodex codes and the food categories for authorised uses of food additives laid out according to Commission Regulation (EU) No 1129/2011. In some cases they do not refer to the same thing (e.g. an iced biscuit is a single category in Foodex but the legislation separates the icing (decoration) and biscuit (fine bakery ware); whilst it is likely that different colours are used in each section. There are also situations where categories are aggregated (e.g. 'Ices and desserts') whilst use levels for additive may be very different. The situation is also difficult because neither the Foodex coding system nor the Regulation (EU) No 1129/2011 system allows for different sub-categories within food groups that are important when considering use of food additives. For example, certain colours are used in only certain soft drinks (e.g. colas) and other additives, such as antioxidants are used to a much reduced extent in in low fat products. It is not clear how the data should be expressed in order to take all these factors systematically into account within the template.

Concentrations of additives are not necessarily the same as the amount added as at the point of the consumption. Available data of losses on storage, processing and handling should be included if available.

The term 'market share' is presently included. This should be replaced by 'occurrence', which is the proportion of available products in a given food category that have the additive listed in the ingredients on the label. This term does not include volume of sales of each product, which are more difficult to obtain and may be commercially sensitive.

Table 2. Proposed additional template fields with stakeholder comments

Missing fields	**Comment**
Country of consumption	Country(s) where food product is consumed
Presentation	Concentrate, powder, or as consumed?
Dilution factor	Factor to be applied if concentration values relate to concentrate/powder, etc.
Application	Whole product / coating / filling / etc. or if linked to fat content, etc.
Application factor	Factor to be applied if usage corresponds to only a part of the food (coating / filling / etc.) or fat content, etc.
Limitations of use	Particular colour/flavour/variety, etc.
Limitation factor	Proportion of the supply that corresponds to particular colour/flavour/variety, etc.
Loss on storage	e.g. amount present after average shelf-life
Loss on processing	e.g. loss on cooking prior to consumption
Loss on handling	e.g. effect of exposure to air,
Expression of additive concentration	Formulated product, additive as defined, active principal, etc. (should be linked to ADI definition, if available)
Occurrence	Proportion of supply that contains the additive