Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids

Minutes of the 50th Plenary meeting

Held on 21-23 October, 2014, Brussels (Belgium)

(Agreed on 25 11 2014)

Participants

- **Panel Members**

  Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Konrad Grob, Trine Husøy, Wim Mennes, Maria Rosaria Milana[1], André Penninks, Fátima Poças[2], Vittorio Silano, Andrew Smith, Christina Tlustos, Detlef Wölfle, Holger Zorn

- **Hearing Experts[3]:**
  - Andy Hart[4] (for item 6.1); Sirpa Kärenlampi[5] (for items 6.2, 6.3, 6.4);

- **European Commission and/or Member States representatives:**
  - Jonathan Briggs (DG SANCO), Gudrun Gallhof (DG SANCO), Miguel Angel Granero Rosell (DG SANCO), Rafael Luis Perez Berbejal (DG SANCO), Bastiaan Schupp (DG SANCO);

- **EFSA:**
  - Food Ingredients and Packaging (FIP) Unit: Margarita Aguilera-Gomez, Eric Barthélémy, Anna Federica Castoldi, Maria Correia, Cristina Croera, Marina Goumenou, Claudia Heppner, Georges Kass, Annamaria Rossi
  - Legal and Regulatory Affairs (LRA) Unit: Simone Gabbi[1]
  - Communications: Jan Op Gen Oorth

[1] Participated via teleconference
[2] Participated on 22 October 2014 PM and on 23 October 2014 PM via teleconference
[3] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[4] Participated on 21 October 2014
[5] Participated on 22 October 2014 PM via teleconference

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- **Observers: (In application of the guidelines for Observers[6])**
    1. Mr. Nicklas Amelin, Swedish Food Federation, Sweden
    2. Mr. Nigel Baldwin, INTERTEK, United Kingdom
    3. Mr. Ruud Bremmers, Regal B.V., The Netherlands
    4. Dr. Jan Demyttenaere, European Flavour Association – EFFA, Belgium
    5. Dr. Sven Gestermann, Bayer MaterialScience AG; Industrial Operations-Product Safety and Regulatory Affairs, Germany, Representing PlasticsEurope, Member of PC/BPA Group
    6. Ms. Anne-Marie Hamelton, PlasticsEurope, Belgium
    7. Mrs. Alison Joy Hardinge, ENZYBEL, United Kingdom
    8. Mr. Marc Jamin, SABIC, The Netherlands, Representing PlasticsEurope, Steering Member of PC/BPA Group
    9. Ms. Sara Lewis, EU Food Law, Belgium
    10. Dr. Francesca Martucci, Istituto Zooprofilattico Sperimentale Piemonte, Italy
    11. Dr. Melanie Möthrath, Bayer MaterialScience IO-PSRA, Germany, Representing PlasticsEurope, Chairperson of PC/BPA Group
    12. Dr. Peter Oldring, VALSPAR, United Kingdom. Representing CEPE & VALSPAR
    13. Dr. Donald Prater, U.S. Food and Drug Administration, U.S.A.
    14. Mr. Miguel Angel Prieto Arranz, The European Chemical Industry Council – Cefic, Belgium;
    15. Mr. Remy Reboullet, LABORATORY, France
    16. Ms. Rachida Semail, KELLER and HECKMAN LLP, Belgium
    17. Ms. Kate Trollope, EU Food Policy, Belgium
    18. Dr. Petrus W.M. Van Dijck, DSM, The Netherlands
    19. Dr. Rob Veraart, KELLER and HECKMAN LLP, Belgium
    20. Ms. Angelik I Vlachou, FoodDrinkEurope, Belgium
    21. Dr. Claudia Zoani, ENEA-UTAGRI, Italy

Items for Closed Session

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Roland Franz, Rainer Gürtler and Fidel Toldrá.

Fátima Poças did not participate in agenda point 6.1, 6.2, 6.3, 6.4, 6.8, 6.9, and 6.10,

[6] http://www.efsa.europa.eu/en/stakeholders/observers.html

2. Adoption of agenda

The agenda was adopted with the following changes.

Item 6.5 (Glass fibre sizing agents (EFSA-Q-2013-00838) was withdrawn from the draft agenda as DG Sanco (E6) indicated recently to submit revised Terms of Reference which requires a revision of the draft opinion.

Item 6.11 (FCM Guidance (EFSA-Q-2011-00107) was not presented for discussion and possible endorsement for pubic consultation as DG Sanco (E6) recently expressed the view for a two step approach outlining first the scientific rational for amending the existing FCM guidance and the current approach used to assess the safety of food contact materials substances as well as on the objectives to be pursued with the revision, and in a second step after having received information on the level of protection from the EC presenting the updated data requirements for the applicant and the overall data evaluation procedure .

3. Declarations of Interest of Scientific Committee/Scientific Panel/ Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[7] and the Decision of the Executive Director on Declarations of Interest[8], EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 49th Plenary meeting held on 23-25 September 2014, Parma (Italy)

The minutes of the 49th Plenary meeting held on 23-25 September 2014 were agreed.[9]

5. Report on the written procedures since 49th Plenary meeting

No scientific outputs were adopted by written procedure since the last plenary meeting.

6. Scientific outputs submitted for discussion and possible adoption

6.1 Bisphenol A (EFSA-Q-2012-00423)

The Chair of the WG on BPA presented, based on the comments received during the public consultation process, a revised approach how to assess uncertainties for the toxicological endpoints besides kidney weight, a revised conversion of the threshold dose in animals into its corresponding human oral equivalent dose and the implications on the uncertainty factor and the health based guidance value. The Panel generally agreed with these proposed revisions but an in depth discussion is needed once the revised text outlining these changes will be available.

6.2 Xylanase from genetically modified *Aspergillus oryzae* (strain NZYM-FA) (EFSA-Q-2013-00789)

The rapporteur introduced the draft opinion on the safety assessment of xylanase from a GM

[7] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[8] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[9] http://www.efsa.europa.eu/en/events/event/140923-m.pdf

strain of *A. oryzae* (NZYM-FA) and presented the main points for discussion. The CEF Panel members asked further clarifications to the CEF WG on Food Enzymes on some toxicological findings, particularly compared to the historical control data. The draft opinion will be scheduled again for possible adoption once this issue has been addressed.

6.3 Asparaginase from genetically modified *Aspergillus oryzae* (strain NZYM-SP) (EFSA-Q-2013-00587)

The rapporteur introduced the draft opinion on the safety assessment of asparaginase from a GM strain of *A. oryzae* (NZYM-SP) and pointed out that the exposure assessment is not yet available. The main points for discussions were the technical and toxicological data and the chapter on allergenicity. The members of the CEF Panel endorsed all these chapters. The draft opinion will be scheduled for possible adoption once the pending chapters on exposure assessment, risk characterisation (discussion), conclusion and summary will be available.

6.4 Alpha-amylase from genetically modified *Bacillus licheniformis* (strain NZYM-BC) (EFSA-Q-2013-00685)

The rapporteur introduced the draft opinion on the safety assessment of alpha-amylase from a GM strain of *B. licheniformis* (NZYM-BC) and pointed out that the exposure assessment is not yet available. The main points for discussion were the technical and toxicological data and the chapter on allergenicity. The members of the CEF Panel endorsed these chapters. The draft opinion will be scheduled for possible adoption once the pending chapters on exposure assessment, risk characterisation (discussion), conclusion and summary will be available.

6.5 Glass fibre sizing agents (EFSA-Q-2013-00838)

This agenda item was withdrawn (see item 2).

6.6 Roxane RECYC017 (EFSA-Q-2009-00916) ; Stute RECYC104 (EFSA-Q-2013-00613)

The rapporteurs introduced the draft opinion on the safety assessment of the recycling processes Roxane and Stute to the members of the CEF Panel and presented the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and adopted the opinion subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the Authority's webpage.

6.7 Pelestat (EFSA-Q-2014-00124)

The rapporteurs introduced briefly the draft opinion on the safety assessment of the substance, dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α-hydro-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1-propene for use in food contact materials. Due to lack of time the members of CEF Panel could not discuss in detail the different parts of the risk assessment. The chair of the CEF Panel proposed to adopt this opinion by written procedure.

Items for Open Session

Brief introduction of Panels members and Observers

A short introduction of the Panel members, the Observers participating in the open plenary meeting and EFSA scientific staff took place.

Presentation of the Guidelines for observers[10]

The Head of FIP Unit briefly presented the "Guidelines for observers" to the meeting participants.

6.8 FGE.12 Rev5 (EFSA-Q-2014-00343 to -00346)

The rapporteurs introduced the draft opinion on the safety assessment of the Flavouring Group Evaluation (FGE) 12 Rev5 to the members of the CEF Panel and presented the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and in principle adopted the opinion. However, the members of the CEF panel were informed by EFFA (Jan Demyttenaere) that additional usage levels were submitted to the European Commission which could be also taken into account. Although this information will not alter the conclusions, the CEP Panel decided to include these additional data into the safety evaluation. The chair of the CEF Panel proposed to adopt the opinion by written procedure**.**

6.9 FGE.300 Rev1 (EFSA-Q-2014-00072)

The rapporteurs introduced the draft opinion on the safety assessment of Flavouring Group Evaluation (FGE) 300 Rev1 to the members of the CEF Panel and presented the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and adopted the opinion subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the Authority's webpage

6.10 FGE.11 Rev3 (EFSA-Q-2014-00145)

The rapporteurs introduced the draft opinion on the safety assessment of Flavouring Group Evaluation (FGE) 11 Rev3 to the members of the CEF Panel and presented the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and adopted the opinion subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the Authority's webpage

6.11 FCM Guidance (EFSA-Q-2011-00107)

The chair of the CEF WG Food Contact Materials presented the scientific rational related to the revision on a guidance for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation. The actual guidance document was not discussed, for details please refer to item 2. EFSA is currently assessing the implication of these changes and a revised timetable will be discussed and shared with the members of the CEF Panel before the end of 2014.

7. New Mandates

The Head of the FIP unit informed the members of the CEF Panel on that overall, 11 new requests falling within the remit of the CEF Panel were received by EFSA since the 49th CEF plenary meeting (23-25 September 2014). Four requests related to safety assessment of food enzymes (EFSA-Q-2014-00667 to -00671) with the following status: under completeness check/registration not yet completed. One request related to the safety assessment of substances used in food contact materials (EFSA-Q-2014-00726) with the following status:

[10] Please refer to footnote 18

under completeness check/registration not yet completed. Two requests relate to the assessment of recycling processes (EFSA-Q-2014-00714, EFSA-Q-2014-00637) with the following status: under completeness check/registration not yet completed. Two requests relate to the re-evaluation of flavouring substances (EFSA-Q-2014-00675 to -00683) with the following status: under completeness check/registration not yet completed. Two requests related to the safety assessment of new flavouring substances (EFSA-Q-2014-00712 and EFSA-Q-2014-00713) with the following status: under completeness check/registration not yet completed.

8. Feedback from the Scientific Committee/the Scientific Panel, EFSA, the European Commission

8.1 Scientific Committee

No meeting of the Scientific Committee was held since the 49th CEF Panel meeting.

8.2 Working Groups

8.2.1 WG BPA Tox

In addition, to the information which is provided under item 6.1. the Chair of the CEF WG on BPA toxicology informed the meeting that based on the comments received during public consultation the revised chapters on non-monotonic dose response, toxicokinetics, benchmark dose calculations using individual data on kidney weight, and immunotoxicity were presented and discussed. The work is in good progress and the WG is confident to finalise the revision of the draft opinion in time, allowing the CEF Panel to possibly adopt the opinion within the current deadline of December 2014.

8.2.2 WG Enzymes

A member of the CEF Panel/ CEF WG on Food enzymes reported from the first WG meeting of the new CEF WG on food enzymes mandate 2014 to 2017 which took place from 30 September to 2 October 2014 in Valencia. Good progress was made on ongoing safety evaluations and refinement of exposure estimates. An applicant was invited, to a short part of the meeting, to provide additional clarifications in relation with an ongoing request for additional data on an enzyme application. In addition, the WG elaborated further on exposure information. In addition, the members of the WG updated further the EFSA technical report "Explanatory Note for Guidance" based on information which was provided during the 2nd APDESK info-session on food enzymes which was held on 27 May 2014. The updated explanatory note for guidance was – except for one item relating to the intake assessment - endorsement by the members of the CEF Panel.

8.2.3 WG Genotox

The FIP sector leader on flavourings informed that members of the CEF Panel on the outcome of the first WG meeting of the new CEF WG on genotoxicity mandate 2014-2017 which took place from 6-7 October 2014 in Copenhagen. To a joint session with the CEF WG Flavouring was held to accommodate a short technical hearing with EFFA to provide additional clarifications in relation with an ongoing request for additional data.

8.2.4 WG Flavourings

A chair of CEF WG on Flavourings reported from the first WG meeting of the new CEF WG on flavouring mandate 2014-2017. Intensive discussion on two FGEs took place and the WG concluded that additional data are needed in order to proceed with the evaluation. A

respective letter will be sent to the applicant. In addition, six FGEs were finalised and could be presented for possible adoption in upcoming CEF Plenary meetings.

8.2.5 WG Recycling Plastic

A chair of CEF WG on Recycling Plastics reported from the first WG meeting of the new CEF WG on recycling plastics mandate 2014-2017. The WG finalised one opinion which was presented to the 50th CEF Panel (see also item 6.6). To the next upcoming WG meeting it is foreseen to invite an applicant to a technical hearing to receive additional clarifications related to an ongoing request for additional data. In addition, the WG is confident to finalise additional draft opinions for presenting them for possible adoption to the next CEF Panel meeting.

8.2.6 SC WGs of relevance to CEF

The FIP sector leader on flavourings outlined mandate of CEF WG Genotox compared to the terms of reference and mandate of the SC WG on genotoxicity. The latter activity is an overarching activity related to all EFSA activities. The 1st meeting of the WG took place covering the following items: safety assessment of novel food application; applicability of QSAR analysis of pesticides and genotoxicity; safety assessment of brilliant black, and the WG commented on a paper which deals with yeast comet assay;

8.3 EFSA

8.3.1 General matters

The Head of the FIP unit informed the members of the CEF Panel on the following matters:

- EFSA's Management Board (MB) is meeting today (23 October 2014) and attention was drawn to some items on the draft agenda such as the election of chairs and vice-chairs for the MB, EFSA continuous improvement initiatives which includes a number of projects (Quality Management, **P**roject **a**nd **R**esource **Ma**nagement approach and **PROM**oting **METH**ods for **E**vidence **Us**e in Science) aiming to pursue EFSA's strategic objectives fit-for-purpose, sustainability and trust) and an update on the renewal and timetable of 8 Scientific Panels and the Scientific Committee which should be operational from July 2015 onwards.
- The main outcome of the last meeting of the Advisory forum which was held on 24-25 September 2014 in Venice: finalisation of the Scientific Cooperation Roadmap[11], a document which indicates the way forward on scientific cooperation, renewal of new of Focal Point agreements with the inclusion of additional tasks; introduction of a new cooperation tool on thematic grants, agreement to develop a procedure dealing with diverging scientific opinions, agreement to discontinue the harmonisation of risk assessment methodologies network and use instead a new approach involving subject specific meetings, and update from the Scientific Committee and CONTAM Panel EFSA.
- EFSA will have its open day for the public on 22 November 2014
- The move to the new document management system – Open text was successfully completed on 20 October 2014. Training to experts was provided and in case experts have difficulties it is recommended to contact the FIP representative for Open Text via the functional mailbox.

[11] Available at URL: http://www.efsa.europa.eu/en/press/news/141030.htm and http://www.efsa.europa.eu/en/corporate/pub/scientificcooperationroadmap1416.htm

- CEF plenary meeting dates 2015: The initially agreed September meeting date (1-3) was considered not suitable and it was agreed to have the meting on 8-10 September 2015.
- Two vacant posts in the FIP unit could be filled pending some administrative procedures. The new staff members will arrive begin of December 2014 and January 2015 and will join the sectors flavouring and food enzymes.
- A scientific officer responsible for the FIP network informed that CEF Panel members that the first FIP network meeting focussing on non-plastic food contact material will be held from 12 to 14 November in Parma. Details are available in the draft agenda.

8.4 European Commission

No information was presented from the European Commission responsible for Food contact materials (DG Sanco E6). The representatives of the European Commission responsible for enzymes and flavourings (DG Sanco E3) informed the members of the CEF Panel on a new way of working in relation with mandates for food enzymes which means that the dossiers will be submitted requesting EFSAs APDESK to carry out the suitability check within 30 working days. Deadlines to carry out the risk assessment will be agreed after March 2015 (legal deadline for the submission of applications). In the area of flavourings the Commission and Member States are discussing the following up of eight opinions which were adopted by the CEF panel.

9. Other scientific topics for information and/or discussion

No information was presented.

10. Questions from and answers to Observers (In application of the guidelines for Observers) [12]

Questions from Miguel Angel Prieto Arranz, The European Chemical Industry Council (Cefic), Belgium:

Question 1. "Workplan of the new CEF panel & priorities for 2014/2015"
Answer:

The workplan comprises safety evaluations of flavourings, food contact materials, recycling processes and food enzymes. For flavourings we expect to receive a higher number of mandates related to the re-evaluation of flavourings than for new applications. For food enzymes we expect – due to the submission date of 11 March 2015 as laid down in legislation -- a high number of applications, and therefore safety evaluation of food enzymes will become a major activity /priority for the CEF Panel over the next coming years. For food contact materials and recycling processes we expect a similar number of applications than in the past. The evaluation of BPA will be concluded in 2014.

Question 2. "Expected timeline and workplan (consultations, meeting with stakeholders, timelines, adoption, etc.) in relation to the "Food Contact Materials Note for Guidance"
Answer:

[12] Pease refer to footnote 18

The scientific content of the draft guidance was discussed during this CEF plenary meeting. Recently DG Sanco expressed the view to produce two parts first a scientific opinion presenting a scientific analysis of the need for amending the existing approach as well as on the objectives to be pursued with the revision and on clear guidance terms of reference for the revision and secondly the updated data requirements for the applicant and of the overall data evaluation procedure. We are currently assessing the implication of these changes and will come back with a revised timetable before end of 2014.

Question from Melanie Möthrath, Bayer MaterialScience IO-PSRA, Germany, Representing: PlasticsEurope, Chairperson PC/BPA Group:

ECHA started a public consultation on an Annex XV restriction report for BPA on 18 June 2014 that will last for 6 months concluding on 18 December 2014.
The proposal to restrict bisphenol A in thermal paper is based on a risk assessment that was forward to ECHA by France in January 2014.

Question 3. "Does EFSA interact with ECHA's Risk Assessment Committee (RAC) on BPA and/or is EFSA planning to submit comments during ECHA's public consultation period?"

Answer:

EFSA and ECHA communicate on a regular basis via videoconference on themes of common interest.

Concerning the specific case of the French restriction proposal this refers to risk management measures and to thermal paper. EFSA is aiming to complete the BPA opinion by end of 2014 and will share it with all the relevant partners including ECHA.

Question from Melanie Möthrath, Bayer MaterialScience IO-PSRA, Germany, Representing: PlasticsEurope, Chairperson PC/BPA Group and from Sven Gestermann, Bayer MaterialScience AG; Industrial Operations-Product Safety and Regulatory Affairs, Germany, Representing: PlasticsEurope, Member of PC/BPA Group:

Question 4. "What is EFSA's view on the scientific reasoning of the Annex XV report?"

Answer:

The restriction proposal is based on the risk assessment of Anses which is concentrated on the effects of BPA seen at low doses and refers specifically to brain/behaviour, mammary gland and metabolism in addition to reproduction. EFSA will adopt its opinion by the end of this year and will draw its conclusions on the risks for consumers based on the analysis of all relevant toxicity endpoints including these ones. In this respect the WG is working on a detailed uncertainty analysis for all the various endpoints. During this whole process EFSA is closely liaising with Anses in line with Art 30 of EFSA's founding regulation to avoid or solve divergences between the Authority and MSs.

Questions from Nigel Baldwin, Intertek, United Kingdom:

Question 5. "Will EFSA be able to amend the guidance on enzymes to allow some rules which may allow on a case by case basis studies in finished products made with enzymes to support the toxicology requirements on the enzyme itself. E.g. if the enzyme is only used to make a novel food and the exposure is covered and measurable etc?"

Answer:

According to EFSA guidance on food enzymes, the requirements for toxicological data may in some cases be reduced or completely waived. The justifications for not supplying toxicological data are explained in the guidance and in the EU legislation.

When it comes to food enzymes used in the manufacturing of novel foods and these enzymes have been evaluated and authorised in France or/and Denmark, the full toxicological dataset should be provided. Unless the enzyme in question comply with the requirements for derogation specified in the EU legislation (Reg. 562/2012).

Question 6. "Regarding genotoxicity studies is it acceptable to provide the following two OECD tests for a novel food submission: Bacterial reverse mutation test in Salmonella typhimurium and Escherichia coli (OECD TG 471) In vitro mammalian cell gene mutation test (OECD TG 476)"

Answer:

The Guidance document for food enzymes suggests conducting two in vitro genotox studies, but stresses that with these two tests all three endpoints for genotoxicity need to be covered: gene mutations, structural chromosomal and numerical chromosomal effects. The guidance is applicable for food enzymes. For Novel foods the respective guidance document should be consulted as they may be different.

Questions from Jan Demyttenaere, European Flavour Association - EFFA, Belgium:

Question 7. "To maximize efficiency in the evaluations program and industry's timely responses, is it possible to pass substances through both the "Evaluation procedure" and the genotoxicity assessment simultaneously? The identification of such potential data gaps or potential needs for additional toxicity data (or biotransformation data or other) much earlier in the entire evaluation process could dramatically streamline the program and reduce the time required for evaluation."

Answer:

According to the procedure a substance need first to be cleared for genotoxicity. This is evaluated by the Genotoxicity WG. After this first step the substance will be evaluated by the Flavouring WG for general toxicity. The simultaneous evaluation of substances prior the clearance for genotoxicity will cause only additional work to the Flavouring WG and therefore a delay for the evaluation of substances for which genotoxicity has been ruled out. Additionally, early submission of full data package by the applicant could contribute to streamline the program.

Question 8. "Would a clear picture of the biotransformation of a substance (or closely related susbstance(s)) under any circumstances be sufficient to waive the requirement for a 90-day study?"

Answer:

A clear picture of the biotransformation of a substance need to be substantiated by appropriate experimental data or by relevant literature.

If these data clearly prove that the substance is metabolised in innocuous products then the substance may be evaluated via the A side of the Procedure. Depending on the decisions taken in the various steps of the A-side, the need of a 90 day can be waived. However, if exposure is above the TTC for the structural class to which a substance belongs, still a 90 day toxicity study may be needed. Under the new guidance, at very

high levels of exposure (expressed as Added Portions Exposure Technique APET) a developmental toxicity study shall be available.

Question 9. "In light of recent discussions on the use of probabilistic modeling on intake (e.g., FACET), can the EFSA Panel envision a future consideration of such data within a safety assessment submission?"

Answer:

For substances covered by the re-evaluation program under Regulation (EU) No 1565/2000 the estimation of dietary exposure is evaluated via MSDI and mTAMDI. For new substances under Regulation (EU) No 1334/2008 following the new EFSA guidance on data required for the risk assessment of flavourings the intake will be calculated using the "Added Portions Exposure Technique". The safety assessment of the new flavouring therefore do not foresee for the time being the sole use of probabilistic models such as FACET. However, it is noted that to conduct a reliable probabilistic modelling rather detailed use levels in food need to be available. Up to now, such data are not commonly provided but would be an interesting development.

Questions from Kate Trollope, EU Food Policy, United Kingdom:

Question 10. "With regards to EFSA's extensive work on Bisphenol A, can you give a short summary of some of the most important points raised on this topic during the private part of this meeting earlier this week?"

Question 11. "Can you explain why it was not possible to have the discussion on BPA in a public session, given that this is not an application and there is no confidential data supplied by firms as there would be for an authorisation request?"

Answer:

To address the two questions on BPA together, EFSA has done a lot to engage with stakeholders and interested parties during its current work on BPA. We launched separate public consultations in a two-stage approach – firstly on the draft opinion focussing on the assessment of human exposure to BPA and subsequently on the potential health risks of BPA for consumers.

EFSA engaged further by following up with a very constructive meeting with stakeholders - representatives of national food safety authorities, NGOs, academia and the food industry – when we were able to exchange views on the wide range of comments received.

EFSA has implemented important measures over the years to support openness and transparency goals and the opening up of Panel meetings such as this one to observers is a step in the right direction. Though EFSA also needs to strike a balance - EFSA depends on the voluntary participation of external independent experts for producing scientific advice and these experts need to be able to feel free to hold open and frank scientific discussion.

What can be said about the session on BPA which took place on 21 to 22 October 2014 is that the Panel was able to further discuss the uncertainties regarding some toxicological endpoints which will lead to the definition of the uncertainty factor to be applied to the point of departure from which we will derive the TDI. The Panel also looked at parts of the opinion text that had been revised in light of the public consultation and finalised them. More work needs to be done and this will be further explained in the final opinion.

Question 12. "With regard to EFSA's work on food flavourings, is it possible to NAME some of the foods that these flavourings are used in and simplify what is being said into normal English? It seems to me that EFSA does a lot of work on flavourings but gets very little credit. It is quite hard to write articles because we just have these enormously long chemical names which don't mean much to anyone. But if in the Opinions, they could make it a bit more user friendly and say that the flavouring x is used in breakfast cereals, soft drinks and mayonnaise (for example!) it would make it a bit more accessible."

Answer:

We are aware that some of the language used in the flavouring opinions can be complex. The Regulation on the evaluation of flavourings can be quite prescriptive, and many of the substances are assessed in classes which can also add to the complexity. In flavouring re-evaluations, EFSA does not receive information about which type of product the flavouring substances are used in. We only have an indication of the potential presence of the flavouring in a food category and these data are generally reported in the exposure table.

However, the Panel will keep your comments in mind for future new evaluations, and we can encourage the Working Group to include data, when these are available, in a more comprehensible way.

In addition, you may be aware that EFSA's Scientific Committee recently adopted a revised template for the structure and content of EFSA's scientific assessments and this is aimed at providing greater transparency in relation to data, methods and assumptions. This may also go some way to making our opinions friendlier to the reader.

Question from Alison Joy Hardinge, Enzybel, United Kingdom:

Question 13. "A number of joint dossiers have been submitted, covering a lot of producers in one dossier and I wonder if the Panel could comment on how they will deal with these. Previous dossiers have either been company specific or covered only 2 producers and for these a number of producer-specific details have been requested such as strain deposition. I am interested to know how this will be dealt with when the dossier covers an enzyme produced by many different companies."

Answer:

The legislation has foreseen that food enzymes may be grouped under one application provided that they have the same catalytic activity, are processed from the same source material and with a substantially same production process, and have been obtained from either from edible parts of plants or animals intended to be or reasonably expected to be ingested by humans; or from micro-organisms having the status of Qualified Presumption of Safety; or from micro-organisms which have been used in the production of food enzymes that have been evaluated and authorised by the competent authorities in either France or Denmark in accordance with the SCF guidelines of 1992.

The applicants will have to demonstrate and substantiate with data that the requirements as requested in the legislation, e.g. same catalytic activity, processed from the same source material and with a substantially same production process are met. This procedure will not apply to GMM derived enzymes.

Further to the above mentioned questions which were submitted with the registration of 21 observers the following additional questions were raised during the meeting:

Question from Peter Oldring, VALSPAR, United Kingdom:

Question 14. "Related to the draft food contact material guidance this is an important step forward to recognise exposure. By when will be the scientific opinion be likely to be published as there is not a harmonised European legislation in place for non-plastics."

Answer:

See answer to question 2.

Question from Rob Veraart, Keller &Heckman, Belgium:

Question 15. "A new guidance document on food contact materials will be produced. What is the transition time when this new guidance will come in place?"

Answer:

The new draft guidance document will be published for public consultation which allows applicants to view and comment on the draft output. In case applications which have been submitted under the old guidance the process would allow to ask for additional information related to the new guidance document if needed. Applications which will be submitted after the guidance document is published should follow the new guidance's document. The study which EFSA conducted to assess the implication of the revised draft guideline indicated that only a very small percentages would need to be re-evaluated.

Question from Petrus W.M. Van Dijck, DSM, the Netherlands:

Question 16. A question of clarification was asked related to the explanatory note for guidance section 3.2.1.3., particularly "is a re-testing needed also if additional mutations are introduced by classical mutagenesis or would this apply to GMM stains only?"

Answer:

This section should refer to the statement that "neither pathogenic nor toxigenic microorganisms are used for food enzyme production", thus the re-testing would also apply to strains modified by additional classical mutagenesis. Specific text will be updated in the explanatory note (EFSA supporting publication EN:689).

Question from Sara Lewis, EU Food Law, United Kingdom:

Question 17. How will the Panel deal in the area of food contact materials and the upcoming revised guidance with non-linear and low dose effects?"

Answer:

The draft food contact materials guidance does not foresee to include non-monotonic dose response as there is no general agreement in regulatory toxicology on this observation yet. EFSA SC is currently working on this matter.

Question from Rachida Semail, Keller & Heckman, Belgium:

Question 18. A question was asked in relation with the item which was withdrawn from the agenda (6.5). "What is the timeline which will be given to EFSA to produce the

output as in the plastic regulation it is indicated that by end of next year Commission should have set measures, will the timeline which is indicated in the legislation be postponed?"

Answer:

This question is not falling into EFSA's remit and thus the representative of the European Commission (EC) was invited to respond. EC indicated that there was a hearing with industry and EC will submit revised TOR to EFSA soon. As regards the legal timeline and next steps this will be communicated in the near future.

11. Any Other Business

No any other business was raised.