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

Minutes of the 57th Plenary meeting

Held on 8-10 September 2015, Parma (Italy)

(Agreed on 27 October 2015)

Participants

a) Panel Members

Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel, Konrad Grob, Rainer Gürtler, Trine Høysæ, Sirpa Orvokki Käräjälampi, Wim Mennes, Maria Rosaria Milana, André Penninks, Fátima Poças, Vittorio Silano, Andrew Smith, Christina Tlustos, Detlef Wölfle, Holger Zorn, Corina Zugravu

b) Hearing Experts:

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c) European Commission and/or Member States representatives:

- Miguel-Angel Granero Rosell (DG SANTE)
- Bastiaan Schupp (DG SANTE)


d) EFSA:

- Food Ingredients and Packaging (FIP) Unit: Margarita Aguilera-Gomez, Maria Anastassiadou, Magdalena Andryszkiewicz, Eric Barthélémy, Mary Carfi, Anna Federica Castoldi, Maria Correia, Cristina Croera, Marina Goumenou, Claudia R oncancio Peña, Annamaria Rossi, Kim Rygaard Nielsen, Rositsa Serafimova, Anne Theobald, Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Paul Fowler, Roland Franz and Fidel Toldrá.

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1 Participated on 9 September 2015
3 Participated via teleconference
2. Adoption of agenda
The agenda was adopted without any changes.

3. Declarations of Interest of Scientific Committee/Scientific Panel/ Members
In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest,⁵ 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. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 56th Plenary meeting held on 23-24 June 2015, Parma (Italy)
The minutes of the 56th Plenary meeting held on 23-24 June 2015 were agreed.⁶

5. Report on the written procedures since 56th 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 Request for safety assessment of San Miguel Industrias PET recycling process to produce recycled plastic for food contact uses - Starlinger IV+ technology (EFSA-Q-2014-00167)
The draft opinion on the safety assessment of the recycling process San Miguel Industrias PET was presented to the members of the CEF Panel together with 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 opinion is available on the Authority’s webpage.

6.2 Request for safety re-assessment of 2,4-di-t-amylyphenol (impurity and hydrolysis product of the substance phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4- (1,1-dimethylpropyl)phenyl triesters) (EFSA-Q-2015-00091)
The draft opinion on the safety assessment of the substance 2,4-di-t-amylyphenol was presented to the members of the CEF Panel together with 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 opinion is available on the Authority’s webpage.

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⁶ http://www.efsa.europa.eu/sites/default/files/event/150623a-m.pdf
6.3 **Mandate for supplying additional information following the recent publication: an inconclusive opinion on HDPE recycling processes** *(EFSA-Q-2015-00238)*

The CEF Panel discussed and agreed on the approach to take in addressing the 1st step of a mandate received from the EC to supplement the inconclusive opinion on HDPE recycling processes. Such mandate requires to identify the substances for which - on the basis of the Carcinogenic Potency Database - the most severe exposure threshold value (i.e. 0.15 μg/person/day) in the context of TTC is applicable and to provide the list of these substances.

The Panel proposed that some comments to the draft Panel statement could be collected from the experts early in October and addressed in the revised document to be presented for discussion and possible adoption at the 58th CEF Panel meeting later in October 2015.

6.4 **Scientific statement on the refinement of exposure estimates for food enzymes** *(EFSA-Q-2015-00468)*

The CEF Panel was informed that the self-tasking mandate proposed to EFSA by the CEF Panel for a scientific statement on the refinement of exposure estimates for food enzymes was accepted and the rapporteur presented the draft statement which explains the tiered approach for the refinement. The Panel suggested some modifications and endorsed the document. It was also suggested complementing the draft statement with examples how the tiered approach will be applied. Both documents will be presented to stakeholders for discussion during a technical meeting taking place on 24 November 2015 and will be made available at the EFSA webpage announcing this event: [http://www.efsa.europa.eu/en/events/event/151124a](http://www.efsa.europa.eu/en/events/event/151124a). The adoption of the final statement is planned for February 2016.

6.5 **FGE.213 Rev2: FL 07.014 Maltol** *(EFSA-Q-2015-00138)*, **FL 09.525 Maltyl isobutyrate** *(EFSA-Q-2015-00139)*

The draft opinion on the safety assessment of the Flavouring Group Evaluation 213, Revision 2, was presented to the members of the CEF Panel together with 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 opinion is available on the Authority’s webpage.

6.6 **FGE.09 Rev6: FL 07.219 trans-3-methyl-2-(2-pentenyl)-2-cyclopenten-1-one** *(EFSA-Q-2015-00318)*

The draft opinion on the safety assessment of the Flavouring Group Evaluation 09, Revision 6, was presented to the members of the CEF Panel together with 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 opinion is available on the Authority’s webpage.

The draft opinion on the safety assessment of the Flavouring Group Evaluation 35, Revision 1, was presented to the members of the CEF Panel together with 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 opinion is available on the Authority’s webpage.

6.8 FGE.49 Rev1: FL-no 16.032 Theobromine ([EFSA-Q-2011-00049]), FL-no 16.016 Caffeine ([EFSA-Q-2011-01015])

The strategy on safety assessment of the Flavouring Group Evaluation 49, Revision 1, was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the strategy on the risk assessment and agreed with the approach of the Flavouring Working Group.

The draft opinion will be presented to the CEF Panel for adoption in a next meeting.


The Chair of the SWG on flavourings introduced the draft opinion on the safety assessment of the Flavouring Group Evaluation 51, Revision 2, 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 asked the Flavouring WG to request to the applicant additional clarification.

7. New Mandates

The Head of the FIP unit informed the members of the CEF Panel that seventeen new mandates for the safety assessment of enzymes, eight new mandates for the safety assessment of food contact materials and two new mandates for the safety assessment of flavourings had been received since the last Plenary meeting.

7.1 New applications since the previous meeting

<table>
<thead>
<tr>
<th>Food Sector</th>
<th>EFSA-Q-Number</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENZ</td>
<td>2015-00395</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme lysozyme from hen’s egg</td>
</tr>
</tbody>
</table>
| ENZ | 2015-00406 until 410 | Request for EFSA to perform a scientific risk assessment on the food enzyme Hexose from a genetically modified strain of *Hansenula polymorpha* (strain DP-Jza21)  
Request for EFSA to perform a scientific risk assessment on the food enzyme Pectin lyase from a genetically modified strain of *Aspergillus niger* (strain NZYM-PN)  
Request for EFSA to perform a scientific risk assessment on the food enzyme Xylanase from a genetically modified strain of *Bacillus subtilis* (strain LMG-S-27588)  
Request for EFSA to perform a scientific risk assessment on the food enzyme Beta-galactosidase from *Klyuveromyces lactis*  
Request for EFSA to perform a scientific risk assessment on the food enzyme Lysophospholipase from a genetically modified strain of *Trichoderma reesei* (strain RF7206) |
| --- | --- | --- |
| ENZ | 2015-00445 until 449 | Request for EFSA to perform a scientific risk assessment on the food enzyme: Carboxypeptidase C from a GM strain of *A. niger* (PEG)  
Request for EFSA to perform a scientific risk assessment on the food enzyme: Maltogenic amylase from a GM strain of *E. coli* (BLASC)  
Request for EFSA to perform a scientific risk assessment on the food enzyme: Triacylglycerol Lipase from a GM strain of *A. niger* agg. (FL100SC)  
Request for EFSA to perform a scientific risk assessment on the food enzyme: Glucan 1,4-alpha-maltotetrahydrolase from a GM strain of *B. licheniformis* (DP-Dzf24)  
Request for EFSA to perform a scientific risk assessment on the food enzyme: Catalase from *A. niger* (AE-CN) |
| ENZ | 2015-00450 until 454 | Request for EFSA to perform a scientific risk assessment on the food enzymes: Pullulanase from *K. pneumoniae* (AE-PUL)  
Request for EFSA to perform a scientific risk assessment on the food enzyme: Pullulanase from *P. naganoensis* (AE-PL)  
Request for EFSA to perform a scientific risk assessment on the food enzyme: Rhizopuspepsin from *R. niveus* (AE-N)  
Request for EFSA to perform a scientific risk assessment on the food enzyme: Rennet paste from abomasum of goat (*Capra aegagrus hircus*), sheep (*Ovis aries*) and cattle (*Bos primigenius*)  
Request for EFSA to perform a scientific risk assessment on the food enzyme: Cellulase from a GM strain of *T. reesei* (DP-Nzc36) |
| ENZ | 2015-00468 | Self-Tasking mandate proposed to EFSA by the CEF Panel for a scientific statement on the refinement of exposure estimates for food enzymes |
FCM 2015-00404 Request for the evaluation of Polisan Hellas S.A. recycling process for poly(ethylene terephthalate) for direct food application – Starlinger iV+ technology.

FCM 2015-00411 Request for safety evaluation of VINNAPAS® LL 8324 for use as additive in plastics

FCM 2015-00414 Request for the evaluation of poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate).

FCM 2015-00427 Request for safety evaluation of ground sunflower seed shells (lignocellulose) for use as additive plastics

FCM 2015-00434 Request for the evaluation of an additive: α-Tocopherol acetate (CAS Reg. No 7695-91-2 and 58-95-7)


FCM 2015-00444 Request for the evaluation of Pokas Arcadian recyle Ltd recycling process for Polypropylene (PP) and High Density Polyethylene (HDPE) for food contact application

FCM 2015-00480 Request for safety evaluation of Coopbox recycling process to produce recycled plastic for food contact uses

FLAV 2014-00712 8-Methyldecanal

FLAV 2014-00713 8-Methylnonanal

7.2 Valid applications since the previous meeting

Applications considered valid for the start of the assessment:

<table>
<thead>
<tr>
<th>Food Sector</th>
<th>EFSA-Q-Number</th>
<th>Subject</th>
<th>Valid on</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENZ 2015-00275</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Beta-amylase from a genetically modified strain of Bacillus licheniformis (strain NZYM-JA)</td>
<td>24/06/2015</td>
<td></td>
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<tr>
<td>ENZ 2014-00851</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Microbial Rennet from R. miehei</td>
<td>24/06/2015</td>
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<tr>
<td>ENZ 2015-00065</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Xylanase from a genetically modified strain of B. subtilis (LMG S-24584)</td>
<td>30/06/2015</td>
<td></td>
</tr>
<tr>
<td>ENZ 2015-00288</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Ribonuclease P from Penicillium citrinum (strain AE-RP)</td>
<td>30/06/2015</td>
<td></td>
</tr>
<tr>
<td>ENZ 2015-00289</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Glutaminase from Bacillus amyloliquefaciens (strain AE-GT)</td>
<td>30/06/2015</td>
<td></td>
</tr>
<tr>
<td>ENZ 2015-00323</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Beta-fructofuranosidase from Saccharomyces cerevisiae</td>
<td>30/06/2015</td>
<td></td>
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<tr>
<td>ENZ 2015-00338</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme Trypsin from porcine pancreatic glands</td>
<td>30/06/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00339</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme Triacylglycerol lipase from <em>Candida cylindracea</em></td>
<td>30/06/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00129</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Chymosin from a genetically modified strain of <em>K. lactis</em> (CHY)</td>
<td>10/07/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00084</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Alpha-amylase from a genetically modified strain of <em>B. licheniformis</em> (NZYM-AN)</td>
<td>21/07/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00372</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Trypsin and Chymotrypsin from porcine pancreatic glands</td>
<td>22/07/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00373</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Peptidase from a strain of <em>Aspergillus oryzae</em> (strain NZYM-EX)</td>
<td>22/07/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00067</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Cellulase from <em>Trichoderma viride</em> (AE-CT)</td>
<td>23/07/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00097</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Glucanase from <em>S. violaceoruber</em> (pGlu)</td>
<td>06/08/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00127</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Pullulanase from a genetically modified strain of <em>B. subtilis</em> (NZYM-AK)</td>
<td>06/08/2015</td>
</tr>
<tr>
<td>ENZ</td>
<td>2015-00395</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme lysozyme from hen’s egg</td>
<td>06/08/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00407</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme Pectin lyase from a genetically modified strain of <em>Aspergillus niger</em> (strain NZYM-PN)</td>
<td>13/08/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00408</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme Xylanase from a genetically modified strain of <em>Bacillus subtilis</em> (strain LMG-S-27588)</td>
<td>13/08/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00274</td>
<td>Calcium Phosphoryl Oligosaccharide (POs-Ca®) added for nutritional purposes to foods, food supplements and foods for special medical purposes</td>
<td>27/08/2015</td>
</tr>
<tr>
<td>ENZ</td>
<td>2015-00446</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Maltogenic amylase from a GM strain of <em>E. coli</em> (BLASC)</td>
<td>3/09/2015</td>
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<tr>
<td>ENZ</td>
<td>2015-00447</td>
<td>Request for EFSA to perform a scientific risk assessment on the food enzyme: Triacylglycerol Lipase from a GM strain of <em>A. niger agg.</em> (FL100SC)</td>
<td>3/09/2015</td>
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<td>ID</td>
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<td>Description</td>
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<tr>
<td>SMK</td>
<td>2015-00313</td>
<td>Smoke Flavouring Primary Product RS1003</td>
<td>26/06/2015</td>
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<tr>
<td>FLAV</td>
<td>2014-00713</td>
<td>8-Methylnonanal</td>
<td>27/08/2015</td>
</tr>
<tr>
<td>FLAV</td>
<td>2014-00712</td>
<td>8-Methyldecanal</td>
<td>27/08/2015</td>
</tr>
<tr>
<td>FCM</td>
<td>2015-00121</td>
<td>Request to evaluate Methanone,(2,4-difluorophenyl)(4-fluorophenyl)-</td>
<td>01/07/2015</td>
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<tr>
<td>FCM</td>
<td>2015-00114</td>
<td>Request for safety evaluation of Sumilon Eco PET SARL recycling process to produce recycled plastic for food contact uses (Starlinger Iv+)</td>
<td>14/07/2015</td>
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<tr>
<td>FCM</td>
<td>2015-00245</td>
<td>Request for the evaluation of ITD recycling process for poly(ethylene 8erephthalate) for direct food application (Starlinger Iv+)</td>
<td>06/08/2015</td>
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<tr>
<td>FCM</td>
<td>2015-00238</td>
<td>Mandate for supplying additional information following the recent publication: an inconclusive opinion on HDPE recycling processes</td>
<td>07/08/2015</td>
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<td>FCM</td>
<td>2015-00434</td>
<td>Request for the evaluation of an additive: ?-Tocopherol acetate (CAS Reg. No 7695-91-2 and 58-95-7)</td>
<td>25/08/2015</td>
</tr>
</tbody>
</table>

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

8.1 Scientific Committee and Scientific Panel including their Working Groups

The Scientific Committee Plenary was held 23 July 2015. A presentation was made by the Chair where the proposed work-programme 2015-2018 of the Scientific Committee was presented.

8.1.1 CEF SWG Food Enzymes

8.1.2 CEF SWG Genotoxicity

8.1.3 CEF SWG Recycling Plastics

8.1.4 CEF SWG Food Contact Materials
8.2 EFSA including its Working Groups /Task Forces

- A presentation made by the Legal and Regulatory Affairs was made on issues related with the management of confidentiality and data protection, according to the provisions of Regulation (EC) No. 1935/2008.
- The Work Program 2015 – 2018 for future Guidance documents was discussed at the meeting.
- The Panel was informed that Benzenepropanamide 3,5-bis(1,1-dimethylethyl)-4hydroxy-, N-C16-18-alkyl derivs (EFSA-Q-2013-00425) data will be requested to the applicant.

8.3 European Commission

Not discussed due to lack of time

9. Other scientific topics for information and/or discussion

None

10.Any Other Business

None