European Food Safety Authority

Food Ingredients and Packaging Unit (FIP UNIT)

FIP Scientific Network
on Food Contact Materials
Minutes of the 1st meeting
Held on 12-14 November 2014, Parma

(Agreed on 19 January 2015)[1]

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	Name
Austria	Roland Grossgut
Austria	Johanna Foisner
Belgium	Fabien Bolle
Bulgaria	Snezhana Todorova
Croatia	Nino Dimitrov
Czech Republic	Jitka Sosnovcová
Denmark	Gitte Alsing Pedersen
Denmark	Jens Højslev Petersen
Finland	Marja Pitkänen
France	Gilles Rivière
France	Stephane Leconte
Germany	Stefan Merkel
Germany	Karla Pfaff
Greece	Zoe Mousia
Hungary	Katalin Frecskáné Csáki
Italy	Riccardo Crebelli
Lithuania	Paulius Pavelas Danilovas
Luxembourg	Sandy Nosbusch
Malta	Flavia Zammit
Netherlands	Bianca Van de Ven
Portugal	Maria Fátima Poças
Slovakia	Milada Sycova
Spain	Perfecto Paseiro Losada
United Kingdom	Emma Bradley
Norway	Inger-Lise Steffensen

[1] The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.

European Food Safety Authority – Via Carlo Magno 1/a, 43126 Parma, ITALY
Tel: (+39) 0521 036 111 • Fax: (+39) 0521 036 110 • www.efsa.europa.eu

* No nominations were received from Cyprus, Estonia, Latvia, Romania, Slovenia, Sweden, Iceland and Liechtenstein

- **Scientific Committee Panel Members:**
  - Laurence Castle, Maria Rosaria Milana (CEF Panel)
- **Other members/observers:**
  - Bastiaan Schupp (EC_DG SANCO)
  - Barbara Raffael (EC_JRC)
  - Catherine Simoneau (EC_JRC)
  - Susanne Bahrke (CoE)
  - Vincent Dudler (Switzerland)
  - Gordana Milojevic Miodragovic (Serbia)
- **EFSA:**
  - FIP Unit : Eric Barthélémy (chair for agenda points 11-14; speaker for agenda point 10), Claudia Heppner (chair for agenda points 15-16; speaker for agenda point 5), Georges Kass (chair for agenda points 1-10 and 17-19; speaker for agenda point 6), Joaquim Maia (secretariat), Maria Luisa Escudero Hernandez, Rositsa Serafimova
  - Repro Department: Per Bergmann participated in agenda point 1 as speaker
  - EDIT Unit (Anthony Smith: participated in agenda points 10, 14 and 16

1. Welcome and apologies for absence

Georges Kass, as the Chair of the first session, opened the meeting and welcomed the participants.

Per Bergman, Head of the Scientific Evaluation of Regulated Products Department welcomed the participants and introduced EFSA Scientific Networks. He highlighted the publication of the EFSA Scientific cooperation roadmap[2] on 30 October 2014.

The participants were invited to introduce themselves during a tour de table.

Apologies were received from 5 Network Representatives of Member States (Nino Dimitrov (HR), Rhodri Evans (IR), Nikiforo Iliopoulos (GR), Marzena Pawlicka (PL) and Marja Pitkänen (FI)) and from 2 Observers (Ivana Jokimovic (ME) and Martine Jequier (CoE)).

Representative Karla Pfaff (DE) and Stefan Merckel (DE) did not participate in agenda points 1 to 13.

Representative Catherine Simoneau (JRC) did not participate in agenda points 1 to 16.

Representative Vincent Dudler (CH) did not participate in agenda points 17 to 19.

Representative Fabien Bolle (BE) did not participate in agenda points 18 and 19.

[2] http://www.efsa.europa.eu/en/corporate/pub/scientificcooperationroadmap1416.htm.

2. Adoption of agenda

The agenda was adopted with the following changes: a presentation from the representative of Denmark was added to agenda point 15 and agenda points 7 and 8 were presented in a single presentation by DG SANCO representative.

3. Topics for discussion

3.1 Presentation of the FIP Network mandate

Claudia Heppner, Head of the Food Ingredients and Packaging (FIP) Unit, gave a short introductory presentation on EFSA organization and FIP's place within the agency. The FIP Network mandate[3] was outlined, and the terms of reference and objectives of the network were described. A focus was given to harmonization of risk assessment practices and cooperation between risk assessment experts. The adopted working methods were also outlined.

The participants welcomed the initiative.

3.2 Introduction to the meeting on non-plastics food contact material

Georges Kass introduced the topic of the meeting on non-plastic food contact materials. From the different types of food contact materials referred in annex I of the Regulation (EC) No 1935/2004[4], only a few are object of EU specific measures like for plastics (Regulation (EU) No 10/2011[5]). Coatings, printing inks and papers and boards have no specific EU regulation whereas they are regulated at national level. Georges Kass highlighted the need to share ongoing activities and approaches used for risk assessment at the national level.

It was emphasised that "non-plastics" means food contact materials and articles without EU specific measure as mentioned in article 5 of the Regulation (EC) No 1935/2004.

3.3 European legal framework on non-plastics food contact materials and EU baseline study on non-regulated materials

The DG SANCO delegate presented an overview on the current EU legislation on food contact materials (FCM) and risk assessment policies. It highlighted that an explicit EU risk assessment policy does not exist for food contact materials. Focus was given to twelve elements of EU risk assessment policy which follow from FCM legislation, and which have implications to risk assessment. The general situation on non-harmonized food contact materials was summarized. In this context, the FCM roadMap project[6] was mentioned, highlighting objectives and main operational steps (baseline, development of policy options, impact assessment).

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[3] http://www.efsa.europa.eu/en/fip/fipnetworks.htm.

[4] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4-17.

[5] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance. OJ L 12, 15.1.2011, p. 1–89

[6] http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_sanco_005_fcm_specific_provisions_for_materials_other_than_plastics_en.pdf.

The importance to consider the intended use of a substance in its safety assessment was outlined during the discussion.

3.4 International activities on non-plastics food contact materials

The Council of Europe (CoE) delegate presented ongoing work on coatings, papers and boards, printing inks and metals and alloys.[7] A brief resume of the resolutions adopted for each of these FCM was given. The ongoing work program of the Committee of experts on packaging (P-SC-EMB) for the 4 materials mentioned above was presented.

It was clarified during the discussion that CoE does not carry out risk assessment as such but undertakes a critical review of collected evaluations, e.g. from Member States (MS), Food and Drug Administration (FDA), EFSA.

3.5 EFSA activities: Non-plastics food contact materials and Draft revised guidelines on plastics

Eric Barthélémy presented EFSA activities on non-plastic FCM focusing on the report of the EFSA Scientific Cooperation (ESCO) Working Group (WG) on non-plastics published in 2011[8]. It was reminded that "non-plastics" meant FCM without EU specific measure. The ESCO WG collected and registered evaluations made by Member States of substances used in non-plastics and provided general principles for prioritisation of the evaluation of those substances not evaluated yet and for advice in case of emergency. The ESCO WG stressed that the threshold of toxicological concern (TTC) is a useful tool when the chemical structure is known but does not replace a full safety assessment. Substances for which dietary exposure is likely to exceed the corresponding exposure threshold value should be considered as a priority for risk assessment.

The CEF Panel representative presented the development for new EFSA guidance for safety assessment of a substance to be used in plastics. The need to better protect infants and toddlers due to their higher food consumption per kg body weight than adults was pointed out as well as the importance of using exposure over migration data. Therefore, taking into account that food consumption data are now available through the EFSA Comprehensive database[9] and the need to align with new EFSA positions (e.g. on genotoxicity testing, nanomaterials, TTC), the current EFSA guidance (SCF guidelines[10]) should be revised. Considerations for the evaluation of oligomers and non-intentionally added substances (NIAS) were indicated.

During discussion, it was clarified that the EFSA guidance for safety assessment of a substance to be used in plastics is now being developed following a two-step approach. First, the scientific necessity to revise the existing guidelines would be rationalised in an opinion that would undergo public consultation. On this basis the Commission will review whether there is a need to change the current risk management approach. On the basis of the outcome of that review and possible amendments to existing legislation, draft guidance on data requirement for the presentation of an application for safety assessment of a substance to be used in food contact materials will be prepared. Following endorsement by the CEF Panel, it will undergo public consultation. EFSA proposed to share the draft opinion and guidance endorsed by the CEF Panel with the Network before public consultation.

[7] http://www.edqm.eu/en/consumer-health-protection-1415.html.
[8] http://www.efsa.europa.eu/en/supporting/pub/139e.htm.
[9] http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm.
[10] http://www.efsa.europa.eu/de/search/doc/21r.pdf.

3.6 Belgium database on substances that are or were used in FCMs

A database[11] of substances known by Member States (MS) of the CoE to be used in FCM was presented by the Belgian delegate. The database is a compilation of existing lists such as the Union list (plastics regulation), the ESCO WG lists and the lists from resolutions of the CoE. So the database lists substances evaluated by SCF, EFSA, MS and other institutions (e.g. FDA) with their evaluation outcome as well as other substances used by Industry and not evaluated by any institution yet. It provides some information on the genotoxicity potential based on structure-activities relationship (SAR) softwares. Examples of practical applications of the database were presented for plastics, coatings and papers and boards. And a strategy based on genotoxicity potential was proposed for the prioritisation and the evaluation of migrating substances.

During the discussion, it was clarified that Belgium would welcome the contribution from MS to keep the database up to date. MS could inform the Belgium Institute of Public Health on their evaluation of new substances.

It was highlighted that it would be useful to include more information on the origin of the substances (e.g. impurities, starting substances) in the database. The database could also highlight the limitations from SAR and quantitative structure-activities relationship (QSAR) modelling.

3.7 MS workshop on non-harmonized FCMs

The French delegate provided an overview on the national legislation and the role of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) in the risk assessment in France of non-harmonised FCM. French specific measures on materials and processes and general requirements for adding a substance to a positive list were stated. Ongoing activities in risk assessment were presented along with examples of ANSES opinions. It was noted that environmental issues are taken into account, whenever possible. ANSES informed about ongoing scientific cooperation on assessment of non-harmonised FCM (e.g. rubber, coatings, papers & boards and printing inks) in collaborations with other MS (including Technical University of Denmark (DTU), German Federal Institute of Risk Assessment (BfR), National Institute for Public Health and the Environment (RIVM) and EFSA).

3.8 Coatings: Approaches used for risk assessment

The representative of the Netherlands presented the national regulation[12] and risk assessment on FCM and more extensively on coatings. Provisions and general and specific purposes of coatings were indicated. Ongoing activities in risk assessment especially applications for coatings, papers and boards and plastics were reported. Dossiers submitted for safety evaluation of substances should be in conformity with the SCF guidelines and EFSA explanatory guidance (same tiered approach for toxicity data requirement). A highlight on the draft guidance to the attention of the Industry for using TTC approach for assessing NIAS was given.

It was clarified that evaluation then authorisation of substances used for coatings are given as for plastics, i.e. following the principle of positive list (generic authorisation with restrictions on specific uses when needed).

[11] https://fcm.wiv-isp.be.

[12] http://ec.europa.eu/enterprise/tris/en/search/?trisaction=search.detail&year=2013&num=407.

Concern was raised regarding pre-polymers. According to Regulation (EU) 10/2011 on plastic materials, pre-polymers used as monomers or other starting substances are authorised without being included in the Union list if the monomers or starting substances required to synthesise them are included in the Union list. Hence pre-polymers are usually not being subject to risk assessment. Some participants questioned, in general terms, the need and difficulties to assess pre-polymers.

3.9 Printing Inks: Approaches used for risk assessment

An overview on the evaluation of substances for printing inks listed in the Swiss Ordinance on FCMs was given by the representative of Switzerland. Approximately 5000 substances are listed in two lists,[13] the part A with about 1000 substances evaluated and the part B with about 4000 substances not evaluated. A general description of the different steps of the process for the (re-)evaluation of substances was given, including the fast-track evaluations based on evaluations by international and national organisations along with evaluation by the Federal Food Safety and Veterinary Office (FSVO). Data requirements are principally based on SCF Guidelines. The evaluation of a photo-initiator was shown as an example of possible challenges in the evaluation. Generic challenges covering printing inks, NIAS and oligomers were presented. The collaboration with BfR for the evaluation of new substances was highlighted.

The representative of BfR presented the main points of the project "Extent of migration of substances from printing inks into food" and its results[14]. Following on, the draft German Ordinance on printing inks[15] was summarized. The scope covers printing inks and print varnishes for food contact materials for direct and indirect contact with food. Substances from inks laid on the non-food contact side can be used provided that their migration into food is below 10 ppb and they are not classified as carcinogenic, mutagenic, reprotoxic (CMR). For other substances, the draft Ordinance follows the principle of positive list which is developed in close collaboration with the Swiss FSVO and is based on the Swiss list A. The BfR guidelines for evaluation of substances for printing inks make reference to the EFSA Note for guidance and provide specific advice on the tests to be performed (by defining exemplary packaging structures and test conditions). Evaluations of applications include the evaluation of NIAS.

The delegate of Norway made a short description of the Norwegian Scientific Committee for Food Safety (VKM) and gave a comprehensive description of the evaluations by VKM of the substance N-ethyl-toluene sulfonamide (NESTA) used in printing ink[16, 17]. In these evaluations and in the absence of data for setting a Tolerable Dietary Intake (TDI), TTC was used as a key tool to reach a preliminary conclusion of the safety of the substance and to request additional toxicity data to Industry. It was noted that NETSA was further evaluated by a joint FSVO/BfR experts group.

The Network emphasized the relevance and importance of harmonization of safety assessment of substances regarding the approach, the safety factors and the application of read-across. EFSA reported about the EFSA Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data[18].

[13] http://www.blv.admin.ch/themen/04678/04887/04891/index.html?lang=en.
[14] http://download.ble.de/09HS007.pdf.
[15] http://www.bmelv.de/SharedDocs/Downloads/Service/Rechtsgrundlagen/EntwurfVerordnungBedarfsgegnstaende.pdf?__blob=publicationFile.
[16] http://vkm.no/dav/c699b99ca7.pdf.
[17] http://vkm.no/dav/20e93afc10.pdf.
[18] http://www.efsa.europa.eu/en/efsajournal/pub/2579.htm.

It was stressed that the 10 ppb (µg/kg food) which is the limit of detection (LOD) generally recommended by the Regulation (EU) 10/2011 is questionable. Analytical methods have been improved, i.e. LOD have decreased. For instance, the limit of detection for primary aromatic amines could be decreased to 2 ppb.

3.10 Papers & Boards: Approaches used for risk assessment

The Italian delegate presented the general provisions and the national risk assessment approach applicable to papers and boards. Specific rules apply such as positive lists on constituents and processing aids and requirements on composition and purity. Differently to the Union list for plastics, the evaluation and authorisation are given for the requested uses only. Requirements for the submission of toxicological and non-toxicological data in the context of evaluation prior to authorisation were presented. Dossiers should be prepared according to the EFSA Note for guidance including the testing conditions for migration. Examples of risk assessment were given. The delegate expressed the need for harmonisation with the provisions in place in other Member States.

The German delegate presented the BfR recommendations XXXVI for the four types of regulated papers. Approximately 900 substances, monomers and polymers are listed in the recommendations whereas about 25 applications are currently being evaluated. Applications to add new substances should follow the EFSA Note for Guidance along with special requirements. Depending on the type and the use of papers, different migration methods from theoretical calculations to measurement into foodstuffs are proposed. Thermostability tests are also required under certain circumstances.

The representative of the Netherlands briefly presented the general provisions and national risk assessment approach applicable to papers and boards. Requirements were described for the two main kind of regulated papers. The existence of positive lists for auxiliaries and refining agents as well as the reference to EFSA guidance for the submission of dossiers were highlighted.

The Danish delegate presented some of the activities of the National Food Institute, Technical University of Denmark (DTU). The work on the development of a test strategy for *in-vitro* bioassay guided chemical analysis for identification of “unknown” substances in extracts of paper and board was reported. Also future activities possibly leading to a national or common Nordic legislation on fluorinated substances in paper and board were mentioned. Finally, a cooperative PhD project on the topic “Quantification (at DTU) and risk assessment (at ANSES) of “unknown” contaminants migrating from Paper and Board” will start in December 2014.

The Overall Migration Limit (OML) for paper and board was questioned. Being a very heterogeneous material, it may be difficult to comply with this requirement. It was pointed out that OML is a quality measure of the material and it does not reflect its safety.

3.11 General discussion on issues and challenges common to coatings, printings inks and papers and boards

The participants were invited to discuss on issues and challenges on coatings, printing inks and papers and boards. The participants expressed their opinions on the strategies used for risk assessment on FCM. They underlined that harmonization is desirable and could be facilitated by sharing guidelines notably the EFSA draft guidances with the Network.

Discussion dealt with oligomers, NIAS, TTC, database, read across, endocrine disruptors, biotests and migration testing. The usefulness of guidelines specific to issues (e.g. migration tests from printing inks) was flagged.

It was also underlined that MS have high experience in the safety assessment of non-harmonised food contact materials and cooperation and harmonisation indeed require MS involvements/resources.

3.12 Ba, Co, Cu, Mn, Ni, Se in ceramics and metals & alloys: Approaches used for risk assessment

The delegate of the Netherlands introduced the national regulation on metals and alloys. There are two positive lists, one for packaging materials and one for utensils. They both include specifications for base materials, solders, coatings and other agents. In addition, restrictions for metal elements release apply.

The representative of Norway presented two risk assessments of heavy metals performed by the Norwegian Scientific Committee for food safety (VKM) and published in 2004[19] and 2007[20]. The first assessment evaluated lead, cadmium and barium and the second evaluated nickel, cobalt, zinc, iron, copper and manganese used as pigments. Results and main conclusions were detailed. Migration of lead, cadmium and barium from hand-made pottery might be a concern. The lack of harmonised legislation especially on the migration of barium, nickel, cobalt, zinc, iron, copper and manganese from ceramics was underlined.

The Joint Research Centre (JRC) delegate presented an ongoing EC project that aims, on the basis of new scientific information provided in EFSA opinions, to review the limits for lead and cadmium set in the Directive 84/500/EEC on ceramic food contact materials. The JRC project also takes into account the migration of other elements (e.g. Ba, Co, Mn, Ni, As, and Al) from these materials and from other articles (e.g. glass), to which new migration limits may be proposed. The approach for testing the migration of heavy metals from ceramics, domestic glass and crystal using different simulants such as citric acid and acetic acid and foodstuffs such as wine and tomato sauce was described.

The CoE delegate introduced the resolution (2003)9 of the CoE on Metals and Alloys[21] focusing on the assessment of cobalt, copper, manganese, barium and nickel. Different model approaches were taken according to the information available for each metal. Specific release limits are proposed for the different elements resulting from the harmonization of data from 23 agencies. The limits aim to be not over-conservative and to make compliance possible. The limits were set considering toxicological references values, exposure assessments, allowance factors, data on the release and repeated uses. “As Low As Reasonably Achievable” (ALARA) principle was in some case used. An additional limit based on the sum of the two first releases was recommended.

3.13 Proposal for possible follow up in terms of scientific cooperation and future activities

The participants shared their thoughts on common interests and possible topics for future Network meetings on food contact materials. Possible strategies were referred and it was agreed that it is necessary to cooperate on horizontal issues (e.g. NIAS, oligomers) in parallel to specific materials. The Network highlighted the issue related to non-harmonised migration limits across Europe.

The Network outlined the interest to be informed on EU and national activities related to risk assessment. This includes evaluations, ongoing research and other projects as well as cooperation between Member States.

[19] http://vkm.no/dav/dcd16164a5.pdf.
[20] http://vkm.no/dav/ebc8d55983.pdf.
[21] https://wcd.coe.int/ViewDoc.jsp?id=2075683&Site=CM

The Network underlined the interest to share EU and national guidelines/guidances as it should facilitate to find common approaches for common benefit. In particular, the endorsed draft opinion of the CEF Panel outlining the scientific rationale for revisiting the current guidance (SCF guidelines) could be shared with the Network before it undergoes public consultation. The Netherlands draft guidance for industry on NIAS as well as the French draft guidelines/guidance for evaluation of non-harmonised food contact materials could be shared too.

The network finally emphasised that cooperation was essential to improve and harmonise risk assessment on FCM and the Network on food contact materials should be continued.

4. Concluding remarks

Claudia Heppner summarised that the network meeting has improved the cooperation with MS on risk assessment of non-harmonized FCM.

A second meeting will be organised in 2015. EFSA took note of the proposals for possible follow up and will come back to the Network with a draft agenda likely to focus on guidelines/guidances.

The participants were thanked for their attendance and valuable contributions to the discussions and network. The meeting was closed.