Scientific Network of the food ingredients and food packaging (FIP) Unit on food contact materials (FCM), the 'EFSA FCM Network'

Minutes of the 5th meeting[1]

These Minutes published on 18th August replace the earlier version published on 1st August

Held on 10-11 July 2017, Parma

(Agreed on 22 July 2017)[2]

Participants

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

Country	Name
Austria	Christa Hametner
Belgium	Els van Hoeck
Bulgaria	Snezhana Todorova
Croatia	Nino Dimitrov
Cyprus	Antigoni Achilleos
Czech Republic	Jitka Sosnovcova
Denmark	Gitte Alsing Pedersen
Estonia	Katrin Kempi
France	Gilles Rivière
Germany	Stefan Merkel
Greece	Zoe Mousia
Hungary	Katalin Frecskáné Csáki
Ireland	Karl McDonald
Italy	Riccardo Crebelli
Lithuania	Skirmante Ambraziene
Netherlands	Dirk van Aken

[1] The updated version of the Minutes includes minor changes in 5.6 for transparency and completion, see footnotes 8 and 9. To avoid confusion, the original version of the Minutes has been removed from the website.

[2] 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.

Poland	Marzena Pawlicka
Portugal	Maria de Fatima Tavares Pocas
Slovakia	Milada Sycova
Slovenia	Viviana Golja
Spain	Perfecto Paseiro Juana Bustos Garcia De Castro
Sweden	Susanne Ekroth
United Kingdom	Richard Burden
Iceland	Grimur Olafsson
Norway	Inger-Lise Steffensen
Switzerland	Stefan Kucsera

- **Intergovernmental organisation Council of Europe:**

Eugenia Dessipri as substitute of Susanne Bahrke

- **European Commission:**

Jonathan Briggs (DG SANTE)

Eddo Hoekstra (DG JRC)

- **European Chemicals Agency (ECHA):**

Henna Piha, Classification and prioritisation Unit

- **Member of Committee and Panels invited as speakers:**

Laurence Castle (member of EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) and Chair of the Standing Working Group on Food Contact Materials)

Vittorio Silano (Chair of EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel))

Maria Rosaria Milana (member of EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel), member of the Standing Working Group on Food Contact Materials, and Chair of the Standing Working Group on plastic recycling)

- **Hearing Experts:**

Matthias Henker, European Printing Ink Association EuPIA (for agenda item 23)

Martin Kanert, European Printing Ink Association EuPIA (for agenda item 23)

- **EFSA:**

Food Ingredients and Packaging (FIP) Unit:

Claudia Roncancio Peña, Head of the FIP Unit

Eric Barthélémy, FCM Network Coordinator, Chair for Agenda points 11-22

Anna Federica Castoldi, FCM Team Leader, Chair for Agenda points 1-10

Cristina Croera, FCM Team

Alexandros Lioupis, FCM Team

Carla Martino, FCM Team

Claudio Putzu, FCM Team

Ellen Van Haver, FCM Team

Katharina Volk, FCM Team

Scientific Committee and Emerging risks (SCER) Unit:

Jean-Lou Dorne, participated in agenda item 10

Tilemachos Goumperis, participated in agenda item 13

Reinhilde Schoonjans, participated in agenda item 8

Advisory Forum & Scientific Cooperation (AFSCO) Unit:

Nicoline Le Gourierec, participated in agenda item 11

Sérgio Potier Rodeia, participated in agenda item 12

1. Welcome and apologies for absence

Claudia Roncancio Peña, Head of FIP Unit, opened the meeting.

She informed that at the end of 2016 the mandate of this Network was extended for another 3 years by the Advisory Forum. It was underlined that the Network represents an important initiative for collaboration and harmonisation. This is also fully in line with the EFSA Strategy 2020, one of which strategic objectives is to build the EU's scientific assessment capacity and knowledge community. By fostering collaboration, exchanging knowledge and promoting harmonisation, the Network serves as a platform supporting these objectives.

The members of the Network were informed about the on-going call for the renewal of EFSA's Scientific Panels in 2018. The timelines for the application were shared with the participants and they were invited to promote this initiative, which is still open until 8 September 2017, also in their MS organisations.

The Chair welcomed the participants and informed about changes as regards new MS representatives and alternates. All the participants introduced themselves in a tour de table.

Apologies were received from 4 Member States, Finland, Luxembourg, Malta and Romania, as well as from Bianca van de Ven for the entire meeting and Eugenia Dessipri for the first day.

2. Adoption of agenda

The agenda was adopted with the following changes: a technical hearing with representatives of EuPIA (agenda item 23) was added on the first day of the meeting (after item 9). As concerns the second day, the presentation by ECHA (agenda item 16) was anticipated before item 14 on "Promoting cooperation and European risk assessment capacity and knowledge. The revised agenda will be published on EFSA website.

3. Agreement of the minutes of the 4th meeting of the EFSA FCM Network – group of interest on Coatings, held on 16 February 2017, Parma.

The minutes were agreed by written procedure on 7 March 2017 and published on the EFSA website on 9 March 2017.

4. Declaration of interests and statement of confidentiality

All Network representatives signed a statement of confidentiality either through the submission of Annual Declaration of Interest or at the beginning of the meeting.

5. Topics for discussion

5.1. Compilation of Member States projects/researches (DMS)

Resulting as a proposal for possible follow up in terms of scientific cooperation and future activities from the 3rd Network meeting in May 2016, Eric Barthélémy, Coordinator of the Network, presented the "Advisory Forum forthcoming risk assessment activities" database. The database was initiated in 2015 and comprises information on more than 600 MS risk assessment activities for all areas falling within the interest of EFSA. It is based on MS input and is confidential. This database should replace the existing FCM Network excel sheet, and contribute to avoid duplication and promote collaboration, by increasing awareness therefore supporting the objectives of the Network.

FR volunteered to take on board the task to identify and extract information on activities related to FCM, and to share them with the Network and EFSA.

5.2. Revision of the EFSA Note for Guidance

Carla Martino presented the revision of the EFSA Note for Guidance. The summary provided by the speaker is reported below.

"The former 2008 EFSA 'Note for Guidance for Food Contact Materials (FCM)' has been updated with the aim to provide a clearer advice to applicants on how to submit dossiers on substances to be used in plastic food contact materials, falling under the scope of Regulation (EC) No 1935/2004 and Commission Regulation (EU) No 10/2011, before they can be put on the market in the European Union. Previously covered in one guidance document, EFSA has now published the following separate administrative and scientific documents:

- The administrative guidance, which details the application procedure and introduces new forms applicants should use when preparing and presenting an application to the Competent Authority of an EU Member State and providing samples and analytical methods to the European Reference Laboratory for FCM. The document also describes the different ways to interact with EFSA during the evaluation process.
- The 2017 EFSA 'Note for Guidance for FCM', which contains the scientific requirements to be considered for the presentation of an application to be evaluated by EFSA. It extends and details the information requested by the 2001 Guidelines of the Scientific Committee on Food (SCF) for FCM. It also updates the information on the dataset required to assess the genotoxic potential of a substance, in line with the requirements of the 2011 EFSA Scientific Committee opinion on genotoxicity testing strategies."

In the discussion, it was suggested to use a common template for the "technical dossier" on applications for substances in order to support harmonisation of the risk assessment process and to facilitate exchange of information among MSs and with EFSA. The updated version of the EFSA technical dossier template for applications on plastic substances recently published in the Administrative Guidance could be used, especially since the SCF/EFSA template is already the basis for several Member States.

5.3. Report from the 4th FCM Network meeting dedicated to coatings

Laurence Castle and Dirk van Aken reported back from the 4th FCM Network meeting dedicated to coatings, which took place on 16 February 2017. An extract of the Minutes of the meeting (section 5.7 "analysis and discussion" [3]) and the summary provided by The Netherlands on "Proposal for objectives and plan for future work" are reported below.

Extract of the Minutes of the 4th meeting (section 5.7 "analysis and discussion"): "In order to have a common understanding and to provide the basis for harmonisation in the area of coatings, clarifications on the definition/terminology of coatings and substances used in their manufacturing (e.g. pre-polymers) are needed. Once this is done, for the sake of harmonisation, a common approach

[3] http://www.efsa.europa.eu/sites/default/files/170216-m.pdf

that considers the setting of restriction should be agreed. Considering the "starting substances" in more detail, it was discussed how far pre-polymers and oligomers are covered by their already authorised monomers, or whether they should be risk assessed on their own. This should be addressed...
BE, IT and the NL reported to make reference to the SCF guidelines/EFSA Note for guidance to carry out safety assessment of substances intended to be used in coatings. Although there are a few differences reported only by the NL …, the SCF tiered approach for defining the set of toxicological data required is the same. No use of the TTC is made for the safety assessment of substances intended to be used in coatings and genotoxicity studies are requested in any case when migration is below 0.05 mg/kg food.
There was a consensus that the safety evaluation of coatings should consider all migrating substances including NIAS, not only the substances intended to be used in coatings. Ideally, an inventory list of risk assessed NIAS should be developed. Meanwhile a follow up should be made in relation to the already in place distinction between those NIAS specifically linked to the substances evaluated/authorised and those that might vary from coating to coating.
Migration testing was identified as an important topic ... It is a prerequisite for estimating exposure and consequently defining the toxicological data requested in the context of a safety evaluation. BE, IT and the NL reported to make reference to the testing conditions defined in the Regulation (EU) 10/2011 to evaluate the potential migration level needed for setting the toxicological data requirement. Close collaboration between Member States, involvement of EC DG JRC (notably with the Task Force on kitchen and tableware) and industry association representatives is desirable in order to define and validate appropriate testing methods."

Proposal for objectives and plan for future work from The Netherlands: "A teleconference dedicated to coatings was held in February this year. The participants in the meeting discussed what steps could be taken to achieve more harmonisation in the area of coatings. The Netherlands delegation agreed to take the lead of a dedicated working group.
After the meeting, the NL drafted an action plan for the group and shared this with the other participants. Responses and suggestions were received from several participants, which were used to revise the action plan. This work plan was presented at the meeting and supported by the other MS. The WG will continue working on the deliverables and present these at a next occasion.
Main steps that are proposed:

- Set the scope and clarify terminology and definitions.
- Verify the information in the JRC Baseline Study on national rules and limits
- Compare national legislation (limits) for specific substances regulated in several Member States and discuss the reasons behind different limits (including risk assessment methodology)
- Develop recommendations for the safety evaluation of coating substances: required toxicological data, evaluation criteria.
- Define different coating types where considered useful.
- Compare migration conditions used by Member States and if necessary propose harmonisation.
- Compile a list of NIAS for which risk assessment has been carried out, and list of other NIAS relevant for coatings (with links to evaluated substances)."

In the discussion, it was questioned why certain substances have different limits/restrictions in different countries whereas they were likely evaluated on the same basis, i.e. the SCF guidelines/EFSA Note for Guidance. The same was reported in the JRC Baseline study, which also underlined the lack of transparency on the risk assessment methodology and the grounds for setting the restrictions (incl. whether the limits are based on the Plastics Regulation (EU) No 10/2011). This might be due to policies and approaches not commonly applied by all the MSs, e.g. limitations based on the intended use levels requested by the applicant rather than Specific Migration Limits (SML). The risk assessment process and methodology used in Member States would benefit to be more transparent.

Setting list(s) of NIAS was considered challenging but necessary by many of the participants. Prioritisation may be needed and may consider the recurrence of certain NIAS as well as non-testing methods such as (Q)SAR, read-across or TTC to identify substances of possible concern.

DE clarified that BfR has no recommendation on coatings in general, but on coated paper and boards. France also clarified that ANSES ANSES very rarely receives request of the ministries for safety assessment of coatings.

The MSs involved in the 'MS task force on coatings' (BE, HR, IT, SL, ES) all agreed with the work plan proposed by NL. By the end of 2017, definitions and terminologies should be agreed, and substances evaluated by several Member States with a different conclusion/restriction should be analysed and discussed in order to identify the reason(s) for that different conclusion/restriction. This will help to possibly harmonise the approach. The need for a database and the development of suitable and validated methods for migration testing was reiterated.

5.4. Feedback from the Scientific Committee Nano Working Group and the EFSA Nano Network

Reinhilde Schoonjans presented the work of the Scientific Committee's Working Group on Nanotechnologies and the EFSA Nano Network. The summary provided by the speaker is reported below.

"Substances to be used in agri/food/feed products are subject to scientific risk evaluation. For Europe, it is the European Food Safety Authority (EFSA) that carries out the scientific risk assessment. Subsequently, the European Commission takes the decision based on all risk management considerations. The use of nanomaterial in the agri/food/feed chain is on the rise as confirmed by the EFSA Inventory in 2014[4]. Already in 2011[5], EFSA published Guidance on how to address human and animal health risks. Experience in risk assessments of nanomaterials in agri/food/feed is increasing, but the availability of relevant

[4] See EFSA nano inventory: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/621e.pdf

[5] EFSA Scientific Committee; Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011;9(5):2140

data and standardised test methods is still needed. EFSA is currently working on updated Guidance, including advancements in physico-chemical characterisation of nanomaterial in complex matrices, best practice for ADME studies, experiences with toxicological studies and implementation of new legal requirements[6]. In this context, a procurement contract was launched to collect information for nanocarriers.
Furthermore, EFSA will develop Environmental Risk Assessment Guidance to cover also the environmental fate and impact of nanomaterials used in the agri/food/feed chain. The purpose is to help stakeholders and risk assessors in the Member States to prepare authorisation dossiers and ultimately to help protect the consumers' safety.
These activities will be carried out by a working group of the Scientific Committee. The EFSA Nano network with Member States representatives[7]will be consulted prior to public consultation foreseen in January 2018."

The discussion focussed on the importance of having a legal definition of "nanomaterial" (e.g. on the 50% cut-off, 100 nm) overarching all areas.

In addition, it was stressed that, due to the particular physicochemical characteristics of nanomaterials, special considerations should be taken into account during the toxicity testing, i.e. the test conditions should be realistic and allow the detection of the substances during/after ingestion.

The terminology used for the transfer of nanoparticles from FCM into food was questioned by Austria (release from the surface *versus* migration).

FR informed that ANSES received the request to work on nano in food considering all sources of exposure and has funded research on micro/nanoplastic in fish and seafood (outcome expected by 2017).

5.5. Research on release of nano TiO2 from quasi-ceramic coatings

Viviana Golja presented the research project on release of nano TiO_2 from quasi-ceramic coatings. The summary provided by the speaker is reported below.

"In the presentation, food contact materials containing nanoparticles were reviewed and concerns about their possible release into food were mentioned. Then, the characterisation of food contact non-stick coatings containing TiO2 nanoparticles was presented followed by a study of their release into food. The release was studied by migration testing into different simulants and by matrix degradation. Release of nano TiO_2 into simulant 3% acetic acid was confirmed as well as release due to mechanical degradation of the matrix.
In conclusion, different approaches to the assessment of possible health risks through exposure to released particles were presented. The assessment indicated a possible health risk. However, refinement of exposure assessment and specific toxicological data for the nano particles considered are needed."

6 EC Recommendation of 18 October 2011 on the definition of nanomaterial http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

7 See latest annual report of the EFSA network with Member States experts: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/939e.pdf

In the discussion, some clarifications were given on the samples preparation, the method of analysis (including counting) and the interpretation of the results. As a follow-up of this research project, it was suggested to consider the exposure assessment methodology used in the evaluation of TiO_2 as a food additive by the EFSA ANS Panel in 2016.

5.6. EuPIA "The safety assessment of substances used in printing inks for food contact materials"

Martin Kanert and Matthias Henker from EuPIA (European Printing Ink Association) were invited to a technical hearing in order to present how the safety assessment of substances used in printing inks for food contact materials is performed. The summary provided by the speakers is reported below.

"EuPIA outlined its policies, key concept documents and processes. The first step covered the general criteria for the selection of raw materials. This is followed by a risk assessment process, which includes three principles:

- Fully evaluated substances (e.g. Union list)
- Self-derived TDI or SML based on public toxicity data
- Self-derived TDI or SML based on TTC concept.

Exposure assessment uses the EU cube model as default; other models, such as EFSA food consumption data or FACET, can be used if appropriate. The presentation included the flow chart, which gives more details on the safety assessment process."

During the presentation it was mentioned that EuPIA has set up a working group for developing analytical methods for which a report should be published soon. [8] Participants expressed their interest in receiving the document as it could contribute to harmonisation and to validation of suitable migration testing methods in the area of printed FCMs.

As concerns the NIAS and Non Listed Substances (NLS, i.e. pigments and related additives) risk assessment flow chart, it was clarified that industry submitting information to EuPIA also uses publically available data e.g. from REACH and literature, and that members of EuPIA are being trained to derive the correct and reliable information. EFSA stressed that a careful selection of these data is crucial as in many cases data from the REACH database are neither validated nor available as raw data. Raw data and right expertise are recommended to be used.

EuPIA clarified that the use of bioassays is not recommended in the flow chart yet. However, for complex compositions as printing inks/printed FCMs, bioassays may be useful and should deserve more consideration in the future.

[8] On 10th August, EuPIA informed about the finalization of the "Guidance on Migration Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials" (http://www.eupia.org/uploads/tx_edm/2017-07-31_EuPIA_Guidance_on_Migration_Test_Methods.pdf).

EuPIA clarified that if migration is expected/measured to be above 10 ppb, industry is advised to send an application for evaluation of the substance to DE and CH Authorities (see also point 5.14.).

On the question on activities related to pigments in nanoform, EuPIA answers that *"The German Paint and Ink Association VdL had discussed the results of its study "Nanoscale pigment particles: Analysis of the migration behaviour from printing ink layers of printed food packaging into food" (http://www.eupia.org/uploads/tx_edm/DLR_nanoscale_pigment_particles.pdf) with the German Federal Ministry of Nutrition and Agriculture (BMEL) and later on also with the BfR. The study results were acknowledged. Currently, there is no further discussion."* [9]

On a question from EFSA, EuPIA answered that approx. 20 to 30 new substances are *"being used"* per year. *"This does not mean that in each and every case the substance manufacturer (being a supplier to the ink industry) submits a dossier to a competent authority for evaluation. This would be mandatory only in Switzerland for the time being. Outside Switzerland, safety assessments such as those described in the EuPIA NIAS/NLS guideline could be performed."* [9]

5.7. Presentation and use of the EFSA database on chemical hazards "OpenFoodTox"

Jean-Lou Dorne presented the EFSA database on chemical hazards "OpenFoodTox". The summary provided by the speaker is reported below.

"Chemical risk assessment in the food safety area involves the classic steps combining hazard and exposure analysis for risk characterisation. In the food safety area, sound hazard identification and characterisation require an understanding of both toxicokinetic (TK) and toxicodynamic (TD) processes for compounds entering the human body via the oral route. This enables the translation of external dose (exposure) into internal dose (TK processes incorporating absorption, distribution, metabolism, excretion of chemicals (ADME)) and toxicity for sound dose-response modelling.

Since its creation in 2002, EFSA has applied the overarching principles of risk assessment to determine safe levels of exposure of substances for human health, animal health or the environment. These safe levels are then combined with exposure estimates (exposure assessment) to determine the risks (risk characterisation). In January 2017, EFSA published Openfoodtox, an open source database which summarises toxicological data in the human health, animal health and the ecological areas from 1650 EFSA scientific opinions for over 4400 substances. Openfoodtox can be searched and downloaded from the opensource microstrategy tool (https://dwh.efsa.europa.eu/bi/asp/Main.aspx?rwtrep=400) and can be downloaded under EFSA's knowledge junction.

Recently, Openfoodtox has also been the basis for developing QSAR tools for the prediction of toxicity in the absence of data and as alternatives to animal testing. Finally, further work is ongoing in EFSA through the development of open

[9] This information was further clarified by EuPIA on 10th August.

source toxicokinetic tools and models to further integrate exposure, TK processes and toxicity in the human health, animal health and ecological area."

Following the presentation it was clarified that the "OpenFoodTox" database is in a continuous improvement phase and that an update can be expected in autumn 2017, with inclusion of recently evaluated substances, improved search and download tools. Due to common interests and overlaps as regards the evaluation of substances, the possibility of harmonisation of data between EFSA, ECHA and EMA was discussed. A close collaboration between the agencies is desirable in order to facilitate evaluations, but due to different assessment approaches the exchange of data still remains a challenge.

5.8. EFSA EU Fora

Nicoline Le Gourierec presented the EFSA EU Fora fellowship programme. An extract from the EFSA website was provided by the speaker as summary of the presentation.

"EFSA's EU-FORA fellowship programme offers a unique opportunity to motivate early to mid-career scientists from EU national risk assessment authorities and any other Article 36 organisation to increase their knowledge and experience in food safety risk assessment.
The programme's principal focus lies on chemical and microbiological risk assessment. It is aimed at professionals with a background in fields such as molecular biology, biology, microbiology, veterinary/human medicine, agronomy/agricultural science, biochemistry, chemistry, environmental science, food technology or toxicology.
How does it work? For a period of 12 months of 'learning-by-doing', fellows will be placed at another European organisation involved in food safety risk assessment outside their home country. They will be fully integrated in the hosting organisations, participate in their work, gain first-hand experience and increase their knowledge of many scientific aspects relevant to food safety risk assessment.
EFSA's fellowship initiative contributes to building the EU's scientific assessment capacity and knowledge community. It will enhance the cooperation between Europe's food safety agencies and with EFSA and contributes to the harmonisation of food risk assessment practices across Europe.
Are you interested? Is your organisation keen to host a fellow? The next calls for expression of interest for the second 12 month fellowship cycle starting in September 2018 are expected to be launched in October 2017."

5.9. EFSA Partnering Grants

Sérgio Potier Rodeia presented the EFSA Partnering Grants. An extract from the EFSA website was provided by the speaker as summary of the presentation.

"Partnering Grants aim to transfer or exchange knowledge and expertise between two or more organisations in different Member States, Norway and Iceland. By stimulating joint initiatives between these countries, this new Grant

type will support EFSA's efforts to build the EU's scientific assessment capacity and knowledge community. Partnering Grants cover all areas of risk assessment that fall within EFSA's remit. Any organisation included on the List under Article 36 of EFSA's Founding Regulation is eligible to apply for this new Grant type. The maximum duration for projects under the scheme is two years. EFSA will co-finance half of the project costs up to a maximum of €100,000. The overall ceiling for this call is €600,000. The Call for Proposals – run on a pilot basis this year – is open until 15 September 2017. Please see here to learn more about EFSA's main Grant types; and here for more information on Partnering Grants and on the application procedure. We also recommend contacting national Focal Points in case there are questions concerning the Article 36 List or EFSA Grant procedures."

During the discussion, it was clarified that this is a pilot project. Depending on the evaluation of the outcome of this first cycle, calls could be opened on a regular basis. This would offer a good possibility for the MSs that want to collaborate and exchange knowledge. Initiatives that could be funded to support development of competence in the MSs include e.g. workshops, trainings, data collection etc. It was suggested that the MS task force on coatings under the leadership of NL considers this funding opportunity in relation to support its planned work on developing common risk assessment tools/approaches for the evaluation of coatings.

5.10. Scientific technical assistance to RASFF on chemical contaminants (incl. FCM)

Tilemachos Goumperis presented the EFSA RASFF (Rapid Alert System for Food and Feed) Working Group. The summary provided by the speaker is reported below.

"The European Commission asked EFSA to provide scientific and technical assistance concerning methodologies in order to arrive to simplified approaches for risk evaluation of RASFF notifications in the area of chemical contaminants in food and feed.
EFSA was requested to evaluate and propose a methodology that would allow for a risk-based classification of RASFF notifications on chemical contaminants. The methodology should clearly reference available sources of data for calculation of exposure and sources of toxicological parameters used. The proposed tool(s) should be able to translate the analytical findings (quantities found) into a quantifiable risk level in the area of chemical contaminants. EFSA proposed a step wise approach with the first deliverable to be completed by end of July 2017. An EFSA working group has been established consisting of EFSA staff from four units/teams (Scientific Committee, contaminants, food contact materials, exposure assessment/data collection) and external experts. The first output will focus on the development of a decision tree based on hazards and associated data sources of toxicological."

The objective of the mandate was further clarified after the presentation: The working group should propose a methodology for a risk-based classification of

RASFF notifications on chemical contaminants to allow harmonisation of the RASFF notifications. The mandate does not refer to the risk management actions taken at MS level prior to and following to a RASFF notification. Upon a question by NL, Tilemachos Goumperis replied that the working group had discussed the concept of 'serious risk' which is important in both RASFF and RAPEX, but it had not taken any definitive decisions; this is in fact a matter of risk management.

Assessment of the exposure to contaminants originating from FCMs was briefly discussed. The EFSA Consumption Database and the FAIM model (used for food additives) were mentioned. Nevertheless, this topic has not been dealt with by the EFSA RASFF WG as this is a task of the second workpackage. In the third and last workpackage, a software will be developed to combine information from the two first workpackages.

5.11. ECHA "Using REACH and CLP data to prioritise substances"

Henna Piha presented the prioritisation of substances by use of REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and CLP (Classification, Labelling and Packaging) data. The summary provided by the speaker is reported below.

"REACH and CLP are key regulatory tools helping to protect humans and the environment from the adverse effects of chemicals. REACH makes manufacturers and importers of chemicals responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. Companies are required to document the information on the substance they manufacture or import in a registration dossier and submit it to ECHA. Where needed, the European Union can take additional regulatory risk management measures on the most hazardous substances. ECHA's goal is to prioritise substances where the impact on human health and the environment is highest, and to identify the most effective way of addressing the concerns.

Screening is used as a tool to identify substances that may require further regulatory actions. In screening, both hazard properties and use/exposure are considered. In order to make best use of available information and ensure efficient generation of missing information, ECHA together with member states is shifting focus from working with single substances towards groups of substances and to having dialogues with industry."

In the discussion, the importance of a close collaboration between EFSA and ECHA was underlined.

ECHA is currently working on a sector approach with industry for plastic additives. At the moment, 900 substances are included in ECHA's initial inventory, which are not all used in food contact materials. The list is currently being validated by industry, with the goal of knowing for each confirmed substance their function type and in which types of articles and polymers the substance is used in. The purpose is to be able to develop a method to rank the plastic additives based on their release potential.

Further REACH registration data will become available by the middle of next year, when the registration for substances with a production volume from 1 to 100 tonnes will be closed. REACH registration data could be used to draw comparisons between what is registered under REACH and what is authorised for use in plastic food contact materials under Regulation (EU) No. 10/2011. The use of different definitions between REACH and notably the Regulation (EU) No. 10/2011 for instance on 'polymer' was mentioned and should be taken into account where relevant.

5.12. Council of Europe activities on printing inks

Eugenia Dessipri presented the activities of the Council of Europe (CoE) Working Group on printing inks. The summary provided by the speaker is reported below.

"The work of the Council of Europe in the area of public health started in 1959 with the Partial Agreement (18 member states) in the social and public health field. In 2008, the Council of Europe Committee of Ministers decided to dissolve this Partial Agreement and to transfer the activities related to cosmetics and food contact materials to the EDQM (37 member states). Thereafter, P-SC-EMB (Committee of Experts on Food Contact Materials: group of experts that examines health-related matters in the area of FCM and prepare reports and recommendations concerning regulatory approaches) has begun a review of the existing resolutions and technical documents (https://www.edqm.eu/en/resolutions-policy-statements). Concerning printing inks, the last Council of Europe's Policy Statement (Version 2, 10/10/2007) comprises of "Resolution ResAP (2005)2 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs" and three Technical Documents (Guidelines). Current work of the P-SC-EMB group and its subordinate *ad hoc* working group focuses on the revision of the Technical Document that addresses Test Conditions. Among the various components of printing inks, photo-initiators (PIs) have been identified as of priority interest for testing. A list of all the currently used PIs together with their corresponding decomposition products is being compiled. Another list containing additional information on the physicochemical properties (essential in deciding the most suitable method of analysis) of 119 printing ink components is available from Spain. Relevant literature is being shared in the EDQM extranet site. With due support of official control laboratories a method for the determination of PIs in cereals will be validated via an interlaboratory study and published. The need for a guideline containing a generic strategic approach for the comprehensive analysis of printed FCMs has been identified. An outline will be prepared, pointing out areas in which further research (and therefore funding) is needed."

Eugenia Dessipri clarified that efforts for developing and standardising testing methods had already been undertaken by the CoE for other areas, e.g. cosmetics, and control laboratories welcomed this initiative. This initiative is now extended to the area of food contact materials, more specifically to photoinitiators from printing inks.

EFSA proposed to make use of the FCM Network to share information on that activity and, if needed, to inform on data collection request.

5.13. EC DG SANTE activities on printing inks

Jonathan Briggs presented the EC DG SANTE activities on printing inks. The summary provided by the speaker is reported below.

"Printing inks represent a large and complex group of substances, the majority of which are not intended to come into direct contact with foods but may migrate through a substrate, through set-off migration or via the gas phase. Rules on printing inks have been set at national level, most notably in Switzerland where a positive list of substances exists as well as a similar proposed list in Germany. For those substances that are commonly regulated at national level, there seems to be little agreement on the restrictions that have been laid down. Guidance and good manufacturing practice (GMP) within the industry appears to be relatively well implemented.
Following the notification from Germany on its proposed legislation as well as issues related to certain substances highlighted in a recent publication by the JRC, the Commission has started working on a draft measure concerning the regulation of printed food contact materials at EU level. Current issues that are known to exist in the current traditional approach to regulating plastic food contact materials will be taken into account in the development of the legislation, as well as the complexity of the supply chain, the number of substances that exist and rules for verifying compliance. There is a need to ensure a comprehensive and transparent risk assessment process, including clarifying the role of industry, EFSA and the Member States. A study to support the work is foreseen to start in 2017, with completion of the project in 2018."

It was clarified that, as soon as timelines have been agreed, an EC roadmap on the project on printed FCMs will be published for a 4 week period in order to gather feedback from stakeholders. Then a general discussion will be needed on approaches for risk assessment, including who is involved in this process and what role they play.

In Switzerland, around 5000 substances are listed, thereof about one fifth is included in the positive list for toxicologically evaluated substances (List A), while the remaining substances are not evaluated (List B; they can be used if they are not CMR, and are not detectable at an LOD of 10ppb).

Participants questioned the number of substances really used *versus* those '5000' listed in Swiss legislation. It is likely that some or many substances are not used anymore and this should be clarified to avoid unnecessary work/consideration. JRC reported the case of plastics for which samples are not available for many authorised substances. This also questions their use and how this should be addressed.

The possible evaluation process for FCM was discussed and the "Rapporteur MS model" existing for other food sectors, e.g. pesticides was highlighted as one example where efficiency is increased by utilizing resources of Member States. The challenges in assessing individual substances was underlined including the

number of substances, lack of available methods and the need to know the composition of the final material in order to ensure compliance. It is important to take into account knowledge and resources that exist when considering rules for assessment of printed FCMs.

Prioritisation could help in reducing the number of substances that may need to be evaluated by EFSA and/or MS in practice. *In silico* methods, e.g. (Q)SAR, and considerations regarding the use of substances could be used. In this respect, the registration data provided to ECHA by industry could contain useful information (see also 5.11.).

5.14. DE and CH activities on evaluation of printing inks

Stefan Merkel and S. Kucsera presented the activities on the evaluation of printing inks. The summaries provided by the speakers are reported below.

"In this presentation an overview on the joint safety evaluation of printing inks for food contact materials by German (BfR) and Swiss (FSOV) authorities was given.
Procedures of safety evaluations according to the SCF guidelines as done for food contact materials by EFSA are compared with the processes used in joint safety evaluations by the BfR and FSOV. SCF guidelines are followed except for analytical data for migration in some cases[10]. Petitions are submitted to German and Swiss authorities based on the templates found in the EFSA Note for Guidance. In a bi-annual joint panel a critical discussion of separate, agency-specific toxicological assessments takes place and a mutual consensus on a dossier is reached. Analytical data are discussed by mail or phone conversation in an analogous fashion. In case of need a panel discussion may take place.
A letter to the petitioner laying down migration limits for a substance and the corresponding NIAS as well as purity requirements is sent by the BfR and endorsed by the FSVO. In Switzerland, migration limits and remarks concerning purity requirements for an evaluated substance are published in part A of Annex 10 to the Swiss ordinance on FCM.[11]"

After the presentation, it was clarified that the Draft German Ordinance on Printing Inks has been notified to the EU but it is not in force yet. Further steps in that procedure will also depend on the EU measure on printed FCMs that is currently being prepared by the European Commission (see also 5.13.).

As concerns the list B of the Swiss ordinance (Annex 10), it compiles substances not evaluated but that could be used if their migration is not be detected (LOD of 10 ppb) and if they are not CMR. By 'not CMR', it means not 'known to be CMR' with regard to CLP. This does not mean "known to be not CMR". This should be clarified as in such case a conservative approach could be suggested. In case substances are known to be CMR, the cut-off value of an LOD of 10 ppb does not

[10] "If the petition is filed by an association which has no possibility to hire a lab. In those cases summarization of real case migration data are submitted without information on the analytical details."

[11] "It is important to note, that for the SML the migration from the printed food packaging as a whole and not only from the printed layer has to be considered. The responsibility for the compliance has to be fulfilled by the company who places the product on the market."

apply and further risk assessment is required. It should be noted that in Germany, there is no list "B", nevertheless 'not listed' hence 'not evaluated' substances can be used based on the same grounds as in Switzerland (not CMR, Not Detectable with a LOD of 10ppb).

The submission of migration data is required for inclusion in the Swiss Ordinance with some minor exceptions (e.g. for some solvents). Migration data are also required for the evaluation carried out by BfR but in some cases not to the same extend as required in the note for guidance (see note 10 on petitions from associations).

With regards to the evaluation made by BfR and FSVO, the SCF tiered approach and EFSA Note for Guidance are followed. The exception was said to be that sometimes data on migration into food or food simulant are not provided. In those cases data on residual content with total mass transfer is considered, but often in the absence of raw and validated analytical data (according to the EFSA Note for Guidance). In addition, it was reported that 'analytical data' are evaluated but usually not discussed in a panel.

It was reported that 6 new petitions were received by CH and DE in 2016 and 2017.

5.15. NL activities on printing inks

On behalf of Bianca van de Ven, Dirk van Aken presented the NL activities on printing inks. The summary provided by the speaker is reported below.

"Colourants and pigments is the term for all substances used to impart a colour to a packaging or utensil intended for contact with food. They may be added to the material in various ways, e.g. by mixing them with the material, or by using them in printing inks. No Positive Lists are in place for colourants and pigments in the Netherlands. All substances (incl. processing aids) should comply with Art. 3 of Regulation (EC) No 1935/2004.

Provisions on colourants and pigments include however restrictions in terms of the amount of specified cations and primary aromatic amines that can be extracted from a colourant or pigment. For soot and other carbon products, restrictions apply on particle size, UV absorption, BaP content and % toluene extractables. Furthermore, restrictions are set for the coloured final product: SMLs are set for specified cations and primary aromatic amines, and the coloured final product should not give off colour in a filter paper test."

5.16. Analysis and discussion on the evaluation methodologies, difference and commonalities, challenges, and next steps on printing inks, group of interest for the harmonisation of evaluation

The discussions of agenda items 19 and 20 have been merged.

There was an exchange on the approach undertaken by DE and CH in relation to the use/request of migration and 'analytical' data. This should be further clarified especially with respect to the evaluation made by FSVO and BfR for the list A. With regards to the list B, the meaning of "no CMR" should be clarified too.

The application of printing inks on different substrates (e.g. plastics, paper and board) adds complexity to the already existing challenge of not having available harmonised and validated analytical methods for migration testing of substances from printing inks. Therefore it should be discussed whether the setting of compositional limits is a more suitable approach for the area of printed FCMs than setting SMLs.

It is interesting to take note of the number of new petitions received per year by CH and DE (6) and the number of new substances estimated by EuPIA (20-30) in contrast with the approx. 5000 substances listed. This gives an indication of the workload related to the assessment of new substances.

With regards to the '5000' substances already listed by CH (list A +B), a mechanism to identify the substances really used *versus* those not used would allow to refine the list, and to better grasp the situation. The use of existing databases and work (BE database, JRC baseline, REACH) could also help in that objective. In addition, a screening of substances left from the list B with *in silico* methods such as (Q)SAR would allow prioritising hence reducing the number of substances that would need to be further evaluated.

A clear need for harmonisation of the risk assessment was identified and this is pending the update of the SCF guidelines along the lines proposed in the EFSA CEF Panel opinion on "recent developments…" published in 2016[12].

There are several activities ongoing, e.g. the preparation of the EU Draft measure on printed FCMs, the development of harmonised analytical methods for measuring photo-initiators into foods by the CoE. Also PT referred to activities on printing inks. It is important to join forces in order to work into the same direction and a first step for the Network could be to compile all ongoing activities in the MSs as regards printing inks. As a follow-up from the 3rd Network meeting, GR, PT, SI, DE and CH were identified as MSs with interest in printing inks. It could therefore be suggested to make use of a similar approach as undertaken for the coatings in order to create a taskforce. Based on the discussion and the above analysis, the following topics could be addressed. The analytical methods or more generally the methodology for evaluating the migration. Information on which substances are really used by industry could be gathered making use of the Belgian Database, the outcome of the JRC Baseline study or the information gathered by registration of chemicals under REACH. Substances of concern could be identified and prioritised by using in silico tools. Currently, there is a project ongoing in BE on printed paper and board, where different QSAR tools are used to prioritise substances for evaluation. The related published paper will be circulated. It should nevertheless be noted that, despite the development of new tools, expert judgement is needed to assess the relevance of the in silico results and possibly use more in silico tools in parallel to increase the reliability of the results.

[12] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4357/epdf

5.17. Proposal for possible follow up in terms of scientific cooperation and future activities (including research)

Vittorio Silano summarised the most important points raised during the discussions of the FIP FCM Network meeting.

The Network represents an interesting and highly constructive platform for the exchange of information and collaboration.

As a first promising outcome to increase the Network collaboration between the MSs, the taskforce on coatings can be mentioned. Another positive example is the joint evaluation of substances in printing inks by Switzerland and Germany. In the light of the foreseen EU measure on printed FCMs, a task force could also be initiated to gather and share knowledge and experience between interested MSs.

Methodologies in the assessment of NIAS is another relevant topic. Further exchanges of practical examples of evaluations by MSs with experience would be useful.

The update of existing and the development of new risk assessment tools is considered as a permanent challenge. The presentation of initiatives, like the Scientific Nano Working Group, the "OpenFoodTox" database or trainings offered by EFSA, is an important channel for MSs to get familiar with EFSA methodologies and to develop competencies. Network members were invited to participate in the sessions organised by EFSA in 2017 on BMD modelling, computational tools (QSAR), statistics training programme or systematic review. The possibility of participation in some FCM Working Group meetings was mentioned and the Network members were invited to express their interest as a follow-up of the meeting.

An important source for funding of collaboration and exchange of knowledge are the Partnering Grants (see 5.9.), which can for example offer a possibility to the MS task force on coatings in their work on harmonising risk assessment approaches.

'Paper and board' was suggested by AT as a possible topic to be discussed in more detail in the next meeting. A Draft Resolution is being prepared by the CoE and could be presented in a session dedicated to 'paper and board'. It was proposed to include 'recycled paper and board'. A project conducted by BE on prioritisation of substances from printed P&B by *in silico* tools could also be of relevance for this session.

DK expressed interest on exposure assessment and data collection on migration into food. FR suggested looking at the Total Diet Study (TDS) and proposed to liaise with DK to explore what data on food migration can be found.

The importance of sharing information that can be of relevance for the whole Network, e.g. publications, research projects, etc., was stressed. The Network members were invited to actively support this by addressing issues of interest to the Coordinator of the Network.

6. Date for next meeting

The next meeting of the FIP FCM network will be organised in 2018. EFSA took note of the proposals for possible follow-ups and will submit a draft agenda to the Network members.

7. Concluding remarks and closure of the meeting

The FIP FCM network coordinator Eric Barthélémy reminded about important aspects for further intensifying the work of the Network: collaboration and communication among MS and between EFSA and MS is of high importance. Use should be made of various types of resources, as mentioned in the meeting, to further build risk assessment capacity and develop approaches for areas of common interest. EFSA took note of the proposals for possible follow-ups and will submit a draft agenda for the next Network meeting (2018) to the members.

The Minutes of the meeting and public versions of the given presentations will be published on the EFSA website within 15 working days.

The Coordinator of the Network closed the meeting by thanking the speakers and all the participants for their contributions to the discussions and the colleagues from EFSA who participated in and supported the meeting.