EFSA scientific network for the cooperation and harmonisation of risk assessment of food contact materials - the 'EFSA FCM Network'

Minutes of the 4th meeting

Group of interest on Coatings

Held on 16 February 2017 by TELE-conference

(Agreed[1] on 7 March 2017)

Participants

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

Country	Name
Belgium	Els Van Hoeck
Croatia	Nino Dimitrov
Italy	Maria Rosaria Milana
Netherlands	Dirk van Aken Bianca van de Ven
Slovenia	Viviana Golja
Spain	Perfecto Paseiro Losada Juana Bustos Garcia de Castro

- **Observers/ Intergovernmental organisation**

Susanne Bahrke (Council of Europe, CoE)

- **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 (FCM))

- **European Commission:**

Jonathan Briggs (DG SANTE)

Eddo Hoekstra (DG JRC)

Catherine Simoneau (DG JRC)

[1] by written procedure

- **EFSA:**

Eric Barthélémy, FCM Network Coordinator, Chair

Anna Federica Castoldi, FCM Team Leader

Cristina Croera, FCM Team

Alexandros Lioupis, FCM Team

Claudio Putzu, FCM Team

Ellen Van Haver, FCM Team

Katharina Volk, FCM Team

1. Welcome and apologies for absence

The Chair welcomed the participants to the first meeting of the 2nd Mandate of the FCM Network. The mandate of the FCM Network was renewed in December 2016[2] for a period of three years. The Chair summarised the context and objectives. **The meeting was dedicated to the safety assessment of coatings**, especially to the methodology. The objective was to clarify what safety assessment was carried out by participant Member States, particularly with respect to commonalities and differences amongst the evaluation of substances used to manufacture coatings, oligomers and other NIAS as regards the SCF Guidelines/EFSA Note for Guidance[3].

The Chair also welcomed Els Van Hoeck, new representative for Belgium in replacement of F. Bolle.

Apologies were received from Riccardo Crebelli (Italy) who was substituted by Maria Rosaria Milana.

Jonathan Briggs participated only in agenda items 1 to 8.

Catherine Simoneau participated only in agenda items 1-4 and 6.

2. Adoption of agenda

The agenda was adopted with changes in the item orders, i.e. item 6 was moved before item 5.

3. Agreement of the minutes of the 3rd meeting of the Network on food ingredients and food packaging (FIP) Unit "FIP Network", subgroup on food contact materials (FCM), held 24-26 May 2016, Parma

The minutes were agreed by written procedure on 5 August 2016 and published on the EFSA website on 12 August 2016.

[2] Terms of references of the mandate renewed in December 2017: https://www.efsa.europa.eu/sites/default/files/assets/fipnonplasticsnetworktor.pdf

[3] EFSA Note for Guidance, 2008 – including the SCF Guidelines (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2008.21r/epdf)

4. Declaration of interests and statement of confidentiality

All Network representatives signed a statement of confidentiality through the submission of their Annual Declaration of Interest.

5. Topics for discussion

5.1 Council of Europe (CoE) activities on coatings

Bianca Van de Ven presented, on behalf of Susanne Bahrke and the CoE, the organisations' activities in relation to coatings. The summary provided by the speaker is reported below.
The aim of European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe is to contribute to cooperation between countries in Europe, in order to promote health, to ensure legal coherence and to make better use of resources available. The committee 'P-SC-EMB' deals with food contact materials. A Resolution on coatings was adopted in 2004 and the corresponding Technical Document No.1 was updated twice since, most recently in 2009 (Policy statement concerning coatings intended to come into contact with foodstuffs (Version 3 dated 12.02.2009). It contains 4 lists of substances, 2 for monomers and 2 for additives. Because of the upcoming new Framework Resolution, of which the scope will cover *all* FCMs that are not EU-harmonised, the Resolution on coatings and accompanying Technical Document No.1 should be rewritten into a Technical Guide on coatings. Also, the lists of substances (and restrictions) should be updated. Guidance on migration testing methods could be incorporated as well, containing additional specifics for coatings. Other requirements specific for coatings could be added, for instance, restrictions for some commonly found NIAS. The working group has not started yet.

Following the presentation, the Technical Document No.1 was discussed with regards to the evaluation of the listed substances. In particular the safety of substances in lists "B" and "D" (monomers and additives approved by Member States of former Partial agreement or by US-FDA) was questioned. The Categorisation of coatings in the Resolution AP(2004)1 was discussed with regards to the testing conditions and consistency with other categorisations reported by Member States. With regards to migration testing methods, the EC DG JRC mentioned that the Task Force on kitchen and tableware is collecting information on test conditions and methods of analysis for all relevant materials and articles including coatings using the Baseline study and questionnaires to the NRLs.

5.2 European Commission (EC) feedback from the baseline study

Catherine Simoneau presented the outcome of the EC DG JRC baseline study[4] with respect to the area of coatings. The summary provided by the speaker is reported below.
The EC DG JRC released an EU wide review at national and sectorial level on food contact materials (FCMs) for which there are no specific EU measures. The study reveals a number of shortcomings such as variations in national risk

[4] https://ec.europa.eu/jrc/en/news/mapping-industry-and-regulatory-frameworks-food-contact-materials-support-better-regulation

assessment approaches, risk management and enforceability. This presentation focused on the sector of coatings and presented the regulatory frameworks specific to this area. There is a lack of common guidelines and transparency in undertaking risk assessment (RA) work across Member States. Specific protocols are difficult to access or share and they may differ between MSs and from that of EFSA. National measures can also be difficult to access and are not always consistently structured or sufficiently detailed. Measures are based on lists of authorised substances, but show disparities among MSs in the nature of substances considered, and their numerical restrictions. This leads to multiple testing requirements and further complicates mutual recognition. Practical implementation and enforcement is impeded by the lack of access to or availability of methods to test compliance with legislative limits. It also makes it more difficult to demonstrate that food safety is consistently ensured. This baseline study will support the Commission's evaluation, which will assess the suitability of the current EU framework for both the harmonised and non-harmonised sectors and help decide on future steps at EU level.

Following the presentation, some clarifications were given on the methodology to assess the convergence on restrictions among Member States as well as between Member States and CoE. A number of national provisions (but not all) for authorised substances for use in coatings make reference to the positive list of Regulation (EU) No. 10/2011. Others have developed lists of substances specifically for coatings. Excluding substances authorised for use in plastics that are common to Member States, there is little convergence amongst the lists' developed at national level or between the national lists and the CoE list.

5.3 Slovenia (SL) activities on evaluation of coatings (monomers, oligomers, other NIAS and additives)

Viviana Golja presented the activities of SL in relation to coatings. The summary provided by the speaker is reported below.
In the presentation, the evaluation of coatings in Slovenia was described. There is no evaluation of substances prior to authorisation and no national legislation. Evaluation of coatings is performed on the samples from official controls. Testing is performed according to the rules from Regulation (EU) No. 10/2011. Specific migration limits (SMLs) listed in the Regulation are taken into account for organic substances. For released metals the specific release limits (SRLs) are used from the Council of Europe Practical guide for Metals and alloys. If concentrations exceed SMLs or SRLs, or if substances found are listed as CMRs (carcinogenic, mutagenic, reprotoxic), then exposure assessment is done by use of the EFSA Comprehensive European Food Consumption Database followed by risk characterisation. Research on "characterisation of food contact non-stick coatings containing TiO_2 nanoparticles and study of their release into food" was presented as well[5]. Different approaches to assessment of possible health risk through exposure to released particles were presented.

Following the presentation, the NL reported that they have also carried out national research project(s) on assessment of exposure to nanoparticles from food. Although the focus was more on food additives (silica, titanium dioxide)

[5] http://www.tandfonline.com/doi/full/10.1080/19440049.2016.1269954?af=R

than on food contact materials, the challenges in characterising the particles and quantifying nanomaterials in complex matrices are quite similar; see for example: Peters et al, J. Agricult. Food Chem. 62 (27), 6285-6293. It was proposed to pick up the topic of nanoparticles for further discussion, exchange and collaboration between Member States in following meetings of this subgroup. The use of SRL instead of SML for metals listed in the Regulation (EU) 10/2011 was questioned.

5.4 The Netherlands (NL) activities on evaluation of coatings

Bianca Van de Ven presented the activities of the NL in relation to coatings. The summary provided by the speaker is reported below.
In the Netherlands, legislation on coatings contains both general provisions as well as positive lists. The scope is: all coatings, on any substrate, including these on metals and paper and board, but excluding adhesive layers, printing inks, coatings on regenerated cellulose, and coatings not in direct contact with food. In the upcoming update of the coating chapter (Chapter 10 of part A of the 'Packaging and Utensils Regulation'), four types of coatings will be distinguished: general purpose coatings, wax coatings (solvent free), metallic coatings and temperature resistant coatings. For each type of coating separate positive lists apply. A 'Declaration of Compliance' is needed for all coatings.
New substances are evaluated by Commission G4 in a similar way to how EFSA evaluates plastics. 'One safe use' should be demonstrated by testing a typical sample coating. Fate of the substance should be described; migration of it and its reaction- and breakdown products should be measured or calculated from the residual content. All migrants that are typical for the substance have to be assessed with respect to safety, while no such assessment is performed for NIAS that might vary from coating to coating (depending on the recipe). Oligomers are evaluated in a general way, for instance by looking at their migration (fraction <1000 Da), or by comparing the total amount and molecular weight distribution of oligomers in the polymer with that of a conventional coating. No restrictions are set for oligomers in Dutch legislation so far.

During the discussion following the presentation, it was identified that the approach of the NL in terms of categorisation of coatings, i.e. general or specific purpose coatings, differs from the ones presented by e.g. CoE or BE. In order to achieve a common understanding and harmonisation in the area of coatings, the topic of categorisation is an important point of discussion that should be addressed in the follow-up meetings. The importance of distinction between NIAS as described above was stressed by the group. It was clarified that NIAS "typical for the substance used" (i.e. "arising in probably all uses") are evaluated and listed in the same list as the substances used but are not authorised to be intentionally used. Concern was reiterated regarding the use of pre-polymers in coatings. For plastic materials, according to Regulation (EU) No. 10/2011, 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. Therefore, those pre-polymers are usually not assessed for risks. This approach was questioned in previous FCM Network meetings and would need to be addressed.

5.5 Italy (IT) activities on evaluation of coatings

Maria Rosaria Milana presented the activities of IT in relation to coatings. The summary provided by the speaker is reported below.
In Italy, coatings are under the Ministerial Decree 21.3.1973 (DM 21.3.73 and amendments), where extension of rules for plastics to coatings is laid down. No specific national guideline for the safety assessment of coatings is settled in the legislation. Currently for coatings it is applicable the positive list of substances for plastics (Regulation (EU) No. 10/2011), the positive list of polymers (DM 21/3/73) and a case by case addition to the IT list of new substances other than those used for plastics (DM 21/3/73). OML and SML are applied to coatings. NIAS are under the responsibility of the business operator who has to perform the risk assessment. When a new substance, material or component is requested by an applicant for introduction in the positive list, risk assessment is performed by public bodies. In this case the content of the technical dossier submitted by the applicant has to follow the same EFSA rules as for plastics. For the risk assessment IT follows the EFSA standard approach for substances that have to enter the positive list (the same tiered approach migration/toxicity data, and default assumption for exposure scenario), while for NIAS, impurities, oligomers other approaches can be applied (read across, SAR, Margin of Exposure). There is no default application of the TTC, but instead a case by case approach is followed. When necessary, a SML for any other migrant in addition to the listed substance can be set.

In the discussion following the presentation, the demonstration of a practical example of the safety evaluation of a substance to be used in coatings was welcomed by the participants. On one hand, it was considered a possible way to share experience and facilitate work. On the other hand, duplication of evaluation by different Member States of the same substance for the same use was acknowledged. Cooperation at early stage starting by sharing requests received by Member States competent Authority for safety evaluation of substances (intended to be) used in coatings would benefit to all.

5.6 Belgium (BE) activities on evaluation of coatings

Els van Hoeck presented the activities of BE in relation to coatings. The summary provided by the speaker is reported below.
In the presentation, an overview was given of the Belgian activities on the evaluation of coatings. In September 2016, a Belgian Royal Decree on varnishes and coatings intended to come into contact with food was published. This Royal Decree describes the authorised substances. Furthermore, a new substance can be evaluated by the Belgian Superior Health Council. More details on the procedure were given during the presentation. However, no applications have yet been received.
The Royal Decree on varnishes and coatings also describes the testing conditions for specific and overall migration. It is based on the provisions laid down in Regulation (EU) No. 10/2011 on plastics, but has introduced the use of the simulant '5 g/L citric acid' for compliance testing in correspondence with the Resolution of the Council of Europe on Metals and Alloys CM/Res(2013)9. Furthermore, this simulant will also be recommended for the safety evaluation of

varnishes on metal substrates. Finally, an overview was given of the analyses included in the Belgian yearly control plan.

Following the presentation, the applicability of overall migration testing for thin coatings and related testing conditions (e.g. use of chloroform) was discussed. The exemption criteria for using substances not being part of the plastic positive list and not evaluated by a Member State competent Authority were debated. In particular, the associativity of the criteria and the application of non-migration and non-CMR principles were discussed.

5.7 Analysis and discussion on the evaluations methodologies, differences and commonalities, challenges

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 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 as it is a recurrent question from Spain.

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 (e.g. the possibility to use the OECD "Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test" (test No. 422) instead of the recommended 90-day oral toxicity study on a case by case basis), the SCF tiered approach (i.e. based on 3 tiers) 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 in relation to the safety assessment of FCM in general, and coatings more specifically. 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.

5.8 Confirmation of membership

In a '*tour de table*', all the Member State participants confirmed their willingness to be members of this group on evaluation of coatings.

5.9 Proposal for Leadership and Secretariat

Following considerations on their expertise and experience in the safety evaluation of coatings at national level, EFSA proposed the NL to take the leadership of this group on coatings for the harmonisation of their safety assessment methodology. The NL representatives agreed with this proposal which was supported by the other Member State participants.

5.10 Proposal for objectives, plan of actions, outcome, timeline and next meetings

The present meeting was a platform for a first exchange of information between the Member States with regards to their activities in this specific field. Identifying the common and different aspects among Member States in applying the SCF guidelines and/or EFSA note for guidance for the safety assessment of substances, oligomers and other NIAS was considered important to set the starting points for further work in the area of coatings among the members of the group.

Upon appointment as the leader, the NL stressed the importance of defining clear objectives and deliverables to be achieved by the group. Further steps should be agreed upon by the group in order to achieve progress in harmonising risk assessment methodologies. In the following meetings, other Member States with expertise and experience in the evaluation of coatings such as Germany and industry association(s) might also be invited to share their knowledge and provide input to the process of harmonisation.

The leaders of the group are expected to stimulate exchange among the members in order to propose, based on the outcomes of this first meeting, an action plan, to define objectives and provide a timeline for the next meetings. The outcome will be reported at the next meeting of the whole FCM network.

In addition to these minutes, an event report of the meeting, containing more details, will be published at a later stage.

6. Concluding remarks and closure of the meeting

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

The newly appointed leader of the group from the NL together with the Coordinator of the FIP FCM Network closed the meeting by thanking the organisers. They also thanked all of the participants for their commitment and informed them that they would keep in contact to carry forward a programme of work on coatings.