



CHEM Trust
Protecting humans and wildlife
from harmful chemicals

Workshop notes

Notes from a workshop to discuss the role that REACH could have in assisting with regulation of chemicals in Food Contact Materials

Monday, 29 April 2019, 11.00 – 17.45

Introduction

This workshop was organised by CHEM Trust to facilitate an informal discussion between regulators from MS, the Commission, EFSA and ECHA about deficiencies and synergies between REACH and the food contact materials (FCM) legislation.

*****Please be aware that the opinions reflected in the following notes may not be shared by all or even most of the participants, and not all opinions are necessarily shared by CHEM Trust.*****

The notes have been circulated amongst the participants for comments, but statements may still be incorrect or incomplete and this document should not be used as a reference document, but simply as notes, that may be of interest in the further discussions on how to regulate food contact materials in the future.

CHEM Trust would like to thank all those who participated in the workshop for their time and engagement.

There is a full list of participants in Annex 2 on page 11; the agenda is on page 10.

These notes, with the presentations, are available on the CHEM Trust website at: <https://chemtrust.org/workshop-fcm-reach/>

Factual presentations before the discussion:

- **Andreas Ahrens, ECHA** gave an overview of how REACH data could be useful for assessing substances in FCM and how legal provisions in REACH bring together the knowledge of the substance manufacturer and the knowledge of the substance user in order to ensure a basis for adequate risk management in each supply chain.
 - Talk available here: <https://chemtrust.org/echa-reach-fcm/>
- **Eric Barthélémy, EFSA** explained the current methods and data requirements for assessing plastic FCMs, presented FCM peculiarities and put in context the use of REACH data in FCM assessments.
 - Talk available here: <https://chemtrust.org/efsa-reach-fcm/>
- **Mette Holm, Danish Veterinary and Food Administration** presented principles for information flow in the FCM supply chain and proposed possible solutions to reach safe articles.
 - Talk available here: <https://chemtrust.org/denmark-reach-fcm/>
- **Els Heyvaert, Health, Food Chain Safety and Environment Authority of BE** presented a national approach and highlighted how guidance from the Council of Europe can be useful in the absence of common guidance for non-harmonised materials.
 - Talk available here: <https://chemtrust.org/belgium-reach-fcm/>

Notes from the discussion

The following is a compilation of points made at the workshop as related to the issues for discussion chosen by the participants.

1. Migration data and REACH, what role could REACH data have in ensuring safety of FCM

EFSA and the Commission provided background information about the current rules for FCM. In addition to the general rules laid down in Regulation 1935/2004 applicable to all FCMs, there are a number of specific measures including primarily the union list (for plastic food contact materials), which authorises substances for use in the manufacture of plastic FCMs. It also provides Specific Migration Limits (SML) and/or other restrictions and specifications for certain substances and an Overall Migration Limit (OML) for the total amount of substances that may be released from any material covered by the plastic regulation¹.

Data requirements are progressively more stringent depending on the migration level. The higher the migration, the more hazard data the applicant must submit to EFSA for a substance to be authorised for use in food contact plastic, - starting with genotoxic properties as a minimum requirement². The **data requirements are not established in the legislation** itself, as in REACH, but in the EC SCF guidelines³ and the EFSA Note for Guidance⁴. EFSA may ask for additional data, if deemed necessary by the CEF⁵.

¹ Commission regulation 10/2011 on plastic materials and articles intended to come into contact with food

² see EFSA's presentation from the workshop

³ SCF, 2001 https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out82_en.pdf

⁴ <https://www.efsa.europa.eu/en/efsajournal/pub/rn-21>

⁵ Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

Some participants regarded the existing migration levels as quite conservative, and **a good starting point for prioritisation** of the need for further information. Others suggested renewed **comparison with relevant reference values**, such as TDIs⁶, from multiple information sources, including REACH dossiers.

The participants discussed how data generated under REACH could be useful when assessing food contact material. Even though there are still gaps and missing data in REACH registrations, it would be beneficial for EFSA and companies assessing the safety of FCM to make sure to include data generated under REACH. This could e.g. reduce the use of Thresholds of Toxicological Concern TCCs⁷ for filling in data gaps.

It was emphasised that REACH has, to a large extent, **cleaned the market of chemicals with unknown compositions** and that this increased knowledge about the parent substance should be helpful for producers of food contact materials aiming to identify unintended breakdown products in the FCM.

Under REACH, there is a mechanism to ensure in principle that **information on chemicals does not grow outdated** as the registrants must update their dossier whenever there is new information. This same principle exists in Art 11.5 of the FCM framework regulation which provides that applicants or businesses using the substance **must immediately inform the Commission** of any new scientific or technical information which might affect the safety assessment of an authorised substance. Some participants thought that given the many new data provided under REACH, it seems strange that DG SANTE has received relatively few data under Article 11(5). This indicates a lack of focus on new data obtained under REACH amongst FCM producers and providers.

Participants generally agreed that REACH has significant potential in managing risks by **bringing together the knowledge of the manufacturer and the knowledge of the user** in the CSA (Chemical Safety Assessment): The obligation to do the risk assessment (RA) is on the manufacturer of each chemical. However, as the manufacturer doesn't know all customer's uses, REACH includes a provision that the Downstream users (DU) can report his use to the registrants and also that it is unlawful for the DU to use a substance in a way which has not been identified and assessed by the registrant unless the DU makes his own risk assessments. Thus, under REACH it is in principle **not possible to use a hazardous chemical in volumes above 10 t/yr. without a risk assessment**.

The participants regarded the basic REACH system as useful but were also concerned that safety assessments made under **REACH lose track of substances when it is incorporated into an article** (including food contact articles and materials). It was mentioned that if there would be initiatives in the future to include relevant articles more systematically in Chemical Safety Assessments under REACH then it would be logical to ensure a clear focus on the **food contact articles** as these are used by consumers every day in close vicinity to our food and represent a potential significant source of exposure to chemicals compared to other article groups.

Other points made regarding data availability and data generation were that information on the overall **mass flow of a chemical is important to evaluate and manage the overall risks**, in particular to set priorities for action. The required REACH registration data only provide data on use in relatively crude categories and no data on the tonnages for specific uses. Hence a mass flow breakdown into the different areas of use of a substance is often not available.

For FCMs it also is important to have better **information of the specific uses of substances and materials**. There is a lack of instruments to get such information. The

⁶ Tolerable Daily Intake (refers to the daily amount of a chemical that has been assessed safe for human being on long-term basis)

⁷ Thresholds of toxicological concern, e.g. see <https://www.foodpackagingforum.org/news/efsa-guidance-on-using-ttc>

FACET – The “Flavourings, Additives, and food Contact materials Exposure Tool” provided by JRC was mentioned as a useful tool for estimating total dietary exposure from different sources, if the identity and levels of chemicals used in FCMs are known. However, a point of criticism was that there is no public **access to the underlying data and algorithms used to model migration and exposure**.

In recent years there has been widespread political focus on e.g. **the phthalates in FCM** and increasing data are available about the harmful effects and the risks related to the use of these substances. However, it is important not to overlook other less/not tested substances found in FCM.

A reiterated point was that there is a need for an **automatic exclusion of substances with certain hazards such as EDCs, DNTs and CMRs** from FCM based on a generic risk assessment and regardless of migration. It was further argued that there is no need to “re-invent the wheel” and that it would be logical to, by default, **prohibit e.g. all annex 14 substances or all SVHCs** in FCM.

A final point in this session was that there is a general **need for more communication between ECHA and EFSA**. There is also need for better communication nationally between the FCM experts and the REACH experts in the MS, not only about safety data but also about legislative processes and initiatives. For instance, after consulting the Commission, ECHA did not **include FCM in the REACH restriction** proposal for phthalates although **75 % of the total exposure to DEHP** was assessed as being from food intake, and FCMs were assumed to be the principle source of exposure to the 4 phthalates from foods. FCMs were seen as belonging to a different area of legislation and under the remit of EFSA.

2. Challenges related to chemicals in non-harmonised FCM materials at EU level

The group recalled the high number of chemicals reported as used in all types of **FCM in total (> 10.000 substances)** and agreed that the number is surprising high e.g. compared to the number of substances registered under REACH (ca. 22.000 substances).

It was a general view that lack of harmonisation is a main problem with the current FCM legislation. Harmonisation was seen as a good solution for all materials, with paper and board and printing inks as priority materials.

The group looked into which **elements should be included in new legislation** and initially agreed that all approval systems (**positive lists**) **have built-in difficulties**. The workload on the Agency responsible for running and maintaining the assessments for approval is often high, and it was emphasised that any system of **authorisation should be related to the materials and finished article**, including the NIAS therein, not only the starting materials.

It was highlighted that if legislation on chemicals product safety is to be workable, **it must be clear which actor has the responsibility** to provide data on the chemicals in the materials and assess the risks. Today, declarations of compliance (DoCs) are used to pass on information for harmonised materials, while for the non-harmonised materials there is no harmonised way of passing on information and assessing risks, and producers of a final food contact article often don't have the necessary information to ensure safety. It was emphasized that in each supply chain there are **stakeholders who do know** about which chemicals are present in the materials. These stakeholders **should be legally responsible** for ensuring and documenting safe use.

Some participants saw a need for **an instrument, such as a database, to compile available data** on chemicals in FCM in a transparent way, including the non-intentionally

⁸ https://echa.europa.eu/documents/10162/63d36637-750b-390c-3410-d0dea806869d_

added substances (NIAS). It was mentioned that the REACH registration system could be (partly) copied.

Besides taking inspiration from REACH processes, when designing the FCM legislation of the future, **the Cosmetics Regulation was also proposed as inspiration**: This Regulation include an approval system - positive listing - for three groups of chemicals: colorants, preservatives and UV filters. Moreover, a (workable) system of product files, safety assessments and safety reports, which must be prepared by industry has been developed for cosmetics. Moreover, **CMRs are restricted** in cosmetic products unless a number of conditions are fulfilled (article 15). Thus, cosmetic products are regulated through a combination of positive listing, negative listing, demands for safety assessments provided by industry as well as other provisions and it is regularly updated⁹.

The workshop acknowledged the **Council of Europe** (CoE) for having done much work to overcome the lack of harmonised legislation by developing tools for risk management for the non-harmonised materials, although the lack of transparency for non-governmental stakeholders on the work of the CoE was criticised. Each MS can choose to transpose the material produced by the CoE - technical documents, resolutions and guidelines - into national law. The goal of the CoE is to have separate guidelines for all non-harmonised materials, which can be seen as a back-up plan if no harmonisation is implemented at the EU level.

3. Plastics and the need for reassessment

There are about 1000 chemicals on the union list (the list of substances approved for use in plastic FCM). The original list started to be compiled in the 1980s and the first union list was adopted around 1990. **Participants saw a strong need to reassess the list** for many reasons: Many substances are not in use anymore and many need to be re-evaluated based on new science. It was pointed out that, currently, the focus of hazard assessments is on mutagenic and/or genotoxic effects, which is certainly relevant and important information, but on top of this there is a need to **include other important hazards such as effects on the nervous, immune and particularly the endocrine systems** systematically in the safety assessments.

EFSA's CEF has advised that default **exposure assumptions must be revisited**¹⁰. EFSA has already re-evaluated a number of SMLs and complemented them with restrictions of certain uses

The large number of chemicals makes further **reassessment cumbersome and there is a need for prioritising** the re-assessment. One way of prioritising could be to **start reassessing substances assessed before 1991** when the original version of the current SCF guidelines were published

One obstacle mentioned was that in cases where EFSA chose to reassess a substance, the applicants are not involved, and updated info on which uses to include may not be available. It was also mentioned that it would have been beneficial if there had been an obligation on industry to notify the Commission, if a substance is no longer in use in FCM and a mechanism for the Commission to remove these substances.

The participants saw a need to evaluate what additional hazards and effects of substances in FCM should be assessed in the future and to have an overview of how many and **which of the substances on the Union list that have been registered under REACH**.

Food packaging Forum informed the group that they will publish a list of FCM starting substances that are also registered substances under REACH.

⁹ see e.g. Commission website DG Grow: https://ec.europa.eu/growth/sectors/cosmetics/legislation_en

¹⁰ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4357>

The group discussed REACH provisions further and concluded that even though **REACH does not provide all what is needed**, REACH can provide some of the tools and data, that are needed to update the legislative system for FCM. For instance, a large number of chemicals have been or are currently being evaluated under REACH. It could be beneficial if these efforts were combined with the evaluation of the same chemicals in FCM. The evaluation efforts under REACH also provide tools for prioritisation, which might be useful in (re)assessing FCM, and the process of prioritising substances without SMLs should at least be reflecting on the information available from REACH.

The applicants for authorisation of chemicals in harmonised FCM must consider all available information, including information that has become available under REACH. However, they may not find much **info about NIAS**, as REACH does not provide detailed data on reaction products. Breakdown products must be dealt with in REACH safety assessment, but generally, current REACH assessments are often not sufficiently detailed on impurities and reaction products. For instance, **if a registered substance is not itself classified** there is no explicit legal requirement on the REACH registrant to do a risk assessment (according to article 14) even if the degradation product would be classified.

In parallel to the evaluation of the FCM legislation, the Commission (DG Sante) is currently in the process of compiling information on FCM plastic substances available under REACH.

In the prioritisation for re-evaluation of the FCM legislation, it must be considered that **NIAS can constitute the majority of migrating chemicals from finished articles and thus** NIAS must be assessed in the finished article.

Another important point was that there is a need to find out how to enhance the **transparency in the FCM supply chain all the way from starting material to final article**. As an example, recent developments related to food safety authorisation under the general food law was mentioned. Here provisions had been proposed stating that EFSA must publish the scientific data and other information used to assess safety and support applications for regulated products.

It was mentioned that although many stakeholders call for better use of available data in EFSA's assessments, there may be legal obstacles. As an example, EFSA may not use data from one applicant to evaluate another's application.

It was questioned to what extent EFSA should redo ECHA's assessments etc. (as e.g. the recent assessment of the need to restrict four phthalates. These were restricted in several consumer articles through REACH, but not in FCM), and to what extent MS and Agencies have (easy) access to each other's data. It was pointed out that transparency does not prevent disagreement, and it is important to ensure continued good collaboration between different agencies working on the same substances such as e.g. the bisphenols.

Round up, summary and close:

The following - additional or reiterated - points were taken from the final round up at the end of the day:

- REACH was developed as a **response to lack of data and insufficient risk management**. The situation with FCM seem to be the same today.
- The REACH regulation and the FCM framework both prioritise data requirements based on a **simple proxy for potential exposure**. In **REACH it is volume** (often the total registration volume as no further break down is available and the extent to which the uses are wide-disperse which is in practice translated to widespread use and outside close systems). In the **FCM framework regulation it is migration**.

- For chemicals regulated through positive listing under the FCM legislation the **responsibility for risk assessment** is on EFSA, while a REACH registration is the responsibility of the producer or importer.
- The question of to **whether REACH data can be used for FCM depends on the stakeholders and on the purpose**. ECHA's website provide a public summary of data (substance ID and hazards and use information provided by manufacturers and importers) from REACH registrations but the registrants' Chemical Safety Reports are not published. However, FCM producers can – and should - use such data, which requires that the applicant obtain the raw data and the authorisation to use them from the REACH registrant in order to use them for their FCM application.
- REACH registrants often **do not provide information on whether a chemical is used in those article categories that are relevant for FCM** even though, in principle, they should. This can be due to e.g. unawareness or misconception regarding use description under REACH, or lack of information regarding FCM uses, or low granularity in use description reflecting the low/no hazard of the substance.
- Other useful data from REACH processes include detailed dossiers from restriction-proposals, substance evaluations, SVHC identifications, classification proposals and the CLP inventory.
- REACH registration dossiers do not provide much information on migration from articles. Moreover, polymers are currently exempt from registration, there are data gaps in the registration dossiers, and oligomers, reaction by-products and degradation products (i.e. some NIAS) are not systematically addressed in industries' current Chemical Safety Assessments under REACH.
- **REACH registrants should learn from the FCM area about NIAS**
- The FCM supply chains need to find ways to **combine hazard info generated/collected under REACH with migration data** generated under the FCM legislation
- There is a need for better understanding of the differences and similarities between the Declaration of compliance concept under the FCM legislation and the Exposure Scenario concept under REACH; including how both approaches work in practice, and whether some cross-fertilisation would be possible.
- New legislation should create a better link between REACH and FCM. **Legislative steps under REACH should also trigger action for the FCM**. As a minimum, there should be a **requirement to re-evaluate the use in FCM of any SVHC** identified under REACH as well as any relevant substances restricted under REACH. This could be one of the starting points for harmonising the non-harmonised materials.
- **EFSA and ECHA already cooperate** on some issues such as biocides used in FCM and EDC-identification. From 2019, an agreement was made for a more strategic partnership.
- There is a need to ensure **sufficient transparency and communication** in the supply chain for all operators to be able to check safety.
- Neither the safety data sheet for substances and mixtures under REACH or the DoC provide **access to underlying calculations** and assessments
- In the future FCM legislation there should be more emphasis on industry's responsibility to assess those chemicals that are present in finished food contact

articles. There should be a clear legal requirement to **assess the migrating mixture** – including the NIAS – from all food contact materials and final articles.

- The issue of **multiple exposure needs to be clearly addressed** in all chemical legislation. This requires more information on all uses of a substance, and triggers a new basic question: **Which sector should get the right to contaminate?** consumers and environment? and how much?
- The work done by the **CoE** is very useful and could also be used when revising the FCM regulation.
- Positive lists take responsibilities for the listed chemicals off the shoulders of industry.
- To focus re-assessment efforts for the harmonised materials, a mechanism or strategy to identify those substances, that are still used in FCM, should be set up.
- It is a good idea to have a **generic ban on CMRs** and other substances of concern in articles and materials which are intended for consumer use. The new FCM legislation could find **inspiration from the Cosmetics Regulation or Toys Safety Directive** as well as REACH' general ban on CMRs in any mixture which is sold to consumers.
- The provisions under the FCM legislation are **difficult to enforce**. However, some MS have experienced that after taking enforcement action on DoCs, these are more often in place than they were before, so inspection does matter.
- Given that **food is such a traded product**, is it strange that the legislation on FCM is not harmonised.
- **Harmonisation is on the wish-list of industry**. Industry generally does not concede to having actual safety problems, but rather that it is difficult to demonstrate safety.
- It is a challenge to ensure safety of **multilayer/multimaterial products** consisting of both harmonised and un-harmonised materials.
- When the framework legislation was adopted, the **Commission chose to start with plastics, but was expecting to move on to more materials**. In 2004, active and intelligent materials and recycled plastic materials were chosen for harmonisation. However, no work has been undertaken to harmonise other materials such as paper and board; a widely used FCM which may include substances of concern such as fluorinated substances, or e.g. printing inks and glues.
- The explanation for these choices in the past may be that we often wrongly **focus too much on new products**, thinking older products are well known.
- It may fall back on the food business and also on providers of consumer goods in general, if there is lack of public trust in chemicals in FCM.
- The REACH regulation includes a clause which demands a **review of the operation of the regulation every 5 years**. The current FCM legislation does not include such a review clause, and it has **not been reviewed for 40 years**.
- Possible ways of **designing the future** could be to revise the plastics regulation and/or the whole framework legislation. Other obvious steps would be to introduce harmonisation for all or more non-harmonised materials.
- It is better to have a **good basic legislation in place** than to implement new rules from time to time based on scandals.
- There may be a **fear of “opening” the FCM legislation** amongst some stakeholders, and it was questioned by some participants whether the core legislation needs to be

revised as the existing framework might still allow for the changes that most stakeholders want.

- On the other hand, others highlighted, **it is a good principle to revise such laws every 20-30 years.**
 - The European **Parliament took a clear position in 2016** calling for massive changes of the current system
 - There is a **need for more discussions between stakeholders**, as in this workshop.
 - This time next year, we will know more.
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- For more on CHEM Trust's work on chemicals in food contact materials, see: <https://chemtrust.org/food-contact/>

Annex 1: Agenda for the event

Workshop to discuss the role that REACH could have in assisting with regulation of chemicals in Food Contact Materials

Agenda

11.00 – 11.20 Welcome, introduction and aim of the workshop,

Michael Warhurst, Executive Director, CHEM Trust

11.20 – 12.30 What information generated by REACH is relevant for FCM regulations?

20 min **REACH** Presentation (Andreas Ahrens, ECHA): Reflections on what information REACH provides that could be useful for risk assessment of chemicals in FCM

20 min **FCM** Presentation (Eric Barthélémy, EFSA): Reflection on the current risk assessment of chemicals in plastic FCM, engagement with Stakeholders and EFSA cooperation with ECHA.

30 minutes questions of clarification, then starting a broader discussion

12.30 – 13.20 Sandwich lunch and post-it session

During the lunch participants will have the opportunity to write post-it notes about concerns and opportunities related to a greater role for REACH in the FCM regulatory process.

13.20 – 14:00 Brief presentations from experts from Member States (Mette Holm, Senior Scientific Advisor; Danish Veterinary and Food Administration; Els Heyvaert, Regulatory Expert on Food Contact Materials; Health, Food safety and Environment, BE) on how data and experience from REACH could be useful for FCM regulation and in the FCM supply chain, based on national experiences on FCM and related processes like Council of Europe

14.00 – 14.10 Assess and prioritise the post-it issues collected during lunch, aiming to select two areas of concern and one potential opportunity to discuss in detail

14.10 – 14.50 Discussion of area of concern 1

14.50 – 15.30 Discussion of area of concern 2

15.30 - 15.45 Coffee break

15.45 - 16.30 Discussion of opportunity 1

16:30 – 16:45 Summary and reflections

Henrik Søren Larsen, Head of Department, Danish Ministry of Environment and Food

Summary of points where the FCM legislation could be more aligned with REACH, based on the discussions in this workshop and national experience with FCM and other product legislation, e.g. on toys and cosmetics?"

16.45 – 17.45 Wrap up – Table round evaluation – and next steps

Annex 2: Workshop Participants

Eric Barthélémy, Scientific Officer for Food Contact materials, EFSA

Andreas Ahrens, Prioritisation Directorate, Exposure and Supply Chain Unit, ECHA

Karin Kilian, Policy Officer, DG ENVIRONMENT, Unit B.2, Sustainable chemicals

Ana-Maria Blass-Rico, Policy officer, DG GROW, Unit D1, REACH

Jonathan Briggs, Policy officer, DG SANTÉ, Unit E.2 Food processing technologies and novel foods

Giulia Martino, Junior Consultant, Policy and Research, Ecorys

Mette Holm, Senior Scientific Advisor, Danish Veterinary and Food Administration

Henrik Søren Larsen, Head of Department, Danish Ministry of Environment and Food

Els Heyvaert, Regulatory expert, Federal Public Service Health, Food chain safety and Environment, BE

Jane Muncke, Managing Director, Food Packaging Forum Foundation

Pelle Moos, Safety and Health Policy Officer, BEUC

Michael Warhurst, Executive Director, CHEM Trust

Sidsel Dyekjær, Science and Policy Consultant, CHEM Trust

Ninja Reineke, Head of Science, CHEM Trust

Eleanor Hawke, Campaign Intern, CHEM Trust