Note from a workshop examining opportunities & deficiencies in the overlap between REACH & food contact materials legislation

10th March 2016

BBL2Meet, Rue des Deux Eglises/Tweekerkenstraat 47, 1000 Brussels

Introduction

This workshop was organised by CHEM Trust (www.chemtrust.org.uk), in order to facilitate an informal discussion of issues around the overlap and gaps between REACH and Food contact materials legislation.

The workshop was under Chatham House rules, and these notes are purely a collection of points made.

There is no implication that these points are supported by all or even most of those present.

This document should not be used as a reference document, but as the notes of a discussion; some of the statements may be disputed or incomplete.

The objective of the workshop, as described in the background note [linked] from CHEM Trust, was:

> *"To explore potential synergies between REACH and Chemicals in Food Contact Regulations, in particular to see if there are routes available that could simplify the process of addressing 'non-harmonised' food contact materials such as paper & inks*

The list of attendees is given in the Appendix.

Summary of agenda

- Presentation on REACH from Bjorn Hansen, Head of Chemicals Unit, DG Environment, see: http://www.chemtrust.org.uk/reach-fcm/
- Presentation on the Regulations on Chemicals in Food Contact Materials, from Jonathan Briggs, Policy Officer of Unit E2 'Food processing technologies and novel foods', DG Santé, see: http://www.chemtrust.org.uk/fcm-regulations/
- Discussion of three subjects, for 30 minutes each (subjects decided by the participants, see below)
- Round up & close

Notes from the 3 discussions

NB: these notes have been circulated around the participants for comment, however CHEM Trust cannot guarantee that every statement made is factually correct. This document should not be used as a reference document, but as the notes of a discussion.

1. Non harmonised materials (e.g. paper and card), how could REACH and Food Contact Materials [FCM] legislation work together to find a solution?

- Most chemicals used to manufacture FCM will also be subject to the REACH registration system as they are likely to exceed the 1 tonne threshold, which means they must be registered under REACH by 2018. The producers/importers will therefore need to provide some safety information according to REACH requirements, which vary with tonnage. However, the required safety information is very limited for chemicals produced or imported in the 1-10 tpa range.
- Within the FCM rules companies should also do specific tests (e.g. on migration) and produce documentation to demonstrate safe use
- In the absence of harmonised legislation, some materials are subject to specific measures in certain Member States e.g. for coatings placed on the market in the Netherlands. Some companies decide to use these national assessment schemes for their operations across the EU.
- Different Member States have different levels of regulation. For example, the Dutch currently regulate the highest number of substances in coatings, and they would evaluate a risk assessment and then list the chemical with restrictions and limits. This Dutch authority assessment helps demonstrate that a company is meeting the overall safety requirement in article 3 of the 1935/2004 EU FCM Framework regulation. There is currently no legal basis for EFSA to do this sort of independent safety evaluation at EU level for chemicals used in coatings.
- No regulatory system is prescribed in the EU legislation for non-harmonised materials, though legally companies must still follow the requirements of the 2004 framework legislation. It is up to each MS to decide whether they wish to adopt a national regulatory system, and companies should show data to authorities on request. Without an effective national regulatory system this this may mean that companies are only controlled if the regulators visit a company. For other MS who have no legislation or different legislation, mutual recognition should apply.
- What about other materials, what is the lead Member State?
    - Paper and board – BFR in Germany
    - Inks – Swiss regulations (though not an EU Member State!)
- Swiss legislation (e.g. on inks) is based on work done in Council of Europe; Germany is also working on legislation on inks.
- If industry did a risk assessment on a chemical used in a non- harmonised material, is there anyone they could submit it to? [NB Competent authorities could ask for such a risk assessment to demonstrate compliance with Article 3 of the framework].
- Industry would like harmonised legislation for everything
- It would be good to have an overview to know which national legislation is there and for which materials? [this will be covered in the JRC report for DG Santé]
- Questions came up regarding the use of the Threshold of Toxicological Concern (TTC) concept where exposure is taken as a starting point before a detailed assessment. Some people wondered whether the tiers are too high.

- The REACH Chemical Safety Report, which is produced by those registering chemicals produced above 10 tonnes per annum, should cover health and environmental endpoints, but REACH specifically states that it does not need to cover human health aspects of use in food contact materials, as this is supposed to be covered by the FCM legislation.
- REACH authorisation cannot cover human health aspects of chemicals in FCM (see Article 56(5b) of REACH), though restrictions can.
- It would be useful to have a comparison of data requirements in REACH and what is needed according to EFSA for FCMs.
- One important difference in the two systems is that in REACH only some chemicals are fully evaluated whereas EFSA does an evaluation of all chemicals on the positive list (= those in materials where there is EU harmonisation) for their use FCMs.
- However, only the human health impact from the use in FCM is covered by FCM legislation, i.e. within EFSA's check. Everything else should be covered by REACH or other sectoral legislation.
- Combination of exposures of the same chemical from different sources (aggregated exposure) is not part of REACH registration, though it can be considered in a substance evaluation, which is done by authorities for a small percentage of chemicals. It was noted that allocation factors can be used in FCM risk management (e.g. by the Commission) to account for the fact that exposure may also take place from other uses, where that exposure has been identified i.e. in the risk assessment.
- The Commission website has a compilation of all positive FCM chemical lists including national lists for FCM [is this kept up to date?]
- REACH is designed as a gap filler, is the minimum, if other regulation requires more information, there is usually justification for this approach– e.g. clear route to human exposure in FCM.
    - Chemicals safety report is generic, very broad tool and experience so far has shown problems in the data quality provided by industry
- FCM and other EU legislation is not generally written with REACH as a base (REACH is quite recent, with the registration backlog only cleared in 2018). Communication and transmission of info between legislation not always clear.
- EFSA produces guidance on tests and safety assessment for harmonised materials
- REACH should deal with issues like chemicals getting into sewage sludge and getting on the land, even if the source is an FCM (i.e. exposure to environment or to humans via environment)
- The presence of substances in materials such as recycled paper and board that are not intentionally added presents an additional challenge, for example contaminates from the source recyclate.
- REACH restrictions can be initiated by Member States or the European Chemical Agency (ECHA), and can consider cumulative exposure.
- Concerns were expressed about the effectiveness of regulatory authorities for REACH and FCM in some Member States.
- The 7th Environmental Action Plan includes a section on needs for future, knowledge base, e.g. monitoring data, exposure and effects knowledge base

- Can't do exposure assessment without effective testing methods, or knowledge of where chemicals (e.g. perfluorocarbons) are used. Lack of harmonised and comprehensive lists of chemicals used in paper and card makes this more difficult.
- Some chemicals are not present in the end material, so there is no exposure.

2. Interaction between REACH and FCM controls: Restriction, Authorisation/Prohibition and Union Lists.

- The REACH authorisation process excludes the human health aspects from the use in food contact materials for a given substance, as it is assumed that it is dealt with in FCM law
- Several of the current SVHCs on the REACH candidate list are used in food contact materials (see study from Food Packaging Forum)
- It was suggested a better link may be needed between the EFSA authorisations for use in food packaging and the status of the substance in REACH (SVHC), but there is currently no automatic connection between SVHC designation and FCM regulations.
- Current problems include the use of PFCs in paper/cardboard packaging, as has been demonstrated in Denmark. For example, Coop Denmark who took microwave popcorn off their shelves.
- The proposed PFOA restriction under REACH would prevent the use in FCM, unless the use is exempted from the restriction or if the limit on PFOA is set so high that FCM uses are unaffected (and it was said this is likely to be the case).
- Under both regimes (REACH and FCM) industry is required to update their dossiers when they have new data on substances. How similar are these processes, and how do regulators enforce these updates, and what do they do with new data?
- REACH authorisations include a time-limited review and an evaluation of safer alternatives; this is not the case for FCM authorisations
- There was discussion about the extent to which assessment of chemicals use in FCMs ensures that the use is safe due to conservative assessments and migration levels, with the level of conservatism disputed. It is also possible to use grouping approaches/restrictions, but cumulative exposures are not usually addressed.
- An EFSA assessment is always the base for approvals/prohibitions/restrictions for use in FCM; this can operate across the board for harmonised materials, or on a substance specific basis for other materials (e.g. new restrictions on BPA migration)
- REACH Restriction is a catch all, can dive into a lot of sectoral legislation. Use REACH as instrument if risk from multiple places; if just under food contact would make more sense to do specific measure
- Restrictions are key aspect of overlap between REACH and FCM. In case of phthalates the REACH restriction didn't cover FCM as plastics are harmonised. In case of PFCs in different materials the FCM legislation is not harmonised, so it's easier for REACH to deal with it.
- Once substances are on FCM harmonised positive list they are normally maintained on the list although further restrictions may apply with additional scientific evidence.
- Substances of very high concern in REACH should probably be called substances of very high hazard. These are substances where uncertainties in the risk assessment are

higher than normal, so only specific uses are authorised. Authorisation is subject to review, but isn't time limited. At the review point the authorisation can be modified only on the basis of new information, including on availability of substitutes, which may then lead to the authorisation being withdrawn.

- REACH generally (though not always, e.g. Nickel in Jewellery) has restrictions based on concentration, EFSA's opinions are generally based on migration. Concentration restrictions may be easier to enforce.
- Chemicals normally get more hazardous as we learn more about their toxicity. This will mean that they were regulated too little in the past (when they were viewed as less toxic).
- The REACH push for substitution of SVHCs is direct implementation of the approach used in worker protection. Worker protection is also relevant in pesticides and biocides.
- Restrictions – whether on content or migration – usually specify a detection limit.
- FCM scientific opinions can be very old, can have re-evaluation, notably if something moves classification e.g. to carcinogen. Commission talks to EFSA, then can draft mandate for EFSA.
- JRC is working on standard testing methods for leaching lead and cadmium; they also look into other existing limits also for cobalt, aluminium.

3. Dealing with Non Intentionally Added Substances (NIAS)

- When you test migration from food contact materials using food simulants, you find unknown compounds. These NIAS are hard to identify, and often have concentrations higher than 10 ppb
- If no toxicity data are available, one can use threshold for toxicological concern (TTC) for some endpoints, but only if the structure is known. You also need to estimate exposure, which is hard
- Currently the TTC approach is applied (by companies/EFSA?), followed by categorisation in Cramer classes followed by setting of ADI.
- Can't do a risk assessment if a chemicals identity is unknown.
- People are trying to resolve NIAS, want harmonised approach
- Analytical methods may not be available. JRC is working on standardised multi-analyte methods, and there is also a possibility of CEN being involved in developing standards for analysing multiple substances.
- Some are using plastics methods for non-harmonised materials, when they may not be suitable.
- Information on which chemicals are supposed to be in a product – and analytical standards (=pure samples of chemical) for these chemicals make it much easier to work out what are the NIAS. A JRC report last year on analytical standards found that they couldn't get standards for around 50% of chemicals authorized for manufacture of plastics FCMs
- Standards difficult for NIAS. Can synthesise a standard of a particular chemical, but expensive/time consuming
- Why is 10ppb a threshold – initially as standard detection limit?

- Oligomers, particularly low MW, are of concern, with a lack of information on toxicity.
- EFSA are looking at reaction products
- It is a complex analytical challenge to identify unknown substances
- In absence of harmonisation, industry is coming up with their own guidance, taking examples from plastic regulation. However, approaches that work for plastics may not be ideal for non-harmonised materials.
- In the US there is a notification process which includes the applicant and the respective production process. This has advantages as approval tied to specific process (and therefore process-specific NIAS).
- How relevant is NIAS in practice? Many people trying to solve this. The levels of NIAS are often in the ppm level, not ppb, i.e. can be really relevant for migration.
- It is important to separate the risk assessment from the risk management.
- It was suggested that other approaches are needed besides chemical analysis: do calculation and modelling instead/as well. But calculation cannot be applied to unknowns.
- Another option would be to focus more effort on maximising purity and minimising by-products, as happens in the pharmaceutical and pesticides areas. These NIAS substances are there because of production and manufacturing processes. It is possible to redesign processes to reduce by-products, and research is being done in this area.

Next steps

These notes – and the personal notes and thoughts of individual participants – are the main output of this workshop.

A number of relevant processes are currently underway, where the issues raised in this workshop could be further discussed and developed, including:

- A report that DG Santé has commissioned from the JRC, looking at the regulation of and market situation concerning non-harmonised food contact materials. DG Santé is also working on implementation measures on ceramics.
- The European Parliament's implementation report into the food contact legislation
- The EU Commission's REFIT on non-REACH chemicals legislation

Appendix – attendees

Name	Organisation	Title
Michael Warhurst	CHEM Trust	Executive Director
Gwen Buck	CHEM Trust	Campaigns Intern
Ninja Reineke	CHEM Trust	Senior Policy Advisor
Bjorn Hansen	DG Environment	Head of Unit: Chemicals
Karin Kilian	DG Environment	Chemicals Unit
Jonathan Briggs	DG Santé	Policy Officer, Food Contact Materials
Bastiaan Schupp	DG Santé	Policy Officer, Food Contact Materials
Jane Muncke	Food Packaging Forum	Managing Director
Peter Oldring	Working on non-harmonised FCMs (for industry)	Regulatory Affairs Manager
Mette Holm	Danish Veterinary and Food Administration	Scientific Advisor
Cristina Nerin	University of Zaragoza	Professor
Stine Müller	Danish Consumer Council	Project Officer, Test and Analysis
Lisette van Vliet	Health and Environment Alliance (HEAL)	Senior Advisor, Chemicals & Chronic Disease Prevention
Pelle Moos	BEUC: The Consumer Organisation	Project Officer, Chemicals and International Trade Agreements
Michela Vuerich	ANEC	Programme Manager, Services & Sustainability Working Groups
Xenia Trier	(just started at European Environment Agency)	Researcher