CHEMTrust
Protecting humans and wildlife from harmful chemicals

Consultation Response

CHEM Trust response to EFSA consultation on a draft scientific opinion on:

"*Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials*"

October 2015

Introduction

CHEM Trust welcomes the opportunity to comment on this draft scientific opinion[1]. CHEM Trust is a charity that works at UK, European and International level in order to prevent man-made chemicals from causing long term damage to wildlife and humans, by ensuring that harmful chemicals are substituted with safer alternatives.

We consider the issue of chemicals in food contact materials to be an urgent, and rather neglected, issue, and we have been in contact with the current and previous EU Health Commissioners on this issue.[2]

We are also aware that Food Packaging Forum (FPF) has made a detailed submission on this document, and CHEM Trust considers that their response is an important contribution to the debate on this issue. FPF has identified many crucial concerns with this draft opinion which must be addressed.

CHEM Trust notes that the one of the main purposes of regulation 1935/2004 on food contact materials and articles is "*securing a high level of protection of human health and the interests of consumers*" – this opinion must live up to this purpose.

This response focusses on our main areas of concern, and is not a detailed response to all aspects of the draft opinion.

[1] http://www.efsa.europa.eu/en/consultations/call/150707

[2] E.g. see http://www.chemtrust.org.uk/hazardous-chemicals-in-food-packaging-chem-trust-writes-to-eu-commissioner-borg/
http://www.chemtrust.org.uk/chemicals-in-food-packaging-eu-commission-finally-publishes-the-scope-of-their-new-study/

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Comments on specific sections

Introduction (Section 1)

In our view this section should refer to the fact that there is no EU harmonised approach for the regulation of chemicals in most non-plastic food contact materials. This is a significant hole in the regulatory system, but does not take away from the responsibility to assess the safety of chemicals in these applications.

The opinion also needs to have a more substantial discussion of assumptions and uncertainties, so that the reader is aware of the limitations of the current assessment approach.

Identify of substances (Section 2)

This section is not clear as it stands. In addition, it should refer to NIAS as well as impurities, in order to make sure that over simplistic assumptions are not made regarding the identity of substances present.

Intended application and exposure(Section 4)

Exposure estimates should take account of joint exposure to similarly acting substances used in food contact material to assess the mixture effects. In addition, it would be important to consider cumulative exposure to chemicals, not just exposure through food. For example, many chemicals have other non-food applications leading to consumer exposure. People are also exposed to chemicals from other sources, for example house dust.

Migration (Section 5)

This section gives a misleading impression of the effectiveness of tests for migration, which is not reasonable in a document that is supposed to be explaining and analysing the issues, not defending the status quo. The statements within it are also largely unreferenced.

For example, lines 277-279:

> *"This means that, as with migration modelling, the use of food simulants and the associated time and temperature test conditions is **designed to overestimate the migration** expected into foods." [our emphasis]*

In reality, researchers have found that migration can be underestimated in these tests, for example in the cases of glass closures[3] and fluorocarbons[4].

Lines 284-285 state that food analysis methods have improved, which is true, but the crucial question is how many of the chemicals that migrate from food packaging are actually tested for in routine analysis? And from which materials?

[3] Mccombie, G., Harling, A., Biedermann, M., Biedermann-Brem, S., Eicher, A., Suter, G., Morandini, M., Pechstein, S., Schmäschke, G., Lauber, U. & Grob, K. 2015. Survey of plasticizers migrating from the gaskets of lids into oily food in glass jars: The second European enforcement campaign shows poor compliance work. Food Control, 50, 65-71

[4] Begley, T. H., White, K., Honigfort, P., Twaroski, M. L., Neches, R. & Walker, R. A. 2005. *Perfluorochemicals: potential sources of and migration from food packaging*. Food Addit Contam, 22, 1023-31.

It is important to add a clarification here about the limitations and assumptions of currently used approaches. This must include the routine presence of considerable quantities of uncharacterised substances.[5]

Toxicity Data (General considerations Section 9.1)

SVHCs

Substances that may have serious and often irreversible effects on human health and the environment can be identified as substances of very high concern (SVHCs) under REACH. Once identified, they may then go on to be controlled through the REACH Authorisation procedure.

In spite of the importance of such substances from a public health and environmental point of view, they are not mentioned in this draft opinion. This is a major omission, and highlights a lack of integration between overall chemicals management and the assessment and control of chemicals in food contact applications.

A paper in 2014 by the Food Packaging Forum Foundation highlighted that several substances of very high concern (SVHCs) are authorised for use as FCMs[6]. We consider that such authorisations are a mistake.

Mixture effects

One of the crucial problems in the safety assessment of substances used in food contact materials is the lack of considering the cumulative effects from combined exposures. Given that it is normal for a mixture of chemicals to migrate into food, this is very surprising.

The general requirements as laid down in the general European food law (Regulation (EC) No 178/2002) do mention "*probable cumulative toxic effects"* as part of food safety assessments. The 2009 Commission report "*State of the Art report on mixture toxicity*" clearly identified the assessment of mixture effects in this area as a gap.[7]

Toxicity testing (The tiered approach to toxicity testing, 9.2)

This section as it stands raises many questions. The triggers for the requirement of toxicity data in addition to genotoxicity seem very arbitrary. Convincing scientific evidence should be provided that justify the approach chosen for setting these threshold limits. The proposal also seems to fall short of many recent research findings, e.g. such as the potential for toxic effects at very low doses and the fact there may be no thresholds for endocrine disrupting chemicals.[8] Moreover, the extent of exposure has often been underestimated in the past, in particular for children, so it is highly doubtful if the triggers will help generating the toxicity data needed for a detailed assessment to be protective for human health.

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[5] Grob, K., Biedermann, M., Scherbaum, E., Roth, M., & Rieger, K. (2006). *Food contamination with organic materials in perspective: packaging materials as the largest and least controlled source? A view focusing on the European situation. Crit Rev Food Sci Nutr*, *46*(7), 529-535

[6] *Hazardous Substances in Food Contact*, July 2014, Food Packaging Forum http://www.foodpackagingforum.org/news/hazardous-substances-in-food-contact

[7] *State of the Art Report on Mixture Toxicity*, December 2009, http://ec.europa.eu/environment/chemicals/effects/pdf/report_mixture_toxicity.pdf

[8] http://www.chemtrust.org.uk/do-edcs-have-thresholds-and-can-safe-exposure-values-be-identified/

Non intentionally added substances (NIAS) (chapter 6.3, now 9.7)

- ***NB: previous 6.3 now listed in the website submission as chapter 9.7***

Section 6.3 in the document is entitled "Toxicological Assessment of substances non intentionally added (NIAS) to plastic food contact materials", yet fails to give this subject the attention it deserves.

The reality is that NIAS can make up the majority of the migrating substances from plastic food contact materials, and in many cases the structure of these migrating chemicals may not be known, e.g. see "*An investigation into the reaction and breakdown products from starting substances used to produce food contact plastics (FD 07/01)*" by the UK Food Standards Agency.

This means that methods to assess the safety of NIAS are challenging but vital, and CHEM Trust don't consider that this guidance provides sufficient content to make this possible.

Threshold for Toxicological Concern

The draft opinion states that in Section 6.3 (lines 766-772)

> *"The TTC approach might be helpful when assessing low-exposure NIAS for which genotoxicity data are unavailable* ***or the substance is only partly identified****. The Scientific Committee concluded that a 768 TTC of 0.15 µg/person per day 18 would provide sufficient protection against (genotoxic) carcinogenic and heritable effects (EFSA Scientific Committee, 2012a). So, where human exposure to NIAS in food is below the TTC of 0.15 µg/person per day, genotoxicity data may be not necessary if, on the basis of the available structural information, it can be ruled out that they are part of the exclusion category (EFSA Scientific Committee, 2012a)." [our emphasis]*

This statement is in direct contradiction to EFSA's Opinion on the use of TTC[9], from 2012:

> *"The TTC approach is applicable to substances for which the chemical structure is known"*

This 2012 opinion re-iterates the point when talking about mixtures such as NIAS, stating that TTC cannot be used with:

> *"Mixtures of substances containing unknown chemical structures"*

CHEM Trust is extremely surprised that the present draft opinion is going against the established EFSA position on the usability of TTC when structures are not fully understood.

This section is also excessively focused on genotoxic and carcinogenic endpoints, when there are many other toxicological endpoints of importance to human health.

It is vitally important that no-one who reads this document gets the impression that TTC is some sort of magic method that can be used to claim that an unknown chemical is safe.

CHEM Trust supports the comments on TTC[10] that were made by WWF in the consultation on the draft EFSA opinion on TTC in 2011, including:

[9] *Scientific Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC)*, EFSA Journal 2012;10(7):2750 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2750.pdf

- Serious concerns about the quality of the underlying data, such as reliability, representativeness, sensitivity as well as the endpoints included.
- The fact that low dose effects are not considered despite scientific studies reporting adverse effects of certain chemicals at very low doses as well as increased risks for adverse effects later on in life following prenatal exposures.
- New toxicological findings and new properties are not automatically covered by the database of existing toxicological knowledge from which the present TTCs are derived.
- TTC does not take account of the cumulative effects of similarly acting substances.
- TTC should not replace the provision of hazard and exposure data for chemical safety assessment or be used for waiving of data.

In addition, other civil society groups have raised concerns about the fact that the TTC concept has mainly been developed by industry scientists.[11]

We question the EFSA approach laid out in lines 766-772 that where human exposure to NIAS in food is below a certain TTC, genotoxicity data are not needed. We do not consider that there is adequate evidence presented to justify this threshold.

Conclusions

We are very concerned that this draft opinion does not properly reflect the science, and if it was followed it would not lead to a high level of protection of public health.

EFSA needs to acknowledge the scale of the scientific challenges created by chemicals in food contact materials, including high levels of NIAS migrating into food. They must not try to brush them under the carpet by pretending that techniques such as Threshold for Toxicological Concern have a magic ability to create an accurate scientific answer as to the toxicity of an unknown or poorly understood substance.

In addition, given that mixtures of migrating chemicals are the norm, not the exception, EFSA should be addressing the cumulative effects from combined exposures and the need to develop a cumulative risk assessment approach as an important part of this scientific opinion. Instead, remarkably, this issue is not addressed here.

Written by Michael Warhurst and Ninja Reineke, October 2015

For more information on CHEM Trust's work:

- http://www.chemtrust.org.uk/
- @CHEMTrust on twitter

[10] WWF comments re draft TTC opinion by EFSA, September 2011; see EFSA on responses to the consultation:
http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/293e.pdf
[11] Pesticide Action Network PAN EU press release and report on TTC, 2011
http://www.pan-europe.info/old/News/PR/110830.html