

16. September 2019

Additional evidence from CHEM Trust for the Ecorys evaluation of the FCM legislation following on from the workshop on 9th September 2019

Dear Ecorys Evaluation Team,

Thank you for the opportunity for stakeholders to provide further evidence for the on-going evaluation of the EU legislation on food contact materials, which was offered at the stakeholder meeting on September 9th. We can provide evidence and comments on a number of issues as presented below:

Evidence of the “cocktail effect” and its relevance to FCM

The combination effects of chemicals have been on the EU policy agenda for many years and are acknowledged by the European Commission as an area where there is an urgent need for intervention. However, some people (including one person who intervened at the end of the workshop) may not have realised the substantial scientific evidence for these effects.

The concern for combination effects of chemicals was addressed in Council Conclusion on combination effects of chemicals (2009) and, together with the continuously increasing number of scientific publications on adverse effects caused by combined exposure to chemicals, this led to a political demand to protect the European citizens from the combination effects of chemicals as part of the 7th Environmental Protection Programme as expressed in Article 50:

*...“The Union will further develop and implement approaches to **address combination effects** of chemicals and safety concerns related to endocrine disruptors **in all relevant Union legislation**. In particular, the Union will develop harmonised hazard-based criteria for the identification of endocrine disruptors. The Union will also set out a comprehensive approach to minimising exposure to hazardous substances, including chemicals in products.”..*

The adverse effects of combined exposure to chemicals have also been acknowledged by legislators from all member states through the restriction of the combined exposure to 4 phthalates and through measures for protecting against combination effects of pesticides.

In spring 2019 the EU Horizon 2020 EDC-MixRisk project (<https://edcmixrisk.ki.se/>), which was initiated to investigate how effects caused by real-life relevant mixtures could be studied, concluded that current regulation of man-made chemicals **systematically underestimates health risks associated with combined exposures to EDCs or potential EDCs**.

Recently, the Non-REACH fitness report stated: “*The issue and risk assessment challenge of combination effects is recognised by the Commission. Efforts are underway to better address this issue. An example is EFSA's development of combination effect assessment methods and guidance for pesticides, based on Cumulative Assessment Groups (CAGs).*” and addressing combination effects of different hazardous chemicals as well as the combined exposure via

different routes is stated as one of the important areas for future improvement or which warrant further assessment.

In conclusion several scientific studies have shown that exposure to mixtures of chemicals may cause adverse health effect even when the concentration of the individual chemicals is very low and considered as safe for the individual substance. Moreover, research has shown that the current regulations of man-made chemicals systematically underestimate health risks associated with combined exposures to chemicals. Combination effects of chemicals are acknowledged by the EU Commission as an area where there is an urgent need for intervention with the aim to protect the health of the European citizens who are daily exposed to a mixtures of chemicals from various consumer products of which food contact materials make up an important contribution.

Information related to cost benefit analysis and efficiency

The difficulties related to assessing the costs to human health as well as the costs to different stakeholders related to the current provisions was discussed at the stakeholder workshop. As a contribution to this discussion we attach a new report, written for us by the specialist economics NGO New Economics Foundation, "**Discounting Future Damage: Do Socioeconomic Assessments In EU Chemicals Policy**". This report analyses some of the fundamental limitations to socio-economic analysis and discusses the severe problems this leads to when policymakers try to monetise health impacts. Please treat this report as confidential for the next few weeks, as it is unpublished; we plan to publish it within the next few weeks on <https://chemtrust.org>.

An important observation, which was not reflected in the discussion of the workshop, is that even if the current FCM legislation benefits the consumers as compared to a situation with no legislation, this does not mean that there are not also currently significant costs related to the health impacts of not having updated and adequate regulation, which would ensure that hazardous chemicals, including the hormone disrupting chemicals, do not migrate into our food. An example of such cost estimates are e.g. [the work of prof. Leo Trasande et al \(2015\)](#).

Another relevant cost, which may have been addressed by industry stakeholders during the evaluation, but which was not mentioned at the workshop, is costs for industry related to [lack of consumer trust](#) in FCMs. These costs are very much dependent on whether the current situation is allowed to continue.

Coherence with REACH and other relevant legislation

Some statements on the workshop document indicate a possible misunderstanding about the main issues related to coherence between REACH and the FCM legislation. The fact that REACH also covers environmental issues does not contradict the need for better coherence. REACH provides a large pool of information on hazardous effects of chemicals which could be used more systematically under the FCM legislation.

Moreover, when harmful substances are scrutinized for restriction under REACH, FCMs are not included, not because they are not relevant, but rather because they belong to a different administrative sector, and finally, the problems we see today with chemical in FCM do in many ways resemble problems that have been tackled under REACH and other legislation such as the cosmetics and toys regulation using a variety of legislative tools. These tools should be assessed by the Commission as related to their usefulness in a future FCM-legislation. One very important tool is **simply banning the presence** of the most hazardous chemicals. There should not be CMRs, EDCs or DNTs in FCM.

Attached are also the draft final **minutes of a regulators workshop organised by CHEM Trust on April 29th** about the role that REACH could have in assisting with regulation of chemicals in Food contact materials. Please treat these minutes as confidential for the next few weeks, as they are still unpublished; they will be published in the next few weeks on <https://chemtrust.org>.

Key studies, test and analysis

We expect that key findings and policy reports about FCMs from recent years will be summarized in the evaluation. These are e.g. the clear [call for new legislation](#) from the European Parliament

2016 backing a [report](#) based on [assessments](#) and the [JRC report on non-harmonised materials from 2016](#), which was also mentioned at the workshop as a thorough analysis of problem related to non-harmonised materials. In addition, we expect the evaluation will include references to key scientific articles which analyse and discuss the migration from and safety of food contact materials as well as to relevant product tests performed by consumer organisations which document the presence and migration of hazardous chemicals from of hazardous chemicals from food packaging that are marketed to European consumers.

Scandalous findings in the past have led to emergency actions as [described by e.g. Koni Grob \(2017\)](#)

References to scientific literature and product tests were submitted to the public consultation in May 2019 (e.g. <https://chemtrust.org/wp-content/uploads/chemtrust-fcm-position-paper-may19.pdf> and https://www.beuc.eu/publications/beuc-x-2019-029_beuc_comments_to_food_contact_materials_refit_evaluation.pdf).

In addition to this, CHEM Trust's [briefing](#) from 2016 and the FCM page of our web site: <https://chemtrust.org/food-contact/>.

When reviewing such studies, it may be relevant to focus on specific substances such as **the bisphenols, the phthalates and the PFAS**.

The reports and references mentioned above, including studies describing the relative importance of the NIAS and the effects of exposure to very low concentrations of EDCs put into perspective the claim from the workshop document that for plastic materials “*Severe restrictions always apply*” and “*migration into food is non-detectable*”, and moreover, it is important to note that with the current broad political focus on problems related to the use of plastic, there will be a stronger need for ensuring the safety of the alternative materials such as paper, glass, metal etc.

NGOs have developed 5 key principles, which provide a condensed description of what is missing in the current legislation

Civil society has high expectations on the outcome of this evaluation. As a direct result of the Commission's initiative to evaluate the FCM-legislation, a group of key European NGOs working for environment, health and consumer protection have cooperated to pinpoint the central problems with the current legislation. As a result, we developed [5 basic key principles](#) (see below), which must be in place in order to ensure consumer protection.

These principles were [published in April 2019](#) with a call for new legislation and we offered the opportunity for more NGOs to [sign on to this call](#). Many organisations have already done so, and more signatures are continuously added to the document.

As they stand today, **these five principles constitute a short and condensed description of what is missing** in the current legislative framework.

We hope you find this submission relevant for your evaluation. We are looking forward to seeing the final report.

Please let us know if you would like to receive more information and clarification from us. We remain available for additional information, and we may also wish to forward additional evidence during this week.

Yours sincerely,

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CHEM Trust

The 5 key principles:

The new EU regulation of chemicals in food contact materials must ensure:

1. A high level of protection of human health

All substances used in food contact materials should have adequate safety data, provided by industry and should be regularly reviewed for this use by public authorities. The presence of substances that are already restricted in the EU, and those meeting the REACH criteria for Substances of Very High Concern, such as CMRs, sensitizers or endocrine disrupters, should be automatically prohibited.

2. Thorough assessment of chemicals in materials and final articles

The presence in, and migration of, chemicals in food contact articles – including Non-Intentionally Added Substances (NIAS) – should be measured, assessed and controlled. Absence of reliable migration data should imply presumption of full migration. Assessments of migration should include mixture effects and take a precautionary approach to exposures from non-FCM sources. Both industry and regulators should ensure that any migration is understood and limited to ensure a high level of protection of public health.

3. Effective enforcement

National governments must ensure effective enforcement, including checks on both imported and EU-manufactured finished articles using the best available analytical methods. Producers and importers of chemicals used in FCM should always be responsible for providing adequate analytical standards and analytical methods to regulators and test laboratories. In the event of contamination of products with problematic chemicals, producers should be obliged to notify the regulators.

4. A clean circular economy based on non-toxic material cycles

As the EU's transition to a circular economy gains momentum, it is vital that the EU's efforts to encourage recycling do not perpetuate the use of harmful chemicals in FCM. Adequate regulation and enforcement of all types of recycled FCM is required to ensure that recycled food contact materials are never less safe than virgin materials.

5. Transparency and participation

Supply chains and final consumers should have a right to know the identity and safety information on chemicals used in, and migrating from, food contact materials. Regulatory and policy processes should as a minimum adhere to the same standards of openness and stakeholder participation that have been established in REACH.