Reviewer’s report

Title: Impacts of food contact chemicals on human health: a consensus statement

Version: 0 Date: 26 Jun 2019

Reviewer: Konrad Grob

Reviewer's report:

I totally agree with the statement that more needs to be done to ensure the safety of migrants from FCMs. Such information is intended to reach the public, which, however, is not primarily the scientists in the field. The strategy of the authors might be that going public is supported by a "scientific" paper.

Here a manuscript to be published in a scientific paper is to be evaluated. It runs under the title of a "statement", which frees from the requirement of a scientific innovation. Nonetheless, statements need to be precise, solid and not slanted to be more powerful. It is written for experts, not for the public on the street or politicians.

Although sharing the opinion of the authors, I have problems in receiving the message.

Firstly, to convince somebody who is not already of the same opinion, statements must be undisputable. The paper will be invalidated even through minor sweeping/incompletely supported statements and exaggerations. There are several of them and the impact of the paper could be enhanced by being more modest.

Secondly, the manuscript is written far away from the immediate reality and feasibility. It just about wants everything, including requirements and methods which are out of reach or have serious flews or limitations which are neglected in the manuscript. Sorry to be drastic, for me the text sounds a bit like a baby laying on the floor, crying and wanting everything without taking notice of what it could reasonable get. It has little effect and readers go back to what is feasible in the nearer future.

Presently the basic FCM regulation is re-evaluated, which is the moment at which changes could be introduced - specific and hopefully realistic ones. I regret that authors do not come down to earth with their requirements and even mention this process.

In my view the main problem is that we all speak about a few well known migrating substances, such as phthalates (which are hardly used anymore in food contact) and BPA, but leave out a far larger number of non-evaluated chemicals (point 5). Silly to say that no long text can be written about unknowns, even if it is the main issue.
Some specific points:

82: what is “previously”? when the FCM legislation was conceived (1970es?)

128: exposure assessment is not the dominant problem: as it is linked with uncertainty, estimates are mostly grossly exaggerated.

140: not migration as such is of concern, but migration exceeding a level of potential concern. This is an old objection, criticized for previous papers, and needs better differentiation. Most soaps and detergents for hand washing, tooth pastes and shampoos are made with ethyleneoxide, a genotoxic carcinogen. All of concern?

145: NIAS may have a function, such as oligomers of polyolefins serving as plasticizers.

152: di-tert. butyl phenol is not a good example, since the BfR evaluated it.

154: what is meant by "framework"? Why is this Section and Section 7 under "area of certainty"? Hopeless cases? It is just as certain as that not all combinations of substances can be tested and that testing mixtures has severe shortcomings.

If section 6 stipulates that mixtures should be tested, every mixture still needs to be analyzed for composition. Going through individual substances (what you probably call "conventional risk assessment") as far as possible is still the best (not perfect) way.

167: …and to many chemicals from natural foods and generated by cooking! How should this be considered?

175: in its title, ref. 102 refers to mammalian species, not to humans

181: I do not think that this is what ref. 2 says: exposure to pesticides is 100 times lower from conventionally produced food than to chemicals released from FCMs. This is not necessarily related to what is permitted.

186: hardly any plasticized PVC is used anymore in food contact: some of the gaskets of lids. Cling films are largely from PE. What else? Phthalates are largely from diffuse background sources.

190: please be more precise on the 10 ppb threshold: this is a detection limit, not a level of no concern. It was used in the past for numerous monomers. Today it is the 0.15 µg/d/person. 10 ppb is used when substances are no CMR.

Section 9 is a mixture of several subjects without an outcome. 10 ppb is too high? For many or most FCMs it would already be progress to reach 100 ppb. Please be more specific would you think should be done. Also for other points: requirements and proposals must be realistic. It is too easy just to ask.
191: please add article number to the reference 110.

194: generally the 1 kg food/d is used, as the exposure is unknown. This is highly conservative in most cases. This is why an exact exposure estimate is not of high priority (see above).

208: Exposure from sources other than FCMs are taken into consideration by allocation factors. For officially evaluated substances this is always considered (as far as known). However, allocation factors are not frequently applied, since the other sources are mostly negligible compared to the TDI.

213: in vitro testing of mixtures may seem to be the golden solution. However, a closer look reveals severe shortcomings (see also above).

214: combinations also with substances in food!

224: it is impossible!

228: you certainly know that this is not a promising approach. Only severe effects can be detected through epidemiology - not even for acrylamide, the exposure of which is far above the limit considered safe.

242: Many monomers are genotoxic. You want to have them being removed from the list of authorized substances? Several widely used polymers would disappear (but also most detergents). These monomers migrate at very low levels, perhaps with styrene as an exception - a case under reconsideration. I guess that this point needs clarification.

250: You have a suggestion on how this could be implemented?

256: it is not true that regulatory authorities are blind for "modern" assessment, but methods need to be solid

258: Is re-assessment of the (few) regulated substances really first priority?

To have the intended alerting effect, I recommend to reduce the many open subjects to the main ones, avoiding the most hypothetical points, and give specific directions on how to achieve improvements. Who should do what? Naming obvious shortcomings and omissions as well as responsible stakeholders have a stronger impact than wishes for Christmas. However, it also forces to be more realistic in what can be asked.

It would be a pity to reject an initiative with such a broad authorship, but it is also a pity if the text fails to convince those who are not already of this opinion and has the effect of polarizing, marking the authors as radicals.
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