HEAL input to DG SANTE Roadmap BPA
"Proposal for a new measure on Bisphenol A (BPA) in food contact materials"

HEAL is a leading European public interest organisation addressing how the environment affects public health in the EU. With 65+ member organisations, we represent health and medical professionals, non-profit insurers, patient/disease groups, and other public interest constituencies. We have been working on hazardous chemicals policy, including BPA, since our inception.

HEAL welcomes the fact that DG Sante is examining Bisphenol A in food contact materials (FCM) with its roadmap on Bisphenol A. Action on Bisphenol A in FCM is urgently needed and long overdue. We also have extensive concerns about the impacts on public health from other hazardous and unknown chemicals in FCM which have individual and combination effects. Moreover, some of these chemicals may act in an additive manner with Bisphenol A, so their presence in FCM should also be swiftly addressed. We do not think that proceeding with 'Mutual Recognition' between national rules, instead of EU legislative action, will effectively reduce the public's exposures to harmful FCM chemicals.

Regarding the Bisphenol A roadmap, we have the following points:

Consultation process – for this roadmap and for FCM more generally

The consultation process for this roadmap is not clearly laid out and to date has not been fully transparent. Despite having significant implications for citizen's health, the consultation on the BPA roadmap is not even listed on the DG Sante FCM consultation webpage.
http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/consultation/index_en.htm

The roadmap content shows that DG Sante has been in dialogue with FCM industry and food industry, but does not show that prior inputs from environmental, health, consumers' organisations were sought or received. Another neglected stakeholder group are the trade unions whose workers are exposed to the chemicals during the manufacturing of FCM, with corresponding health impacts. The resulting imbalance in the roadmap between the protection of health and convenience for industry contradicts DG Sante's mission.

This lack of contact with non-commercial stakeholders seems to be a more general issue: the DG Sante FCM Consultations page, aside from Member States[1], only lists a 'Technical expert group for food contact materials', which is limited to European associations representing food contact material manufacturers and/or their supply chain.
http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/consultation/index_en.htm
In contrast, DG GRO and DG ENV have been hosting a Competent Authorities group on the REACH chemicals legislation (CARACAL) for many years, where environmental, health and other public interest / union groups have been actively participating alongside associations of commercial industry. Many of these NGOs also participate in the more technical committees of the European chemicals agency.

We believe that consultation with stakeholders representing public and workers interests in environmental health are crucial in all phases of FCM policy development, and the current imbalance should be immediately remedied.

Roadmap Content – general comments

Overall, discussion of the impact on/ perspective of consumers' health is paltry. A simple analysis shows consumers are mentioned 11 times, whereas industry is mentioned over 40 times. Further perusal shows close re-iteration of industry-furnished information but no close attention to chemicals exposures issues, or to health concerns which remain despite EFSA's opinion.

HEAL believes a ban at EU level on all bisphenols with suspected endocrine disrupting properties for food contact materials is necessary. Given the ongoing criticism of the EFSA opinion from national bodies (France's ANSES, Denmark's National Food Institute[2]), and scientists, we believe that laying all

[1] Working Group on food contact materials of the toxicological safety section of the Standing Committee on Plants, Animals, Food and Feed

[2] National Food Institute, Technical University of Denmark maintains that the EFSA t-TDI does not does not adequately protect consumers against endocrine disrupting effects of bisphenol A, and should be 0.7 micrograms /kg bodyweight/day or lower. See

the EU BPA FCM risk management eggs in the EFSA no/low concern basket is a poor policy choice. At the very least, a Specific Migration Limit that reflects the temporary TDI should have already been installed for all types of FCM.

PART A. Context, Subsidiarity Check and Objectives

This section does not contain any summary or detail on the proportions of the different FCM types (plastics, coatings & varnishes, printing inks, adhesives, paper & board, other) which contribute to the public's BPA exposure.

Secondly, variations across Europe in consumer exposure are omitted. Hence the initial assessment of the options (Part B) does not lay out in any credible way how the various options would yield benefits of exposure reduction, and how these reductions might reduce BPA-related and other EDC-mixtures related diseases or disorders. Recent studies have estimated significant costs of these diseases, including from BPA, and these are not mentioned here.

Thirdly, there are no specific objectives related to consumers' health – only to their 'trust in safety of FCM' (more a public relations issue).

Fourthly, there is no discussion of how the uncertainties in the EFSA opinion, and the temporary nature of the current TDI imply a range of possible health benefits and disadvantages for each policy option. Such discussion is also markedly absent for option 5 in Part B.

Fifthly, there is no consideration that EFSA is only addressing BPA from dietary and non-dietary sources, but not exposure to similarly acting other endocrine-disrupting chemicals that can act additively with BPA (the cocktail issue), and hence it ignores the benefits arising from further reduction of BPA exposure despite EFSA's view that no concern for any age group from dietary exposure and low concern for aggregated exposure exists.

PART B. Option Mapping & Assessment

In this section, again we find any solid discussion of public health interests or concerns missing. (Consumer concern and confusion will not be resolved by a

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http://www.food.dtu.dk/english/News/Nyhed?id=1C4245AE-B133-4D8B-9448-FAAC26CA4B9A

new SML when national governments and independent scientists continue to criticise the EFSA opinion and take national measures).

This section firstly does not properly discuss how the various options would yield health benefits of exposure reduction, (the efficacy of exposure reductions and contributions to EDC-related disease incidence reductions) let alone industry innovation in safer alternatives.

Secondly, it neglects to mention that BPA in thermal paper is undergoing a restrictions process in the REACH system, and that a final decision is soon pending. Although this may mean BPA if restricted would no longer appear in thermal paper, its gradual elimination from recycled paper and board would take some time. Again, given concerns about low dose and mixtures effects of BPA and other chemicals to which the public is in aggregate exposed, we see no justification for exempting paper and board from an SML on BPA, let alone from its elimination.

Thirdly, it neglects the already existing alternatives in the market. A number of companies have already announced or achieved the phase out of BPA from their food packaging, including Nestle. General Mills has already done so for one of its product ranges (Muir Glen and here it is for a product line containing acidic foods – tomatoes- where the coatings are supposedly less easy to substitute)[3].

Fourthly, the issues around innovation and efficacy are misrepresented. Whilst industry might argue that resources are being diverting away from possible investment on other new approaches that may benefit consumers through the quality of the food and efficiency of the packaging, we argue this reasoning rests on denial of the increasing and long accumulating evidence against BPA, particularly in regard to low dose and mixtures effects. Industry has an obligation (both from its general legal duty of care and from its specific responsibility as laid out in Article 3 of EC 1935/2004) to spend resources on developing products that are safer than those made from BPA-based materials, and it has an obligation to ensure that the potential health hazards from any new 'innovative' approaches that may otherwise meet food quality and packaging efficiency needs be thoroughly tested and publically disclosed. FCM using chemicals with suspected endocrine disrupting properties or other properties of serious concern should not be brought to market. Hence this is not a matter of 'diverted and misused resources and investment', and there

[3] http://www.independent.co.uk/life-style/health-and-families/health-news/major-producers-to-ditch-bpa-from-packaging-2121837.html

are positive effects on innovation and efficacy from developing safer alternatives to BPA.

The phrasing of the roadmap reveals that options 4 and 5 are not being seriously considered by DG Sante, and hence the absences of issues and considerations mentioned above are serious faults.

PART C. Data Collection & Better Regulation instruments

This section again reveals a regrettable lack of intention to consult environmental, health and trade union organisations with respect to this initiative, and to engage us in both technical and broader discussions.

Here too the wording reveals that a preferred option has already been identified, although it is not named. However, given the prominence of the discussion about the concerns and interests of industry, and concomitant lack of mention or discussion about public health concerns from BPA throughout the whole document, it is clear that the option (5) which requires the closest attention for its enormous potential health benefits has not been properly investigated, which prejudices its fair and balanced consideration.

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