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From: personal data (RTD)
Sent: 01 April 2016 13:41
To: personal data (SANTE); personal data (SANTE); personal data (SANTE)
Cc: personal data (RTD); personal data (RTD); personal data (RTD); personal data (RTD)
Subject: Commenst from DG RTD on the ED IA

Dear personal data,

Please, according to the instructions received, find below the comments from the team of RTD staff, who read the IA document during its display on the 30 and 31 March. We might take advantage of the access offered also on the 4 April, so more comments may follow.

1. On P44 the EHBMI is referred to. Although we welcome this reference it is important to recognise, that the deadline for submission of the proposal is only on the 13 April and the evaluation process only ends in the last week of August this year.
   Before the final results have been communicated the EHBMI cannot be taken for granted and therefore it is important to re-convert to the wording as originally provided to you, see below in a shortened version to more easily replace what is in the IA now:

   To address the lack of information about exposure of citizen to chemicals, Horizon 2020 Societal Challenge 1 has published a call in the work programme 2016-2017 for a joint European programme on HBM (the European Human Biomonitoring Initiative – EHBMI). The goal of the programme is to coordinate existing HBM initiatives in Europe, to establish a single European reference hub, build capacity and through state-of-the-art research advance our understanding of the nature and level of chemical exposure of EU citizens of all ages and the associated potential health risks. A strong EU-wide evidence base of comparable and validated exposure and health data for sound policy-making at EU and national level will be established.

2. From a scientific point of view EDs are not a recent issue – research has been going on for years. The text should not vehicle the message that there is no consensus on EDs in the scientific community, the ED experts do agree with each other (see WHO 2012 report), the discrepancy is with the toxicologist community.

3. The importance of other scientific reviews (e.g. WHO/UNEP, EEA report on EDs) has been downplayed compared to Commission commissioned reviews.

4. The reader gets the impression that the point of view taken consistently throughout the document is that banning some pesticides or biocides will have a negative impact (less disinfectants, higher risk of mycotoxines in food, etc.) or strongly advocates that the evidence linking exposure to diseases is still weak. It would give the reader more confidence in the neutrality of the IA

if in each case pro and cons are more balanced and also possible benefits are highlighted.

5. Along the same lines, the fact that option 4 and policy option C always stand out as the strongest, no matter what permutation of number is done in the MCA, gives the impression of a biased analysis. The weightings used for the different criteria should be better explained.

6. In general the annexes give an interesting overview of available studies and possible reference points for gathering the information but it is difficult to see how these reviews have than been applied in the MCA. The working methodologies behind the annexes are often not well explained and give the impression of lack of rigour. E.g. in Annex 9 it is difficult to see how the ESTAT and OECD data on exposure links to the MCA criteria on health impacts, conclusions or an opinion on the section of health costs analysis are missing, in Annex 3 there is no clear description of the toxicity records and the categories, details on the tests used for the classification of substances are missing, in Annex 5 what is meant by 'screening' is not described nor how the results were obtained etc.

7. Are you expecting to publish the IA before the results of the screening exercise in June? It would have been helpful to include, in the Annex dealing with the screening exercise, an analysis of what kind of data has been used (zebra fish, mammal, human) and how much data is available for each substance. This would have given scientific weight to the exercise and would have given the reader an informed viewpoint on the current statement that a lot is based on the experts judgements on the data.

8. The biocides screening seems to have touched only relatively few substances, compared to the pesticides screening – can it still be considered relevant?

9. It would be good to have the same kind of graphs for the biocides and pesticides showing the overlaps of substances between the different options.

10. It is nice to know that our current regulations prohibit substances for which we now know they have ED properties, but this does not tell us how we will avoid losing 20 years again before being able to ban new substances brought on the market. On this point the document should be more forward looking.

11. I would avoid claiming that the MCA have been agreed in consultation amongst services (p34), and simply omit that sentence.

12. On page 185 the H2020 project EURO-MIX should also be referred to, not only EDCMIXRISK

13. No results from the US Agricultural health study are reported in the text, the study is only referred to as such. This should be remediated to be able to compare to the ANSES study. It is questionable if data from France only (ANSES study) is enough to draw conclusions at EU level.

14. The title 'transmissible diseases' is misleading as the corresponding annex only deals with lack of disinfectants. In that case it is better to simply talk about lack of disinfectants.

15. The descriptions of graphs and pictures e.g. page 199 could be improved to make the reading easier.

Best regards,
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