From: personal data (SG)
Sent: 01 April 2016 14:53
To: personal data (SANTE); personal data (SANTE); personal data (SANTE)
Cc: personal data (SANTE); personal data (SG); JUELICHER Sabine (SANTE); personal data (SG)
Subject: Draft IA, feedback in preparation of the next meeting of the ISSG

Dear colleagues,
Thanks for the draft IA. This is an impressive piece of work. The text reads nicely in large parts. Other parts are not so clear or not yet sufficiently convincing. As requested, I send you herewith the main comments I intend to make on Monday:

1. Section 1 needs to be revised. It does not answer the question "what is the problem" and it does not provide for the background information needed for a non-expert to understand the IA. I suggest to start of by explaining the basic notions along the following lines:
    a. Background
        i. Hazard vs. risk (the example of the knife is good, but comes too late in the text; see some text at p. 244);
        ii. Regulation of toxicological risks by looking at the end-point vs. mode of action (examples needed, maybe a graph, see also pp. 170, 184, 244);
        iii. Show how the PPPR and the BPR enter into this logic (see some wording at p. 210) and explain the core of the legislation (but only once – at the moment this is repeated several times all over the annexes, see for example pp. 320 and 321);
    b. Endocrine disruptors
        i. Explain the logic of EDs, ideally with a scheme, see attached; the explanation in p. 5 ("EDs are chemicals that can interfere with the endocrine systems in animals and humans") is wrong for several reasons;
        ii. Explain the core of the disagreement between scientists (see p. 27);
        iii. Explain the regulatory repercussions (immediate repercussions; including treated articles. A clearer explanation of MRL is needed).

    All this information is more important than the list of papers on page 7 (which is anyway in Annex 1).

2. A clear "Sprachregelung" is missing what are the regulatory consequences if a substance is an ED. The text uses very different terms and descriptions: I found the following: "regulatory consequence is a ban", "potentially affected", "no experience with derogations", "uncertainty", "withdrawal" (anyway the wrong term, because withdrawal is done by an authorisation holder), "non-approval", "additional data has to be generated", "MS authorises under specific conditions", "potentially removed from the pesticides portfolio", "might disappear from the market", "substances affected" (but confusingly it also says "crops affected"), "cut-off" (a technical, somewhat bizarre term that would need to be introduced), etc. See pp. 227, 268, 271, 273, 276, 291, 302, 358, etc. The text also needs to be very clear how the possibilities for derogations under PPPR (negligible exposure and Art. 4(7)) and the BPR are factored in. Stakeholders will carefully look at this. This is a tricky issue but there is clarity needed here. This should be stated (at the latest) on pp. 22 and 23.

3. Annexes 9 through 14: Each annex looks at another impact, which is good. However, the annexes should be coherent in terms of

    a. structure (I found the structure of Annexes 12 and 15 the most convenient to read)
    b. terminology and abbreviations
    c. style (on page 347 the personal pronoun "we" is used, which is more the U.S. style)
    d. formatting

    Moreover, there are several repetitions, for example about the regulatory principles of the PPPR and the BPR.

4. Throughout the document the text considers as "problem" that the BPR and the PPPR are not aligned (for example, pp. 19, 20, 25, 26, but it is all over the text and tables). But different regulatory consequences are not a "problem" per se. They may be well justified, even when talking about the same substances (actually, it is quite common that the same substance is regulated differently in different legislations; there may be other exposure scenarios, or other justifications). The point is more that the PPPR does not give any margin to the risk-manager to consider societal benefits of a PPP, or to consider the actual risk posed by a hazardous substance.

5. The fact that substances are not (any more) on the market is not an argument per se against modelling impacts (all over the text e.g. pp. 248, 250). This has to be better explained (for example, this weakens the argument of causality, or this shows that a risk-assessment approach provides protection).

6. In the discussion of the studies in annex 9, the text has to be stronger in explaining why these studies are not convincing. The main issue is causality, but this point is only made very clearly for the "nordic study". Are there authoritative statements (peer-reviewed journals etc.) that dispute the link between ED exposure and the various diseases and that put in doubt the methodology (good example on p. 208)?

7. There should be many more references to responses from consultations. Also, the type of stakeholder should be mentioned (i.e. not "it was mentioned that"…). A good example is on p. 26. But there are not-so-good examples, for example on pp. 25, 33, 230, 29, 255, 266, 315, 330, 333. Also, there seems to be a bias towards certain views expressed by stakeholders.

8. I do not understand the logic for impact on the aquatic environment, whereby "the more substances banned, the better" (pp. 30 and 247). This is not convincing, and not coherent with what is said about other dimensions (human health).

9. The text should not allude to other sectors (e.g. p. 6) because it triggers questions that are not responded to in the IA (because it is not the point of the exercise).

10. The presentation of the options (pp. 18 and 19) should be more simple, supported with a scheme, and not reproducing technical text from the RM.

11. The draft IA rightly does not consider EDs which would be covered by the hazard-based ban for other reasons. But this has to be better explained (for example, table 2 on p. 23 is not clear). The text on p. 23 announces that these substances are considered separately – but where?

12. The first "dimension" and the first four "MCA criteria" are not coherently presented across the text and tables. I would also not agree to put "effectiveness" as a criterion (effectiveness would require an objective, i.e. "effective" to achieve what) or proportionality (because this implies balancing with another criterion). "Legal clarity" is not the same issue as "proportionality". Actually most "clear" rules are not proportionate, while proportionate rules often increase complexities. See p. 25. This is also important in Annex 8, section 2.

13. I did not understand the presentation of the figures on pp. 278, 305, 308 and 310.

14. Why does the text mention 8 MS, then 11 MS (pp. 267, 273, 302)?

15. The text does not say anything about how the 4 sectors presented in Annex 14, section 2 (pp. 315-325) are affected. Idem on the single market (p. 325). In fact, considering that the exceptions apply for approvals (negligible exposure etc.) it is not clear why there would be differences in the internal market. P. 328 is not convincing in this respect.

16. Why is the toxicity from mycotoxins singled out so prominently? Was this raised by stakeholders, or is it really a big issue in the area of food safety? (p. 229 gives some answers, but very late in the text).

17. In annex 9 it is not clear what is the difference between section 1.1 and 1.2; section 1.4 does not seem to belong into this annex (p. 191). Nor does section 3 belong there.

18. Why is the focus in Annex 10, section 2.2 on alcohol? – clearly not an ED.

19. Section 2.3 of Annex 10 is not convincing: the reader expects information as to whether or not active substances for BP used in health setting are affected, in view of the results of the screening. Instead there are very general statements. In section 3.4 (p. 238) there is a good example.

20. The description of the impact on the vertebrate population is too superficial, considering that this is one of the most visible topics in the debate (p. 30). P. 247 (Annex) is better. With regard to wildlife, a discussion is needed whether option 4 is actually feasible. Is it possible to have safety tresholds and potency considerations in such population-related endpoint? My understanding is that this is not the case, but I might be wrong.

21. The statement as to whether Aspect II, options B and C could be implemented with the PRAC procedure (pp. 39 and 40) have to be carefully checked by LS. I think both options require amendments by the co-legislators.

22. When discussing evaluation, explain how much time will be +/- needed before affects can be seen on the market. Why do you say that the ongoing evaluation will look at this? (p. 44)

23. The text looks at the impacts of imports of food, feed, and treated articles, but what about the PPP and the BPs themselves?

24. I do not understand section 5.2.4, 4th section, last sentence. Why are less PPP affected?

25. Check the table 5 on page 353 against the very recent DG SANTE - SWD on imported feedstuff: https://ec.europa.eu/transparency/regdoc/rep/10102/2016/EN/10102-2016-61-EN-F1-1.PDF

26. I will have a couple of other drafting comments, for example on pp. 47 and 48 (at the meeting).

In terms of drafting in general, please double-check all footnotes (several are missing, for example footnotes 4, 5, 6 on page 1…). I would not use the CLP acronyms for substances (say "carcinogenic substance", not "C1-substance"). I would advise to double-check the headings of all figures and tables (pp. 316 and 317 are not clear, albeit important). Use EUR, wherever possible, and use the drafting convention of the EU institutions for currencies ("EUR", not "€").

Kind regards,

personal data
Unit E1 - "Citizens and Security "
Directorate "Policy Co-ordination II"
Secretariat-General
Ext. perso