From: personal data (SANTE)
Sent: 12 April 2016 16:42
To: personal data (GROW); personal data (SANTE); personal data (JRC-SEVILLA); personal data (GROW); personal data (JRC-SEVILLA); personal data (SG); personal data (GROW); personal data (AGRI); personal (JRC-SEVILLA); personal data (ENV); personal data (JRC-ISPRA); personal data (RTD); personal data (JRC-ISPRA); persona personal (TRADE); personal data (JRC); personal data (RTD); personal data (GROW); personal data (JRC-SEVILLA); pers personal data (JRC); personal data (JRC-ISPRA); personal data (JRC-ISPRA); personal data (JRC-ISPRA); personal data (SJ)
Cc: personal data (JRC-SEVILLA); personal data (SG); personal data (SANTE); personal data (SANTE); personal data (SANTE); personal personal (SANTE); personal data (SANTE); personal data (SANTE); personal (SANTE-EXT); personal data (SANTE); personal data (GROW); personal data (ENV); personal data (JRC-ISPRA); JUELICHER Sabine (SANTE); personal data (AGRI); personal data (GROW); personal data (GROW); personal data (RTD); personal data (JRC-SEVILLA); personal data (SANTE)
Subject: RE: Draft minutes of IASG meeting Endocrine disruptors, 4 April 2016

Dear Colleagues,

FYI too,
please find the comments sent yesterday by SANTE C (in Luxembourg),

personal data

FW: Draft minutes of IASG meet...

From: personal data (GROW)
Sent: Monday, April 11, 2016 12:07 PM
To: personal data (SANTE); personal data (JRC-SEVILLA); personal data (GROW); personal data (JRC-SEVILLA); personal data (SG); personal data (SANTE); personal data (GROW); personal data (AGRI); personal (JRC-SEVILLA); personal data (ENV); personal data (JRC-ISPRA); personal data (RTD); personal data (JRC-ISPRA); personal data (TRADE); personal data (JRC); personal data (RTD); personal data (GROW); personal data (JRC-SEVILLA); personal data (JRC); personal data (JRC-ISPRA); personal data (JRC-ISPRA); personal data (JRC-ISPRA); personal data (SJ)
Cc: personal data (JRC-SEVILLA); personal data (SG); personal data (SANTE); persona pers (SANTE); personal data (SANTE); personal data (SANTE); personal t person (SANTE); personal data (SANTE); personal (SANTE-EXT); personal data (SANTE); personal data (GROW); personal data (ENV); personal data (JRC-ISPRA); JUELICHER Sabine (SANTE); personal data (AGRI); personal data (GROW); personal personal (GROW); personal data (RTD); personal data (JRC-SEVILLA); personal data d t

(SANTE)
Subject: RE: Draft minutes of IASG meeting Endocrine disruptors, 4 April 2016

Dear colleagues,

Please find attached the draft minutes of the 11th IASG meeting with comments from GROW/D.1.

Best regards,
personal
d t

<< File: Draft minutes 11th IASG_04-04-2016 clean before circulation_perso comments_clean GROW D1.docx >>

personal
personal
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European Commission
DG for Internal Market, Industry, Entrepreneurship and SMEs
REACH Unit - GROW/D1

BREYperso
B- 1049 Brussels/Belgium
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d t

Follow us on
Facebook: EU Growth
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Our Websites: ec.europa.eu/growth
ec.europa.eu/bienkowska

DG GROW REACH pages are available at:
http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm
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From: personal data (SANTE)
Sent: Friday, April 08, 2016 2:59 PM
To: personal data (JRC-SEVILLA); personal data (GROW); personal personal (JRC-SEVILLA); personal data (SG); personal data (SANTE); personal person (GROW); personal data (AGRI); personal (JRC-SEVILLA); personal pers (ENV); personal data (JRC-ISPRA); personal data (RTD); personal data

(JRC-ISPRA); personal data (TRADE); personal data (JRC); NORAGER Sofie (RTD); personal data (GROW); personal data (JRC-SEVILLA); personal data (GROW); personal data (JRC); personal data (JRC-ISPRA); personal data (JRC-ISPRA); personal data (JRC-ISPRA); personal data (SJ)

Cc: personal data (JRC-SEVILLA); personal data (SG); personal data (SANTE); personal data (SANTE); personal data (SANTE); personal data (SANTE); personal data (SANTE); personal data (SANTE); personal data (SANTE); personal data (SANTE-EXT); personal data (SANTE); personal data (GROW); personal data (ENV); personal data (JRC-ISPRA); personal data (SANTE); personal data (AGRI); personal data (GROW); personal data (GROW); personal data (RTD); personal data (JRC-SEVILLA); personal data (SANTE)

Subject: Draft minutes of IASG meeting Endocrine disruptors, 4 April 2016

Dear colleagues

Please find attached the draft minutes of the IA Steering Group meeting “Endocrine disruptors”, which took place on 4 April 2016. I appreciate to receive your **comments by Monday, 11 April 13:00 h at the very latest**. The short deadline is required as IA has to be submitted to the RSB on13 April 2016.

1. Draft minutes

<< File: Draft minutes 11th IASG_04-04-2016 clean before circulation_personal comments_clean.docx >>

2. Addendum to the minutes of the 10th IASG meeting submitted by DG ENV

<< File: ENV additional comments to the Minutes 10th IASG.docx >>

Please return your comments to my e-mail address, to personal data @ec.europa.eu and personal data @ec.europa.eu

Kind regards,

personal data
personal
d t
<< OLE Object: Picture (Device Independent Bitmap) >>
European Commission

DG SANTE

Unit E3, Pesticides and Biocides

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EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Brussels, April 2016

MINUTES

Place: EC Charlemagne building	Date: 4 April 2016
Subject: 11th Meeting of the Impact Assessment (IA) Steering Group on the definition of criteria for the identification of Endocrine Disruptors (EDs)	

Attendees:

DG SANTE: Sabine Juelicher (chair), personal data , personal data , personal data , perso personal , personal data , personal data , personal , personal data , personal perso, personal data

DG ENV: personal data

DG AGRI: personal data

DG GROW: personal data , personal data , personal data , personal data

DG RTD: personal data , personal data

DG TRADE: personal data

JRC: personal data , personal data , personal data , personal data , personal data person , personal data , personal data , personal data , personal data , personal data , personal data

SG: personal data , personal data ,

LS: personal data

Discussion

1. AOB: no other AOB

2. Introductory remarks from SG
   SG gave an introduction on the context and procedures of the IA highlighting the political interest in the file. The work of the Impact Assessment Steering Group (IASG) has been progressing well. Following influences from other EU Institutions, a more ambitious timetable was set and the College is intending to present ED criteria in draft legal measures before the end of June. To keep this timeline, the IA report needs to be

submitted by SANTE to the Regulatory Scrutiny Board (RSB) by 13/04. This implies high pressure, also on the other DGs for commenting with tight deadlines.
The aim of this IASG meeting is to discuss the IA report before submission to the RSB and to reach the highest quality for the IA report. It does not mean that full agreement on the text must be achieved during this meeting.
The minutes of this meeting will be submitted to the RSB together with the IA report. Therefore, they should be seen as an opportunity for the Services to underline their main comments on the draft IA and to communicate this to the RSB. The draft minutes will be circulated for comments with a very short deadline.
SG pointed out that due to the sensitivity of the file, appropriate security measures were adopted, as done previously for other IA. The document was made available for 2,5 days before the meeting in a reading room (see attachment with the attendants of the reading room).

ENV raised concern about the insufficient time for commenting, which made it impossible to consult internally and to provide appropriate input. According to ENV there could have been other ways to prevent possible leakages, and wondered whether SECEM would not have been enough to ensure security. SG replied that SECEM was considered to be not sufficiently secure and that the procedure chosen was the only feasible alternative.

3. Minutes of the 10th IASG meeting

SANTE indicated that, following consideration of comments received, the final minutes were circulated and are now ready for adoption.
ENV was not prepared to adopt these minutes as they considered that many of their comments, were not integrated and they would like to resend comments for consideration.
SANTE pointed out that all other Services did not voice discontent with the draft minutes and believed these appropriately reflect and integrate comments from all Services. Unless ENV had any new comments, the Chair suggested to take note of the ENV position that comments were not sufficiently taken on board and not to amend the minutes as they are considered comprehensive.
ENV replied that the report is not sufficiently clear in the final draft and that his hierarchy will not be able to understand what has been proposed to be revised. It was agreed that DG ENV would send again comments to the 10th IASG meeting minutes which will be attached to the final minutes of the 11th IASG meeting as an addendum.

4. Sections 1 to 4 of the main report (problem identification, objectives, options)

The Chair thanked services for sending their first comments by email, i.e. SANTE C,
….(others?). These comments will be helpful to improve the draft IA based on the expertise of the services.

ENV asked whether their comments to the draft IA report sent in writing would be attached to the minutes of the present meeting. SANTE clarified that the discussions held during the meeting would be reflected in the minutes and the previously provided written comments to the IA report would not be attached to the minutes. ENV indicated in that case it would have to repeat orally the written comments in the meeting.

GROW asked whether they could send further editorial comments by 05/04/2016 which was accepted.

SANTE C thanked for the opportunity to consult the draft IA from a reading room in Luxembourg and stressed the first objective to assure a high level of human and environmental protection. The group was informed about the main points sent by e-mail including that options should better reflect the situation with regard to the controversy existing around option 4 (potency) so that conclusions can link to this section and be better balanced.

SG congratulated SANTE for the very good draft IA report. SG suggested to: 1) use a more educational language; 2) explain why endocrine disruption is a new way of looking at toxicity (focus not only on adverse effects but also on mode of action); 3) improve presentation of the description of options; 4) explain what are repercussions if a substance is identified as an ED and to use consistent terminology throughout the whole text; 5) be careful in referring to other legislation (WFD, REACH, cosmetics) early in the text: the reader may not understand that the consequences for these legislations are less direct. The message to pass should rather be that other legislations have different legal situations 6) when listing scientific statements, differentiate better the role of EU agencies versus scientific organizations. Also, in Annex 1, it would be better to distinguish clearly the positions of the different players (Commission, Agencies and other stakeholders).
The Chair took note of the raised points and indicated to do as much as possible to improve the text; she suggested moving the reference to other pieces of legislation to a footnote, as deleting the references to other legislations would be disproportionate.

ENV stressed that the IA report in its current form would not be acceptable for them, in particular as regards the issue of horizontality of criteria. ENV recalled that a recent Cabinet meeting concluded that criteria would become horizontally applicable, and that some sectors (e.g. REACH, Caracal meetings) are waiting for criteria before taking actions on EDs.
ENV added that the IA should take into account derogations (emergency measures, negligible exposure) when assessing impacts with the interim criteria as baseline. ENV asked whether the past IA from SE, UK, DK and EP should be mentioned more extensively in the IA report, since these were considered in the co-decision process for the adoption of legislation on PPP.
ENV requested that the assessment of the impacts is not only based on the number of chemicals identified as EDs. They asked to consider in the MCA analysis to what level the criteria are scientific, applicable to other legislation, compliant with court ruling and hazard based.
ENV asked not to use in the IA economic arguments and asked to remove from the analysis options B and C as a consequence of the Court ruling. ENV considered that facts in the assessment of the options were missing and the analysis was overly simplified. ENV stated that IA is basically only about the question of integrating potency or categories in the definition of EDs.
ENV suggested that, considering the time pressure, the current IA should be limited to options 1-4 and a separate IA should be carried out for options B and C at a later stage.

ENV stated to have argumented several times that criteria should be set according to option 3, since potency should not be included and categories would be beneficial.

The chair pointed out that ENV raised important points of the implication of the Court ruling for the IA. SANTE indicated to disagree with the interpretation of ENV on the Court ruling. The judgment is merely looking at the past to see if there was a failure to act and is not addressing the ongoing decision-making. The Court itself points out this at para. 75 (note of the editor : "*l'appréciation du bien-fondé d'un recours en carence dépend uniquement de la question de savoir si l'institution sur laquelle pèse une obligation d'agir a effectivement agi ou s'est illégalement abstenue de le faire*") and afterwards states that the judgment does not focus on the consequence of the failure to act. Moreover, the Court has no competence to judicially review preparatory acts of the EU institutions (such as the IA) and cannot annul them. The Court can annul only acts that produce legal effects towards third parties. Therefore, according to SANTE, paras 71-72 of the judgment cannot be interpreted as if the Court were ruling on the validity of the content of the ongoing IA. On the contrary, from para 71-72 of the Court ruling SANTE infers that the Court implicitly recognised that in the absence of a scientific agreement (like in the present case) the adoption of the criteria is not merely objective (and straightforward) but needed more time in order to assess the impact of the different policy options by the Commission.

SG commented that the aim of any IA is to present all evidence available to the College to allow it to take an informed decision. So it is not appropriate to split the assessment of the options as suggested by ENV. In such event, the RSB may consider that the overall information which was available was not presented.
The Chair concluded that there is at this stage no agreement to discard options in relation to the Court ruling and that, in view of the need to inform the College as widely as possible, the comprehensive information available should be given in the IA without coming forward with a preferred option.
ENV explained the reading of the Court ruling by their lawyers: the Court went further in this case since it gave explanation of the obligations of the Commission (no economic aspects should be considered, because the socio-economic aspects were already considered when setting the legislation).

SG added the following comments: 1) it is difficult to understand from the presentation of the problem in the IA report (page 17) why the existence of two pieces of legislation can be a problem: the different regulatory consequences of being identified as ED between BP and PPP regulations is not a problem *per se*. It may be justified that substances are regulated differently in different legislations. It would be better to state that the PPP does not provide sufficient tools. 2) on interim criteria we should be careful to say they are not up to date with science, because the latest scientific developments did not come only in the last 3 years. The reality is that interim criteria were set pending adoption of new criteria; therefore, they need to be substituted.
SANTE explained how derogations are taken into account in the IA report. Due to the time constraints and the complexity, they could not be considered on a case by case basis. It was instead assumed that derogations would apply to all options in the same proportion, and thus not influence a comparative relative assessment among the options. As regards the consideration of double-counting impact due to other cut-off

criteria, SANTE reminded that due consideration of this issue is given already in the main IA report and in annexes (e.g. annex 12, on EU agriculture, and annex 15 on international trade). The Chair concluded that the two points raised by SG can be considered.

SANTE also indicated that the MCA analysis had been updated taking into account previous comments received from SG about legal certainty, coherence between PPP/BP and compliance with international obligations of the EU.

RTD mentioned that the topic of EDs should not be presented as something new in science. SANTE offered to address the comment.

ENV asked to stress in the IA report that the precise wording about EDs differ in different pieces of legislation and thus justifies the need of categories: e.g. in some cases EDs are just mentioned as such, in other cases, they are referred to as "ED which may determine effects". ENV view is that if different wording is there, it means that different consequences were intended by the legislator. This had been mentioned in the roadmap and it should be indicated in the IA report as well. ENV also reminded that extensive scientific work on EDs is ongoing since years in the US with the endocrine disruptor screening program. The IA should also point out that substances are already identified as ED in the EU under REACH.
SG disagreed with the suggestion of ENV to mention the different wording on EDs in the IA report: the report already needs simplification and this discussion about the wording in different legislation (including REACH, WFD and cosmetics) would confuse the reader. ENV agreed it is important the text should be readable; however, the different wording is crucial for IA and pointed out that the wording is already different between PPP/BP and it should be included, and that if horizontality of criteria is intended reference to other pieces of legislations is needed. The chair concluded it is important to focus the IA on the PPPR and BPR without omitting that there is other legislation.
It was asked to amend the term "not applicable" in the matrix with the overall options to options.

5. <u>Sections 5.1 to 5.2.3 (screening, results of screening, effectiveness and coherence, human health and environmental impacts)</u>

JRC Sevilla indicated to have questions on the application and the use of the criteria. The quality of the assessment is driven by the fact that most of the MCA criteria depend on the number of substances identified in the screening. JRC understands the time constraint but believes that the MCA analysis can be improved by qualifying the criteria further. Looking at the impacts for agriculture, rather than considering only the number of crops affected by each PPP identified as ED, the importance of crops for EU agriculture could be considered, similarly to the approach for the impacts on trade which was looked at the value of commodities affected. JRC added that the weighs in the three MCA criteria for human health could be more balanced to give a higher weight to the MCA criterion for ED related diseases. It is noted that there are more economic dimensions and this implies more weight for economics.
JRC Ispra thanked SANTE for the huge work done in a short timeframe. They added it has been difficult for them as well to provide comments in this short time in order to

improve understanding. JRC asked to better clarify how the MCA results were reached and which data were used. JRC expressed surprise that the policy ranking of options remains the same in all scenarios. As an example it could be stated more explicitly that on ED related diseases there was not enough information to allow drawing conclusions. JRC added that they do not fully agree that categories under option 3 would require more animal testing with respect to criteria without categories. Finally, JRC asked further explanation on why the hazard-based options (A options) perform the same as the risk-based options (B options). On human health it was noted that for dimension human health three criteria are included of which only one related to human diseases. Two go in the same direction, another in opposite direction. This can explain the no change in the order of the sensitivity analysis. Also, for the Environment dimension, option 3 would be less favourable for the criterion on animal welfare (number of animal tests needed), and that the assumption is that the industry will trigger additional testing.

SANTE thanked JRC for the useful comments. SANTE confirmed that further explanation to distinguish between ranking of criteria and final ranking of the options will be provided.
SANTE pointed out that in scenario 5 (called “aim exposure zero”), decision making based only on hazard is considered, rating hazard (Option A) better than risk (Option B) for human health and environment MCA-criteria related to ED. Also the performance of options 1 to 4 is different with respect to the other scenarios. SANTE explained that this scenario (together with its sub scenarios) were included in the respective MCA-Annexes and the results section of the main report (e.g. pages 38, 39, 117, 123), however it has been overlooked to add the corresponding paragraphs to the sections of the main report and the annexes where the performances of the options are explained. The report will need to be amended accordingly where applicable adding a paragraph explaining the different performances of the options. This MCA-scenario increases the weight to human health up to 40% and 20% to environment, and this is not affecting the final policy ranking of the options.

> **Post-meeting note:** the paragraph which needs to be added to human health, hormone related diseases, is the following. *In addition, the MCA-scenario "aim: exposure zero" assessed the performance of the options based only on the number of relevant ED substances identified: the longer the list of relevant EDs identified, the better an option is performing. As a consequence, the options performed as 2/3 > 4 >*
>
> *1. Regarding options A to C, the assessment was based on the number of relevant identified ED substances which will not be approved. As option A would take from the market (non-approval) more substances identified as EDs than options B or C, it would perform the best. The options consequently perform as A > B > C.*
>
> Similar paragraphs need to be added to environment (wildlife) and chemical quality of water (only for options A to C).

SANTE also clarified that in the MCA all available evidence is used to the extent possible. For example, as regards the impacts on agriculture, SANTE explained that it had qualified the information further. However, data from MS were provided late and only from 8 MS. These data are not representative for the EU and extrapolations are not

possible. Nonetheless, data used were not limited to active substances which may eventually be non-approved, but also to PPP which may eventually be non-authorized.
SANTE clarified that the MCA-sensitivity analysis was done to check whether the method is robust. This meant applying different scenarios with different distribution of weighs. Considering that results remained stable when changing the scenarios, it can be concluded that the method is robust and that the uncertainty linked to the method is taken into account in the final results.

> **Post meeting note:** SANTE run additional simulations on the most conservative MCA-scenario ("aim exposure zero 5B") by changing the weight previously assigned to the human health criteria (increasing hormone related diseases to 25 % of weight). This translated into a different policy ranking for options A to C, while the policy ranking for options 1 to 4 remained unchanged.
> This finding will be added to the report for transparency reasons.

ENV indicated that in their view the MCA is unnecessary as the results could be derived directly from the assumptions made and from the number of substances identified as EDs in the screening. ENV referred to the analysis in the written comments. ENV added that there is no evidence for assuming that regulatory decision making based on risk protects as much as a hazard based regulatory decision making. ENV considers that the IA is overestimating the impacts because substances classified as toxic for reproduction category 2 are in some cases identified as EDs in the screening performed by the contractor. ENV also indicated that according to their analysis, one substance which had been identified as an ED (linuron) should be taken out of the whole analysis of impacts as it falls under the cut off criteria. SANTE indicated that this was already the case and that linuron was not considered for the assessment of the impacts in AGRI and TRADE, as clearly stated in the report in the corresponding annexes.
JRC clarified that the screening methodology is not following the approach suggested by ENV and that a harmonized classification R2/C2 did not prevent the classification of a substance as ED.

RTD asked to better indicate in the IA report which kind of data has been used in the screening, and that it was not clear how the data from the good health related annexes were used in the MCA. They also commented that the term “transmissible disease” may be too wide if only disinfectants are discussed and to better explain the link between Annexes and the MCA. SANTE clarified that also insecticides used to control vectors of diseases were assessed, but would consider if a better wording could be found. As regards the information used in the screening, official dossiers for approval of PPP/BP plus databases focused on ED, including information from public literature were used. SANTE clarified that the final IA report will be published together with the screening report providing further details on the screening and its methodology. SANTE will check whether some more clarification can be included in the IA report.

SANTE C supported RTD comment with regard to better linking the content of the Annexes with the MCA and therefore with the conclusions too. The wording chosen for Options 3B and C stating that they are 'not applicable' should be revised: this is not because it is similar to Options 2 B and C that it is not applicable.

GROW asked to indicate the number of the substances screened under REACH (Table 2 at pag 23) and to clarify that only a subset of substances is screened. SANTE informed that results for substances under REACH are expected to be available in mid-May. These results will not be included in the IA, but will be published in the final report of the screening, which is expected to be published in one single package together with the IA report. GROW asked to refer in IA to this report of the screening for REACH substances.

SG asked to better specify that double counting of substances falling under other cut-off is avoided (e.g. on pag 23 and 92). SG also asked to not use the term "cut-off" unless it is clearly explained in the text or define if not clarified. On "effectiveness and efficiency", SG reminded that these terms are normally used in relation to the aim of the IA (e.g. to protect the environment or to protect human health). Therefore the text of the report should be clarified or otherwise refer only to operability and coherence. SG asked to better explain the coherence of the scenario "aim exposure zero" with the rest of the IA. SG pointed out that Annex 9 on human health will receive much attention. If it is concluded that the available studies are not convincing to demonstrate causality, this has to be clearly established. It is unclear why sections 1.1., 1.3 and 1.4 are included in this Annex. SG also asked to explain why so much attention is given to mycotoxins and asked whether mycotoxins are the most important food safety issue. In the same annex the reference to alcohol based hand disinfectants was questioned.
SG did not agree with the rationale in the annex concerning the chemical quality of water where it is basically stated that the less substances on the market, the better. It was suggested to have a coherent approach in the analysis in the IA. SG also suggested providing an explanation in Figure 2 of page 24 of the meaning of ED + cut off. SANTE reminded that mycotoxins were flagged in the public consultation and, although not considered as the major food safety issue, their consideration is of importance as PPPs (fungicides) are useful to control certain mycotoxins.

ENV repeated that they do not agree with the assumption that the hazard based approach is equally protective than the risk based. If this is the view of the Commission this would have a wide impact on other hazard-based legislation. It may have an impact on the ongoing fitness check for chemical legislation. ENV pointed out that the established ED criteria will have impact on other sectors. Substances identified as ED under REACH may need to be re-identified according to the new criteria set. ENV considered that it would have been much better to have REACH in the IA and at least the 6 substances identified as EDs under REACH should be included in the IAs. ENV pointed out that drinking water policy is based on having no risks. This IA should not change policies. ENV disagrees that causality is lacking for hormone related diseases. At least a certain level of causality is established.

SANTE explained that the IA report (page 68) mentions in a disclaimer the limitations of the screening. Moreover, EFSA classifications were also considered where existent. SANTE clarified that no substance will be removed from the screening as the method was agreed as such in the ISG previously. However, in the results the substances falling under the cut-off criteria are clearly indicated. The disclaimer included in the IA - mentioning that the screening results cannot be seen as regulatory results and the

possible inconsistency of the screening results with respect to formal regulatory decision making - will be highlighted further.

6. Sections 5.2.4 to 5.2.6 (agriculture, trade, industry impacts)

TRADE expressed satisfaction with the overall TRADE analysis. They would like to see more details from the contribution given via the public consultation (e.g. the fact that many third countries support option 4 and among them some important trading partners of the EU). TRADE indicated that the most important WTO issues had been correctly highlighted. TRADE considers option 4 the best change to avoid dispute settlement procedures. TRADE congratulated SANTE for the good choice of case studies. TRADE asked the basis for choosing: 1) the cut-off value of 1 billion euro in 2014 for most important commodities; 2) 5% of BP considered as treated articles.

SANTE clarified that answers from third countries are mentioned in relation to the public consultation (at pag 43). Details on the specific option indicated as preferred may be given. The assumption of 1 billion euro was made including consideration of oilseed rape and 5% of BP considered as treated articles was chosen as a low value to avoid overestimation.

SG asked to have a wider perspective of the contributions received via the public consultation (e.g. at pag 32).
SANTE clarified that input from the public consultation is already included in all annexes and in the main report. SANTE added that it is not considered appropriate to mention preferred options of single third countries.

ENV indicated that the IA should refer to previous IA performed for adopting PPP and BP Commission proposals. This would help to explain general approach applied for these proposals and the set objectives.
SANTE pointed out that IA for secondary legislation is rare. SG reminded that the cut-off criteria were not discussed in the IA before adoption of PPP/BP legislation as for the PPP legislation; they were introduced during trilogue negotiations.

JRC asked to highlight further that the ban of substances might foster innovation in the EU and this might also lead to innovation in the rest of the world.
SANTE explained that according to evidence most of research on PPP is moving since years outside the EU. In addition, in the analysis, also the impacts on products and downstream industry were considered. It is stressed that indeed there is an ongoing discussion whether stricter regulation trigger more research or not. Stakeholders are divided on this. This issue is explained in the annex. JRC suggested giving the same ranking to all options on research and innovation to reflect this idea.

7. Sections 6 and 7 (comparison of options and monitoring)

RTD asked to reword the paragraph on human bio monitoring. SANTE agreed.
SG suggested not mentioning in the IA planned or on-going evaluations.

ENV commented that option 4 on potency in their view does not comply with the Court ruling. In ENV's view, option 4 is not scientific, as it is not part of hazard identification

(ENV referred to EFSA opinion, 2013). In ENV view, introducing potency in the criteria would mean introducing elements of risk assessment in hazard assessment. This could trigger another Court case, as the Commission is supposed to develop hazard-based criteria. This could be interpreted as going beyond the powers given to the Commission. Moreover, potency cut-off would hinder the implementation of policies on mixtures because low potent ED substances would not be flagged to be included in the evaluation of mixtures. Option 3 is ENV preferred option because it gives more possibilities to the assessors to decide; it would trigger identification of a lower number of EDs, with consequent less impact on economy; categorisation would also urge substitution. The term "blacklisting effect" is too negative and neglects positive elements such as a future confirmation of a category II substance as an ED. Categories give predictability to operators. Categories are also best in line with GHS and CLP on CMR substances. SANTE indicated that ENV comments and preferred option are noted and reminded that the choice of option is not for the IA report as its aim is to provide decision makers with all available evidence and not to indicate a preferred option.

SANTE C highlighted that possible impacts identified in the IA should also be reflected in the monitoring chapter, which is not the case yet (e.g. trade missing).

8. Concluding remarks

The Chair informed that comments made during this meeting and submitted by email last week will be considered. However, it is unlikely that all of them can be taken into account. The remaining pending comments (editorials and minor comments from GROW, TRADE, JRC) can be provided at the latest within 24 hours via encrypted email.

SANTE committed to try to accommodate as far as possible under the given time constraints the comments received. It is reminded that the IA report shall be submitted to the RSB by 13 April. The minutes of the 11th IASG will be circulated as soon as possible this week and DGs should expect tight deadlines to comment on them.

The Chair concluded that, considering the comments received in writing and during this meeting, a wide consensus on the approach taken in this IA report was acknowledged, with the exception of ENV. Several technical comments were made which were useful and which will be taken into account wherever possible.

AGRI thanked SANTE colleagues who worked on this IA. AGRI was one of the DGs asking for this IA in order to have a solid base for the political decision to be taken by the College, but also by the MS and the EP. AGRI said the report is easy to read, well structured, and provides a clear overview of the impacts to be expected.
The Chair recognized the difficult circumstances and thanked the participants for the very good technical comments, which will allow the report to be improved. As lead
service SANTE aims to present a clear, unbiased and technically correct IA.

Annex: participants to the reading room (30 and 31 of March, and 4th of April AM)

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personal data (TRADE)

From: personal data (SANTE)
Sent: 11 April 2016 09:38
To: personal data (SANTE); personal data (SANTE); personal data (SANTE)
Cc: personal data (SANTE); personal data (SANTE)
Subject: FW: Draft minutes of IASG meeting Endocrine disruptors, 4 April 2016

Importance: High

Dear person , personal and perso ,
Thank you for these draft minutes.

Please find my quick comments in track changes reflecting briefly the 3 interventions from SANTE C in Luxembourg (which is totally absent from your actual minutes), knowing that main points have been sent the week before and will also be taken into account, as mentioned during the meeting.

Thank you for reflecting them as it is important from a steering point of view to know who stated what, in particular during our last meeting.

Thank you for the good follow-up and for taking these changes into account.
Kind regards,
person , for SANTE C

Draft minutes
11th IASG_04-04...

From: personal data (SANTE)
Sent: Friday, April 08, 2016 2:59 PM
To: personal data (JRC-SEVILLA); personal data (GROW); personal data (JRC-SEVILLA); personal data (SG); personal data (SANTE); personal data (GROW); personal person (AGRI); personal (JRC-SEVILLA); personal data (ENV); personal data (JRC-ISPRA); personal data (RTD); personal data (JRC-ISPRA); personal data (TRADE); personal data (JRC); personal data (RTD); personal data (GROW); personal data (JRC-SEVILLA); personal data (GROW); personal data (JRC); personal data (JRC-ISPRA); persona person (JRC-ISPRA); personal data (JRC-ISPRA); personal data (SJ)
Cc: personal data (JRC-SEVILLA); personal data (SG); personal data (SANTE); personal data (SANTE); personal data (SANTE); personal data (SANTE); personal data (SANTE); personal person (SANTE); personal data (SANTE); personal (SANTE-EXT); personal data (SANTE); personal data (GROW); personal data (ENV); personal data (JRC-ISPRA); JUELICHER Sabine (SANTE); personal data (AGRI); personal data (GROW); personal data (GROW); Hpersonal data (RTD); personal data (JRC-SEVILLA); personal data (SANTE)
Subject: Draft minutes of IASG meeting Endocrine disruptors, 4 April 2016

Dear colleagues

Please find attached the draft minutes of the IA Steering Group meeting "Endocrine disruptors", which took place on 4 April 2016. I appreciate to receive your **comments by Monday, 11 April 13:00 h at the very latest**. The

short deadline is required as IA has to be submitted to the RSB on13 April 2016.

1. Draft minutes

2. Addendum to the minutes of the 10th IASG meeting submitted by DG ENV

ENV additional comments to th...

Please return your comments to my e-mail address, to personal data @ec.europa.eu and personal data @ec.europa.eu

Kind regards,

personal data
personal

European Commission
DG SANTE
Unit E3, Pesticides and Biocides

F101 person
B-1049 Brussels/Belgium
+32 personal
personal @ec.europa.eu
d t

EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Brussels, February 2016

MINUTES

Place: F 101 01/89	Date: 1 February 2016
Subject: 10th Meeting of the Impact Assessment Steering Group on the definition of criteria for the identification of Endocrine Disruptors (EDs)	

Attendees:

DG SANTE: personal data (chair), personal data , personal data , personal data , personal data , personal data , personal data , personal data , personal data , personal data

DG ENV: personal data , personal data

DG AGRI: personal data

DG GROW: personal data , personal data , personal data , personal data

DG JUST: personal data

DG RTD: personal data , personal data

DG TRADE: personal data , personal data

JRC: personal data , personal data , personal data , personal data , personal data , personal data , personal data , personal data , personal data

SG: personal data , personal data

Discussion

1. AOB: no other AOB

2. Minutes of the 9th IASG meeting

The draft minutes circulated before were not yet approved because some last-minute comments were still to be included; a revised version of the minutes will be circulated with a view to approve it at the next IASG meeting latest.

3. Update on general planning.

SANTE informed about the ENV WP Council meeting on ED held during the same morning (1st February), where the Court judgement of 16 December 2015 was discussed.

The statement of the Council is expected to be on the agenda of the ENVI Committee on 4 March.

On 2nd February, the Commissioner will answer to an oral question at EP in Strasbourg. The GRI-fiche clearly mentions that the Commission will present scientific criteria for endocrine disruptors before the summer 2016.

The corresponding internal SANTE-deadline to send the draft IA report to the Cabinet is beginning of March and to submit the IA to the Regulatory Scrutiny Board by mid-April. The deadline for finalising screening of Cosmetic, REACH and WFD substances remain unchanged – mid April. SANTE is under high time-pressure over the next few weeks: therefore, deadlines for commenting for the IASG will also need to be tight. Constructive comments from participants are highly recommended.

4. Proposal for the MCA-criteria

   SANTE reminded that a MCA analysis was chosen for the IA because of the different amount and reliability of evidence available in the different areas expected to be affected, as discussed in the previous IASG-meeting.

   The objective of this meeting was to discuss the criteria to be used in the context of the MCA (MCA-criteria). Regarding the weighting attributed to the MCA-criteria, a sensitivity analysis will be carried out according to different scenarios where various weights will be assigned to the different criteria.

   The proposed MCA-criteria circulated as preparation to this meeting were developed according to the standard methodology, i.e.: considering all areas where an impact is expected and the evidence available, etc. Duplications across MCA-criteria were avoided in order not to measure the same aspects twice.

   Further, the criteria circulated were cross-checked before with the outcome of the public consultation as well as the impacts needed to be considered according to the Better Regulation Toolbox, to verify that no significant potential impacts are left out.

   It was reminded that assessing performance of each MCA-criterion across the various options means qualitatively ranking how the options perform with respect to each other for that particular criterion, rather than assessing the absolute performance of each option.

   SANTE then explained the proposed MCA criteria, illustrating the rationale for their choice and the main evidence available for each of them. SANTE clarified that "animal welfare" was considered under environmental impacts according to the Better Regulation Toolbox. It was also raised in the public consultation.

   ENV suggested to always refer to MCA-criteria and not only to criteria in order to avoid confusion and highlighted that impacts could be negative or positive. ENV was concerned that benefits do not feature significantly in the document. Considering, for instance, the availability of crop protection methods, there is not much consideration of whether there are alternatives which are not PPP-related (e.g. biological control methods, integrated pest management tools). *Editor's note: the PPP Regulation covers both chemical and biological control agents (microorganisms, therefore biological control methods, are alternatives already considered with the term PPP*). *Integrated pest management tools are mandatory in the EU since 1 January 2016.* ENV asked whether the following was considered: how the different options can be coherent with the regulatory systems existing in different countries; how different

options can take into account mixture effects; cost of extracting EDs from drinking water; impacts on invertebrate species (e.g. effects of tributyl tin on molluscs); benefits for workers safety and employment when using alternatives to EDs; wider considerations, including the availability and impacts of alternatives, for biocidal products (analogous to the agricultural considerations for PPP). ENV asked whether criterion 10 on the availability of products could not be informed by data on the number of crops affected or the volume of imports. ENV also asked whether the availability of products was only referred to the availability of food or also to other treated products (e.g. products treated with biocides). SANTE answered that both products treated with PPP and BPs are considered, but that regarding PPPs and BPs product, the focus is on PPPs because of their effect on agriculture (BPs are covered via treated articles).

In relation to the potential impacts on trade, ENV asked for clarification of legal provisions regarding reducing MRLs for a pesticide as a consequence of the pesticide being identified as an endocrine disruptor. SANTE clarified that when MRLs are lowered to default values based on human health concerns, import tolerance (higher than default values) cannot be granted. When a substance is non-approved based on concerns not related to human health (e.g. environmental concern) the MRLs are not lowered to default values and import tolerance values can therefore be set.

ENV asked whether only EATS-pathways will be considered for MCA-criteria on human health. Further, ENV asked to include in the assessment also impacts on invertebrates as they are well documented cases of ED disruption of mollusc, e.g. tributyl tin and its effect on mollusc population.

SANTE explained that the screening methodology developed by the JRC-Ispra took into account only EATS-pathways and only vertebrate species because sufficient OECD validated methods are not yet available for other pathways and for invertebrates.
SG pointed out that the EFSA opinion on EDs (2013) emphasizes that there are major gaps in knowledge for invertebrates, which makes it difficult to draw robust conclusions. SG, referring to the EFSA opinion on EDs (2013), also recalled that mixture effects are not an issue specific to EDs.

ENV pointed out that it is essential that the Impact Assessment evaluates impacts of the entire legislation, while the introductory text of the MCA-criteria states that the derogations (regarding negligible exposures (under PPPR) and negligible risk (under BPR) and regarding socio-economic impacts (under both regulations)) are not considered because they apply equally to all options. ENV argued that avoiding consideration of derogations might lead to significant overestimation of impacts. SANTE clarified that the IA will consider that impacts may be lower if derogations in the legislation are taken into account. However, derogations apply for all options in the same proportion and, therefore, would affect all options the same way with – as a consequence – limited added-value for assessing the performance of the options (ranking, no absolute values). Besides, it will be clearly stated in the report which assumption was taken (eg: the worst case scenario). On the other hand, derogations

are considered, as they might imply an additional effort for industry and public authorities and this could be proportional to the number of substances affected.
ENV disagreed with this clarification and explained that it is essential that the College when deciding about the criteria is aware of absolute impacts and not relative impacts as it is huge difference if we are talking about some 20 or some 120 substances.

GROW indicated that the number of PPP that will be "banned" was not an indicator per se because it didn't give any information on the impacts.
SG suggested modifying the wording in the first proposed MCA criterion from “PPP banned” to “PPP affected” in order to acknowledge existence of derogations. Concerning the terminology used, SG asked whether the term “sustainability of EU agriculture" was used to refer to competiveness and enquired about what was meant with the words "good administration".

JRC noted that the criteria cover all the relevant areas, although most of the MCA-criteria relate to costs and few to benefits and thus the weighing of criteria should be well considered. It warned against an assessment of health benefits just using the number of substances banned; it questioned whether health impacts will only rely on assumptions of associations between number of substances affected and health impacts or also consider other factors since these diseases are mainly multifactorial. JRC felt the weighing of criteria could be assigned depending on quantity/reliability of evidence available, that the proportion of costs/benefits could be adjusted through the weights assigned to the criteria, and that the complexity of the IA has to be managed. Alternative agricultural systems could be considered in addition, but this would make the analysis too complex.

SANTE agreed and invited participants to send constructive suggestions for measuring benefits, pointing out that some indicators can be interpreted in both ways, e.g. banning PPPs can be considered a benefit or a cost.

TRADE had sent written comments and asked clarifications about the indicators on trade. SANTE clarified that trade impacts will be considered as a function of the imports into the EU (Eurostat /TRADE database) and the number of MRLs which will need to be lowered to the limit of determination (LOD) (SANTE database). Food and feed impacts are separated because feed may impact livestock production, which in the EU relies heavily on imported feed.
SANTE suggested considering the use of different weights in the MCA to reflect benefits vs. costs.

ENV recalled the statement of SANTE from the introduction of MCA that there are high uncertainties as regards impacts of EDs on human health. ENV pointed out the importance to adequately analyse benefits to human health and the environment as this is essential part of any impact assessment.

SG recalled the controversies about the associations between epidemiological observations of human diseases/disorders and exposure to EDs. It will be challenging to present objectively the costs and benefits in relation to human health. SG also

questioned how the IA will consider that the current regulatory framework may capture adverse effects often associated to EDs.
SANTE clarified that the IA will not double-count substances which are already expected not to be approved because of other provisions (e.g. substances classified as carcinogens or toxic for reproduction category 1A/B). On the other hand, many other substances not falling under these classifications but identified as EDs in the screening, might still be non-approved based on risk assessment, irrespective of their formal identification as an ED. Consideration of this issue is more complex because the outcome of regulatory risk assessment is case-by-case.

ENV mentioned papers (e.g. Trasande et al.) which estimate the disease costs arising from exposure to EDC in the EU. These papers were presented at a recent ECHA meeting and were well received by the experts. They are suitable to feed into the assessment of costs and benefits in relation to human health..
GROW warned to be cautious with the papers by Trasande et al., whose methodology has been severely criticized and is still controversial.

ENV asked whether classification proposals for CMRs by industry (self-classification) will be considered in the screening. SANTE clarified that for PPPs, rather than self-classification from industry, EFSA proposals for classification were considered.

ENV welcomed the possibility to provide written comments and promised to send them within the given tight deadline. At the meeting ENV already flagged the need to include the following additional MCA-criteria: :

- Criterion on to what level is each option coherent with other policies (e.g. with policies on chemical mixtures, international agreements,); as regards mixtures, ENV further clarified that it agrees that we should not assess mixture effects within the impact assessment but we should definitely assess how each option is coherent with the EU policy on mixtures and whether some of the options does not obstruct the protection of human health and the environment from mixture effects;
- Criterion on to what level each option is able to ensure coherence with existing relevant regulatory decisions on substances;
- Criterion on to what level is each option applicable and usable across all relevant legislation;
- Criterion on to what level is each option based only on science and to which level it is also based on socio-economic considerations;
- Criterion on changes in consumer trust in products as a result of selected options for criteria;
- Criterion on impact on health of farmers.

SG opined that DGs calling for additional criteria should also endeavour to provide evidence and data.
SANTE concluded that, considering the tight deadlines for SANTE to finalize the IA report by early March, comments should be provided by 2 February COB.