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EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

~~MINUTES~~

~~Place: EC Charlemagne building Date: 4 April 2016~~

Brussels, April 2016

~~**Subject:** 11th Meeting of the Impact Assessment (IA) Steering Group on the definition of criteria for the identification of Endocrine Disruptors (EDs)~~

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~~**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~~

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

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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. The consultation mechanism used significantly hampered the impact assessment from benefiting from the in-house experience and insights which ENV, and possibly other DGs, could have contributed. 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. In addition, there are factual mistakes, e.g. reference to climate change discussion. 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.~~
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~~ for several reasons identified in our written comments. First, the IA does not address the issue of horizontality of criteria~~.~~, i.e. its applicability to other legislation with provisions on endocrine disruptors than Plant Protection Products and Biocidal Product Regulations. ENV recalled that this issue is addressed in the Roadmap for the criteria, a recent Cabinet meeting concluded that criteria would become horizontally applicable, and that some ~~sectors (e.g.~~Competent Authorities under REACH~~, Caracal meetings) are waiting for~~ argued at the last CARACAL meeting to await the criteria before ~~taking actions on EDs~~deciding on identification of some substances as endocrine disruptors under REACH.
~~ENV added that~~ Second, the IA should be as close as possible to the reality and it should take into account the baseline. Therefore, the number of chemicals identified under each option and associated impacts should be corrected for the derogations ~~(emergency measures,~~ set in the legislation as regards negligible exposure~~) when assessing impacts with~~, and negligible risk and as regards emergency situations, public health threats and socio-economic considerations.
Third, the ~~interim criteria as baseline. ENV asked whether~~ IA should refer more extensively to the conclusions of the past IA from SE, UK, ~~DK~~ and EP~~ should be mentioned more extensively in the IA report~~, since these were considered by the co-legislator in the co-decision process for the adoption of legislation on PPP and hence constitutes a part of the balance agreed by the co-legislator in 2009.
~~ENV requested that~~Fourth, the ~~assessment of the impacts is~~IA should not be only based on the number of chemicals identified as EDs~~. They asked to consider~~ but it should also cover the Better regulation aspects. ENV asked to include in the MCA analysis to what level the

options for criteria are (I) scientific, (II) coherent with other chemical policies, (III) applicable to other legislation~~, compliant with court ruling and~~ and their provisions, (IV) robust as regards scientific development in the ED field, and (V) hazard based.

~~ENV asked not to~~ Fifth, the IA should be adapted to be in compliance with the General Court Ruling. According to ENV, the General Court states that scientific criteria should not be based on the economic impact. 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 current IA should be limited to options 1-4, concluding the work on the IA by stating that on completion of the work and on careful considerations of the General Courts Judgement, we have eliminated a number of options, leaving only Option 3 – using arguments provided in writing for not including potency and for including categories.
- a separate IA should be finished for options A, B and C and prepared, independently to the work on the development of scientific criteria for identifying EDs, an amendment to the PPP Regulation.

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 General Court went further in this case since it gave explanation of ~~the obligations~~some very general issues regarding the delegated act:

- the specification of ~~the Commission (no economic aspects~~ scientific criteria for the determination of endocrine disrupting properties should only be ~~considered, because~~

~~the socio-economic aspects were~~conducted in an objective manner based on scientific data related to the endocrine system, independently of any other consideration, in particular economic ones;

the legislator already ~~considered when setting the legislation).~~ laid down the balance between improving the internal market and that of protecting human health, animal health and the environment, and that the Commission may not question this balance via the powers delegated to it. .

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~~address in the IA report that the ~~precise~~legal wording about EDs differ in different pieces of legislation and ~~thus justifies the need~~among different provisions of ~~categories:~~the same legislation, e.g. in some cases ~~EDs are just mentioned as such,~~ reference is made to "*substances having endocrine disrupting properties*" only, in other cases, ~~they are referred to as "ED~~ a reference is made to "*substances having endocrine disrupting properties that may cause adverse effect …"* or "*substances having endocrine disrupting properties for which* ~~may determine~~*there is scientific evidence of probable serious effects*~~".~~…" ENV view is that if different wording is there, it means that different ~~consequences~~scope were intended by the legislator. This had been ~~mentioned~~addressed 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~~ 1996 in the US with the endocrine disruptor screening program~~.~~ and therefore supports RTD comments that EDs should not be presented as something new in science. 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~~provisions of BPR and it should be included, and that if horizontality of criteria is intended reference to other pieces of legislations is needed. ENV argued that the consideration of different wording will have impact on decision which option for the criteria is more suitable and goes in line with the Better Regulation principles. 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. Sections 5.1 to 5.2.3 (screening, results of screening, effectiveness and coherence, human health and environmental impacts)

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.

~~ost~~

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 IA assumes that (I) all negative impacts (agriculture, industry, SME, trade, ….) of an option is proportionate to the number of substances ~~identified as EDs in~~ the ~~screening. ENV referred to~~ option identifies, (II) for all positive impacts (health, environment) that Options 2, 3 and 4 and Options A ad Option B deliver the same protection. Through the construction of the Options, evidently

point I means that for all the negative impact criteria (Sections 5.2.1 and 5.2.4 onwards) the relative option 4 is preferred over Option

2/3 and Option C over Option B over Option A. The assumptions placed on the positive impacts (see Sections 5.2.2 and 5.2.3) in point 2 result in these criteria having no impact on the MCA results independent of the weighting factors. That these two assumptions determine all the mathematics of the MCA is confirmed by the sensitivity analysis ~~in the written comments. ENV added~~performed in the impact assessment showing that the overall ranking of the options is independent of the weighting factors applied. Mathematically this result can be proven. The MCA is a weighted average approach of the 19 criteria. As the ranking of an option on any negative impact criterion has a clear direct relationship with the number of substances the option identifies as an ED, it follows directly that the same relationship must hold for any weighting of any of the criteria used in the MCA. If we would introduce an option 5 which is defined as "no criteria for ED, all ED go through risk assessment", then it is clear from the assumptions made that this option would be best This is because the impact assessment assumes more substances is worse for all economic and trade criteria and there is no benefit for human health and the environment. In short, there is no need for the application of the MCA methodology and the many pages of results, as the outcome can be derived theoretically for any weighting factors directly based on the two above assumptions.

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. Although not stated explicitly in the IA, though often hinted to, these two assumptions can only be made if one believes that in effect the cut-off criteria in the PPP and BP Regulations result in unnecessary bans of substances. This approach contradicts the approach used when the Commission introduced the cut-off criteria in the PPP and BP Regulations and would therefore need to be underpinned by clear evidence. These assumptions can be seen as direct attack on all the cut-off criteria in PPP and BP regulations (incl the CMR cat 1). If the Commission agrees to these assumptions, then this might have wide ranging effect on all 'hazard based regulation'.

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~~2 are in some cases identified as EDs in the screening performed by the contractor. In the time given it was possible to consider only some information readily available to us for the 15 substances which fulfil the screening criteria applied for Option 2/3 but did not fulfil the screening criteria applied for Option 4. From these 15 substances, 6 substances (Maneb, Myclobutanil, Propyzamide, Tebuconazole, Tralkoxydim, Triflusulfuron) are classified as toxic to reproduction cat. 2 and at the same time they are identified as endocrine disruptors under option 2 and as endocrine disruptors cat. 1 under option 3. Considering that the adverse effects for classification as toxic to reproduction cat. 2 are the same as those leading to classifying these substances as endocrine disruptors, ENV requested to remove these 6 substances from being identified as endocrine disruptors. ENV argued that the text of the criteria for endocrine disruptors is strongly based on the criteria for toxic to reproduction and therefore the different interpretation of the criteria is unjustified.

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.

ENV warned that the assessment of the options along the MCA dimensions and criteria is overly simplified and inconsistent. An example of over simplification is the MCA-Dimension 'Environment', MCA-Criterion 'Animal welfare'. The impact assessment assumes that "*Option 3 with inclusion of additional categories, might trigger additional animal testing, as companies or authorities would want to verify if the chemicals, classified in Category II or III, are actually EDs or not".* If this is assumed then the consequences of such testing should also be considered under the other Dimensions and Criteria. Experience in applying the categorised hazard identification approaches under the CLP Regulation show that testing for substances in Category II will lead either to Category I (hence an increased protection which should be considered under MCA-Dimension 'Environment', MCA-Criterion 'Wildlife vertebrate populations' and 'chemical quality of water') or no categorisation (hence an increased competitiveness under MCA-Dimension 'Sectorial competitiveness'). An example of inconsistency is in MCA-Dimension 'Environment' and 'Effectiveness and Coherence'. The second full paragraph (page 28) presumes that Options 2, 3 and 4 will be equally protective. If this is the case then the assessment in 5.2.1 should have concluded that Options 2 and 3 are more efficient (provide better legal certainty, are easier to operate and provide better regulatory decision making) as they will overall be less work and easier to apply.

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 or reassess other policies. There might be a good reason why drinking water policy is established the way as it is. ENV disagrees that causality is absolutely lacking for hormone related diseases. At least a certain level of causality ~~is established.~~ is established. For example, there is a well-documented case of a drug DES which caused severe disease in children of women treated with this drug.

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 ~~thepossible~~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 as well as to indicate which impacts were considered acceptable when adopting the legislation.
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~~with potency in their view does not comply with the Court ruling. In ENV's view, option 4 is not scientific, as ~~it~~ potency 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.~~identification. 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 chemical mixtures because low potent ED substances would not be flagged to be included in the evaluation of mixtures. In addition, in addition potency cut off would obscure communication regarding EDs., as low potent EDs would not be identified as EDs but they could be Carcinogens or Toxic to Reproduction Cat. 1. Option 3 is ENV preferred option because it allows to address the different wording of provisions as

regards EDs; it gives more possibilities to the assessors to decide~~;~~ by avoiding yes/no decisions; 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. ENV argued that its objective was not to show what option is preferred but to list arguments on potency and categories.

~~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 ~~leadservice~~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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