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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)~~

MINUTES

~~**Attendees:**~~

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

~~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.~~

Attendees:

DG SANTE: Sabine Juelicher (chair), personal data, personal data, personal data, perso personal, personal data, personal data, personal data, 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 of the IA and procedures at this stage. The work of the Impact Assessment Steering Group (IASG) has been progressing well and was consistent with a political target set for a College orientation before the end of June. This in turn meant it was important to keep to the timeline and to submit, the IA report to the

Regulatory Scrutiny Board (RSB) by 13/04. The understanding of all services for this was appreciated.

The aim of this IASG meeting ~~is~~was to discuss the IA report before submission to the RSB ~~and to reach the highest~~ by DG SANTE as chef de file responsible for the text and to use the input from all services to maximise the the 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~~the final meeting ~~will be~~ of an IASG were submitted to the RSB together with the IA report. ~~Therefore, they should be seen as~~ and therefore provided an opportunity ~~for the Services~~ to ~~underline their main comments~~record the positions of all services on the ~~draft~~ IA ~~and to communicate this to the RSB. The draft minutes will be circulated for comments with a very short deadline~~, including differences of opinion.

SG pointed out that due to the sensitivity of the file and previous cases of leaks, appropriate security measures ~~were adopted, as done previously for other IA.~~ had been required. The document ~~was~~ had been 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~~ considered that time for commenting was insufficient ~~time for commenting,~~ , which made it ~~impossible~~more difficult 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~~no other ~~Services did not voice~~service had voiced 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.~~all services. It was agreed that DG ENV would send again comments ~~to~~ on 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~~give more ~~educational language~~explanation for non-experts in the introduction; 2) explain ~~why~~ what is new about endocrine disruption ~~is~~as a ~~new~~ way of looking at toxicity (focus not only on adverse effects but also on mode of action); 3) improve and simplify the 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~~ avoid misunderstandings of the interplay of this IA with 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 (legal consequences not defined in the legislation) 6) when listing scientific statements, differentiate better ~~the role of~~ EU regulatory agencies ~~versus~~ and scientific ~~organizations.~~committees versus other stakeholders. 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~~the options A, B and C. Regarding options 1-4, only option 3 should be presented. ENV stated to have argued several times that criteria should be set according to option 3, since potency should not be included and categories would be beneficial.

~~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. However, 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~~Both the College and the RSB would expect an IA with the scope agreed in the roadmap.

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 description in the IA report (page 17) why the existence of two pieces of legislation ~~can be a problem: the~~with different regulatory consequences ~~of being identified as ED between BP and PPP regulations is not~~ are 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 for risk-managers to regulate hazardous substances other than by banning them. 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. 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~~option) perform the same as the risk- based options (B ~~options~~option). On human health it was noted that ~~for~~the dimension human health ~~three criteria are included of which~~ only one criteria of three 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~~ by 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 following 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."*

~~*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~~highlight more clearly that ~~double counting of~~ substances falling under other cut-off ~~is avoided (e.g.~~ have not been counted/considered in the assessment of impacts (e.g. on pag 23 and 92). SG also ~~asked~~suggested to ~~not use~~clearly explain/define 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~~ an objective (e.g. to protect the environment or to protect human health). Therefore the ~~text of the report~~first dimension 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~~ recalled that Annex 9 ~~on (~~human health~~ will receive much attention. If it is concluded that the~~) has to clearly explain why available studies are not convincing ~~to demonstrate~~ (causality~~, this has to be clearly established.~~ etc.). 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~~wondered 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.~~

SG stressed the need to have a coherent approach in the analysis of the options (e.g. regarding the section on water quality).

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~~ argued that the established ED criteria ~~will~~ may 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 ~~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 from all groups of stakeholders 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 ~~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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