Ref. Ares(2020)4002281 - 29/07/2020

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for Food Safety responsible for Directorates D, E, F and G

Brussels,
SANTE/E2[redacted] (2020)4579742

REPLY OF DG SANTE

AVAILABLE IN DECIDE CONSULTATION

***Interservices consultation initiated by*: DG ENVIRONMENT**

Reference: ISC/2020/05158

Title: Inter-service consultation on Chemicals Strategy for Sustainability

Contact person in DG SANTE: Sabine Jülicher[redacted]

☒ **Comments: "Favourable opinion taking into account the following comments"**

Thank you for consulting DG SANTE on the proposal for a Communication on a Chemicals Strategy for Sustainability.

DG SANTE gives a favourable opinion subject to the following being taken into account. In particular, DG SANTE would like to recall that most of the points have already been raised during the earlier work of the ISG.

1) **A simple and effective approach to manage risks: Simplified and faster risk management (3.3.2)**

   DG SANTE is concerned that an expansion of a hazard based approach to managing chemicals in EU legislation (so-called 'generic risk management') could paradoxically impede protection of health due to more complex and lengthy decision making processes, as experience shows. Whilst DG SANTE underlines its support for dealing rapidly with chemicals that present a risk to consumers, we cannot support a general expansion of hazard-based decision making as outlined in the draft Communication, for the following reasons:

   a) In addition to the hazardous properties of a chemical, other factors, primarily exposure, determine the extent to which chemicals present a risk to consumers. This basic and fundamental science is enshrined in the general principles of food law under which there is a legal obligation to carry out a risk assessment consisting of the four steps of hazard identification, hazard characterisation, exposure assessment and risk characterisation. The current system is working well[1] and enables the Commission to introduce measures in a timely manner in order to restrict chemicals, for which risks have been identified or sufficient doubt exists; or where a safe level

[1] https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

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of exposure cannot be derived such as carcinogens acting via a genotoxic mode of action.

b) The EU has accepted obligations under World Trade Organisation rules and in particular, the Sanitary and Phytosanitary (SPS) Agreement to establish measures based on an appropriate assessment of the actual risks involved, including the element of exposure and probability. The Technical Barriers to Trade (TBT) Agreement further aims to ensure that technical regulations do not create unnecessary obstacles to trade. In DG SANTE's view, expanding the scope of decision-making in EU legislation based on hazard alone will decrease the credibility of the EU's position to support respect of international rules and its capacity to defend itself against criticism from and possible disputes lodged by trade partners. This approach will also antagonise many third countries and will thus jeopardise the aims and objectives of the Chemicals Strategy's "Cooperation with Third Countries".

c) Whilst exceptionally some hazard-based decisions are made in the area of pesticides and biocides, the REFIT evaluation of the pesticides legislation[2] has found that the hazard-based decision-making is not simpler and faster than risk based decision-making, while it has, however, provided clarity to economic operators in determining whether to apply for approval (or renewal of approval) of active substances. We would also like to highlight our experience of the difficulties in introducing justified derogations that are inevitably sometimes required for certain uses, which do not present a risk to consumers but nevertheless fuel controversy amongst stakeholders and unnecessary concern for the public.

d) Lastly, the action does not follow from the conclusion of the Commission's Fitness Check on non-REACH chemicals, which acknowledges that both approaches (hazard based/ generic approach and risk based) have a role to play, whereas Member States in particular are content with the current balance of use. The conclusions of the Fitness check in fact are that we should speed up the identification and risk assessment of hazardous chemicals (not expand the use of the hazard-based approach). Ignoring such findings of the Fitness Check brings the Commission's Better Regulation approach into disrepute and undermines it's transparent decision making process.

Notwithstanding the above comments on this approach, SANTE does recognise that the introduction of rules for certain substances based primarily on their relevant hazardous properties has merit in certain circumstances. DG SANTE will assess the need and eventual impact of a similar approach in, for example, the planned revision of food contact materials (FCM) legislation. Such rules would need to consider the use, possibility for safe substitution, relevant characteristics of the hazard (e.g. oral rather than dermal or inhalation toxicity), whether the concerns are over vulnerable populations, ability to determine a safe level of exposure and lack of exposure data or lack of confidence in the exposure data.

2) Addressing endocrine disrupting chemicals (3.1.1)

DG SANTE would like to underline that "banning" substances based on their hazard properties alone is at odds with a scientific risk assessment process. Such a blunt approach may also inadvertently compromise the timely introduction of health protection measures, or lead to the introduction of less safe alternatives. Pending an assessment of the impacts, DG SANTE is in favour of more conditional language that allows the implementation of an approach to Endocrine Disruptors (EDs) that is based on a scientific assessment and a risk management decision.

[2] https://ec.europa.eu/food/plant/pesticides/refit_en

Furthermore, banning chemicals used in Food Contact Materials does not solve the issue since some chemicals that migrate from the final packaging or article are present unintentionally due to chemical reactions, degradation and impurities during the manufacture and processing and cannot be directly regulated in such a way. This is particularly true for materials, including paper and cardboard, that are processed from recycling streams and derogations would be required as is the case in the French law banning bisphenol A (BPA). DG SANTE will seek to address these issues further as part of its revision of the FCM legislation but this must be carefully balanced with the need to deliver on the commitments of the Green Deal, particularly on the use of recycled materials.

Nevertheless as indicated under point 1, we will assess whether any hazard based approaches may have further merit, particularly for substances such as EDs taking into account the ongoing debate over whether health-based guidance values can be established for certain EDs due to their potential to cause harm at very low levels of exposure. We therefore kindly remind DG ENV of the ongoing evaluation of FCM legislation and the forthcoming Impact Assessment for the new FCM initiative that will address these matters.

3) Protecting people and the environment from the combined effects of chemicals ('chemical mixtures') (3.1.2)

DG SANTE is concerned about the introduction of a 'mixtures assessment factor' (MAF) for all chemicals being registered under the main chemicals Regulation REACH. The use of a blunt unscientific approach with no defined value may lead to unintended consequences in the regulation of products in downstream legislation and compromise the ability to assess accurately the risk to consumers.

DG SANTE already takes into account combined exposure wherever possible e.g. for FCMs and is fully committed to addressing the potential risks from exposure to multiple chemicals. EFSA has been leading on combination assessments of pesticide residues having started work on this over a decade ago and we are pleased to see that this is acknowledged in the draft Communication. Although the work has been extremely complex, EFSA and the Commission will prepare an implementation plan by the end of 2020 on further work priorities. Results so far from two studies looking at acute toxic effects of pesticide residues on the nervous system and their chronic effect on the thyroid indicate that single substance assessments are actually sufficient to ensure adequate consumer protection from residues of pesticides for those specific effects. An analysis of the factors influencing the highest exposures revealed that those were driven by single substance/commodity combinations and not by co-exposures to several substances. Whilst acknowledging the complexity of the issue, DG SANTE is satisfied that the work already achieved by EFSA and its partners has made significant progress in understanding the possible risks from combined exposure and can be developed further and applied in the future as routine, across relevant SANTE legislation and beyond.

DG SANTE notes that available documents and outputs on the MAF discuss its use as one possible tool for taking account of cumulative exposure but do not advocate its broad application for all substances. DG SANTE is concerned on the impact the MAF may have on the availability of chemicals regulated under both REACH and SANTE legislation for which there is no risk. We consider it too early to commit to introducing this as standard in EU legislation and further development of its potential practical use, feasibility and consequences must first be investigated.

4) One substance, one assessment (3.3.1)

DG SANTE notes the work carried out so far in progressing this initiative with the cooperation of key Agencies including ECHA, EFSA and EMA. We consider this

important in working towards the common goal of ensuring chemicals are managed appropriately to fully protect humans and the environment regardless of the actual use and route of exposure. We fully support the need to have a common outcome on establishing relevant hazard properties in order to undertake further risk assessment and risk management in legislation specific to routes of exposure. The emphasis on this common understanding of hazard should be highlighted in the Action Plan.

We support the need for an EU mechanism for better coordination, prioritisation and increased transparency of safety assessment work but consider that this cannot be achieved alone by improvements to an IT tool such as the (Public) Activities Coordination Tool (PACT). In this sense, we feel that the text could and should be more ambitious in providing for more formal governance that is present early on in the regulatory process, particularly for certain widely used groups of substances. Such a mechanism should then ensure that there is a comprehensive overview of all uses and presence of chemicals, particularly those in consumer products – and facilitate the move away from a substance by substance approach to assess groups of substances collectively by the relevant EU Agencies. We believe that this is currently lacking and would allow us to prioritise and deal with the risks accordingly, with faster and firmer regulation in those areas where prompt action is needed. It would reinforce the legitimacy, predictability and coherence of the EU's regulatory actions.

Lastly, on this point, we support the reattribution of assessment work of SCHEER and SCCS to ECHA and are pleased to see this reflected in the draft Communication.

5) A strengthened chemical science-policy interface (3.4.2)

The scope and potential of human biomonitoring as evidence for policy making should be balanced in the overall context of research and innovation. It should be listed alongside (and with similar high-level detail for this type of document) with the other research and innovation elements that could contribute to innovation in risk assessment and regulatory science.

While the proposals presented in the draft Communication address the short and medium term, it falls short in the 'long-term vision' e.g. post-next MFF/Horizon Europe in the case of the research framework programme. The ongoing work designing the Partnership PARC under Horizon Europe is an opportunity for a future EU coordinated action (complementary to research and innovation funding) for a consolidated 'EU Toxicology Programme', e.g. similar to US National Toxicology Programme but in the context of EU programmes/funding instruments and naturally seeking a solid foundations with Member States. This possibility was discussed internally during the preparatory work for the recently adopted Transparency Regulation amending the General Food Law as a solution for better independent science and research for EU chemical safety policies. We would like to see this conveyed as a long-term vision in the draft Communication.

In addition to these points above, you will find detailed comments in track changes mode in the draft Communication attached, addressing these points with a compromise text as well as further suggested improvements. The Annex containing the Action Plan should reflect the main Communication, taking into account our comments.

Please do not hesitate to contact the Director of Food Safety Sabine Jülicher for any clarification.

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Electronically signed on 29/07/2020 14:06 (UTC+02) in accordance with article 4.2 (Validity of electronic documents) of Commission Decision 2004/563