EUROPEAN ENVIRONMENTAL BUREAU

Att:
Mrs Luisa Prista
Mr Otto Linher
Mr Maurits-Jan PRINZ

CC:
Mr Bjorn Hansen
Mrs Cristina de Ávila

Brussels, May 18, 2017

Dear Mrs Prista,

Thank you for the opportunity to share our views on the "Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation. Evaluation Report.", commissioned by DG Grow to the consultancies RPA, Okopol, Milieu and Riacrdo-AEA.

Indeed, the consultants did not have an easy task given the broad scope of the study and the number of pieces of legislation to be considered, and you will also have a hard work when summarising the results of the different studies and activities carried out under this exercise

When the study was launched last year, we already raised our concerns regarding the methodology[1], as the study seemed to be designed to focus on gathering the opinions and evidence from industry on the costs and burden of chemicals legislation, neglecting other stakeholders such as academia or health professionals who could give input on the societal benefits of regulating hazardous chemicals in the EU. We note that these shortcomings have now been reflected by the authors in the section on study limitations and would like to stress that these need to be clearly communicated when the final study will be published and discussed.

Although this refit exercise has given industry stakeholders a very good opportunity to provide evidence supporting their arguments made against EU chemicals regulatory framework, they have failed to seize this opportunity, as the consultants state when listing the study limitations (page 12): "The inability or unwillingness of companies to provide certain data creating difficulties in quantifying the impacts of CLP and other legislation".

Therefore we note that the **input to this study comes mainly from industry comments and opinions** provided through the public consultation and interviews rather than from data or studies supporting their claims and conclusions from this exercise need to be drawn carefully and would like to refer to the OECD's guidance for *Measuring Regulatory Performance: A Practitioner's Guide to Perception Surveys* for recommendations on how to refer to perception survey's in policy making annexed to this letter.

We welcome the general conclusion that the CLP Regulation is considered to be effective, efficient, relevant, coherent and to provide and added value to the EU. **Industry has not demonstrated the need for the radical changes in the EU Chemicals Regulatory Framework** that they have been asking for.

That said we remain concerned by a number of conclusions drawn which are either un balanced or not supported by evidence. :

1 NGO letter to Mr Timmermans, Ms Bienkowska and Mr Vella. http://www.eeb.org/?LinkServID=7398D6A8-5056-B741-DBADAFE73501741C&showMeta=0&aa

- The Executive Summary (page vi) and the Evaluation Report findings (page 17), state that current CLP rules may lead to over-classification and market distortions. The examples provided are the classification of skin corrosion/irritation and eye damage/irritation in mixtures. However, although the study reflects also that CLP may be leading to under-classification of industrial chemicals and negative impacts to human health and the environment, as several hazardous endpoints are not considered, such as endocrine disruption, immunotoxicity, neurotoxicity, terrestrial toxicity persistence or bioaccumulation, this is not included in the findings of the study or mentioned at all in the executive summary.

- When comparing generic risk considerations versus specific risk assessment, the Evaluation Report (section 3.2.8.4) states that *the generic risk approach may be leading to over-regulation where the route of exposure (e.g. via oral route inhalation, inhalation, etc.) is not relevant to the products covered by downstream legislatios."* The single example used to support this claim is etanol and the authors disregard the derogations that all regulations based on generic consideration include. However the study does not include any statement on how specific risk assessment may lead to under-regulation, given ist shortcommings when considering all negative health and environmental effects or assessing real life exposures.

- The statement regarding tests methods of the summary (page vi), stating that "*new test methods are to adhere with Good Laboratory Practice requirements or, for certain tests, relevant standards..",* however, the study does not come to this conclusion at all. Actually, section 3.2.5.2 Good laboratory practice (page 21) states that *"the experience of GLP monitoring authorities is that self -regulation does not work particularly effectively*" and referring to scientific research that "*not being GLP compliant should not undermine the validity of their work*".

- Page viii of the Executive Summary states: "*Other case study examples highlight the potential for significant costs to arise as a result of the automatic triggers that exist under the generic risk considerations approach (e.g. in relation to plant protection products) and the potential for regrettable substitutions or unintended consequences (e.g. impacts on recycling activities)*".

  The reference for this is Annex IV (page 62). However, looking at this text, again you find that the evidence provided comes from comments by industry stakeholders: "*ındustry stakeholders are of the opinion that the impacts on manufacturers, downstream supplychains and consumers are not adequately taken into account in most of the risk management decision making processes considered here. One industry association stakeholder opined that "the way regulations operate now is over protective and as such, valuable substances, the essential tools for farmers, are being lost and thus putting EU farming at a disadvantage in the global market".*
  Another stakeholder has commented that "if society wants affordable food commodities all year round then the continued use of PPP is essential and necessary. To realise a sustainable agricultural market in Europe, farmers must be allowed the tools to deliver crops competitively in a global market".

  As currently phrased by the consultants a false impression is given that there is substantial evidence supporting these claims which is not the case. At the same time, the consultants have not considered it important to highlight the societal benefits from reducing pesticide exposure through generic approaches, although evidence was provided by NGO through the public consultation.

- The executive summary as well as the evaluation report repeat several times the need for derogations based on socio-economic grounds:

  Page viii of the Executive summary states "*A major question concerns the extent to which endocrine disrupting substances are linked to health impacts and the magnitude of any effects from biocidal (or plant protection) exposures, which is not currently known. In the interim, the availability of derogations on the basis of risk, technical feasibility and economic grounds may be important to ensuring the overall efficiency of thelegislative framework in the future*".

  Page X of the Executive summary states: "*At the minimum, there need to be derogation possibilities based on a specific risk assessment approach and which includes consideration of more than just scientific criteria".*

Page 61 of the Evaluation report states: *The automatic triggers that exist as part of generic risk considerations may lead to disproportionate effects, given that they do not take into account substance and exposure specific factors, or technical and economic feasibility. ... In particular, the lack of derogations under the Plant Protection Products Regulations (and which is inconsistent with those for biocidal active substances) may result in disproportionate costs...(see section 6 of Annex IV and Case Study 11).*

However neither Annex IV or case study 11 provide any evidence on the need for such derogations.

On section 6.3. of annex IV you find again a statement: "*Derogations may increase the efficiency of the generic risk considerations approach, but only if they also take into account technical feasibility and socio-economic factors*", but no references or justification for this statement is provided in the text. Furthermore, Case Study 11 does not provide any evidence to support its conclusion that "*On balance, the most efficient way of avoiding outcomes which do not reflect a balance between costs and benefits is for legislation to take technical and economic feasibility into account as part of risk management decision making"".*

- The consultants sentence questioning if endocrine disrupting substances are linked at all to health impacts, which neglects not only the vast scientific knowledge on the issue, but also neglects the EU political consensus on the issue, exemplifies the bias towards industry stakeholder positions of the consultants delivering this study.

In light of the severe limitations stemming from the study's methodology, the lack of balance and the lack of justification of several of the conclusions stated by the consultants as highlighted above, we ask you to reflect on these conclusions with extreme caution when moving forward in the decision making process on the outcome of this Fitness Check and treat it for what it effectively is: the opinions of the vested regulated interests who have failed to provide any evidence for supporting these opinions.

Kind regards,

Dolores Romano

Senior policy officer- Chemicals and nanotechnology
European Environmental Bureau