Für Mensch & Umwelt

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Consultation on the regulatory fitness of chemicals legislation (excluding REACH including Annex XIII)

Attachment - 1

Dear Madam, Sir,

In March 2016 the European Commission launched a public consultation on the regulatory fitness of chemicals legislation (excluding REACH but including Annex XIII).

Being highly involved in chemicals legislation from different perspectives, the German Environment Agency (UBA) participated in the public consultation with focus on the following legislations:

- Biocides Regulation (EU) No 528/2012)
- Plant protection products (Regulation (EC) No 1107/2009)
- REACH-Chemicals (Regulation(EC) No 1907/2006)
- Classification and labelling (Regulation No (EC) 1272/2008)
- Detergent (Regulation (EC) No 648/2004)
- Persistent organic pollutions (Regulation (EC) 850/2004).

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- Pharmaceutical Directives 2001/82/EC and 2001/83/EC (as amended)
- Drinking water directive 98/83/EC

UBA also answered a MS specific questionnaire for CLP which was sent to RPA separately.

It is our impression that the questionnaire alone might not be sufficient to collect the most relevant information on the topic. Thus we would like to address some aspects we consider crucial with regard to evaluating the regulatory fitness of chemicals legislations:

In general, benefits of legislation for humans and environment are not adequately addressed in the questionnaire. Environmental impacts seem to be considered of lower priority than economic impacts and aspects of human health. As the healthy environment is the basis for healthy life, environmental impacts are equally relevant as economic impacts for society as a whole.
Even if hazardous substances are necessary to combat diseases, other regulative frameworks (e. g. the water framework directive, Drinking water directive and Groundwater Directive) have to address the environmental concerns of these substances adequately.

Some of the questions in the questionnaires are very generic. Answering them, having a wide variety of chemical legislations in mind, seems not appropriate in our point of view. Statistical analysis of tick-off boxes for such questions has a high risk of being flawed. More weight should be put on the free text answers.

The following paragraphs summarize the main aspects that should be considered during the fitness check from an environmental point of view:

With regard to effectiveness of legislation it is our opinion that improvement is needed in order to ensure a high level of protection for the environment. Implementing and considering the precautionary principle is of high importance to ensure a high level of protection for the environment. Enforcement needs improvement, and a careful analysis is needed whether or not current practices of granting authorization despite concerns raised during risk/hazard assessment are in line with the protection goal.

In general hazard identification for all chemicals and a subsequent hazard based risk management in line with the precautionary principle is supported by UBA.

In addition we are of the opinion that the following aspects need further considerations:

- Hazards such as persistence and bioaccumulation (including the terrestrial compartment) and endocrine disruption are not included in the CLP system although they are relevant parameters in regulation. Including them may improve consistency and reduce regulatory burden.
- With regard to nanomaterials, a harmonised definition for the various legislations is needed. Nanomaterials need to undergo an adequate risk assessment for which specific identification and information requirements are needed.
- The combined effects and exposures of complex environmental mixtures (e.g. sequential/parallel applications such as tank mixtures, discharge, coincidental or environmental mixtures) are not adequately addressed in all respective substance regulations. Different uses of the same compound under different legislations as well as the concurrent use of thousands of compounds in commerce can result in spatial and temporal peak exposures that are acceptable for the respective authorized use, however, adding to an overall environmental concern. This fact is not yet covered by any of the current risk assessment procedures.
- In some areas our knowledge is still scarce and e.g. specific test methods (OECD guidelines) are needed to improve hazard and/or risk assessment such as long term effects on invertebrates and endangered species.

With regard to efficiency we see possibilities for improvement such as decreasing double work among agencies, reducing unnecessary vertebrate testing and improving cooperation in the monitoring of substances. Implementing legal harmonized classifications for aspects not covered yet, which would also induce legal certainty for manufactures could reduce regulatory burdens for MS authorities.

The questionnaire is mainly focused on costs and we consider this inadequate. Although legislation puts a monetary burden on industry and society, those costs would need to be compared to benefits for humans and the environment and costs of non-regulation. With regard to the environment, it is our understanding that benefits of chemical legislation today are outweighing costs.

All chemical legislation is considered highly relevant with regard to the environment. From our point of view, the principle of precaution is essen-

tial in order to address emerging areas of concern in a sufficient time frame.

With regard to coherency gaps are identified which are considered significant and should be corrected as soon as possible:

- While Regulations (EC) No 1107/2009 and (EU) No 528/2012 cover the application of plant protection products and biocides they do not cover manufacture and formulation of such products and at the same time these substances are exempted from REACH registration requirements.
- Both directives 2001/82/EC and 2001/83/EC (as amended) do not cover the manufacturing and formulation of pharmaceuticals and at the same time these substances are exempted from REACH legal requirements.
- Cosmetics may contain environmentally hazardous substances, but are exempted from classification and labelling according to Regulation No (EC) 1272/2008
- For biocides, until now no harmonised approach has been established to minimise hazards and risks of biocides to human health and the environment during the use phase and on sustainable use of biocidal products. Moreover, there are gaps in the Biocide Regulation (EU) No 528/2012 concerning treated articles.
- An EU wide harmonized regulation for material in contact with drinking water is still missing. According to the drinking water directive 98/83/EC this is in the responsibility of member states but this is not in line with regulation 2679/98 on the functioning of the internal market in relation to the free movement of goods among the Member States.

REACH is not part of the current fitness check. However, REACH is one of the key regulations within the field of chemicals legislations and is substantially contributing to archive the global sustainability agenda (SDGs). By aiming for safe products and processes within the chemicals industry, REACH is an important driver also for other legislations.

One important aspect is the substitution of substances of very high concern (SVHCs). Improvements within REACH are needed for assuring the data quality (e. g. in registrations), by obligations to label SVHC in articles, by regulating chemicals in imported articles (e. g. in the authorization regime) and by better taking into account benefits for the environment when taking risk management measures (e. g. in socio-economic assessments within authorization or restriction procedures).

Yours sincerely

On behalf of

Klasen

Dr. Jutta Klasen
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