KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

MESSAGE/INFORMATION

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General comments from The Swedish Chemicals Agency in response to the Fitness Check on EU Chemical Legislation

The Swedish Chemicals Agency wish to append a Word version of the electronic consultation format with comments that are too extensive to fit in the format (see a separate, accompanying document) and this document where we set out our view on the broad issues and then some comments which address some specific issues not covered by the public consultation.

General Comments

EU legislation on chemicals is broad in its scope and often ambitious in its objectives to protect humans, the environment and animals within the EU.

In many ways the legislation is founded on sound principles. Improvements in detailed legislation and in implementation are always possible and we are able to identify several in this document and in our responses to the different questionnaires that have been distributed as part of the Fitness Check.

Sweden has an environmental goal to achieve a toxic-free environment. As part of the work towards that goal we are working to reduce chemical risks in our everyday environment. A sufficient knowledge about the chemicals to which we are exposed and an understanding of the risks from those exposures are prerequisites to being able to limit those risks to acceptable levels.

In our comments we identify several areas where we think that gaps exist in the legislation and where we would like to see legislation developed. However, we would point out that many improvements to chemical regulation within the EU could be made through better implementation throughout the legislative process - from writing clearer provisions, to improving application of provisions, to increased enforcement. These improvements in effectiveness can be made immediately and in many cases the costs involved would be offset by savings made by increased efficiency.

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A harmonised EU legislation is necessary for a high level of protection for human health and for the environment

A harmonised EU chemicals legislation is necessary to uphold a high level of protection for human health and the environment, as the effects of chemical use are transboundary and working towards harmonisation will ensure a high competence level of risk/hazard assessors and risk managers, and saves resources both for the authorities and for the industry. The high levels of protection are both a sign and a consequence of the relatively high level of development that we have within the EU. While restrictions should be reasonable, practicable and proportionate including a weighing against competitiveness issues, we should not let the balance weigh heavier for competitiveness than for protection. That would be to reverse the values of developed countries that lie at the heart of the EU.

Moreover it is important to look at the consequences, including economic consequences, of not having EU chemical legislation, both where we have it and where we lack it. There are several studies conducted showing costs of inaction for the society. For example the overall estimates of the cost of illness related to negative effects on human male reproduction due to the current yearly exposure to endocrine disruptors in the Nordic countries amounts to approximately EUR 36 million*. Other examples are given in the response to the public consultation.

At a practical level, EU legislation also enables work-sharing and avoiding of the double work that occurred before EU legislation was enacted. Additionally, national legislation would never have got as far in this time in all the EU Member States.

However, to achieve an even higher level of protection for the human health and the environment there is a need for a better implementation and enforcement to ensure that all companies substitute restricted chemicals as the law dictates.

A harmonised EU legislation also stimulates innovation when legal restrictions are being imposed to move the markets away from chemicals posing risks. That situation may be even more improved as more decisions are taken on risk reduction measures which involve the substitution of chemicals.

High priority issues

CLP – a hazard-based system

A hazard-based approach is important: The hazard-based classification system is a key part of the chemical legislation in the EU and it is, in our view, essential that it remain hazard-based and that it is only based on intrinsic hazardous properties. It forms a common starting point for all down-stream hazard- and risk-based measures that need to be taken within the context of different use areas. The classification system is a codification of hazardous effects which enables risk managers (and others) to understand the essence of the hazardous properties that have been identified for a substance.

*http://www.norden.org/sv/publikationer/publications_results_view?SearchablePublicationsText=edc

It does not of itself limit how a substance is to be used or not used unless lawmakers, policy makers or risk managers wish to use the code to do that in later, separate stages of chemical risk management. Where risk assessment is necessary and consideration of socioeconomic factors is required in order to reach decisions over the possible continued use of hazardous chemicals, these processes can and should take place according to "downstream" legislation but the classification system itself should remain hazard-based so that it is more easily applied to a variety of downstream uses.

One of the advantages of CLP is that companies can apply the classification criteria themselves to their substances. This triggers the application of all following label and packaging requirements, and even downstream risk reduction measures in other legislation, so that a lot of risk reduction is achieved without harmonised decisions having to be made on all substances.

Further development of CLP: The development of alternative test methods to refine, reduce and replace animal testing is welcomed by the Swedish Chemicals Agency. In some areas the test methods are quite advanced. The potential to apply these methods to tests for regulatory purposes (within both the EU and OECD) is limited by companies' need in downstream legislation to know what the classification of the substance should be for a given endpoint (sensitisation, cancer etc.). As stated elsewhere, we support the generic risk management approach of downstream legislation referring to classifications.

Consequently if these two areas of development (alternative test methods and generic risk assessments) are to be compatible, there is a need for development of classification criteria for the alternative test methods. This is an area of work that could give considerable increases in effectiveness and efficiency in regulatory processes.

Implementation of GHS: Thanks to CLP (and partly REACH) the implementation of GHS have reached a high level of harmonisation and been cost effective for the EU member states.

There is an urgent need for scientific criteria for endocrine disruptors

We regret that the European Commission has not fulfilled their legal obligation to deliver scientific criteria for identifying endocrine disruptors for decision making. This represents a significant difficulty in our ambition to reduce exposure to endocrine disruptors from our everyday environment. This means that incomplete interim criteria and work arounds are at present used for pesticides and industrial and consumer chemicals under REACH.

Combination effects have to be taken into account

The chemical legislation does not in general take into account the exposure to multiple substances. Therefore, the setting of quality standards and thresholds for individual chemicals is insufficient for ensuring a non-toxic environment and the protection of human health. Hence, the chemicals legislation needs to be developed to consider exposure from chemical mixtures.

A nanomaterial-specific regulation is needed

There is a need to provide specific regulations for nanomaterials. In the absence of such legislation then revisions of current legislation should clarify how provisions apply to nanomaterials for example, in the way that the Biocidal Products Regulation clarified that nanoforms are not covered by approvals of normal substance forms.

Non-toxic environment for children not just about toys

Specific provisions for the protection of vulnerable groups such as born and unborn children and youths should be incorporated into all chemical legislation and not only that for toys.

A circular economy without recirculation of hazardous substances

In order to obtain a toxic-free and resource-efficient recycling and to create a market for secondary material of high quality, the content of hazardous substances in materials/articles must be addressed in the Waste legislation. The same requirements of risk reduction should be set for secondary materials as for virgin materials, since hazardous substances are equally hazardous in both cases. This is vital to avoid secondary materials being regarded as of lower quality. Information on the composition of materials throughout the lifecycle, including the waste and recycling stages, is crucial in order to achieve a circular economy with an improved level of protection for human health and the environment.

Other specific comments

These short comments address some specific issues.

Simplified environmental risk management

We consider that the methods for environmental risk assessment are complex and resource-intensive for both Governments and businesses, in particular for plant protection products. The current trend is, moreover, that the complexity of the assessments is increasing with new guidance documents. It is even questionable whether this is a scientifically sound development. It is therefore important to analyse how environmental risk assessments can be simplified in such a way that the

scientific quality remains high, it becomes easier to compare risks between different preparations and resource requirements are reduced.

Grouping of substances for a better protection of human health and the environment

The number of substances that need to be regulated (restricted, approved, not approved etc.) within different chemical legislations has grown dramatically. Grouping of substances with similar properties has become a necessary strategy to get an overview of the existing substances in the society of today. The grouping of substances facilitates prioritization and later a regulation of substances for a better protection of human health and the environment. Where regulations permit a collective control is often a more effective way to achieve results.

Requirements and procedures for the evaluation of groups of substances should be developed by taking into account lessons learnt from relevant evaluations. The choice of which substances are included in a group is important, especially in the early days, to maximize the possibilities for read-across and other alternative approaches to animal studies.