Ref. Ares(2014)94701 - 17/01/2014

Brussels, 16 January 2014

Cefic paper on Commission impact assessment on criteria for endocrine disruptors

Summary

With the expectation that the European Commission will initiate an impact assessment (IA) on the policy options for endocrine disruptor (ED) criteria for biocides, this paper makes a number of suggestions to ensure a reliable outcome.

We suggest that:

- The impact on the biocides industry should be assessed separately and individually, recognising that the number of active substances still available for use in biocidal products has already been reduced by 75% since 2003 (i.e. from approx. 1000 to 250);
- The IA should be sufficiently detailed to provide a meaningful assessment (i.e. including specific uses and targets within each product type (PT)) upon which to compare policy options and to make decisions.
- When defining the policy options, including a baseline reference, the envisaged purpose of the IA needs to be upheld, namely to establish clear criteria that will enable the regulators to identify with legal certainly the ED substances of high regulatory concern;
- Both intended and unintended impacts of the policy options should be assessed for the following: impacts on human health and the environment; socio-economic impacts (risk-benefit), trade impacts and global competitiveness of the European biocides industry, competition implications of generating a published list of "suspected" ED biocides (used as a "black list");
- To provide a credible evaluation, the IA should be adequately resourced and should be undertaken by a group of experienced and independent experts. Given the relatively small but specialised and fragmented nature of the biocides market, we strongly recommend that input from stakeholders (including producers, formulators and end-users) should be actively solicited from the outset.

Background

The biocides industry in Europe is extremely diverse and composed of primarily SMEs, operating in many niche markets that are gathered within 22 product types, according the Regulation 528/2012 which governs the placing on the EU market of biocidal products. In the last decade, the number of existing active substances available for use in biocidal products has decreased from close to 1000 down to around 250, with just 5 new actives submitted for evaluation and approval. Many of the decisions to cease support for existing actives have

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been driven by the scale of costs involved in complying with the requirements of the legislation versus the market size available to the corresponding products.
Since 1 September 2013, the Biocidal Products Regulation (528/2012) applies to the biocides market and includes a provision to exclude active substances that meet the criteria for endocrine disruption (ED). To date, these criteria have not been agreed but interim criteria are referred to in the legislation and apply to existing active substances.
During 2013, DG Environment presented a draft recommendation for the criteria for the identification of ED intended to be applied to pesticides, biocides, general chemicals and cosmetics. DG Environment and DG Sanco have since been asked to prepare an IA comparing possible policy options for the criteria. Based on the outcome of the IA, DG Environment and DG Sanco are expected to prepare legislative proposals specifying the criteria for the determination of ED.
This paper describes Cefic's suggestions on the elements and information that we believe should be considered by the Commission in preparing and undertaking the IA for biocides.

Scope and level of analysis

Cefic recommends that the impacts on biocides should be assessed separately and individually.
The IA should be sufficiently detailed to provide a meaningful assessment (i.e. including specific uses and target organisms within each product type (PT)) upon which to compare policy options and to make policy decisions.
It is essential that specific consideration be given to the potential occurrence of resistance in target harmful organisms where further loss of active substances/chemical classes within an already greatly reduced portfolio would be a consequence of applying the criteria.
Cefic strongly recommends that if the Commission does undertake a substance by substance evaluation on all or a subset of substances, then the results of this assessment should not be published in way that creates a public list of suspected endocrine disruptors: past experience has shown that some stakeholders may use such a list as a "black list" thereby introducing the potential for unfair competition.

Gathering information and consulting stakeholders

Cefic encourages the Commission to ensure that the appointed experts who conduct the IA will actively solicit input from industry and other stakeholders in this diverse and fragmented market. Further to information relating to the number of substances concerned, data on the socio-economic, risk-benefit impacts should also be included as well as information relating to anticipated health and environmental benefits.
In addition to an active stakeholder consultation, Cefic supports a public consultation period of at least 3 months (via written, web based procedure).

Defining the policy objective

According to Regulation 528/2012, one key objective of Commission's policy is to ensure a high level of protection for human health and the environment, while recognising that biocidal products are necessary to provide and support a healthy and safe living environment for European citizens. Cefic believes that measures to achieve this objective should be

underwritten by scientific risk assessments that recognise the benefits (economic, health) provided by the correct and safe use of biocidal products.

Defining the policy options

The Commission is expected to define different policy options upon which the IA will be performed. In developing the policy options, we ask that the following considerations are made:

- A baseline reference needs to be established;
- The regulatory consequences of each policy option need to be clearly identified and should not leave any ambiguity. In this context, we believe that the purpose of the IA is to establish such criteria that enable the regulators to identify with legal certainly the ED substances of high regulatory concern;
- A hazard characterisation option, including potency, irreversibility, severity, lead toxicity needs to be included. Also, as no single toxicological endpoint can characterise a substance as ED, a weight-of-evidence approach of all the scientific data submitted as part of the biocides regulatory regime is necessary.

Intended and unintended impacts of the above policy options should be assessed for the following: impacts on human health and the environment; socio-economic impacts (risk-benefit), trade impacts and global competitiveness of the European biocides industry; and competition implications of generating a published list of “suspected” ED biocides (used as a “black list”)

Assessing economic, social and environmental impacts

We understand that the Commission is expected to assess the likely economic, social and environmental impacts, both intended and unintended for each policy option. The analysis should provide information on the impacts of the options as net changes. Thus the options can be compared against one another and against the baseline reference.

Cefic believes that the following specific factors and indicators should be included in the IA:

- potential occurrence of resistance in target harmful organisms
- availability of affordable and effective alternatives
- CO2 emissions of available chemical or non-chemical alternatives
- Life Cycle Analyses
- market value of biocides
- prices of products to end users
- costs
- employment (including downstream sectors and especially SMEs)
- impact on innovation

Comparing options

The results of the impact assessment across the different policy options are expected to be evaluated considering the criteria of effectiveness, efficiency and coherence. A summary overview of all the positive and negative economic, social and environmental impacts for the options analysed is expected to be prepared together with a ranking of the options. A cost-benefit analysis should also be part of this analysis.

Resourcing

In order to provide a credible and meaningful evaluation, Cefic appreciates that significant resources will be required, and that these should be independent. Nevertheless, the evaluation needs to reflect a thorough knowledge and appreciation of the diverse and fragmented nature of the European biocides industry. We therefore strongly recommend that seeking direct input from stakeholders, including producers, formulators and end users is absolutely fundamental to completing a reliable impact assessment.

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