

DRAFT AGENDA – BIOCIDES INFORMATION EVENT, BRUSSELS, 23 MAY 2008

The European Parliament and Council Directive 98/8/EC (hereafter 'the Directive'), adopted on 16 February 1998, regulates the placing of biocidal products¹ on the EU market. It sets out a Community harmonised system for the authorisation and placing on the market of biocidal products; for the mutual recognition of these authorisations within the Community; and for the establishment at Community level of a positive list of active substances which may be used in biocidal products.

Before the Directive came into force, many Member States did not have any form of authorisation regime for these products and little was known about the wide range of active substances and products being used on the European market. Over the last eight years, active substances that were of marginal use, along with a number that had unfavourable environmental or health profiles have been removed from use as part of a significant streamlining of the market in these products. A robust process of assessment of the active substances has been set up, with a system of peer review that delivers a high level of protection of human health and the environment.

However, the Directive is now due for revision, and the report into the implementation of the Directive has revealed a number of issues that need addressing. These are divided into four sessions, each focusing on one of the key aspects of the revision.

10:00 – 10:50 – OPENING SESSION – *Chair – Commission representative*

Welcome and introductory presentation on the Commission's principal objectives for the revision.

Outline and progress of the impact assessment by a Commission representative

Each session will allow time for questions, comments, and discussion from the floor.

10:50 – 12:00 FIRST SESSION – **Simplified procedures and data requirements**

Presentation by a Commission representative

Although there are a number of articles in the Biocides Directive that allow for simplified procedures or reduced data requirements, it comes out clearly from the implementation report that these are either not clear in the Directive or are not currently well used. Remaining questions include:

- The functioning of the data waiving regime – would making the circumstances in which data waiving should be applied clearer and more binding improve the operation of data waiving? Should Member States play a more active role in informing companies of their rights and possibilities?
- Should the concept of frame formulation be abandoned and replaced by the notion of major and minor changes?
- Should the concept of low-risk products/substances be modified, perhaps in line with a notion of tiered data requirements, or focusing more clearly on low hazard substances (for example, the US concept of 'biopesticides').

¹ Formerly known as 'non-agricultural pesticides'.

- Should there be a list of commodity substances generated in co-decision (as opposed to the current approach where only examples are given)?

12:00 – 13:00 SECOND SESSION – **Data sharing and protection**

Presentation by a Commission representative

The aim of the Commission is to find a balance between protecting and rewarding innovation, whilst not allowing the Biocides legislation to be used to stifle competition. In addition, the Commission wishes to reflect the outcome of the REACH Regulation whereby vertebrate animal testing is reduced through forced data sharing and a compensation mechanism.

Relevant questions include:

- The Commission has encountered a number of data sharing/data protection issues at substance level, notably around a commercial interest in being considered as a participant in the review programme. Should forced data sharing also apply to new active substances in order to address this?
- On what basis should compensation be allocated – equal share, based on market shares, should there be an obligatory recourse to arbitration beyond a certain point?
- What data should be protected and for how long? Should older studies be protected?

13:00 – 14:15 – LUNCH

14:15 – 15:30 – THIRD SESSION - **Product authorisation and fees**

Presentation by a Commission representative

It is clear that as a minimum, the mutual recognition system should be made clearer in order to achieve a genuine internal market for biocides, one of the key objectives for the EU biocides legislative framework. More centralised options such as a single Community authorisation (one Member State decides for all) or a centralised system with or without Community Agency are also being assessed in the impact assessment.

Remaining questions include:

- What could be done (whilst retaining the same fundamental structure) to improve the operation of mutual recognition?
- Are there some types of products – industrial products, those with low exposure, or those that are not used by consumers for which a differentiated (and more centralised) procedure might be useful? What could such differentiation involve?

One of the outcomes from the study on the implementation of the Biocides Directive is that the fees charged are extremely variable from Member State to Member State. In addition, these fees may be disproportionately high for SMEs. Given that many Member States charge according to the actual work done, it seems difficult to have full harmonisation, or to offer reductions per application for SMEs. However, we would welcome your views on:

- The utility of partially harmonising the fee structure – ie one fee per product or additional fees for each product type in which the product will be used
- The possibility of an obligatory annual fee, incorporating reductions for SMEs

15:30 - 17:00 FOURTH SESSION - Scope issues – treated objects and relationship between biocides and other legislation

Presentation by a Commission representative

The current state of play under the Biocides Directive, where objects that are treated with or contain biocides that have no external effect (wood preservatives on railway sleepers, preservatives in paint cans, textiles treated to prevent mould) can be freely imported into the Community, even where those biocides are not legally authorised in the EU, to be discriminatory against EU business and to have potential health and environment implications. An extension of the obligation to use only approved biocidal products on such treated objects, accompanied by a labelling obligation, would be the basis for remedying this problem. However, key questions remain around the implementation and enforcement of this obligation:

- Should the ban apply to active substances only, or should biocidal products that are only used on treated objects have to be authorised? Alternatively, should treated objects that use active substances allowed under the Directive have to be authorised as biocidal products?
- Should the obligation be accompanied by a labelling obligation (for all treated objects) in order to facilitate enforcement and inform consumers?

CLOSING – 17:00 – 17:30

Conclusions from the Chair.