

## BIOCIDAL PRODUCTS DIRECTIVE 98/8/EC

According to the provisional list of notified substances, there are now more than 380 substances listed as notified - many of which are classified as conditionally accepted or fully accepted. If you are involved in the supply chain as a producer, importer or formulator, it is important to check that the active substances you wish to continue to supply into the EU have been notified and, more importantly, that the notifications have been fully accepted. Only fully accepted notifications will move to the evaluation phase for Annex I listing. Also, please note that non-notified substances will be removed from the market.

The list of identified substances is considerably longer than the list of notified substances, but it contains substances that appear on both lists. Following publication of Commission Regulation (EC) No. 1687/2002 regarding the additional period for notification of certain active substances already on the market for biocidal use, it is of value for companies who only identified substances to review their position and consider upgrading their identifications to the status of a notification. Because cost is a major factor associated with full approval, the formation of, or joining, a consortia may considerably reduce the capital outlay.

Under the First Review Regulation, (EC) No. 1896/2000, those wishing to support an active substance for eventual inclusion on to Annex 1, 1A, or 1B of the BPD (98/8/EC) had to first notify the substance to the Commission before March 28<sup>th</sup> 2002, provide a limited amount of data and specify the product types in which the substance is used. From this information, the Commission began to compile a list of substances for which they had received notifications. A similar list of identified actives has also been compiled. As the information contained in the compiled lists was not available to all interested parties until after the deadline date, it was agreed that an additional period of time be granted to allow companies to:

1. Upgrade an existing identification to a notification
2. To add product types to an existing notification

The new deadline for upgrading or adding a notification is 31<sup>st</sup> January 2003. Submissions must be made in accordance with Article 4(1) of the First Review Regulation, (EC) No. 1896/2000.

Discussions are ongoing to find the most suitable way to allocate accepted notified substances for evaluation by the Rapporteur Member States (RMS). It is critically important that suppliers covered by the first review for Product Types 8 (Timber Preservatives) and 14 (Rodenticides) know who to talk to regarding the preparation of dossiers due for submission in March 2004.

At present, active substances could be allocated according to the number of votes a member state has in the Council. This would mean that Germany, France, UK, Spain and Italy, who have a total of 48 votes between them, will together be responsible for over 50% of the active substances, whilst countries such as Denmark and Finland with 3 votes each will have an allocation of 3.3% each.

There is a desire to maximise existing expertise in the member states, particularly those where regulatory assessments have already been carried out or are "in progress." To accommodate this, member states can "volunteer" for active

substances particularly where there is previous experience with one or more actives under other regulatory initiatives, e.g., HPV, PPV, and new and existing substances. Another proposal is for the allocation of substances of similar chemical type to a RMS. Preference from industry is not one of the criteria under consideration, so it may be in the supplier's best interest to watch this exercise carefully.

Critical to the evaluation process is the pending publication of the new risk assessment Technical Guidance Documents (TGDs). They are aimed at protecting all aspects of the environment including air, soil, sediments and water and take into account manufacture, formulation, downstream users and disposal. Changes have been made to almost every section of the original TGDs, with a new section covering the assessment of risk from chemicals in the marine environment. A major change is the application of the risk assessment TGDs to biocidal products, the first of which will go into review in March 2004.

For the environmental assessment, there are new requirements such as the use of Predicted No Effect Concentrations (PNEC) for protozoa in sewage treatment plants and secondary poisoning. The marine risk assessment allows for the use of data on freshwater organisms but allocates an additional assessment factor. There are criteria for chemicals classed as PBT (Persistent, Bioaccumulation and Toxic) and vPvB (*very* Persistent *very* Bio-accumulative) as well.

The Exposure risk assessment will take into consideration service life emissions, intermittent releases, the use of monitoring data and the effect on waste treatment facilities. The human health risk assessment features a preference for NOAELs, the use of epidemiological data, a greater flexibility in the choice of tests to be performed and a move towards the use of benchmark doses. There is a preference for *in vitro* test methods and a greater emphasis on the inclusion of toxicokinetic data. As the risk assessment process will be applied to a wider range of chemicals, it will inevitably lead to an increase in regulatory and technical input and financial expenditure.

Commission regulation (EC) 1112/2002 sets forth detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the marketing and use of plant protection products. This regulation came into force in August 2002 and the deadline for compliance is November 1, 2002. Notifications of an intention to support active substances listed in Annexes I and II need to be submitted by the deadline date. Failure to do so will lead to the removal from the market of products containing unsupported active substances.

#### What can Steptoe & Johnson do for you?

If you want further information or assistance with any aspects of the BPD, please call:

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