The BPD in Germany

June 2004 saw the publication by the Federal Institute for Occupational Safety and Health (BAuA) of the "Guidance for authorisation of biocidal products." Although the BAuA is the authorising authority, the review and authorisation of biocides involves a number of departments including:

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU).
Federal Environmental Agency (UBA)
Federal Institute for Risk Assessment (BfR)
Federal Institute for Materials Research and Testing (BAM),
Robert-Koch Institute (RKI)

The Guidelines provide information on a number of key topics.

Frame-formulations

This allows authorization of a group of biocidal products that are essentially the same and are to be used in the same use categories. Changes in formulation are allowed where there is :

- a reduced concentration of the active biocidal substance
- a change in the ratio of substances which are not active biocidal substances
- changes in the pigment, colouring agent or fragrance used. Any substitution must have the same or a lower risk and should not have an adverse effect on the efficacy of the product.

Data Protection

A letter of access is necessary where a second applicant requires use of protected data owned by the original registrant. Anyone planning to start a new toxicity study involving vertebrate animals must first send an enquiry to the authorities to determine if that data already exists.

Where the data is still protected, the authorization unit will inform both the data owner and new applicant of the requirement to use the data and pass on contact details of both parties.

Financial compensation is payable to the data owner for use of such studies and is set at 50 % of the costs saved by the new applicant.

Should the owner refuse to allow the use of their data, the registration process will be placed on hold until the applicant is able to produce the necessary study reports.

Classification, packaging, labelling and advertising

As of 30 July 2004, all active biocidal substances and products must be classified, packaged and labelled in accordance with:

Directive 1999/45/EC - the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations (New Preparations Directive).

Ordinance for the Protection against Hazardous Substances (Hazardous Substances Ordinance – GefStoffV) (§§ 12 Section 11, 54 Section 7 Hazardous Substances Ordinance).

Phrases considered to be misleading, e.g. low-risk biocidal product", "non-toxic" or "harmless," cannot appear on the label or in supportive literature

The label must also include the name of the active substances, an authorization number, type of preparation, use categories, instructions for use and any direct or indirect side effects. Where possible, reference should be made to an enclosed information sheet.

All advertising must include the phrases: Use biocides safely; Always read the label and product information before use. Both must stand out from all other wording.

Fees for the authorization of biocidal products

A range of fees payable for the authorization of active substances and biocidal products are described in the guideline document.

Key are the fees for the assessment of a biocidal active substance which range from 75.000 € to 100.000 €, whilst authorization of a biocidal product will cost between 10.000 € and 45.000 €. Where the biocidal product is the subject of a frame formulation, the fee is reduced to 750 €.

Poisons Information

Information about biocidal products on the market must be passed on to the BfR. This includes, the trade name, composition, labelling and emergency measures in case of accident.