EUROPEAN COMMISSION
DIRECTORATE-GENERAL
Joint Research Centre

Joint Research Centre

Occupational Safety and Health issues in the Biocidal Products Directive

Kirsten Rasmussen

Workshop: "Occupational Safety and Health during the Use of Biocides". BAuA 3-4 April 2006

ihcp

This presentation:

Occupational Safety and Health in the Biocidal Products Directive

- Under which aspects does the BPD refer to occupational risks?
- Which decisions depend on workplace risk assessment?
- What instruments are foreseen for risk management in the BPD?
- Which aspects are relevant for Annex I inclusion?

Legal Frame: Under which aspects does the BPD refer to occupational risks

Directive 98/8/EC concerning the Placing of Biocidal Products on the Market

Two steps:

1. Active substance that is evaluated and entered onto Annex I (or IA or IB) of the BPD.
2. Biocidal products are authorised in the Member States, and MS work with mutual recognition.

i.e. the directive aims at placing safe products on the market

Legal Frame: Under which aspects does the BPD refer to occupational risks

The data requirements are divided into 4 parts:

Core data (Annex IIA) and additional data (Annex IIIA) for the active substance, and

Core data (Annex IIB) and additional data (Annex IIIB) for the biocidal product authorisation

Legal frame: Under which aspects does the BPD refer to occupational risks

The Directive has 4 Main Groups (MG) divided into 23 Product Types (PT):

- MG 1. Disinfectants and general biocides (5 PT)
- MG 2. Preservatives (8 PT)
- MG 3. Pest control (6 PT)
- MG 4. Other biocides (4 PT)

Legal frame: Under which aspects does the BPD refer to occupational risks

About 375 Substances are listed in Annex II of Regulation (EC) No 1048/2005 and should go through the review programme

The substances may be used in several product types and for EACH product type a risk assessment, including an exposure assessment, has to be made.

Legal Frame: Under which aspects does the BPD refer to occupational risks.

Exposure data requirements for active substances

Annex IIA 2.10 : Exposure data in conformity with Annex VIIA to Directive 92/32/EEC (New industrial Chemicals).

Annex IIA 5.6 : User: industrial, professional, general public

Annex IIIA 3 : Studies related to the exposure of the active substance to humans

Legal Frame: Under which aspects does the BPD refer to occupational risks, cont.

Annex IIIA 5. If any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, are considered necessary, then the test(s) referred to in Section XI, part 2 shall be required.

Annex IIIA XI.1.4. Estimation of potential or actual exposure of the active substance to humans through diet and other means.

Annex IIIA XI. 2. Other test(s) related to the exposure to humans

Legal Frame: Under which aspects does the BPD refer to occupational risks.

Annex IIB Ch. V. INTENDED USES AND EFFICACY

- 5.2. Method of application including description of system used
- 5.3. Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes

Legal Frame: Under which aspects does the BPD refer to occupational risks.

Annex IIB V. INTENDED USES AND EFFICACY

- 5.4. Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals
- 5.9. User: industrial, professsional, general public (non-professional)

Legal Frame: Under which aspects does the BPD refer to occupational risks.

Annex IIB 6.6. Information related to the exposure of the biocidal product to man and the operator.

Annex IIIB XI.2. Other test(s) related to the exposure to humans

Legal Frame: Under which aspects does the BPD refer to occupational risks.

Annex VI (Product Evaluation), definitions:

(b) *Dose (concentration) — response (effect) assessment*

This is the estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

Legal Frame: Under which aspects does the BPD refer to occupational risks.

Annex VI, cont.

Definitions cont., (c) *Exposure assessment*

This is the determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

Legal Frame: Under which aspects does the BPD refer to occupational risks.

Annex VI, para. 33. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly via the environment) for which exposure to a biocidal product occurs or can reasonably be foreseen. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.

Legal Frame: Under which aspects does the BPD refer to occupational risks.

Conclusion for the legal text:

The occupational risks are vaguely described for the active substance.

For the product, there is a requirement to assess if it can be used safely. This includes professional use; it is unclear if how far the manufacture of the product is included.

This presentation:

Occupational Safety and Health in the Biocidal Products Directive

- Under which aspects does the BPD refer to occupational risks?
- **Which decisions depend on workplace risk assessment?**
- What instruments are foreseen for risk management in the BPD?
- Which aspects are relevant for Annex I inclusion?

Which decisions depend on workplace risk assessment?

Under the BPD there are two kinds of basic legal decisions:

1. Entry (or not) of an active substance onto Annex I (or IA or IB) of 98/8/EC, based on risk assessment of the active substances.
2. Authorisation of a product based on product evaluation

Which decisions depend on workplace risk assessment?

An a non-inclusion of an active substance into Annex I can not be justified based only on risks (exposure) related to manufacture of that active.

A product may be refused authorisation based on risk, this includes products for professional application only.

This presentation:

Occupational Safety and Health in the Biocidal Products Directive

- Under which aspects does the BPD refer to occupational risks?
- Which decisions depend on workplace risk assessment?
- **What instruments are foreseen for risk management in the BPD?**
- Which aspects are relevant for Annex I inclusion?

ihcp

What instruments are foreseen for risk management in the BPD?

The risk management under the BPD are divided into two categories :

(A) Outside the BPD:

- Classification and labelling
- Community Legislation that limits or ban certain uses (76/769/EEC)
- Legislation for the protection of workers
- Council decisions on international conventions (UN, OSPAR)
- National rules to control local emissions

What instruments are foreseen for risk management in the BPD?

(B) Within the BPD for the active substance

- Risk Assessment of active substance
- Time limited Annex I entry
- Re-evaluation if new information is available
- Non-inclusion of the active substance in Annex I
- Comparative assessment
- Poison control centre information
- 76/769/EEC

What instruments are foreseen for risk management in the BPD?

(B) Within the BPD for the product

- Product authorisation, necessitating information both for the active substance and substances of concern in the product, and information on the use of the product (to derive the exposure).

Which aspects are relevant for Annex I inclusion?

Annex I inclusion requires a complete dossier for an active and one safe use of a product [MS actually wish representative uses(s)] demonstrated with a product dossier.

Annex IA requires that the active substance is not: CMR or sensitizing, or bioaccumulative

This presentation:

Occupational Safety and Health in the Biocidal Products Directive

- Under which aspects does the BPD refer to occupational risks?
- Which decisions depend on workplace risk assessment?
- What instruments are foreseen for risk management in the BPD?
- **Which aspects are relevant for Annex I inclusion?**

Which aspects are relevant for Annex I inclusion

For the Annex I inclusion it is relevant to demonstrate that the active substance can be used safely in product(s). This includes safe use of product aimed at professional use.

If the active substance / product is manufactured outside the EU, no information regarding manufacture is needed.

Which aspects are relevant for Annex I inclusion

If the active substance / product is manufactured within the EU the ‘standard’ risk reduction measures (option (A) previous slide) apply, and are in most cases sufficient to address occupational risks.

Other requirements are vague in the legal text.

A substance cannot be excluded from annex I based on occupational risks related only to manufacture.

Exposure Assessment

Exposure Assessment under the BPD is based on Use Pattern. The following guidance is available:

- TNsG Human Exposure to Biocidal Products, Guidance on Exposure Estimation (2002)
- User's guidance for human exposure assessment for wood preservatives and rodenticides

In addition the TGD on Risk Assessment contains some guidance

Exposure Assessment

The TNsG on Human exposure to Biocidal Products recommends:

Use available data

Use models to fill data gaps

Use a Tiered approach, exposure combined with hazard information:

- **Operators, professionals, workers and bystanders**
  - Step1: Worst Case Approach
  - Step 2 and 3: Refined exposure estimation (e.g. with PPE)
  - Step 4: Field study

Further information on the Review Process

ECB web page: http://ecb.jrc.it/Biocides

- Lists of identified and notified substances (reg. 2032/2003 and 1048/2005)
- Technical Notes for Guidance on Annex I inclusion
  TNsG on data requirements
  TNsG on dossier preparation
  TNsG on product evaluation
  TNsGs on environmental emission scenarios/on human exposure

DG ENV: http://europa.eu.int/comm/environment/biocides/index.htm

- Basic Principles
- Scope/Borderline documents, manual of decisions

These homepages are updated on a regular basis.