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Development of a concept for the environmental risk assessment of biocidal products for authorization purposes (BIOEXPO)

- Executive summary -

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1. Introduction

The Biocidal Products Directive (Draft 97/C69/03; latest version December 12th 1997, 95/0465 (COD); PE CONS 3633/97) will complete the European chemicals regulation, which consists of the directives on existing substances (Council regulation 793/93), new substances (Directive 92/32/EC) and agricultural pesticides (Directive 91/414/EC). Biocides include a wide range of product types, such as pest control products, disinfectants, preservatives, and antifouling products. In Annex V of the Biocidal Products Directive, 23 different product types are defined. The Biocidal Products Directive will regulate the authorisation of biocidal substances and products on the European market. It will also harmonise the authorisation schemes for biocidal products, through the use of common principles, with these authorisations being mutually acknowledged in all member states (with certain exceptions). Three Technical Guidance Documents are being prepared in 1997-1998 to facilitate the implementation of the Biocidal Products Directive.

The objective of the BIOEXPO project is to develop specific data requirements for biocidal product types, taking into account:
- Product-specific characteristics, such as formulation and application;
- The life cycle, including the manner of application, the use of treated products, and disposal;
- Exposure, including the identification of the main environmental compartments which are expected to be exposed.

The results of the project can be used as input for the discussions on the elaboration of Annex III of the Directive, were data requirements are proposed (in addition to the common core data set of Annex II of the Directive).

The project focuses on the data requirements necessary for an environmental risk assessment of biocidal products; occupational exposure and human health fall outside the scope of the project. Furthermore, the project is focused on chemicals; biocidal products containing fungi, micro-organisms and viruses as active ingredients are not considered. In this project, the application phase of the life cycle of biocidal products is considered, as well as the disposal of treated materials. The Directive is not conclusive as to whether or not the production and formulation phases should be considered. Due to the fact that that the project focuses on environmental releases during the use of specific biocidal product types, and that they can only be regarded as products after formulation, these phases have not been included in this report.

2. Project organisation

Intermedate results were discussed as technical notes at three workshops, organised by the Umweltbundesamt. The workshops were attended by experts from UBA and international experts on biocides and exposure assessment. The following institutions were represented at one or more of the workshops:

- Bundesministerium für Umweltschutz, Naturschutz und Reaktorsicherheit, Germany
- College Toelating Bestrijdingsmiddelen (CTB), The Netherlands
- European Chemicals Bureau (ECB), Italy
- European Commission, Belgium
- Finnish Environmental Institute (FEI), Finland
- Ministère de l'environment, France
- National Chemicals Inspectorate (KEMI), Sweden
- Rijksinstituut voor Volksgezondheid en Milieu (RIVM), The Netherlands
- Robert Koch Institut (Bundesinstitut für Infektionskrankheiten und nicht übertragbare Krankheiten), Germany
- Umweltbundesamt, Germany

3. Framework for setting data requirements

Environmental compartments and product types

The BIOEXPO project has a compartment-specific and a product-specific component. In the compartment-specific section, the basic question posed is: "What kind of data, in addition to the common core data set of Annex II of the Directive, is necessary for an appropriate risk assessment of a biocide in a given environmental compartment?". Potential data requirements are discussed for the following environmental compartments:

- Fresh surface water (incl. sediments)
- Marine surface water (incl. sediments)
- Soil (incl. groundwater)
- Sewage Treatment Plant (STP)
- Air

Within the product-specific section, the life cycles of the 23 biocidal product types of Annex V of the Directive are analysed, and the main exposed environmental compartments are identified for each product type.

Criteria for setting data requirements

Any test results, which are required in addition to the core data set (Annex II of the Directive), must be weighed and evaluated taking into consideration its pro's (e.g., enabling and improving risk assessment) and con's (e.g., costs). In the BIOEXPO project, additional data is evaluated using four criteria:

1. **Benefits**: Improvement of the risk characterisation due to the use of additional test data (i.e., the need must be clear). Furthermore, additional data is needed to ensure an 'appropriate risk assessment', as laid down in the Common Principles.
2. **Compatibility with risk assessment methods**: Test results must be compatible with generally accepted risk assessment methods (calculation rules); it must be possible to use the requested test results for risk assessment.
3. **Technical feasibility**: The possibility to actually deliver the requested test results; the availability of (international, national, or other appropriate) test guidelines. However, the technical feasibility is not used as a criterion sensu

stricto, as demands (e.g., for risk assessment purposes) can generate the development of test guidelines.

4. **Minimisation of the use of test animals**: As the EC and OECD aim to reduce the use of test animals, the number of animals required for testing should be kept as low as possible.

The benefits are specified more clearly, to be able to use the "benefits" as a criterion. The reliability of a risk assessment (*benefit*) can be improved by:

1. **Compartment specific assessment**: When a risk evaluation includes a compartment-specific assessment of the risks related to the use of a biocide, the requested test data should be sufficient to perform risk assessment for all relevant environmental compartments. This may result in specific test data for each compartment.
2. **Enabling chemical specific assessment**: The specific behaviour, in terms of environmental transport, fate and effects, of various chemical groups (e.g. metals, hydrocarbons, acids/bases, surfactants) may require specific tests to be performed to model such factors.
3. **Increasing field relevance**: When the actual environmental fate and effects cannot be adequately predicted from the test results, additional test data (e.g. from mesocosm experiments, biodegradability simulation tests or monitoring studies) may be useful. This type of test results can also be required in order to decrease the uncertainty in the extrapolation from laboratory test data in the risk evaluation, due to over simplification of environmental processes.

Data items are proposed when the benefit to the risk assessment is evident. The compatibility of these data items with existing risk assessment calculation rules, and feasibility in terms of test guidelines are then discussed

Tiered approach

Two types of data can be distinguished for the risk assessment of a biocidal product. Firstly, data required for a risk assessment in the environmental compartments to which the biocide is directly emitted ('direct exposure compartments') are derived from the life cycle. However, after emission to these compartments, transport to other compartments can occur, resulting in further exposures ('indirect exposure compartments'). Whether this exposure takes place or not, depends on the characteristics of the biocidal product. Therefore, a *tiered approach* is proposed to set data requirements for a specific product type.

In *tier 1*, data requirements for the direct exposure compartments are listed. Then, an assessment as to whether indirect exposure compartments exist has to be made. For this assessment, a combination of techniques, including expert opinion, may be required.

Tier 2 consists of a list of data requirements for the risk assessment in relevant indirect exposure compartments. This tiered approach ensures that only relevant test results are required (see Figure 1).

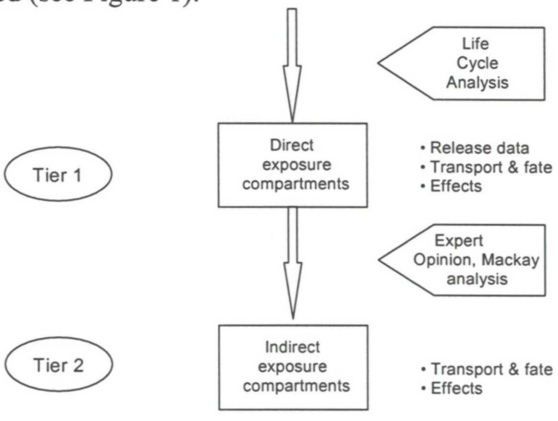

Figure 1 Tiered approach for setting data requirements

4. Data requirements for environmental compartments

Based on the criteria defined, 2 to 13 data items per environmental compartment are proposed for inclusion in Annex III of the Directive (Table 1) In the reports, these items are discussed with regards to their 'benefits', 'compatibility' and 'feasibility'.

5. Environmental release

An inventory of the environmental release of the 23 biocidal product types included in the Directive has been made. Based on literature surveys and communication with relevant experts (especially within TNO and UBA), the environmental compartments to which environmental emissions occur during the application, use and disposal of the biocide and treated material were evaluated. A summary of the exposed environmental compartments ('direct exposure compartments') is included in Table 2 to 5.

6. Use of the tables

The environmental compartments that are likely to be exposed due to the use of a certain biocidal product (for example: 12.1, slimicides in the paper industry) can be derived from Tables 2 to 5. If the exposed compartments are known, Table 1 can be used to find the test data that can be demanded for this product type (or sub-type). However, the resulting list includes all data that could be demanded. Before actually demanding the data by including it into Annex III of the directive, a discussion between competent authorities and industry should take place, based on the arguments provided in the BIOEXPO reports. However, as input for this discussion, some guidance on interpreting the "long lists" can be given on the basis of the life cycle. This guidance can be found in the reports (part 2).

Table 1 *Data requirements (potential tests for Annex III of the Directive) for the environmental compartments fresh surface water, marine water, soil, STP and air.*

Compartment	Nr.	Potential tests for Annex III
Fresh surface water (incl. sediments)	I.1	Die-away biodegradation test with specific chemical analyses or using a radiolabel at environmentally realistic biocide concentrations (fresh water)
	I.2	Aerobic/anaerobic biodegradation in freshwater sediment/water systems, with specific chemical analyses or using a ^{14}C radiolabel.
	I.3	Biodegradation in fresh water microcosms or mesocosms, i.e. field simulation tests.
	I.4	Leaching rate (from treated material to fresh surface water)
	I.5	Chronic fresh water toxicity tests
	I.6	Fresh water mesocosm (semi-field scale) toxicity tests
	I.7	Toxicity test (fresh water) sediment-dwelling species
Fresh or marine surface water	I/II.1	Sediment-water partitioning coefficient (fresh or marine)
	I/II.2	Bioconcentration factor for other aquatic organisms than fish (fresh or marine)
	I/II.3	Specific toxic action tests (biomarkers) (fresh or marine)
	I/II.4	Toxicity test for hazardous degradation products (fresh or marine)
	I/II.5	Toxicity test for fish-eating predators (fresh or marine)
Marine water (incl. sediments)	II.1	Seawater die-away biodegradation test with specific chemical analyses or using a radiolabel at environmentally realistic biocide concentrations.
	II.2	Aerobic/anaerobic biodegradation in marine sediment/water systems, with specific chemical analyses or using a ^{14}C radiolabel.
	II.3	Biodegradation in marine microcosms, i.e. field simulation tests.
	II.4	Leaching rate (from treated material to marine surface water)
	II.5	Toxicity test for marine fish, algae, crustacean
	II.6	Toxicity test sediment-dwelling species (marine)
	II.7	Chronic marine toxicity tests
	II.8	Marine mesocosm (semi-field scale) toxicity tests
Soil (incl. groundwater)	III.1	Aerobic biodegradation in soil, using specific chemical analysis or a ^{14}C label
	III.2	Leaching rate (to ground water) in disturbed or undisturbed soil columns.
	III.3	Biodegradation and leaching rate (to ground water) in lysimeter studies
	III.4	Leaching rate (from treated material to soil)
	III.5	Acute toxicity tests for soil-dwelling species
	III.6	Chronic toxicity test for soil dwelling species
	III.7	Soil micro-organism community test
	III.8	Toxicity test for terrestrial plants
	III.9	Bioconcentration test in soil-dwelling animals and terrestrial plants
	III.10	Toxicity test for worm-eating predators
STP	IV.1	Continuous activated sludge test
	IV.2	Inhibition of activity of micro-organisms in STP
Air	V.1	Photodegradation rate and degradation rate by OH radicals in air
	V.2	Evaporation rate (from treated material to air)
	V.3	Acute and chronic toxicity for exposure by air

Table 2 *Direct exposure compartments for disinfectants. '+' = relevant; '-' = not relevant.*

Product type	Products	Fresh surface water	Marine surface water	Soil	Air (outdoor)	STP
1.1	Suntan products	+	+	-	-	+
1.2	All other biocidal human hygiene products	-	-	-	-	+
2.1	Sewage water disinfection	+	+	-	+	-
2.2	Soil disinfection	+	-	+	+	-
2.3	Disinfection of infectious waste, medical instruments, hospital rooms, human accommodations, air conditioners, laundry	-	-	-	-	+
2.4	Disinfection of chemical closets	+	+	-	-	+
2.5	Swimming pool disinfection	-	-	-	+	+
3.1	Disinfection of farm buildings, closed spaces	+	-	+	-	+
3.2	Disinfection of farm-buildings, outdoors	+	-	+	+	-
3.3	Disinfection for veterinary hygiene on non-farm buildings, in closed spaces	-	-	-	-	+
3.4	Disinfection for veterinary hygiene on non-farm buildings, outdoors	+	-	-	+	+
3.5	Fish farming (aquaculture) disinfection	+	+	-	+	+
4.1	Disinfection of surfaces in food and feed industry	+	-	-	-	+
4.2	Aseptic packaging in food and feed industry	-	-	-	-	-
5	Drinking water disinfection	+	+	+	+	+

Table 3 *Direct exposure compartments for preservatives. '+' = relevant; '-' = not relevant.*

Product type	Products	Fresh surface water	Marine surface water	Soil	Air (outdoor)	STP
6.1	Preservation of canned fluid used in public buildings	-	-	-	-	+
6.2	Preservation of canned fluid used in households	-	-	-	-	+
6.3	Preservation of canned fluid used in industrial processes	-	-	-	-	+
6.4	Preservation of canned fluid used for agricultural purposes	+	-	+	-	+
7	Film preservation	+	-	+	-	+
8.1	Wood preservation, GK 1 and 2	+	-	+	+	+
8.2	Wood preservation, GK 3 and 4	+	-	+	+	+
8.3	Wood preservation, GK5	-	+	+	+	+
8.4	Wood curation, pills and injection	-	-	-	-	+
8.5	Wood curation, brushing and spraying	-	-	-	-	+
8.6	Wood curation, fumigation	-	-	-	+	+
9	Fibre, leather, rubber, and polymerised materials preservatives	+	-	+	-	+
10.1	Building materials preservation (preventive)	+	-	+	-	-
10.2	Building materials preservation (curation)	+	-	+	+	-
11.1	Biocides in once-through cooling systems	+	+	-	-	-
11.2	Biocides in open recirculating cooling systems	+	+	+	+	+
11.3	Biocides in closed recirculating cooling systems	+	+	-	-	+
12.1	Slimicides in paper industry	+	+	-	-	+
12.2	Slimicides for secondary oil recovery	-	+	-	-	-
12.3	Other slimicides	-	-	-	-	+
13	Metalworking-fluid preservation	-	-	-	-	+

Table 4 *Direct exposure compartments pest control products. '+' = relevant; '-' = not relevant.*

Product type	Products	Fresh surface water	Marine surface water	Soil	Air (outdoor)	STP
14-19.1	Fumigation products used outdoors	-	-	+	+	-
14-19.2	Fumigation products for indoors-use, products used on skin (indoors)	-	-	-	+	-
14-19.3	Pest control products for wet surface application, powders, and other products used *outdoors*	+	-	+	+	-
14-19.4	Pest control products for wet surface application, powders and other products used in *closed spaces*	-	-	-	-	+
14-19.5	Pest control products for wet surface application, powders and other products used in *animal housings*	-	-	+	-	+
14-19.6	Baits used outdoors	+	-	+	-	-
14-19.7	Baits used in sewer systems	-	-	-	-	+
14-19.8	Baits used in closed spaces and animal housings	-	-	-	-	-
14-19.9	Pest control products used on skin (outdoors)	-	-	-	+	-

Table 5 Direct exposure compartments for other biocidal products. '+' = relevant; '-' = not relevant.

Product type	Products	Fresh surface water	Marine surface water	Soil	Air (outdoor)	STP
20	See product types 2,4, 14, 18					
21.1	Antifoulings in matrix and ablative coatings for fresh water	+	-	+	+	+
21.2	Antifoulings in matrix and ablative coatings for marine waters	-	+	+	+	+
21.3	Antifoulings in selfpolishing coatings for marine waters	-	+	+	+	+
22.1	Embalming chemicals	-	-	+	+	+
22.2	Taxidermy chemicals	-	-	-	-	+
23.1	Fumigants for control of other vertebrates, used outdoors	-	-	+	+	-
23.2	Baits for control of other vertebrates, used outdoors	+	-	+	-	-
23.3	Baits for control of other vertebrates, used in animal housings	-	-	-	-	-