MANUAL OF DECISIONS FOR IMPLEMENTATION OF DIRECTIVE 98/8/EC CONCERNING THE PLACING ON THE MARKET OF BIOCIDAL PRODUCTS

Last modified: 10.07.2008

GLOSSARY OF ACRONYMS

AFNOR:	Association française de normalisation
BPD:	Biocidal Products Directive
CFR:	US Code of Federal Regulations
CPD:	Cosmetic Products Directive
EC:	European Community
ECB:	European Chemicals Bureau (http://ecb.jrc.it)
EU:	European Union
EPA:	US Environmental Protection Agency
ESD:	Environmental Emission Scenario Documents
FIFRA:	Federal Insecticide, Fungicide, and Rodenticide Act
GLP:	Good Laboratory Practice
MDD:	Medical Devices Directive
MRL:	Maximum Residue Limit/Level
OECD:	Organisation for Economic Co-operation and Development
PPP:	Plant Protection Product
PPPD:	Plant Protection Products Directive
PT:	Product Type
RED:	Registration Eligibility Document
TNsG:	Technical Notes for Guidance (of the ECB)
VMP:	Veterinary Medicinal Product

1. INTRODUCTION

Directive 98/8/EC (the Biocidal Products Directive, BPD) of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market entered into force on 14 May 1998. Member States had to implement it not later than 24 months after its entry into force.

The BPD concerns the authorisation and the placing on the market for use of biocidal products within the Member States. According to Article 1(2) the Directive shall apply to biocidal products as defined in Article 2(1)(a) but shall exclude products that are defined or within the scope of 18 other Directives. Further, according to Article 1(3) the Directive shall apply without prejudice to relevant Community provisions or measures taken in accordance with 5 other Directives, which are explicitly listed.

Article 2 defines biocidal products as "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. An exhaustive list of 23 product types with an indicative set of descriptions within each type is given in Annex V." Furthermore, an active substance is defined as "a substance or micro-organism including viruses or a fungus having general or specific action on or against harmful organisms". A basic substance is defined as "a substance which is listed in Annex IB, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent, which itself is not a substance of concern and which is not directly marketed for this biocidal use". Article 2 also gives definitions on concepts as substances of concern, low-risk biocidal products, frame formulation etc.

According to the BPD, active substances in biocidal products, placed on the EU-market prior to 14 May 2000 (existing active substances), will be reviewed in a Community programme that has to be carried out within 10 years. If, after review, they are accepted for use in biocidal products in specific product types, they will be included in Annex I, IA or IB to the BPD.

The first phase of the review programme is regulated by Regulation (EC) No. 1896/2000, which lays down the procedures for identification and notification of existing active substances. Only substances, which are notified acceptably, will be reviewed in the programme. The first product types to be reviewed are wood preservatives and rodenticides.

The second phase of the review programme is regulated by Regulation No. 2032/2003 that sets out the procedures and details for the rest of the review programme. Identified active substances, notified active substances, prioritisation of the product-types to be reviewed, designated Rapporteur Member States and time tables are listed in Annexes to this Regulation.

As soon as a reviewed active substance is included in one of the Annexes I, IA or IB to the BPD, applications for authorisation of biocidal products containing that active substance have to be made in those Member States, in which the applicant wants to place the products on the market to be used in approved use areas. During the period when an active substance is reviewed and not yet included in one of the Annexes, the Member

States may continue to apply their current systems or practices of placing biocidal products on the market.

The Commission has prepared a document that describes the details of the procedure for notification and a guidance documents on both the preparation and evaluation of the dossier. These documents are to be found on the European Chemicals Bureau's homepage at: http://ecb.ei.jrc.it/biocides (under Public documents).

In the preparation prior to the identifications/notifications both Member States and the industry have put forward a number of questions on various issues, in particular on borderline cases between the BPD and other Directives.

Most of the questions have been discussed 'electronically' in a consultation group with the participation of all the Member States and the Commission. This Manual of Decisions presents a compilation of the questions and answers. They are organised in groups that should facilitate the search for a specific issue.

Many of the questions concern, directly or indirectly, studies required for notifications and full dossiers. Companies are encouraged to submit joint dossiers when notifying and submitting full dossiers. They are also encouraged to explore waiving possibilities for toxicity studies involving vertebrate animals, using available information and arguments on the feasibility of testing and extent of exposure, especially for products where the uses are minor and essential.

Questions, relating exclusively to identification and notification procedures, whilst relevant at the time previous to the closing date for submission of dossiers for these procedures, may have little relevance after that date. Furthermore, the interpretation of some of the provisions of the BPD has been changing over time and it may be the case also in the future. If, after reconsideration of some part of the BPD, an answer given on a specific question is amended, the latest answer should be the one given in the Manual of Decisions. Unless otherwise stated, the answers provided in this Manual were agreed at the 12th meeting of the competent authorities in November 2002.

Some questions raised concern treated articles imported from countries outside the EU. This issue is a serious problem, which is not yet solved.

This Manual should be regarded as a 'living' document. It is not exhaustive and further decisions will be added in the course of time as they are agreed between the Commission and the Member States.

DISCLAIMER: The answers to the various questions represent the views agreed between the Commission services and the Member States. They are not the official view of the Commission. Furthermore, they are not legally binding. Only the European Court of Justice has the highest authority to give authoritative interpretations on the contents of Community law.

2. SCOPE AND BORDELINE ISSUES

2.1. Borderlines with other Directives

2.1.1. Plant protection products

2.1.1.1.Rodenticides

Question: A company sells a rodenticide to control mice in forests to protect beds with seeds or young trees. Is this application covered by the Biocides Directive and if so, which product type is relevant?

Answer *(agreed in January 2003)*: The main purpose of the use of rodenticides on plant products is considered to be for human hygiene rather than for the protection of plant products. In fact, rats and mice can contaminate with their excrements much greater quantity of plant products (with the consequent danger of transmission of diseases) compared with the quantity directly devoured. It is therefore agreed to consider all rodenticides as biocidal products with the exclusion of products used in plant growing areas (agricultural field, greenhouse, forest) to protect plants, or to protect plant products temporarily stored in the plant growing areas. Considering that there could be a need to control the population of rodents in plant growing area not because they devour crops but because they multiply and can subsequently spread to human settlements, it is agreed that products used for this specific purpose are biocidal products.

Products used to control mice or other rodents outside plant growing areas, for example in farms, cities, industrial premises, and in plant growing areas not to protect plants or plant products, are considered as biocidal products.

Rodenticides, used in plant growing areas to protect plants or plant products temporarily stored in the plant growing areas, are considered as plant protection products.

If a product is used in both situations it falls within the scope of both the Biocides Directive and the Plant Protection Products Directive and will need a dual authorisation for the relevant uses.[1]

In this particular case the purpose of the use of the product is to protect plants in plant growing areas. The product therefore is a plant protection product.

2.1.1.2.Product used in storage of cereals

Question: A company uses a product to treat empty storage areas for plant products such as grain and flour. This product is within the scope of the Plant Protection Products Directive. The same or other products are used against cockroaches in storage areas where flour is stored to be used in bread production. Are the latter products within the scope of the BPD and if so, within PT 18 or 19?

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[1] For further guidance see also document **'Biocidal Products and Plant Protection Products'** , available at: http://europa.eu.int/comm/environment/biocides/index.htm

Answer (agreed in June 2003): According to the Guidance Document[2] on the borderline between biocides and plant protection products, products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves are *plant products* in the meaning of the Plant Protection Products Directive. If the target organism is detrimental to plant or plant products then the product used is considered as a PPP either if applied directly on plants or plants products or applied indirectly on empty structures to control pests of plant or plants products exclusively.

Products used for a general biocidal purpose are biocides. These would include general hygiene disinfectants in empty structures when it is not clear which kind of products will be stored after the treatment.

Flour produced at a mill from grain is a plant product having undergone a simple preparation such as milling etc. However, additional steps, such as transport to another food production site, go beyond simple processing.

Therefore, products used to treat storage areas in mills or other installations of 'simple processing' are plant protection products, whereas products used to treat storage areas in installations of more advanced food processing are biocides. If such a product is an insecticide it is in PT 18, if it is a repellent PT 19 applies.

2.1.1.3. Fumigants for food processing installations

Question: A fumigant is used for treatment of mills and pasta factories (both processing and storage areas) which are located directly adjacent to the mills. The factory and the mill will be fumigated at the same time. Is the fumigant to be authorised as PPP or biocide?

Answer *(agreed in June 2003)*: As explained in the preceding answer, the definition of 'plant product' covers "simple processing such as milling..." and therefore the fumigants used anywhere in the mill would have to be authorised as PPP. This, however, does not seem to hold for the pasta factory. Here the processing step is more advanced and fumigants used in the pasta factory are then biocides. Therefore, strictly speaking, the same fumigant has to be authorised both as a PPP and as a biocide. However, if indeed the pasta factories are situated directly adjacent to the mills and are treated at the same time with the same product, Member States could in a pragmatic approach also decide to authorise the product for both uses as PPP.

2.1.1.4.Disinfectants for cut flower treatment

Question 1: Water used to keep cut flowers fresh is treated with a number of substances: ethylene inhibitors, hydrating agents, acidifiers, and disinfectants/bactericides. Whilst the ethylene inhibitors are considered to be plant protection products (as they are growth regulators), the situation for disinfectants/bactericides is different. Disinfectants are included in cut flower treatment products which contain sugars either a) to preserve the products before use, or b) to prevent bacterial or other microbial growth in the flower water and hence keep the water clean and odour-free. Are these disinfectants considered to be plant protection products or biocides?

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[2] For further guidance see also document **'Biocidal Products and Plant Protection Products'** , available at: http://europa.eu.int/comm/environment/biocides/index.htm

Answer 1 (*agreed in June 2004*): Disinfectants used for the purpose to preserve sugar containing products before use in cut flower treatments and/or to prevent bacterial or other microbial growth in the flower water are considered to be biocides and fall under Directive 98/8/EC.

The disinfectants are only added because the sugar would otherwise promote microbial deterioration in the product itself or microbial growth in the flower water. Cut flower treatments would work just as well in terms of preserving the plants themselves without such a disinfectant, but the state of the water would deteriorate more quickly.

Question 2: A disinfectant is added to a product containing sugars as cut flowers nutrients to preserve the sugars against microbial digestion. It is not added to keep the water clean or otherwise to control pests outside the product. However, there is a water cleaning effect of the product as a whole as an unintended side effect. Is such a product considered to be a nutrient that contains a biocide as preservative and therefore itself is not covered by the BPD, or is the product as a whole considered to be a biocidal product and does it therefore fall under the scope of the BPD?

Answer 2 (*agreed in July 2005*): The active substance used to prevent microbial growth and protect the sugars contained in the cut flowers nutrient is a biocide and falls under the scope of the BPD.

Although the primary purpose of the active substance added to the nutrient is to act as an in-can preservative, the substance also prevents microbial deterioration of the sugars in the water when the nutrient product is used. Therefore, the disinfectant fulfils the description of two product types PT 2 and PT 6. In fact, it seems that in reality preventing microbial growth in the flower water is actually more needed than in the packaged nutrient product, where preservation could probably also be achieved through other means (i.e. air- or water-tight sealing). Therefore, the active substance/biocidal product belongs to both product types PT 2 and PT 6.

Question 3: As a supplementary question to question 2, an applicant asked about the status of a product that contains an active substance only to preserve the actual product itself and which makes no biocidal claims for the product itself when either supplied as a concentrate or when diluted.

Typical claims are:

Product X is an all-purpose re-hydrating solution for all cut flowers. It gives cut flowers an extra boost after a period of dry transportation. By stimulating water absorption it prevents 'bent-neck' and limp leaves.

Product Y is a clear solution for treating all varieties of cut flowers during transport and sales periods. It promotes water uptake and provides the blooms with the correct amount of food during the entire distribution and sales periods. It prevents premature flowering.

Product Z (liquid) is a liquid flower food suitable for all cut flower varieties and for foam arrangements. It keeps the flowers in peak condition. Product Z (liquid) ensures complete flower development, an optimum vase life and will guarantee customer satisfaction.

Product Z is a powdered food supplement for all types of cut flowers for vase and foam arrangements. It keeps the flowers in peak condition. Product Z ensures full flower development, an optimum vase life and will guarantee customer satisfaction.

Recommended for companies making flower arrangements.

Answer (agreed at 29th CA meeting): These 4 products all contain an active substance as an in-can preservative (PT 6) but the actual products themselves make no biocidal claims and so should be regarded as 'treated materials' i.e. are outside of the scope of the BPD.

Of course the active substance in the product must be one approved for use as PT 6.

2.1.1.5.Disinfectants for water

Question: Farmers use sometimes surface-, rain- or groundwater to prepare tank mixtures of PPP. That water can be contaminated with plant pathogens. To guarantee that such plant pathogens are not spread out over the crop during spraying of the PPP, the water is disinfected in the tank by adding a disinfectant. Only afterwards the specific PPP with specific uses against specific diseases or pests is added. The purpose of using the disinfectants in that way is to ensure that potentially present – but not specified - plant pathogens in the water are killed in the tank. Water treated that way can also be used for purposes such as:

- sprinkling, pouring, droplets on land/crops as water supply for crops;

- treatment (washing) of products (crops, plants);

Do products used to treat water in this way have to be considered as PPP or as biocides? If they are biocides, what is the correct PT?

Answer *(agreed in June 2004***)**: If there is no other use intended than the general disinfection of water to prevent the contamination of water with bacteria, fungi or other kind of pathogens these disinfectant products are considered as biocidal products.

Even though the treated water might be used to prepare tank mixes with PPP, the substance used to disinfect the water can normally not be considered as a PPP - it is hard to conceive that a farmer would actually know precisely whether there are plant pathogens in the water, and if so, which ones. The main purpose of the disinfectant is clearly to act against any harmful organism in the water (including plant pathogens when they are actually present) in order to have 'clean' water for preparing PPP tank mixes. The same disinfectants could probably also be used to disinfect water for other purposes such as irrigation, washing (where combating bacteria pathogenic to humans could be equally relevant), or others. So to avoid that the same substances need dual authorisation for exactly the same purpose, they should be considered as biocidal products in PT 2 or 4.

2.1.1.6.Products against moles

Question: A company has developed a range of products to control moles in areas where no plants are grown for agricultural purposes. These are for example playgrounds, paths, tennis courts, race courses, airstrips, etc. in order to protect humans or animals (in particular horses) or objects (such as small aircraft) from possible injuries or damage

caused by stumbling and falling over molehills. Other products are used to prevent moles from digging in soil constructions, dams, etc. in order to protect these constructions from deterioration caused by tunnels and molehills. Are these products biocides or plant protection products?

Answer *(agreed in March 2005)*: Products to control moles on playgrounds, paths, tennis courts, race courses, and airstrips to protect humans or race horses from potential injuries or for aesthetic reasons, and for controlling moles in soil constructions such as dams to protect them from damage caused by mole tunnels and hills are biocidal products. The intention of the use of these products is clearly not to protect plants or plant products.

2.1.1.7.Methyl bromide used for pre-shipment quarantine treatments

Question: Methyl Bromide has been notified under the PPP Directive (91/414/EEC). Methyl Bromide is used primarily as a soil sterilant – a PPP use - but it does have other minor uses. There are two cases in which Methyl Bromide would be used in shipping.

(1) to fumigate wood packaging material in shipping containers to protect plants and plant products being shipped to third countries.

(2) to fumigate wood packaging material for the shipping of products other than plants and plant products. This would be to protect plants and plant products in destination countries.

Are these two uses of methyl bromide covered by the Biocidal Products Directive?

Answer *(agreed in July 2005)*: The purpose of the treatments of wooden packaging and pallets with Methyl Bromide is the prevention of the spreading of plant diseases to the countries of import. It is not for the purpose of preserving the wood. Therefore such a use is covered by the PPP Directive. In addition, all provisions of Regulation 2037/2000 on substances that deplete the ozone layer[3] apply.

2.1.2. Human and veterinary medicinal products

2.1.2.1. Ectoparasiticides on animals and humans

Question 1: Should an ectoparasiticide for use on dogs be classified as a veterinary medicinal product or as a biocidal product?

Answer: The classification of products containing active substances with lethal effects on external parasites to be used on animals will depend on the intended use and/or demonstrated claim. Generally, such products used on animals are considered and authorised as veterinary medicinal products with precise medicinal indications (including prevention, treatment or diagnosis of disease)[4].

Question 2: A shampoo containing oils from plants is used against lice on humans. The infestation of lice is usually considered as an illness (pediculosis). The intention with the use of the product is to cure this illness even if the product contains no pharmaceutical ingredients. The action of the product is blocking of vital biological functions in the lice.

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[3] OJ L 244, 29.9.2000, p. 1.

[4] For further guidance see document '**Biocidal products and proprietary medicinal products and veterinary medicinal products**' at: http://europa.eu.int/comm/environment/biocides/index.htm

According to the company a similar product is sold in a Member State as a medical device 'because of the mainly physical effect that disables the respiration'. Is the product a medical device or a biocide?

Answer *(agreed in June 2003)*: In accordance with the Guidance Document on the borderline between medicinal products and biocidal products, products containing active substances with lethal effects on external parasites to be used on humans or animals are in general considered and authorised as human/veterinary medicinal products with precise medicinal indications (including prevention, treatment or diagnosis of disease).

Medical devices are defined as 'any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease'. It is doubtful that a shampoo would be covered by this definition (See also point 2.1.5).

Therefore, anti-lice shampoos are considered human medicinal products as they prevent the illness pediculosis.

2.1.2.2. Iodine on navels

Question: An iodine solution is applied to the navels of calves after birth. The purpose of the application is general disinfection rather than the control of general or specific bovine pathogens. Is the product within the scope of the BPD and if so, is it PT 3?

Answer *(agreed in June 2003)*: According to the guidance document on the borderline between the scope of the Veterinary Medicinal Products Directive and the BPD[5], general disinfectants applied on human and animal skin are veterinary hygiene biocidal products (PT 3). This holds in particular in the absence of an intended and/or demonstrated claim of medicinal effects, which seems to be the case here.

2.1.2.3. Products against varroa mites

Question 1: A product containing pine needle oil and thymol is sprayed on bee hives, while the bees are in the hive, to control varroa mites. The product is applied to cure the bees from infestation by the mites. A product with similar intention containing oxalic acid, reducing the pH in the bees and thereby avoiding growth of varroa mites, was regarded as a veterinary medicinal product by the European Medicines Evaluation Agency.

Is the first product within the scope of the BPD or is it a veterinary medicinal product?

Answer *(agreed in June 2003)*: Both products will be used in bee hives to cure or prevent bees from being infected by varroa mites. Use of the products for treatment and prevention of infestations of bees with varroa mites is thus for medicinal purposes.

Therefore, both products are within the scope of the Veterinary Medicinal Products Directive (2001/82/EC).

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[5] For further guidance see document '**Biocidal products and proprietary medicinal products and veterinary medicinal products**' at: http://europa.eu.int/comm/environment/biocides/index.htm

2.1.2.4.Hand disinfectants

Question: Products containing the active substances ethanol, propan-1-ol and/or propan-2-ol are marketed with the purpose of "surgical disinfection" of hands and forearms as well as "general hygiene disinfection" of hands. One product is intended to be used additionally for hepatitis-B-prophylaxis. Depending on the intended purpose, the use-quantities and the durations of application vary. Are these products considered as biocidal products? Is the product which is also intended to be used for hepatitis-B-prophylaxis a human medicinal product, too (for that use)? If so, would it be possible to put a product on the market, that is a human medicinal product and at the same time (for the other intended uses) a biocidal product?

Answer (agreed in June 2004): In the guidance on the borderline between Directives 98/8/EC and 2001/83/EC (Proprietary Medicinal Products), it was agreed that products would be considered as human hygiene biocidal product disinfectants for skin, scalps and mucous membranes of the oral cavity if the purpose of the use and claim of the products is general disinfection for hygiene purposes without a medicinal claim (including prevention, treatment or diagnosis of disease).

The intended uses of the products in these cases are "surgical disinfection" of hands as well as "general hygiene disinfection" of hands. For one product, additionally, use for hepatitis-B-prophylaxis is specified. In principle, the specification of the efficacy of a product against one identified pathogen agent is not incompatible with a claim of general disinfection efficacy. Therefore, if no medicinal efficacy (including prevention, treatment or diagnosis of disease) is claimed, the quoted agreement for considering this product as biocidal product is still valid, and these specific products should be considered as Human hygiene biocidal products (PT 1) and regulated according to Directive 98/8/EC.

However, the wording "prophylaxis" normally means protection against a disease by using a certain medicine, such as a vaccine for example. In this case, it is clear though, that the effect is only killing the hepatitis-B-virus in the surgical ward. Therefore "prophylaxis" is not the right claim to use here, and should be changed to 'effective against viruses of Hepatitis-B strain'.

Therefore, if the company wishes to sell the product with the wording "prophylaxis", the product should in that case be marketed and regulated as medicinal product with a medicinal claim of hepatitis-B-prophylaxis and thus regulated under the Medicinal Products Directive with all relevant consequences. This product should have a name and presentation different from the one sold for general hand-disinfection and thus regulated under the Biocidal Products Directive. In cases of uncertainty, companies should consult with both sets of authorities (those responsible for biocides and those responsible for medicinal products) to discuss all intended uses, claims, and the consequences thereof.

2.1.2.5.Products to control pigeon populations in cities

Question: A company wishes to market a product, which contains an active substance to be administered to pigeons via baits contained in stations, with the effect to interfere with the hatchability of eggs by two main mechanisms: the substance disrupts the membrane surrounding the egg yolk, creating conditions in which the embryo cannot develop. The substance also inhibits incorporation of cholesterol and vitellogenin into yolk, thereby limiting the energy for the developing embryo. If the yolk does not provide enough energy, the embryo will not completely form and the egg will never hatch. The product is

intended to be used by licensed business of Pest Control Operators. Is this product a biocide or a veterinary medicinal product?

Answer (agreed in December 2004): As the main intention of using this product in the described way of application clearly is to control unwanted pigeon populations, it is a biocidal product in PT 15 (avicides).

However, the same active substance might be found in products used by pigeon breeders who would like to selectively influence fertility of their stock. Products used for this particular application might be authorised as veterinary medicinal products, provided companies request such authorisation and all conditions and requirements of Directive 2001/82/EC are fulfilled.

2.1.2.6. Products to kill flies directly applied on animal skin

Question: A company wishes to market a product with lethal effects on flies to be applied directly ('pour-on') on animal skin. The claim on the product is 'Killing Flies' and it can also be used to treat structures and stables where animals are housed. Is this product a biocide or a veterinary medicinal product?

Answer (agreed in March 2005): For a Veterinary Medicinal Product (VMP), it is required to prove efficacy to make a medical diagnose, to prevent (prophylaxis) or to treat a certain disease in a certain species. "Killing flies" per se is therefore not a medicinal claim in the sense of the VMP Directive – in contrast, prevention of a certain disease which might be transferred by certain flies to a certain species would be a medicinal claim. Any application for such a product to be authorised as a VMP would have to prove effectiveness in form of clinical trials and the product would have to be manufactured according to pharmaceutical GMP standards.

This is somewhat different from the efficacy to be proven for a biocide with the claim 'kills flies'. Here it is sufficient to proven that the product kills flies effectively, independent of whether a disease is transmitted. Still, it is questionable whether such a broad claim can be proven, or whether it is necessary to be more specific regarding certain types of flies.

In order for a product to be considered as a VMP there has to be a precise medicinal (diagnosis, prophylaxis, or treatment) indication. As long as this is not fulfilled, a given product to control flies should be considered as a biocide[6]. Obviously, the topical application will create a necessity to evaluate possible residues of the applied substance in the animal and animal products. However, residues are to be evaluated under the Biocides Directive where relevant, and MRL's are to be established. In this particular case, this might necessitate a close co-operation with the authorities in charge of VMPs, regarding methodology and interpretation of results.

[6] For further guidance see document '**Biocidal products and proprietary medicinal products and veterinary medicinal products**' at: http://europa.eu.int/comm/environment/biocides/index.htm

2.1.3. Cosmetic Products

2.1.3.1. Cosmetic Product / Biocidal Product

Question: An active substance has been identified and notified according to Regulation 1896/2000. This active substance was previously included in a cosmetic product (repellent) before this notification. Should the formulator consider the cosmetic formulation as a repellent within the scope of the BPD?

Answer (*modified in June 2004*): If a product containing an active substance still fulfils the definition of a cosmetic product as contained in the Cosmetic Products Directive (CPD), it is excluded from the scope of the BPD. If, on the other hand, it would no longer be regarded as a cosmetic product, it would fall under the scope of the BPD.

The critical question is which biocidal activities can be considered as secondary to the main cosmetic functions. Several examples are given in the CPD itself (such as anti-dundruff shampoo and anti-microbial soaps). However, for the above-mentioned example of a product (e.g. a sun lotion) containing insect repellents, the biocidal function is not considered to be secondary and therefore the product containing the repellent will most likely be considered a biocidal product.

The practical procedure to find out which regime applies in case of uncertainty in relation to a product that could be a cosmetic product claiming a secondary biocidal activity could be the following: The person responsible for placing the product on the market would approach competent authorities for cosmetic products and those competent for biocidal products within Member States to know if the CPD applies. The authorities, on a case-by-case approach, taking into accounts the claims, the presentation and the ingredients of the product will decide whether it is a cosmetic product or not[7].

2.1.4. Food and feed additives

2.1.4.1. General examples

Question: Which substances could be considered as active substances in products covered by PT 20 (Preservatives for food and feed stocks)?

Answer: Products that have uses covered by those Directives mentioned in Article 1.2 of the BPD are not within the scope of the BPD. Three of these relate to food:

- Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption,

- Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production, and

- European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners.

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[7] For further guidance see also document '**Biocidal products and cosmetic products'** available at: http://europa.eu.int/comm/environment/biocides/index.htm

Consequently, if the use of a substance falls under one of these Directives that application of the substance is not covered by the BPD

2.1.4.2. Propionic Acid

Question: Propionic acid is used for preserving cattle feed. The substance is added directly to the feed. This procedure is regulated by specific legislation e.g. the Directive on additives in feeding stuffs. Is such a feed additive included in the BPD?

Answer: Propionic acid is listed as feeding stuff preservative in Annex I of Directive 70/524/EEC. When the use of a substance falls under that Directive, it is excluded from the BPD.

2.1.4.3. Sorbates

Question: Sorbates are mainly used as food preservatives (food additives), and therefore not within the scope of BPD. There are also other application fields such as wet tissues, soaps, detergents etc, which are within the scope of the BPD but this is a very limited part of the business. No identification or notification has been made since it was not obligatory for the main uses of the sorbates. Will the biocidal products containing sorbates be taken from the market?

Would it be possible to prevent customers, who buy sorbates from the producer to use them in other applications by mentioning eg 'for food use only'? Who is responsible (the producer or the customer) in case this instruction 'for food use only' is not being followed properly?

Answer: The use of sorbates as food preservative is not covered by the BPD, as the relevant Directive is included in Article 1(2), meaning that uses falling under that Directive are exempted from the requirements of the BPD. Any measures taken for non-identified or non-notified substances will only affect their use in biocidal products, not those covered by other Directives.

If 'for food use only' is mentioned on the sales packaging and labelling, that should be a clear enough instruction for users to know that they are not supposed to use the substance for biocidal purposes. So responsibility lies with them. Of course, the producer should also take his own responsibility and not sell to customers where he knows that they would use it for others than the indicated purposes (See also point 2.5.3.1 below).

2.1.4.4. Fruit vinegar

Question: A fruit flies trap contains fruit vinegar as attractant. One active substance among others is probably acetic acid. Article 1(2)(i) excludes products that are defined or within the scope of the Directives 89/107/EEC (food additives), Directive 88/388/EEC (flavourings for use in foodstuffs) and Directive 95/2/EC (Food additives other than colours and sweeteners). As acetic acid is listed in Annex I of Directive 95/2/EC, does this mean that acetic acid as an active substance in a biocidal product is exempted from the BPD or are the listed food additives only exempted of the BPD for their use in foodstuffs?

Answer: Substances listed in the Annexes of Directive 95/2/EC are not exempted from the requirements of the BPD when they are used for biocidal purposes, e.g. as an attractant in a trap. According to Article 1(2) of the BPD, only products that are defined

or within the scope of the Directives mentioned in the Article for the purposes of these Directives are exempted. A biocidal use of a substance listed in the annexes of Directive 95/2/EC is not for the purposes of the Directive (food additive).

In the case of fruit vinegar, a number of individual components can contribute to the desired attractant effect. It would therefore probably be best to consider it as one active substance of natural origin.

2.1.4.5.Bacteriocins

Question: Research is ongoing with a new bacteriocin lacticin (Lactoccus lactis). It is produced by a food grade bacterium Lactococcus lactis and can inhibit Listeria monocytogenes, Clostridium botulinum, Staphylococcus aureus and Bacillus cereus. This lacticin can reduce Listeria monocytogenes in infant foods, cottage cheese and natural yoghurt as well as Bacillus cereus in instant soups. It can also extend the shelf life of pasteurised milk, fresh pork sausages and ham. In addition, the bacteriocins can be used to create bio-active packaging.

Do such products fall within the definition of "biocidal products" as defined in Article 2. 1 (a)?

Answer *(agreed in December 2003)*: The bacteriocin could be regarded as an enzyme in the framework of Directive 89/107/EEC and not considered as a biocidal active substance if the bacteriocin alone (without the microorganism producing it) is used for the preservation of food and foodstock by the control of harmful organisms.

For that purpose and also for the use in food packaging, the Working Group on food additives (managed by the Commission's Directorate Health and Consumer Protection) will be consulted. The answer will be updated according to the outcome of the discussion of the Working group on that issue.

2.1.4.6.Product used in Sugar Mills and other industrial plants

Question: A product with broad-spectrum biocidal properties is used for the control of micro-organisms in the diffusion and washing stage in sugar mills. It comes in direct contact with the raw materials and/or is fed to the wash water or to the sugar juice in the diffuser. It is destroyed and fully eliminated from the final sugar product, as are all other possible break down substances. The product is also used in other industrial water applications where it controls a wide spectrum of micro-organisms.

Is the product a biocide and if so, for which product type should it be authorised?

Answer *(agreed in March 2005)*: The status of the product when added to the food material will depend on whether it remains in the final product or not. If it remains therein, it is to be considered as a food additive and falls under Directive 89/107/EEC. However, if it is fully eliminated and there are no residues, it is a processing aid, which would be exempted from both Directive 89/107/EEC and Directive 98/8/EC. Processing aids – although exempted from Directive 89/107/EEC – are nevertheless defined in the Directive and, therefore, in accordance with Article 1(2) of Directive 98/8/EC exempted from the BPD. They might be regulated by the national legislation in the Member States. So in any case, when the product is directly added to the raw sugar material or during the

processing stage for controlling micro-organisms in the sugar pre-products, it is not covered by the Biocides Directive.

However, if the product is also used in washing water for equipment and machinery in the sugar mills (or elsewhere in the food industry), it would be a biocidal product in PT 4. The intended use in other industrial water applications would fall under the Biocides Directive and the product would be in PT 12.

2.1.4.7.Disinfection of animal drinking water

Question: A company has asked whether a product used for the disinfection of animal drinking water should not be excluded from the scope of Directive 98/8/EC on the ground that it would be covered by Regulation (EC) No 1831/2003[8] on feed additives.

Answer (*agreed in September 2007)*: Drinking water disinfectants are not regarded as feed additives and do not fall under the scope of Regulation (EC) No 1831/2003. Products used for the disinfection of animal drinking water should therefore be regarded as biocidal products and would fall under product-type 5, as defined in Annex V to Directive 98/8/EC.

2.1.5. Medical Devices

2.1.5.1. General disinfectants

Question: Member States have discovered cases where general disinfectants for disinfection of walls, rooms, tables etc. in hospitals are marketed with a CE-mark as Medical Device in accordance with Directive 93/42/EEC. Many of these products are originating in other Member States.

The Biocides Directive excludes products that are defined by or within the scope of Directive 93/42/EEC. However, do such general disinfectants, if not marketed for use with specific instruments, fall under the scope of Directive 93/42/EEC if they bear the relevant CE-mark? What actions should Member States take with regard to such products?

Answer *(agreed in March 2005*): In the light of the exemptions provided for in Article 1(2) of Directive 98/8/EC, if a product is indeed within the scope of the Medical Device Directive 93/42/EEC (MDD) it is exempted from the Biocidal Products Directive 98/8/EC (BPD). The MDD is applicable if a given product fits the definition of a medical device as provided by the MDD.

Medical devices are defined by Article 1(2)(a) MDD as articles which are intended to be used for a medical purpose. The medical purpose is assigned to a product by the manufacturer through the label, instructions for use, and the promotional material related to a given device. As the MDD aims essentially at the protection of patients and users, the medical purpose relates in general to finished products regardless of whether they are intended to be used alone or in combination. The MDD treats accessories to medical devices as if they were medical devices. An accessory within the meaning of the MDD requires that the accessory is specifically intended by the manufacturer to be used

[8] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (*OJ L 268, 18.10.2003, p. 29–43*)

together with a medical device, *e.g.* sterilizers for use in a medical environment are considered as accessories.

In order to decide whether a product is within the scope of the MDD as defined above two criteria have to be fulfilled. The first is the intended purpose of the product, taking into account the way the product is presented. The second is the method by which the "principal intended action" is achieved, i.e. the mode of action. By fulfilling these two criteria a product will be considered as a medical device and consecutively within the scope of the MDD. In accordance with Article 17 of the MDD, a device other than those which are custom-made or intended for clinical investigation must bear a CE conformity marking when they are placed on the market within the purpose of the MDD.

General disinfectants are not considered medical devices - they are within the scope of the BPD. Products that have the intended purpose to be a multipurpose disinfectant or a sterilisation agent, are also not covered by the MDD[9].

The fact that a product bears a CE marking is not a sufficient criterion to define a product or an accessory as a medical device within the meaning of the MDD. The Directive is clear on the definition of a medical device and that when a product falls within the scope of the Directive it shall be CE marked, but not *vice versa*. The MDD also provides in Article 18 a provision on situations where CE marking has been applied on devices and accessories outside the scope of the Directive. According to Article 18 of MDD, where a Member State establishes that the CE marking has been wrongly affixed, the entity that places the product on the market shall amend the mistake by following the conditions imposed by the Member State. Where non-compliance continues, the Member State is obliged to take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market. Identification of borderline products with a possible wrongly affixed CE mark is within the responsibility of the Member States as it constitutes clearly an enforcement measure within the scope of the national market monitoring programs *i.e.* inspection activities.

Whether disinfectants that were wrongly marketed as Medical Devices have to be authorised or not as biocides depends at the moment on the national system applicable to biocides during the transition period. Member States that have a national system in place that includes disinfectants have to apply these rules. Other Member States will have to apply the rules of the BPD, as a function of the progress with the review programme: once a decision on inclusion or non-inclusion for a given active substance is taken, products containing it will have to be authorised in all Member States.

2.1.5.2.Preservatives used in In Vitro Diagnostic Medical Devices

Question: Certain substances may be used for the preservation of In Vitro Diagnostic Medical Devices: for instance, the preservation of control solutions used for the calibration of glucose meters (used by the diabetics). Is this use of a substance covered by Directive 98/8/EC on biocidal products, as PT6 "Preservatives", or is this use covered by Directive 98/79/EC on In Vitro Diagnostic Medical Devices?

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[9] For further information see document 'MEDDEV 2.1/3 rev2' available at: http://europa.eu.int/comm/enterprise/medical_devices/meddev/index.htm.

Answer (*agreed in September 2007*): Preservatives exclusively used for the preservation of In Vitro Diagnostic Medical Devices are not covered by Directive 98/8/EC. In the present case, these control solutions are reagents used for the calibration of an In Vitro Diagnostic (IVD) medical device (the glucose meter), and as such, they are considered as IVD medical devices themselves. These control solutions are covered by Directive 98/79/EC on In Vitro Diagnostic Medical Devices, and must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons, with a quality assurance system and a declaration of conformity (Directive 98/79/EC: article 2 and article 9(2); Annex I, point B, 2) Infection and microbial contamination; Annexe IV).

It shall however be noted that if the substance is used for other preservation purposes covered by the BPD (for instance, to preserve paints etc…), it will have to be included into Annex I or IA of Directive 98/8/EC for these uses.

2.1.6. Detergents

2.1.6.1.Labelling

Question: Shall a detergent with a biocidal active substance be labelled according to the requirement of Article 20 (3) of the Biocides Directive and/or to those of Regulation (EC) No 648/2004 on detergents?

Answer (*agreed in July 2005*)**:** In the light of recital 21 in the preamble of Regulation (EC) No 648/2004 on detergents, it is clear that certain legislation such as Directive 98/8/EC shall be deemed as acting in a horizontal way in regard to the provisions of that Regulation. This is also made clear beyond any doubt in Article 3(1) of the Regulation. Therefore, as a general rule, whenever a product falls within the scope of both legislations, the provisions of both legislations shall apply unless the legislations establish differently.

Article 3(1) of the Regulation establishes that all detergents containing surfactants falling within the scope the Regulation shall conform to the conditions laid down in the Regulation and where relevant with Directive 98/8/EC. In addition, surfactants that are also acting as active substances within the meaning of Directive 98/8/EC are only exempted from certain provisions of the Regulation and not from the whole scope of the Regulation.

In regard to labelling of detergents and surfactants, according to the last subparagraph of Article 3(1), in cases where the surfactants are also active substances within the meaning of Directive 98/8/EC, then the detergents containing them shall also be labelled in accordance with Annex VII A of the Regulation, i.e. Annex VII A shall be considered as additional labelling provisions on detergents, and that without prejudice to other labelling requirements. This is further confirmed by the wording in Article 11 of the Regulation, where it is stated that the labelling provisions in this Regulation shall apply without prejudice to Directives 67/548/EC and 1999/45/EC.

Consequently, whenever a detergent containing surfactants is placed on the market where it falls within the scope of both legislations, the surfactant shall be classified and labelled in accordance with the provisions of Directive 67/548/EEC and the detergent in accordance with the provisions of Directive 1999/45/EC, the additional requirements of Article 20(3) of Directive 98/8/EC and Annex VII A of Regulation 648/2004 shall also apply for the product.

2.1.7. Materials in Contact with Food

2.1.7.1.Use of hydrogen peroxide to sterilize packaging of food-products

Question: What legal framework would apply to the use of hydrogen peroxide to sterilize packaging of food-products?

Answer (*agreed in June 2007*): Regulation (EC) No 1935/2004 sets up general requirements for all food contact materials[10] and substances used in their manufacture.

The question refers however to a substance used to sterilize a final product. It is as such not used to manufacture the material or article itself and thus would not fall under the scope of Regulation (EC) No 1935/2004.

The substance has however an action against harmful organism.

The substance would therefore be considered as an active substance as defined in Directive 98/8/EC and its use to sterilize packaging of food-products would be regarded as a product-type 4: food and feed area disinfectants.

2.1.7.2.Refrigerator linings and kitchen counter tops

Question: A company intends to market refrigerator linings and kitchen counter tops containing biocidal active substances and wants to know whether these products would fall within the scope of the Biocides Directive and if so, what would be the appropriate product type?

Answer *(The original reply agreed in July 2005 has been replaced by the following)***:** Refrigerator linings and kitchen counter tops containing biocidal active substances, fall under the Framework Regulation (EC) No 1935/2004 as they *can reasonably be expected to be brought into contact with food.*

Products within the scope of certain Directives or Regulations, such as Regulation (EC) No 1935/2004, are to be excluded from the scope of Directive 98/8/EC in accordance with Article 1(2)(j) of that Directive.

Refrigerator linings, as well as kitchen counter tops, containing biocidal active substances are not falling within the scope of Directive 98/8/EC in so far as they fall within the scope of Regulation (EC) No 1935/2004. However, this means that the use of biocidal substances in these materials has to comply with the rules laid down in this Regulation and its implementing measures and any relevant national rules that might exist in the Member States.

[10] Food contact materials are all materials and articles intended to come into contact with foodstuffs, including packaging materials but also cutlery, dishes, processing machines, containers etc. The term also includes materials and articles which are in contact with water intended for human consumption but it does not cover fixed public or private water supply equipment.

2.1.8. Secondary claims

2.1.8.1. Biocidal / non-biocidal claims

Question: Are the following products covered by the BPD:

- products which have a non-biocidal main function, and a biocidal secondary function, and which claim to have a secondary biocidal function;

- products which have a non-biocidal main function, and a biocidal secondary function, but for which no claim regarding the biocidal function is made;

- products which have a non-biocidal function, but which may also exert, depending on the conditions of use, a biocidal function (and no claims are made in this respect), such as a deodoriser that may control harmful organisms in the process;

In other words, which are the ways in which the intent to control harmful organisms is deemed to be manifested (e.g. through claims)?

Answer: First, products are exempted when they are covered by a Directive mentioned in Article 1(2) of the BPD for the purposes of those Directives.

The first product has a non-biocidal main function and a biocidal secondary function, for which a claim is made. An example could be a product, which is a cosmetic product but also has some biocidal effects. In this example, it depends on the rules in the Cosmetic Products Directive (CPD). If the product has properties that are allowed by the CPD, then it is covered by the CPD and is excluded from the BPD. If the product is not covered by the CPD then it shall be considered to be a biocide.

The definition of a biocidal product in the BPD is that it is 'intended' as such and this does not necessitate a claim to be made. However, it is reasonable to expect that an intended biocidal action would be reflected in a relevant claim. In the absence of such a claim, on the label or elsewhere, some other relevant matter in the context in which the product is presented beyond its formulation (e.g. presentation of the product, use instruction, main function, etc.) would be needed to justify a conclusions that it was 'intended' to be biocidal. If the main function of the product is not biocidal, the product has no claim for having a biocidal function and the intention is not to use it as a biocidal product, then it is not within the scope of the BPD.

In case of a divergence of views concerning a particular product between the authorities and the person responsible for placing the product on the market, it is up to the latter to demonstrate that no biocidal effect was intended.

2.2. In situ generation and on site formulation of biocides

2.2.1. In situ generation

2.2.1.1. Copper Chrome Arsenic (CCA) and Copper Chrome Boron (CCB) products

Question: CCA (copper/chrome/arsenic) and CCB (copper/chrome/boron) are supplied as premixed concentrates and diluted with water on site to the correct concentration prior to use in the treatment vessel for wood preservation. The treatment of wood with CCA/CCB is very complex. In simple terms, the copper and chrome react with the wood

in seconds, then over hours and days primary fixation takes place and then over weeks and months secondary fixation occurs with the arsenic, copper and chrome being 'fixed' into the wood. In this situation, a biocidal product is being placed on the market and used and therefore under the scope of the BPD.

There is also the possible scenario where the individual chemicals (copper oxide/sulphate, chromium trioxide, arsenic pentoxide, boric acid) could be bought in individually and mixed together on site, and then used to treat timber. In this situation it could be argued that there are two options:

1. The chemicals are placed on the market as chemical reagents and the CCA/CCB is generated 'in situ'. As such the chemicals would not need to be included in Annex I, IA or IB.

2. The chemicals are placed on the market for use in biocidal products and are simply being mixed together at the treatment site. In this case they would require inclusion in Annex I or IA.

Which of the options is correct?

Answer: The intention to use the substances as biocides is maybe not exerted by the person placing the substances on the market, but by the person using them. Nevertheless, the user's intention cannot bring the product within the scope. It is, however, agreed among the Commission and the Member States that the individual components of the mixture copper/chrome and either arsenic or boron have biocidal properties in their own right (precursors which are also active substances) and are simply being mixed at the treatment site. Option 1 is therefore not supported and if copper/chrome and either arsenic or boron are being used as biocides having been supplied in this way, they must have been included in Annex I, or IA. They can not be included in Annex IB as this kind of supply does not fulfil the definition of a basic substance as this is a complex reaction process. There is supply and placing on the market and therefore these substances are within the scope of the BPD[11].

2.2.1.2. Ozone

Question: Is the placing on the market of equipment for generating ozone for subsequent use on site within the scope of the BPD?

Answer: Article 1 of Directive 98/8/EC lays down the scope of the Directive, which concerns the authorisation and the placing on the market for use of biocidal products.

According to Article 3 (1), Member States have to prescribe that a biocidal product shall not be placed on the market and used unless it has been authorised in accordance with the Directive. Authorisation is defined in Article 2(1)(i) as an administrative act by which a Member State authorises the placing on the market of a biocidal product. On the basis of the definition of authorisation in Article 2(1)(i) there is an explicitly link between authorisation and the placing on the market, whereas at present, no reference is made to the use of the product. Placing on the market is defined in Article 2(1)(h) as a supply and there is no reference to use. There does not appear to be any supply when the production

[11] For further guidance see also document '**In-situ generation of biocidal active substances**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

takes place in-situ without involving precursors. In conclusion, the wording of the BPD covers a biocidal product if it is placed on the market. On the basis of these elements:

- placing on the market of ozone generating equipment does not fall within the scope of BPD to the extent that no biocidal product (ozone) is placed on the market.

- the users of the equipment are not within the scope of the BPD to the extent that they use the equipment to produce and use the ozone on their own site, without placing it on the market[12].

2.2.1.3. Advanced Oxidation Technology (AOT)

Question: A company is considering placing on the market a ballast water treatment system and wants to know whether their system falls within the scope of the BPD or not. The system consists of an Advanced Oxidation Technology (AOT) module, a treatment system using the synergetic effects of *in situ* produced free radicals and direct photo-radiation to inactivate microbes. Several metal-oxides exhibiting semi-conducting properties can be used as photo-catalysts in AOT-applications. This system operates without addition of chemicals, using the specific properties of the anatase phase of titanium dioxide in combination with water and UV-light. Titanium dioxide is in the form of a mechanical structure in the treatment chamber. Titanium dioxide is permanently attached as a layer of the titanium metal structure and is used as a pure catalyst, which means that it is not consumed during the treatment process and for that reason not dispersed in the environment.

Answer (agreed in April 2006): This treatment system is very similar to the equipment for generating ozone, described under 2.2.1.2. No precursors are being used and the production of free radicals can be seen in the same way as the production of ozone.

Placing on the market of an equipment generating free radicals without addition of chemicals or precursors should not fall within the scope of the BPD to the extent that no biocidal product (free radicals or precursors) is placed on the market.

However, in the case of a substance generated in-situ from precursors, the biocidal product containing the precursors would fall within the scope of the Directive as indicated under 2.2.1.6.

Lastly, substances used in ships ballast water management systems also need to be assessed and approved in accordance with the procedures established by the International Maritime Organisation.

2.2.1.4. Open Air Factor (OAF)

Question: A company sells to an end user an ozone generator (which produces ozone in-situ) and essential oils. The ozone and the essential oils react together to form a biocidal active substance, the so-called Open Air Factor (OAF), which is used as an indoor air disinfectant to combat harmful organisms in the air. The chemical nature of OAF has not been identified. Efficacy tests have shown a statistically significant difference between OAF and ozone and that OAF is the more effective compound. The essential oils were

[12] For further guidance see also document '**In-situ generation of biocidal active substances**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

found not to have biocidal effects against the test organisms. Is OAF under the scope of the BPD?

Answer: In contrast to the case where only in-situ generated ozone is used, this case involves marketing of a precursor (essential oils) from which the active substance OAF is generated. Therefore OAF is covered by the BPD. It seems, however, difficult to produce a full dossier for this active substance[13].

2.2.1.5.Cu^{2+} from temporary copper electrolysis

Question: A process to combat a species of algae in marine waters works through Cu^{2+} ions which are produced in-situ by electrolysis starting from copper metal. The Cu^{2+} ions are the active substance. Communities observing the algae in coastal areas contact the company having developed the process, which installs the electrolysis equipment producing Cu^{2+} from copper only during the treatment. Neither the equipment nor the copper electrodes are sold. Is this process / service subject to the requirements of the BPD?

Answer: The process/service of electrolysis of Cu producing Cu^{2+}, i.e. the "production" of the active substance, is not covered by the BPD since the Directive is concerned only with inclusion of active substances in the Annexes and authorisation of biocidal products before placing them on the market. However, all other Community (or national) legislation regarding the protection of the aquatic environment has to be respected, which could involve the necessity to have an authorisation under other legislation to carry out the treatment.

2.2.1.6. Cu^{2+}/Ag^{+} from permanently installed copper/silver electrolysis

Question: A system producing *in situ* copper and silver ions is used for the control of *legionella* in hot and cold water systems. The equipment used in the process generates ions from copper and silver electrodes. The system is installed at the water main of the site and the electrodes need to be regularly renewed. Both the equipment for electrolysis and the precursors for the active substances, i.e. the copper and silver electrodes are placed on the market. Does the system fall within the scope of the BPD?

Answer: (expanded in April 2006) Placing on the market of the equipment generating active substances in-situ is not covered by the BPD. However, in this system there is placing on the market of the equipment for electrolysis and also placing on the market of the precursors for the active substances, i.e. the copper and silver electrodes, from which the active substances, i.e. the copper and silver ions are generated.

The Commission services´ and the Member States therefore agreed that the Cu^{2+}/Ag^{+} process is covered by the BPD and that electrodes should be authorised under the terms of the Directive before they can be placed on the market. The equipment itself, as it is out of the scope of the BPD, does not need to be evaluated or authorised under the terms of the Directive; it may however be evaluated and authorised under other legislations.

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[13] For further guidance see also document '**In-situ generation of biocidal active substances**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

2.2.1.7.Washing machine with silver electrodes

Question: A washing machine is equipped with silver electrodes that are intended to release silver ions during washing to form a coating on the washed clothing. It is claimed that the silver ions inhibit the growth of bacteria within the washing machine itself and cause disinfection of the clothes that are washed within the washing machine. It is not anticipated that the washing machine itself will be coated during use. Is such a system within the scope of the Biocides Directive, and if so, under which product type falls this system?

Answer *(agreed in July 2005)***:** As the silver ions are generated in situ via a process of electrolysis, this case is similar to the permanently installed Cu/Ag-electrolysis process against legionella (see 2.2.1.6). Placing on the market of silver electrodes as part of washing machines (or to replace spent electrodes) to generate silver ions via electrolysis is therefore covered by the BPD and would fall under PT 2 'Private area and public health area disinfectants and other biocidal products', as the washing machine is supposed to be used in private areas.

2.2.1.8.Chlorine radicals generated in electrolysis

Question: A company is marketing an electrolysis apparatus, which, using platin electrodes and an aqueous sodium chloride solution as electrolyte, generates different active substances and free radicals containing chlorine. Does this equipment or the substances produced in-situ fall under the scope of the BPD?

Answer *(agreed in June 2003)*: This case is similar to the permanently installed Cu/Ag-electrolysis process against legionella with replacement of the electrodes during use, which is discussed earlier. The equipment, process or service is not biocidal products in the sense of the BPD. However, in this electrolysis process an aqueous sodium chloride solution (precursor) is used as electrolyte to produce active substances and free radicals in-situ. The solution needs to be regularly refilled or replaced. If sodium chloride is marketed for this use then the process is within the scope of the BPD. A full dossier for the active substances is in principle required. Possibilities for waiving and read across of data should be explored for the active substances.

2.2.1.9.Sodium Precursor (sodium dithionite)

Question: A drinking water disinfectant contains sodium dithionite which reacts to sodium sulphite and sodium hydrogensulphite by oxidation. These two substances act as disinfectants. Sodium dithionite itself is not an active substance in this product.

Is it necessary that the company has to submit dossiers for all three substances or just for the two active substances?

Answer *(agreed in December 2003)*: In line with the guidance document regarding the in- situ generation of active substances[14], sodium dithionite is a precursor, sodium sulphite and sodium hydrogensulphite are two active substances generated in- situ (which are notified foras PT 5, disinfectants for drinking water).

[14] For further information see document '**In-situ generation of biocidal active substances**'Doc-Biocides-2002/05-REV1 available at: http://europa.eu.int/comm/environment/biocides/index.htm

The in-situ generated substances are not unstable, whereas the precursor seems to be unstable under the conditions of use. An appropriate dossier should include data for the two active substances and the precursor, taking into account waiving possibilities for data that is unnecessary or impossible to generate.

2.2.2. On site formulation and use of biocidal products

2.2.2.1. Modified wood preservative

Question: A manufacturer of railway construction materials supplies various wood products for outdoor use in an impregnated condition for safety reasons. For impregnating he uses a wood preservative, which is produced on site starting from a wood preservative (creosote) bought from another manufacturer, which is refined in his plant and then used to impregnate the wood in the same plant. Only impregnated wood is sold, not the modified wood preservative. Assuming the first product is authorised, does the modified product, which is produced and used on site, need to be authorised again?

Answer: A combination of a product/article does not have to be authorised, if the active substance is intended to control harmful organisms only on or in the treated product/article. Wood treated with wood preservatives is regarded as such a product/article. Hence, there is no need for an authorisation of the modified wood preservative, if only the wood treated with the modified preservative is placed on the market.

However, if the modification changes the composition of the authorised biocidal product, the risks to humans, animals and the environment from the use of the modified preparation could be different from the authorised product. Hence, these should be assessed at some stage. At present, two options have been discussed. The risks could possibly be assessed at the time of the authorisation of the initial product, where potential modifications of the product composition could be evaluated as well. Alternatively, the label of the authorised product could contain the instruction "Product composition may not be modified".

Note that in any case the provisions of Directive 2001/90/EC adapting to technical progress for the 7th time Directive 76/769/EEC on restrictions of marketing and use of dangerous substances and preparations apply to creosote and wood treated with creosote[15].

2.3. Mode of action

2.3.1. Sticky traps without a biocide

Question: Are sticky traps covered by the BPD?

Answer: Sticky traps usually have a means of entrapment (e.g. glue) for small insects (ants, cockroaches) with no attractant. This mode of action is not considered to be chemical or biological and therefore such traps are considered to be outside of the scope of the BPD. Sticky traps containing an attractant are discussed in point 2.5.9.2.

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[15] OJ No L 283, 27.10.2001, p. 41.

2.3.2. Pond cleaner

Question 1: A chemical flocculating agent is marketed and described as a 'biodegradable clarifier'. The current label claim is that the product will 'effectively coagulate and flocculate a wide variety of suspended solids'. By default this includes organic material (including algae) that will sink to the bottom of the treated water where (naturally occurring) micro-organisms will decompose the plant material, leaving only a fine silt at the pond/lake bottom.

According to the producer, the product does not itself kill or harm plants or micro-organisms, its action is not by chemical or biological means as it does not rely on any selective or active removal of unwanted species, and death of the unwanted species is from entirely natural causes. Is the product within the scope of the BPD?

Question 2: A substance is used in garden pools to flocculate suspended material including algae. Immediately after adding it to the water, it will be transformed into insoluble particles. Suspended material, including algae, will be adsorbed at the surface of these particles. The algae continue to live and to photosynthesize. Due to formed O_2-they continue to float in the water and sink to the bottom of the pond only after natural death where they decompose or can be eliminated. By agitating the water, the flocks can be resuspended. Is this product within the scope of the BPD?

Answer *(agreed in June 2003)*: Both these products seem to exert no chemical/biological action as the control effect is not linked to "the interference of the substance in biochemical/physiological processes through direct chemical interaction (inside or outside the target organisms) or indirect modifications because of the physical/chemical properties of the substance"[16], which is an agreed definition on chemical action in Doc.Biocides-2002-06.

In the first case, the product is used to clean the water in general and not only to remove algae. Death of the algae seems to take place after sedimentation together with other particles to the bottom of the pond. This is the second step in the chain of actions and does not seem to involve direct action of the added substance. This seems to be similar to the case of calcium nitrate used to prevent the growth of bad smelling organisms in chemical toilets[17]. In that case it was agreed that calcium nitrate was not a biocide, since the action on the harmful organisms was only indirect. Therefore, the product used for cleaning ponds does not seem to be within the scope of BPD. However, before taking a definite stance on this case, it would be necessary to know, what substance is actually used and by what precise mechanism it triggers the coagulation or flocculation.

In the second case the algae continue to photosynthesize after flocculation. According to the description of the mode of action, the flocks can also be re-suspended by agitating the water. If the algae after re-suspension behave in the same way as they had done if they had not been flocculated, then there has obviously been no impact on them. Therefore, also in this case the product seems not to be within the scope of the BPD.

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[16] For further information see document '**Mode of action and other issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

[17] For further information see document '**Guidance on treated material/articles and some other scope issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

In general, in case of doubt, it is up to the applicant to give justification that the acting mechanism is exclusively non-chemical and non-biological, which means that the company would clearly have to give more evidence than they have done so far. See also the answer to Question 2 in 2.1.20.

2.3.3. Silica dispersed in water

Question: A ready-to-use product for the control of poultry red mite by inhibiting mite movement is placed on the market. The product contains amorphous silica in a water base, which is sprayed on surfaces. According to the information by the requesting company, after evaporation of water, particles of silica will adhere to the legs of mite, leading to its death by sticking to the mites legs and inhibiting its movements. The activity is not due to dehydration of the mite. The action is neither chemical nor biological according to the producer. Is the product within the scope of the BPD?

Answer *(updated in December 2005)*: According to the description of the mode of action, the amorphous silica particles attach to the tarsi of the mites and thereby inhibit their movements leading to death. However, information on new research presented in 2005 showed that the substance's mode of action is not through inhibiting the movement of insects and subsequent starvation. Instead, silica (either hydrophilic or hydrophobic) seems to act through absorption of the lipid layer covering insects' chitin protection, which then leads to desiccation and death of the target organism. Consequently, the earlier agreement that the substance would not be covered by the Directive needs to be revised. By destroying the natural water barrier, the waxy layer of the cuticle and hence disrupting the functioning of the water preservation mechanism, silica interferes with physiological processes, and the substance is within the scope of the Directive[18].

2.3.4. Dry silica powder used against insects

Question: A company wishes to market a dustable powder of fossile phytoplankton (amporphous silica powder) with a claim against insects. The company indicates that the mode of action is only physical, because 'The plankton has strong absorbing properties, even for oils, waxes and fat. Crawling insects have a natural protective wax-layer on their outer skelet. If the insects are dusted with the product, the protective wax-layer is absorbed and afterwards the insects become dehydrated". Is this correct?

Answer (agreed *in December 2004 and updated in December 2005*): This product is covered by the Biocides Directive. Silica leads to dehydration of the insects (most probably through absorption of the lipid layer covering insects' chitin protection, which then leads to desiccation and death of the target organism. [19]. A substance controlling harmful organisms is regarded as an active substances acting by chemical means when the control is linked to the interference of that substance in biochemical/physiological processes through direct chemical interaction (inside or outside the target organisms) or indirect modifications because of the physical/chemical properties of the substance. This is clearly the case here.

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[18] For further guidance see also document '**Mode of action and other issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

[19] For further guidance see also document '**Mode of action and other issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

2.3.5. Silicone based product against fleas NEW

Question: A company has asked about a product containing a substance which is intended to be used to control fleas. The company claims that the substance does not interact with the insect's biochemical/physiological processes and that it acts by physical means only by sticking the flea's legs together so that they cannot move. Once the product is sprayed, the highly volatile solvent evaporates off the flea's body leaving the substance on the surface of the cuticle, to form a coating which has an 'adhesive or sticky' effect.

The company states that the silicones used in this formulation do not cause desiccation or suffocation of the adult flea, or its larvae or pupae. Further evidence of the lack of desiccation and continuation of vapour transmission after treatment is observed in the dissected pupae that continue to develop, but cannot physically emerge from the pupae case. Is this product under the remit of the Directive?

Answer: (*agreed June 2007*) Organic **Silicones** are structurally and chemically very different to inorganic **silica**. **Silica** based products - both dispersed in water and used as a dry powder – are within the scope of the BPD as described in sections 2.3.4 and 2.3.5, where it was agreed that the mode of action was chemical. By contrast, **Silicones** are biocompatible, as underlined by their numerous applications in foods, cosmetics, medicines and medical devices and by the fact that the company reports that the fleas still develop but cannot move after treatment. This means that the product does not prevent development of the flea (which would be expected to occur if the mode of action was desiccation) and this leads to the conclusion that this product works by non-chemical means and is therefore outside the scope of the Directive.

2.3.6. Control of insects by freezing

Question: A company has asked whether a product intended to control insects by freezing them comes under the scope of the Biocidal Products Directive (BPD).

The product contains a fluorinated hydrocarbon (with a low ozone depleting capacity) which together with a propellant, is held in a pressurised canister as a liquid.

The company states that when the product is sprayed at an unwanted insect the liquid vaporises, absorbing heat and essentially freezing the target insect.

Does the mode of action of this product take it outside the scope of the BPD?

Answer (*agreed November 2007*): The mode of action of this product does not appear to have a **direct** chemical interaction with the insect's biochemical/physiological processes, the absorption of heat ('thermal' energy) by this product presents a change to the physical external environmental conditions around the insect which is considered to be outside the scope of the BPD.

2.3.7. Control of birds eggs

Question: A product derived from oil is used to control birds by coating their eggs to fill the pores of the shells, leading to the death of the embryos. Is the product within the scope of the BPD?

Answer (*agreed in June 2003*): A substance controlling harmful organisms is regarded as an active substance acting by chemical / biological means when the control is linked to the interference of that substance in biochemical/physiological processes through direct chemical interaction (inside or outside the target organisms) or indirect modifications because of the physical/chemical properties of the substance[20].

An earlier agreed example concerned, *mineral oil blocking the breathing tubes of insects* states. Physical blocking of breathing tubes leads to the death of the target organisms through suffocation, hence a severe interaction with physiological processes (and not a pure physical/mechanical action such as a mouse-trap or crushing of an insect). Obviously, suffocating as such is agreed to be a result of a process with chemical/biological action, even if it is achieved through the blocking of breathing facilities through a chemical.

Furthermore, as the shell of bird's eggs is porous it could be the case that some of the substances in the oil penetrate the shell and exert directly a detrimental effect on the embryo. Therefore, this way to control birds seems within the scope of the BPD.

2.3.8. Starvation of bacteria

Question: A product containing a number of chemicals is used to control bacteria by coating and thereby starving them to death. According to the company, the product is not antibiotic and there is no dissolution of the cell wall. Is this product within the scope of BPD?

Answer (*agreed in June 2003*): This method to kill bacteria is within the scope of the BPD, because at least one of the chemicals used to exert the controlling action is known to have biocidal effects and has been identified as an existing active substance.

Also, food is as vital for an organism as air and preventing their intake is a severe interference in biochemical/physiological processes[20].

2.3.9. Tall oil and tar oils

Question: An association of the wood preserving industry has asked whether crude tall oil is regarded as a biocidal product when used in wood impregnation. Crude tall oil contains fatty acids, resin acids and some neutral compounds. The resin acids consist mainly of abietic acid. Crude tall oil does not contain volatile terpene compounds. According to the industry association, these (and other plant oils) work mainly by preventing the entry of water into wood and not by direct action on harmful organisms.

A similar claim has been made for tar oils, which are produced through distillation of pine wood by a large number of very small producers in a rather uncontrolled way. The final product compositions vary greatly and the producers would have great difficulty in finding the financial means to produce all the data necessary to support a notification and an application for Annex I inclusion.

Is the use of tall oil (and other plant oils) and pine tar for treatment of wood and other porous materials outside the scope of the BPD?

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[20] For further guidance see also document '**Mode of action and other issues**' available at: http://europa.eu.int/comm/environment/biocides/pdf/action_mode.pdf

Answer: In these cases it seems difficult to distinguish between an action that is entirely non-chemical (and non-biological) and one which is a combined chemical/non-chemical action. Products acting or having a claimed action by non-chemical/non-biological means – (e.g. inhibition of water absorption), whilst at the same time having a marginal (non-efficacious) action by chemical or biological means should be outside of the scope. Products that have the characteristics of exerting control by both chemical or biological and non-chemical/non-biological means at or above the effective threshold have to be considered as being within the scope.

The case of crude tall oil was discussed at several meetings of the competent authorities, based on a number of studies including studies comparing its effect on the growth of wood decaying fungi in comparison to typical wood preservatives. It was agreed that crude tall oils function by non-chemical/non-biological means through the prevention of water absorption into the wood and only to a marginal extent based on chemical/biological action. The product is therefore not within the scope of the BPD and can not be placed on the market with a biocidal claim. Further similar cases (e.g. for other plant oils) would have to be judged on their own merits[21].

The situation for pine tar seems to be different, as it is virtually impossible to distinguish between pure non-chemical/non-biological action and pure chemical/biological action. Moreover, tar distillates are known to contain a wide range of toxic substances. It is therefore doubtful that it can be proven that the mode of action is not by chemical means. The financial problems for some producers to generate all necessary data apply to many producers of biocides in various product types and are of a horizontal nature. In view of an equal treatment of all operators they must be solved for all cases in a similar way.

2.3.10. Pine tar

Question: During the 19th CA meeting, the Norwegian competent authorities presented a testing strategy to demonstrate that pine tar was not an active substance within the meaning of Directive 98/8/EC (the Directive). After this testing strategy was agreed with the other Member States competent authorities, a project commissioned by the Nordic Council of Ministers, the Danish Environmental Protection Agency and the Directorate for Cultural Heritage (Norway) was launched in late summer 2005 at the Swedish National Testing and Research Institute to confirm that pine tar was not active substance within the meaning of the Directive.

The Norwegian competent authorities presented during the 24th CA meeting the final technical report of that project (*CA-March07-Doc.8.4)*, which concluded that *'the test indicates that none of pine tar products acts as a wood preservative by providing decay resistance to wood, when applied as surface treatment for above ground application."*.

Answer *(agreed in March 2007)*: It was thus agreed that pine tar - used as wood surface treatment - should not be regarded as an active substance within the meaning of Directive 98/8/EC and that pine tar - used as wood surface treatment - does not fall under the scope of the Directive.

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[21] Germany did not agree to the conclusion as in their view there is still non-negligible chemical or biological action. For further guidance see also document '**Mode of action and other issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

2.3.11. Cellulose product as a rodenticide

Question: A rodenticide is produced by 'inert and non-toxic animal food plant material' according to the producer. The action of the product is to serve as a diet replacement. Rats and mice offered the product eat it in large quantities as their sole diet. The animals cannot digest the product properly, which leads to proliferation of their caecal pathogenic bacteria, dehydration and death by blood intoxication. Is this rodenticide covered by the Biocides Directive?

Answer *(agreed in January 2003):* The product, when ingested, swells in contact with water in the stomach and intestines. This impedes further digestion and hence all processes linked to degradation and absorption of nutrients. In addition, the material compacts in the part of the intestine where dangerous bacteria breed, producing toxins, which cause the weakened rodent to die of blood poisoning. Therefore these products are covered by the Biocides Directive, and the active substances have to be notified and evaluated[22]. For these particular products, the possibilities for justifying waiving of data as provided for in Article 8(5) of the Directive should also be examined.

2.3.12. Titanium dioxide NEW

Question: Titanium dioxide (CAS Nr 13467-7, EINECS Nr 236-675-5) is an inorganic oxide and semiconductor, with a band-gap corresponding to wavelengths at near-UV-light and at violet spectral range. Due to this, titanium dioxide is able to act a photocatalyst: it has the ability to create electron-hole-pairs, which generate free radicals able to undergo secondary reactions. Titanium dioxide as a catalyst is not consumed during the reaction.

When titanium dioxide is used for self-cleaning surfaces and windows, as a photocatalyst, it will reduce the adhesion forces between inorganic compounds (dirt/dust) and surface under influence of external light source, especially under UV-light. Rain or humidity will then remove the dirt/dust from surface. Due to diminished adhesion forces it is also more difficult for organic agents to bind onto surface. Also, titanium dioxide could form hydrophilic surfaces, so water forms a smooth sheet instead of tiny droplets, and that sheet gets under dirt/dust to lift it off the surface and get it washed away. Cleaning may also be assisted by the action of non titanium containing, secondary free radicals.

It is notable that titanium dioxide does not per se exert any biological activity, and it is not a precursor for any active titanium agent. The possible action on the harmful organisms is thus indirect.

Does titanium dioxide fall within the scope of Directive 98/8/EC?

Answer (agreed at 29th CA meeting and replacing the one of June 2003): Numerous publications (Carp et al., 2004; Huang et al., 1998; Krishna et al., 2006; Štengl et al., 2007) indicate that characterizes titanium dioxide as semiconductor with band-gap corresponding to wavelength smaller than 388 nm.

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[22] For further guidance see also document **'Mode of action and other issues'** available at: http://europa.eu.int/comm/environment/biocides/index.htm

The photocatalytic reaction occurs when the semiconductor nanoparticle absorbs a photon which is more energetic than its band-gap. Under the band-gap, excitation semiconductor nanoparticles act as short-circuited microelectrodes and initiate oxidation and reduction processes of absorbed substrates. In aqueous solution, the electron holes are scavenged by surface hydroxyl groups to generate °OH radicals. The oxidation mediated by °OH radicals has been successfully employed in the mineralization of many hazardous chemical contaminants and a large variety of organics, viruses, bacteria, fungi, algae, and cancer cells, which can be totally degraded and mineralized to CO2, H2O, and harmless inorganic anions.

From the above, it can be concluded that titanium dioxide is a catalyst only and is not consumed in the reaction.

It is also recognised that titanium dioxide does not per se exert any biological activity, and that it is not a precursor for any active titanium agent. The possible action on the harmful organisms is in addition indirect.

It is therefore concluded that titanium dioxide should not be considered as an active substance within the meaning of the Directive.

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2.3.13. Anti-microbial high molecular weight polymer

Question: A high molecular weight polymer (essentially a polyamine) is used as antimicrobial active compound. A strong electric field presented along the polymer chain interferes with micro-organisms and inhibits their growth. The interaction between the polymer and the cell membrane leads to the reduction of the cytoplasmic membrane potential, resulting in a depolarisation of the membrane, followed by an increased cell permeability, which finally led to the cell death. Is this mode of action considered as physical?

Answer *(agreed in December 2003)*: The biocidal effect of the polymer can not be considered as a non-chemical mode of action: The polymer acts by depolarisation of the

micro-organisms cell membrane of the micro-organisms, which leadsconducts to a biological disorganisation of the membrane structure causing the death of the bacteria.

This is in line with the relevant "guidance document agreed between the Commission services and the Competent Authorities of the Member States", where it is considered that " A substance controlling harmful organisms is regarded as an active substances acting by chemical means when the control is linked to the interference of that substance in biochemical/physiological processes through direct chemical interaction (inside or outside the target organisms) or indirect modifications because of the physical/chemical properties of the substance (chemical means)".[23]

2.3.14. Furfurylated wood

Question: Furfurylated wood is made by impregnating wood with catalyzed liquid furfuryl alcohol which is then heat-polymerized to form a solid polymer inside the wood and results in a solid composite consisting of wood and polyfurfuryl alcohol. Wood and polyfurfuryl alcohol are chemically linked together during the polymerization process. This linking fundamentally changes the chemical nature of the wood, producing a biologically inert material.

Appropriate testing has demonstrated that furfurylated wood contains only small amounts of non-toxic chemicals, including traces of non-polymerised furfuryl alcohol. The amounts of leachable chemicals detected have no more toxic effects than untreated wood on fungi, algae, protozoa and fish. This shows that it is only the modified chemical structure that makes furfurylated wood resistant to biodeterioration. Is this method of wood treatment within the scope of the Biocides Directive?

Answer *(agreed in December 2003)*: Furfurylated wood is a biologically inert material solely due to the modified structure of the wood. This method of wood treatment is therefore excluded from the scope of the Directive.

2.3.15. Wood impregnated with products containing potassium formate

Question: A company has developed near neutral or alkaline wood treatment preparations against fungi and mould on the basis of potassium formate. It has been shown in laboratory filter paper tests that various water-based formate solutions (containing e.g. magnesium sulphate) do not prevent the growth of fungi and mould. In the tests 3-iodopropargyl-N-butylcarbamate (IPBC) was used as a reference substance and it was shown to be effective by preventing the growth of fungi and mould.

Treating wood with potassium formate preparations relies on the delivery of formate -anions and magnesium -cations into the wood cell wall structure. Potassium formate and magnesium-ions change the cellular structure of wood by forming metallic-carbohydrate-formate complexes (e.g. esterification of hydroxyl groups) with the cellulose chains containing weak carbonyl bonds. This prevents effectively the access of wood fungi to the wood cell wall interior, and thus the rot formation

The antimicrobial effect of organic acids such as formic acid has traditionally been attributed to the reduction of pH below the growth range and metabolic inhibition by

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[23] For further information see document **'Mode of action and other issues'**Doc-Biocides-2002/06 available at: http://europa.eu.int/comm/environment/biocides/index.htm

undissociated acid molecules. Because the pK_a value of formic acid is 3.75, the amount of undissociated formic acid is only in the level of ppm at neutral and alkaline pH. Therefore the hydrolysis of formate salt back to the corresponding acid i.e. to formic acid is practically non existent in wood.

Leaching, environmental properties and toxicity of potassium formate and other ingredients have also been discussed in the submitted documentation and did not lead to any unacceptable risks. Are the products containing potassium formate biocides?

Answer *(agreed in December 2005)***:** Potassium formate (and the other components) do not have biological or chemicals effects on fungi and mould but when used to impregnate wood prevent their access into wood by physical means. Therefore, the method of wood treatment is excluded from the scope of the Directive.

2.3.16. Nutrients for beneficial micro-organisms

Question: A product has been developed for "conservation" of additives in the field of paper production. The product contains specifically assorted nutrients and when it is added a displacement-process takes place among the micro-organisms. Those micro-organisms that produce undesired metabolites that have a negative impact on the additives, are overgrown by micro-organisms that produce metabolites that do not have any negative impact. Is this a biocidal product within the scope of the Biocides Directive?

Answer (*agreed in January 2003*): Under the assumption that the product consisting of the nutrients when added to the additives only supports the growth of those micro-organisms that do not produce undesired metabolites, and has no significant direct effect on the other micro-organisms, this product is not a biocidal product. According to the definition in Article 2(1)(d) of the Directive, an active substance must have a direct action on or against harmful organisms, whereas here the action is on a wanted or useful organisms. This is similar to the case of calcium nitrate used to prevent the growth of bad smelling organisms in chemical toilets[24]. In that case it was agreed that calcium nitrate was not a biocide, since the action on the harmful organisms was only indirect.

2.3.17. Lignin

Question: A product is used for improving the runability of paper machines by avoiding chemical deposits in the paper machine circuit and thereby making it impossible for slime-forming micro-organisms to settle down in the paper machine circuit. The main component, lignin, is identical with naturally occurring lignin as far as possible. The product also contains another 3 components for chelating metal ions. The complexing agents are also used in the food industry. This mixture is an effective product that helps to avoid deposits in the paper machine circuit. Since these deposits are primarily of a chemical nature and afterwards settled by micro-organisms, the product has only an indirect controlling effect. This is shown by the fact that the germ-count in the system cannot be reduced by adding the product but the number of slimy deposits (i.e. deposits being settled by slime-forming micro-organisms) is reduced. Is the product covered by the BPD?

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[24] For further information see document '**Guidance on treated material/articles and some other scope issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

Answer: For the purpose of the described product, lignin and the other components should not be considered as biocidal active substances, as their purpose is not to control directly slime-forming micro-organisms but to hinder the settlement of chemical deposits in the paper machine circuit. See also 2.6.4.

2.3.18. Antifouling product acting by physical means

Question: A company intends to market an antifouling product for which it claims action by physical means. The action is based on a process of decomposition of organic material and the resulting depletion of oxygen. The technique takes advantage of the finding that early stages of fouling organisms avoid settling on substrates with low oxygen content.

The product based on this technique will consist of a self polishing coating (SPC) containing organic substance that is exposed to the surface/water interface. The mechanism is described as depletion of oxygen within a thin layer of the treated area. The thickness of the active layer in which the concentration of oxygen is affected is limited to 1.5 mm from the paint surface. The organism about to settle senses the low oxygen concentration and moves away from the active layer.

The company argues that the direct effect on the organisms is of a physical nature by creating an environment with a too low oxygen pressure for the fouling organism to settle and live on.

Answer (agreed in December 2004): The explanation provided is not convincing to demonstrate that the action of the product is neither chemical nor physical. Obviously, the fouling organisms avoid settling on the treated surface, due to the fact that they sense a lack of oxygen on the surface layer – in fact they are repelled from settling, which is fully comparable to the mode of action of other repellents (e.g. insect repellents), which are clearly covered by the BPD. However, the question on how the oxygen depletion on the surface is brought about needs further reflection.

Upon further enquiry, the company informed that oxygen depletion is triggered by the growth of non-harmful micro-organisms, such as bacteria, which degrade the organic material released from the paint and thereby deplete the oxygen in the water immediately adjacent to the surface. It can therefore be concluded that the product does in fact promote the growth of beneficial micro-organisms, which in turn prevents the settling of the harmful fouling organisms. In line with the views expressed in an earlier example, where a substance acts as nutrient for beneficial organisms (see point 2.3.1.12), the product therefore is no biocidal product in the meaning of the Directive.

2.3.19. Cleaning product and antifouling product containing micro-organisms

Question: A company wishes to market a product, containing various species of micro-organisms to aid the cleaning (during maintenance) of surfaces that usually reside under water (hulls of boats etc.). The product's aim is to reduce the adhesion of various fouling organisms onto the surface. The company claims that the product has EPA approval for this use.

The Company claims that the product does not act on the organisms itself but on the adhesive material (cement) that the organisms secret from glands and use to attach themselves to a surface. The formulation is a mixture of enzymes and micro-organisms which hydrolyse the 'cement'. The cleaning product has no known residual effect once

the surface has been rinsed clean. The Company claims that the product is not intended to have a biocidal effect nor is it intended to control growth or settlement of fouling organisms.

In addition the company plans to extend the product range to introduce the same technology formulated into a marine underwater hull coating. Such a product is currently sold to the yacht and leisure craft market in the USA (the company claims that it has EPA approval). This coating contains the same enzyme/micro-organism mix as the cleaning product described above. It deters the settlement of marine growth by hydrolysing the cement adhesive they secret and preventing their adhesion to the surface. The Company claims it does not have a damaging effect on the marine organisms themselves. Are these products within the scope of the BPD and, if so, under which product types?

Answer (*agreed in December 2004 and modified in July 2005*): A biocide is defined in Article 2 of the BPD as active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

For both products, the mode of action of the various enzymes and species of micro-organisms appears to be the reduction of the adhesion of various organisms such as barnacles, clams and other marine growth onto surfaces. This ties in with the deterrence, rendering harmless or prevention the action of the undesired organisms criteria in the definition albeit indirect chemical (hydrolysis) action on the adhesive material (cement) of such organisms. It is clearly not necessary to have a 'damaging' effect on the fouling organisms.

Upon further enquiries, the company itself explained that the product 'acts upon the polysaccharide component of the adhesive material secreted by the settling organism'. So there is obviously an action on or against the harmful organism as contained in the definition of Directive 98/8/EC. Consequently, the product intended to be used in underwater coatings is an antifouling product within the scope of Directive 98/8/EC.

For the cleaning product the situation is more complicated. A normal detergent would most likely not have an effect as described in the preceding paragraph. The fact that in the 'cleaning' product there are 'no residual effects once the surface has been rinsed' is not really relevant - most disinfectants are applied and then washed away without residual effects (e.g. disinfectants used on surfaces). It is therefore considered that the ‘cleaning product’ is also under the scope of the BPD and should fall into PT 2: Private area and public health area disinfectants and other biocidal products.

The company had also suggested that both products had approval with the US EPA. Upon verification with the EPA, it was found that no approvals existed. However, the EPA indicated that both products would require approval given that they made antimicrobial claims.

2.3.20. Slurry additives

Question: Certain additives are added to slurries to resolve homogeneity problems due to crusts and deposits. The additives introduce bacteria and enzymes, and stimulate slurry microflora activity, in order to assure decomposition of straw and faeces of animal origin

and to make liquefaction easier in view of pumping and spreading. There are no disinfecting effects intended. Are such additives biocidal products?

Answer (agreed in December 2004): Slurry additives, which have no intention of disinfection and which are used to stimulate biological processes by promoting beneficial mircro-organisms, rather than hindering them by controlling harmful organisms, are not biocides and do not fall within the scope of Directive 98/8/EC.

2.4. Active substances vs. other constituents

2.4.1. Active substance or an impurity

2.4.1.1. Peroxyoctanoic acid

Question: A company markets a product containing peroxyoctanoic acid (a perfatty acid), generated from caprylic acid added as a co-formulant, to preparations of peroxyacetic acid (POAA). Caprylic acid is used as a co-formulant in POAA to reduce the corrosive activity of the formulation on aluminium and stainless steel. Caprylic acid reacts partly with H_2O_2, which is present in the POAA based preparation, forming peroxyoctanoic acid in small amounts over a period of 7 to 10 days.

Peroxyoctanoic acid might be regarded as an impurity/by-product in POAA, because:

- its effect is the reduction of damage to aluminium and steel equipment by corrosion

- its formation takes place unintentionally

- it is formed in low concentrations of below 0,5 % in the preparation

On the other hand, according to the company, the antimicrobial properties of peroxyoctanoic acid are known from literature. The mode of action of peroxyoctanoic acid is comparable to other strong oxidising agents such as hydrogen peroxide or peroxyacetic acid. Combinations of organic acids and peracids like POAA and peroxyoctanoic acid are known to have enhanced biocidal activity. Efficacy studies have shown that the amount of 0,5 % peroxyoctanoic acid contributes significantly to the efficacy ot the formulation.

Is peroxyoctanoic acid an active substance or or an impurity in this case?

Answer (*agreed in June 2003*): The crucial factors, when considering if the substance is a biocidal active substance, are the purpose behind the addition of the substance and the substance's mode of action. Already the amount of 0,5 % of the substance contributes significantly to the efficacy of the formulation, according to the company. Peroxyoctanoic acid is formed from caprylic acid, which is added intentionally as a co-formulant in POAA. Peroxyoctanoic acid can therefore not be regarded as an impurity and it is a biocidal active substance.

2.4.2. Active substance or an additive

2.4.2.1. Calcium salts in stables

Question: Different calcium salt products are used as powder to be spread on the floor of cow and pig stables with the following effects according to the information provided by the company that wants to place the product on the market: hygiene effect, drying of the sleeping area and supply of sulphur which is available for plants (calcium sulphate and sulphite) when the manure is spread on agricultural land.

The products consist of mixtures of different calcium salts with highly varying contents. The calcium salts of the mixture are: calcium hydroxide, calcium oxide, calcium sulphate and calcium sulphite. The company explains the hygiene effect of the products by the high pH arising from calcium oxide and calcium hydroxide in the presence of water and, consequently, these salts should be considered as active substances. According to the

information from the company the function of calcium sulphite is only as a supplier for sulphur for plants after spreading dung and liquid manure on the field. None of the possible active substances was notified or identified. Are the following conclusions correct?

1) Calcium oxide and hydroxide are active substances due to the high pH value in solution. Is there a limit for the pH (pH 13)?

2) Products that contain at least one of these substances and are marketed and used for biocidal purpose must be withdrawn from the EU market after the second Review Regulation will come into force, probably with consequences for a great sector of the EU market.

3) Calcium sulfite is labelled as sulphur supplier. But according to other information it is also a possible active substance.

4) The product would be assigned to PT 3.

Answer (*agreed in June 2003*): The product consists of mixtures of different calcium salts and both the high variations of the calcium salts and the presence of sulphur containing salts indicate that these products are waste products from smoke desulphurisation processes. This means that it would normally have to be considered as hazardous waste and could not be placed on the market, but had to be disposed off in accordance with the relevant legislation on hazardous waste. To clarify this, information on the origin of the products is needed.

The product is used as powder in cow and pig stables, with the intention of a hygiene effect because of the high pH-value, due to the presence of calcium hydroxide and calcium oxide in the product. The pH-value will probably be very high when the powder comes into contact with water (for pH limits being indicative of biocidal action see 2.6.1.1). There seem to be considerable risks both for the persons applying the product in the stables and also for the animals which are kept in the stables. The product may be corrosive or irritating on the skin of the animals and to eyes and respiratory organs of the persons applying it.

Existing active substance had to be identified under Regulation 1896/2000 to be allowed to be placed on the market for a limited period after the second Review Regulation will have come into force. They had to be notified to be included in the review programme. As they were not identified or notified they cannot be placed on the market for biocidal purposes from the day when the second Review Regulation comes into force.

If calcium sulphite has a biocidal effect in the meaning of the BPD, but the concentration is too small to work as an effective biocide in its own right, and if the product should have similar effect even without the sulphite, then the sulphite could be considered as a substance of concern in the product. If the sulphite is present in big amounts (to have effect as nutrient for plants) it could probably contribute to the biocidal effect of the product and it would be an active substance in the meaning of the BPD. It should be clarified whether or not calcium sulphite has a biocidal action in the sense of the definition of a biocidal product or if it is only a sulphur supplier for plants.

If the product is indeed not to be regarded as hazardous waste and the risks to human and animal health are deemed acceptable, it would be assigned to PT 3.

2.4.2.2. Ni/Cu alloys

Question: A company has applied for an authorisation for an antifouling product in which the active ingredient is a powder of a copper/nickel alloy (90:10). According to the company, the mode of action is formation of a surface film consisting of copper oxide and copper oxychloride (dicopper chloride trihydroxide) or other mixtures of copper hydroxide and copper chloride. The film deters fouling organisms by the toxic action of copper ions and by shedding of the outer layer of cuprous hydrochloride. The company claims that the role of nickel is to stabilise the copper so that it corrodes much slower (one-third of the rate in unalloyed copper). The leaching rate of copper is reduced, too. Nothing is mentioned of the role of nickel in any biocidal action. The question is whether copper can be regarded as the sole active substance with nickel as an additive or an otherwise defined non-active component.

Answer: There is no information available that nickel or nickel compounds would be used as active substances in biocidal products. No nickel compound has been identified or notified as an existing active substance. Nickel could therefore in this specific case indeed be regarded as not being an active substance but a component of the biocidal product. However, should the authority have doubts about this, it is up to the applicant to prove that nickel is not an active substance.

It should be noted, however, that many nickel compounds are classified as toxic or highly toxic for the aquatic environment. This makes nickel compounds clearly substances of concern. Therefore, data on the toxicological and ecotoxicological properties of these substances might have to be submitted in accordance with the Directive as specified in Annex II B, points VI (6.5, 6.6), and VII (7.3), as well as, if considered relevant, Annex III B (in particular 2.1.3).

2.4.2.3.Chromium in wood preservatives

Question: What is the status of chromium in biocidal products used for wood preservation after 1 September 2006?

Answer (agreed in July 2005): There has been much debate on this issue. Chromium had originally been notified as active substance in wood preservatives, but all participants withdrew and no complete dossier was submitted. Therefore, the status of the substance is now as if it had only been identified. This means that existing biocidal products containing chromium as an active substance will have to be removed from the market by 1 September 2006. Any new product, containing chromium as an active substance, will have to be authorised prior to its placing on the market. An application should be made to that effect in accordance with Article 8 of Directive 98/8/EC and requesting inclusion of the substance into Annex I or IA to the Directive in accordance with Article 11.

However chromium could still be used in biocidal products for other purposes (e.g. as a fixative) providing that it can be shown that the chromium is not acting as an active substance. Decisions will be made on a case by case basis for each product and it will be crucial to provide the necessary efficacy data to demonstrate that chromium is not an active substance in the given product. Due to its intrinsic properties, chromium will also be treated as a substance of concern when used as a non active substance in biocidal

products, which will require a substantial amount of data on toxicology and ecotoxicology of the substance to be provided as part of the product dossier[25].

2.4.3. Active substance or a synergist

2.4.3.1. PBO

Question: Piperonylbutoxide (PBO) is used in products as a synergist together with an insecticide (e.g. pyrethrum or pyrethroids). The substance prolongs the degradation time for the insecticide inside the insect body so it can exert its action more effectively.

Is it necessary to notify PBO and what information should be submitted in the full dossier?

Answer (*agreed in January 2003*): According to the definitions of Directive 98/8/EC, an active substance is a substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms.

If PBO by itself showed such general or specific action on or against harmful organisms and was sufficiently effective to be used alone in biocidal products, it would have to be regarded as an active substance and hence identified or notified according to Regulation 1896/2000. The same would hold for the other active substances (pyrethrum or pyrethroids) that might be used by themselves, or in combination with PBO.

However, according to the experience of the Member States, PBO is not used as an active substance on its own, but always in combination with other active substances. For the authorisation of the formulated biocidal product, information on the active substance and all relevant substances of concern, such as PBO, are required as appropriate in accordance with the provisions of annexes IIB and IIIB. The information on the synergist might have to be more extensive than for other substances of concern, due to its specific action. Since the synergist makes these active substances even more 'active', the applicant has to consider which studies on the synergist, or the active substance together with the synergist, have to be submitted in the complete dossier to enable full risk assessment to be undertaken.

2.4.4. Efficacy of products with several potentially active substances

2.4.4.1. Efficacy of a product with a notified and a non-notified active substance

Question: How is efficacy of a formulated product to be determined, which contains a notified and a non-notified active substance? The identified-only active substance is present in the formulation for non-biocidal purposes. Example: an antimicrobial product which contains active substance 1 (notified) and active substance 2 (only identified). Such a product would surely disinfect surfaces, which could be as a result of both active substance 1 and 2. However, active substance 2 is a good limescale remover and would be included in the formulation for that reason. Active substance 1 would therefore provide the biocidal efficacy (e.g. the antimicrobial effects). As a solution, would proving efficacy without the non-notified biocide(s), be acceptable?

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[25] Further information can be found in the document **Guidance on the roles of chromium in wood preservation**, available at: http://europa.eu.int/comm/environment/biocides/main_subjects.htm#Borderlinedocuments

Answer (agreed in December 2004): When active substances are included in a biocidal product for non-biocidal purposes it will be necessary to show efficacy of the active substance(s) in the absence of any other formulants of the biocidal product that are known or suspected to have biocidal properties at the levels they are included in the product. Therefore efficacy data on the final product minus non-notified active substances (or equivalent detailed information from the source which resulted in the determination of the minimum effective concentration of the active substance) should be submitted in the dossier (or a letter of access to the original efficacy study which identified the minimum effective concentration of the active substance). In addition efficacy data on the final formulation will also need to be included.

To disperse any remaining doubts, the interested company could also be asked to test efficacy of the specific formulation without the notified active substance (and all other concentrations unchanged). If such a formulation was not efficacious, efficiency of the real product would solely be due to the notified active substance. However, if efficiency of the formulation without the notified active substance was not significantly lower than that of the real formulation, it would be difficult to argue that the only-identified substance is not an active substance in the formulated product. In any case, as the non-notified substance has been identified as an active substance, it has to be checked whether at the given concentration it could be considered as a substance of concern as it certainly has an inherent capacity to cause an adverse effect on humans, animals or the environment.

2.5. Product type specific questions

2.5.1. PT 1 – Human hygiene biocidal products

2.5.1.1. Anti-viral paper tissues

Question: A company intends to place on the market a facial tissue to which an antimicrobal agent has been added. The biocidal active substance intended for this use has been notifed under the BPD. The company also wishes to make a claim such as "stops the spread of colds and flu viruses" for the tissue. Virucidal efficacy has been performed against a number of viruses. The company believes that the tissue should be considered to fall into PT 2, as the active substance is acting as a disinfectant of a material, i.e. the tissue. The product is not designed to kill the virus either on or in the human body. By killing the virus deposited on the tissue, the biocide is preventing the release of the virus into the air and surroundings. Is this correct?

Answer (*agreed in December 2004*): There are, in fact two questions to be answered:

1. Is the impregnated tissue a biocidal product or only a 'treated material'?

2. What is the correct product type, which will depend on the answer to the first question?

Assuming that the tissue does not release the active substance and that there is no significant exposure outside the tissue one could argue that not the tissue is the biocidal product, but only the active substance used to impregnate it. In that case the active substance would clearly be a disinfectant for materials in PT 2, but as a consequence the impregnated tissue itself would not be regarded as a biocidal product.

However, when looking at the scenarios described in the ESD for PT 2[26] (disinfection of rooms, furniture, objects, instruments, laundry, hospital waste etc.), none of them covers this situation, i.e. the disinfectant remaining in a material with the intention to have a long-lasting activity after treatment with the disinfectant.

In addition, according to examples contained elsewhere in this Manual of Decisions (Chapter 3) and the other relevant guidance document[27] the tissue is to be regarded as a biocidal product, because the intention of using the active substance for impregnating the tissue is not to control organisms harmful to the tissue itself. The tissue would therefore be a kind of delivery system for an active substance that is used for human hygiene purposes and therefore be in PT 1.

Even though it is not intended to have effects on human skin, when blowing their nose or wiping their hands, humans will be exposed to the active substance that will also then affect germs on human skin (in addition to the action on the material blown into the tissue).

Lastly, the claims that the company wishes to use are somewhat problematic, too. Whilst they are no medicinal claims in the sense of the Medicinal Products Directive (including prevention, treatment or diagnosis of disease), it seems somewhat bold to assign the claim 'stops the spread of colds and flu viruses'. This might be true for the exclusive transmission via contact with the tissue, but it is certainly not true for all other ways of transmission from person to person or contact via other means. Using this tissue will probably not prevent the spreading of a cold or the flu in a more significant way than using non-impregnated paper tissues. So the company might want to limit the claim to be sure that the tissue can really deliver what is claimed.

2.5.2. PT 2 – Private area and public health area disinfectants and other biocidal products

2.5.2.1. Hygienic paint coatings for walls and floors

Question: A company intends to market a range of hygienic paint coatings for walls and

floors that are designed to help reduce the number of bacteria and hence risk of infection by the inclusion of an additive that is being constantly renewed to the surface of the paint. The active substance in the additive has been notified by a manufacturer under the BPD.

The additive has been proven scientifically by its working at the surface of the paint product to kill most strains of bacteria including the well known 'super bugs'. This happens because the additive, which is within and is released from the coating, penetrates the cell wall of the bacteria. Normal cleaning procedures are still nevertheless to be observed. Are these paints biocidal products within PT 2 or are the active substances to be considered as film preservatives in PT 7 (with the consequence that the paint itself would not be a biocidal product)?

[26] These are available from the European Chemicals Bureau (ECB) website at: http://ecb.jrc.it/biocides/

[27] For further guidance see also document '**Guidance on treated material/articles and some other scope issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

Answer (agreed in December 2004): Given that the active substance is released from the paint and the intention is to combat bacteria outside the paint film, which are not harmful to the paint itself nor to surfaces covered by the paint, the paint is a biocidal product in PT 2.

2.5.2.2.Antibacterial paints - borderline between PT 2 and PT 7

Question: Paint products which have anti-bacterial properties for the dried paint films generally contain an appropriate active biocide ingredient which through its presence in the dried paint film provides or helps to provide a surface with anti-microbial and in some cases including bactericidal or bacteriostatic properties. In the case of the latter there is specific interest in the application of the products in situations where hygiene is particularly important such as hospitals and food preparation areas.

In what main group and Product Type falls such a paint product claiming or intended to produce a coating with anti-bacterial properties. The anti-bacterial properties may in some cases be in addition to antimicrobial properties leading to film preservation (PT7).

Answer (agreed in December 2004): As in the previous example, the intention of using the active substance is decisive. If the main purpose of adding the active substance is to protect the paint film itself, the active substance (or formulated product added to the paint) should be considered as being in PT 7, whereas if the main intention is to combat bacteria outside the film that could contaminate food, feed, or an operating theatre, then the active should be considered as being in PT 2 (or 4) and the paint is the 'delivery system'.

If the active substance has both effects, there is nothing that would prevent an authorisation for both PTs provided that there are appropriate claims and efficacy data to support them. If the manufacturer still prefers one PT only, it will also be necessary to look at the precise place of application of the paint. For example, if the paint is applied where any outside effect of the antimicrobial substance is irrelevant (e.g. a wall somewhere in the basement of a building), the main function is protection of the paint itself regardless of whether there is an outside effect in addition or not. If, however, it is applied in a public area with high frequentation by humans the main intention is to keep the surface of the film free of micro-organisms that could cause infections, PT 2 might be the more appropriate one.

2.5.2.3. Tiles cleaner

Question: What would be the status of a product used indoors and sprayed onto tiles and other hard surfaces which claims to remove and/or prevent growth of mould, mildew, algae?

Answer: Assuming that the product is not used to actually really protect the building structures and that the spraying of the product on the surfaces will not lead to a lasting protection over time, as it will most likely evaporate quickly after use, PT 2 seems to be the most suitable product-type entry.

This is also more pragmatic an approach as, sodium hypochlorite (CAS No 7681-52-9)having been notified for PT 1 to 6 and PT 11 and 12 only, would then - from 1 September 2006 onwards - no longer be allowed for this type of use if the product was classified under PT10.

2.5.3. PT 6 – In-can preservatives

2.5.3.1.Sorbates

Question: Sorbates are added as in-can preservatives to keep products in good condition. They have no effect when using the end-product and are not added to e.g. soap with the specific aim of killing lice or other vermin. They are used as a preservative in soaps, wet tissues etc. However, the main use is as a food additive. Do sorbates have to be notified according to the BPD? If so, how?

Answer: According to the description, the function of the sorbates is clearly biocidal. When used in this way they are in-can preservatives and they have to be notified for PT 6 to continue to use them. However, their use as food preservative is not covered! (See also point 2.1.4.3 above).

Regarding the dossier requirements: data for the active substance and data for a biocidal product is needed. The biocidal product, however, can be just the active substance if it is placed on the market in that form. If just the sorbates are sold as such to clients, there is no other biocidal product involved, unless for example a pre-diluted formulation is sold.

The final product, i.e. the detergent containing the preservative, is not a biocidal product. The clients do not need to produce a dossier. This holds for all in-can preservatives. However, it would be necessary to know what percentage of sorbates the final product contains in order to assess the safety of the intended use. Actual data requirements would best be discussed with the Rapporteur Member State, to be designated in the 2nd Review Regulation.

2.5.3.2. Preservatives in rodenticide baits

Question: A fungistat is produced and used as a preservative in rodenticide baits. Does the fungistat fall under Product-type 20, *Preservatives for food and feedstocks*, or under Product-type 6, *In-can preservatives*?

Answer (*agreed in January 2003*): Rodenticide baits are not covered by the definition of 'food' in EU legislation and the fungistat can therefore not be classified as a preservative for food and feedstocks. This product falls under Product-type 6, *In-can preservatives.*

2.5.4. PT 7 – Film preservatives

2.5.4.1. Anti-mould paint

Question: A company intends to market an anti-mould paint for use in wet rooms like bathrooms. The paint contains active substance with fungicidal properties. On the label the following use is recommended: " … a water-based anti-fungal wallpaint for indoor use." ....and "suitable to keep out mould from surfaces (walls and ceilings)". The company states that the paint does not fall under the BPD, stating that the fungicide is added to make the paint mould proof. The active substance(s) only have an internal action. However, one could also consider that this type of paint is specifically intended and brought on the market to keep out mould in wet areas like bathrooms and kitchens, which would be an external action of the active substance in the paint. Such a paint would then be is covered by the BPD, falling under PT 10, when no specific claim is made to specific pathogens to humans or animals. Is the paint a biocidal product or not?

Answer *(agreed in December 2004):* This questions seems somewhat complicated mainly due to the claim the company wants to make - i.e. '...suitable to keep out mould from surfaces (walls and ceilings). This could give the impression that the paint would be suitable to combat mould that has 'infected' walls or ceilings. In that case, the whole paint would indeed be a biocidal product, as the paint would only be the 'delivery system' for the active substance, which is supposed to act on or in the wall. But this is probably not the case.

In reality, the active substance will most likely prevent the growth of mould on the paint itself, once it has been painted on a wall or ceiling. Mould would normally feed on the organic components of the paint - the wall itself has probably very little to offer in nutrients as it is made of inorganic material. So in the end the active substance protects the paint-film (which in turn protects the wall). This clearly meets the definition of PT 7 in Annex V, which reads: 'Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surfaces of materials or objects such as paint, plastics, sealants, wall adhesives, binders, papers, art works ... '. And this is also the case for the mould-proof sealant, where the active is added to prevent attack of the sealant material (see point 3.5 further down).

So the paint itself should not be considered as a biocidal product, however the active substance (or preparation) used as a preservative is a biocide in PT 7 and needs authorisation for the intended use. Lastly, to avoid any confusion, it would probably be best if the claims for the paint would be changed to something like 'mould-proof', or 'mould resistant' or 'funghi-resistant' paint - like that the impression would be avoided that there is an external action.

If the company insists very strongly to maintain such claims, however, than the whole paint should be considered as a biocide, needing authorisation itself. Whether that changes very much in terms of necessary data is another question, as some information on possible leaching of the active substance from the paint film will in any case be required - regardless of whether one authorises the paint as a biocidal product or the active used to impregnate the paint.

2.5.5. PT 8 – Wood preservatives

2.5.5.1. Borderline between PT 8 and PT 7

Question: Wood preservatives can traditionally be applied through various means. Some application types such as the Industrial processes using vacuum pressure or double vacuum devices clearly fall within PT8 as the objective is to penetrate the wood to protect it against biological decay and/or discolouration. Other application types, such as dipping, brushing or spraying, limit the extent of penetration into the wood, and hence the active substances may stay in the film formed on the surface of the wood or show a rather limited penetration into the wood.

For example, it is well agreed within the industry that products fulfilling the claims of the efficacy test EN599 belong to PT8. For the stain type D.I.Y. products applied by brush and the like there is an EN test for blue stain fungi that is commonly referred to, and which looks at the extent of penetration into the wood. Different interpretations are possible: One view would be to consider that in order to be a wood preservative, the paint must penetrate; alternatively one could consider that a surface control is sufficient.

Is there already agreed standard tests for wood preservatives that can be used to decide if a product falls within PT8 or PT7?

Answer *(agreed in December 2004):* Although the information contained in the question is not necessarily complete, the understanding is that as long as the intention of applying the active substance (by painting or otherwise) is to protect the wood (and not the paint itself), the product should be regarded as falling into PT 8. The question of penetration or not seems of minor importance. Limited penetration (resulting in a film of protectant) should not be regarded as the defining factor in any differentiation between the PTs in question.

Rather it is the intention to control or render harmless undesired or unwanted wood-destroying organisms, as opposed to protecting film - destroying organisms, that is important. This view also corresponds to what is written in the Emission Scenario Documents for PT 7 and 8.

For example, in the ESD for PT 7, it is written that 'film preservatives are used for preservatio of most types of topcoat paints in outdoor applications by the control of microbial (mainly fungal) deterioration of the **paint film**. Biocides use in priming wood-care products, for which the main function is a protection of the wood against microbial deterioration are included in PT 8 - wood preservatives.

2.5.6. PT 9 – Fibre, leather, rubber and polymerised materials preservatives

2.5.6.1.Textile protection

Question: Are the following products biocides and are their active substances considered as active substances within the scope of the BPD?

- Preparation with a halogenated phenoxy compound to be used for hygiene protection for textiles in contact with human skin.

- Preparation with a halogenated phenoxy compound and isothiazolinone derivative to be used as antimicrobial finish for textiles in contact with human skin.

- Preparation with organozinc compound and isothiazolinone derivative to be used as a mildew– and rot-proof finish for textiles

- Preparation with organotin compound and halogenated phenoxy-derivative in methyl ethyl ketone to be used for antimicrobial treatment of PUR-coated textiles

Answer: The products should be regarded as being in the scope of PT 9.

2.5.6.2.Preservation of plastic, surface materials NEW

Question: A company is seeking clarification on the relevant product-types for the following uses.

1. **Preservation of plastic material used in the production of plastic membranes (foils) for outdoor use:**
The plastic membranes are used to cover buildings or construction materials (e.g. vinyl roof membrane for commercial buildings). The biocidal product is added to the raw material (plastic) at the time of manufacture and the intended use is to protect the membrane against fungi in order to protect the properties of its surface over its service life. The membranes are a few mm thick. The PTs to which this use might be attributed are PT7, 9 or 10.

2. **Preservation of plastic materials used indoor in e.g. vinyl floorings:**
The biocidal product is applied to the raw material (plastics) at the time of manufacture. The intended use is to protect the properties of the plastic film for its useful service life. The PTs to which this use might be attributed are PT7 or 9.

Answer *(agreed at 29th CA meeting)*: The products should be regarded as being in the scope of PT 9.

2.5.7. PT 10 – Masonry preservatives NEW

Question: A company is seeking clarification on the relevant product-types for the following uses.

1. **Preservation of surface materials applied on buildings (e.g. cement layer, plaster) for outdoor use:**
The materials treated with the biocide are applied as a film or layer (up to 1-2 cm thick) onto the surfaces of buildings. The aim of the treatment is to protect the layer during its service life against fungi or algae discoloration, hence to protect the initial properties of its surface. The PTs to which this use might be attributed are PT7 or 10.

2. **Preservation of building materials e.g. tiling joint fillers, grouts, plaster plates for indoor use:**
This use is similar to the previous one, the difference is that it is indoor. The PTs to which this use might be attributed are PT7 or 10.

Answer *(agreed at 29th CA meeting)*: The products should be regarded as being in the scope of PT 10.

2.5.8. PT 11 (Preservatives for liquid cooling and processing systems) vs PT 12 (Slimicides)

2.5.8.1. Oil recovery industry

Question: During oil recovery operations, particularly in the North Sea, sea water is injected into oil reservoirs. During the process, sulphate-reducing bacteria can proliferate underground and they will produce hydrogen sulphide. This gas is very toxic, highly corrosive to mild steel and also potentially explosive, so it presents a severe hazard if it occurs in the water returning to the oil platform. Its presence can also reduce the value of exported gas. The product THPS is used to control sulphate-reducing bacteria in the oil industry. To achieve this it is injected, in seawater, into the water rich phases within the oil reservoir. Which PT is correct, 11 or 12?

Answer *(agreed in June 2003)*: THPS is used in process water to be injected in oil reservoirs to control sulphate-reducing bacteria. As PT 12 concerns specifically products used to prevent slime growth on materials, equipment and structures, that option is excluded. THPS should be designated to PT 11 for this application.

2.5.8.2. Paper industry

2.5.8.2.1 Biocides in paper coating and finishing

Question: THPS is used in the preservation of pigment slurries, starch solutions and coating mixes used in the paper industry. The function is to protect these aqueous slurries or solutions from microbial spoilage before they are used as components for coatings applied to paper. THPS provides short term protection, after which it biodegrades and hydrolyses. It provides no significant protection to the coating once it has been applied to the paper, or indeed to the paper itself. The period of protection covers transport, mixing or short term storage of the pigment slurries or starch solutions. During its functional period, THPS is not in contact with any paper fibre. Which PT is correct, 6 or 9?

Answer *(agreed in June 2003)*: THPS protects against microbial spoilage of the solutions during transport, mixing and storage before these come into contact with paper. PT 9 concerns products used for preservation of fibrous or polymerised materials, which is not the case here. It seems therefore most appropriate to designate this THPS-containing product to PT 6.

2.5.8.2.2 Biocides in treatment of pulp and other raw materials connected to the wet-end of paper machine

Question: What is the most suitable product type for biocides used to treat different raw materials of paper industry (e.g. for pulp, fillers like calcium carbonate and other slurries, starch in stock sizing)?

The aim for most of these uses is to maintain consistence and quality of these raw materials (e.g. to prevent microbiological degradation of starch and to be able to pump these materials further to paper machine process), which implies PT6. However, another aim can be to prevent slime growth on equipment of the process water circulation by providing uncontaminated raw materials into the paper-making process and keep the process in good function, which implies PT12.

Answer (*agreed in June 2007*): The storage towers and tanks of these raw materials are often side by side with a connection to process water circulation and thus are related to same kind of exposure as slimicides that are applied directly to process water circulation at the wet-end of a paper machine. In a paper mill this applies to the towers for pulp (chemical and mechanical pulp and all combinations in-between and recycled paper) and broke (uncoated or coated) and different raw materials in water slurries (e.g. fillers like calcium carbonate). PT12 is the most appropriate product type for these uses as long as the products are only used in the paper industry. However, there are biocidal products used for these purposes that are also placed on the market for general preservative uses in this and other industries. The use of these products in paper pulp, broke and calcium carbonate can be covered by PT6 in case they are not used as slimicides in the process water circulations of paper industry. However, in the case of PT6 relevant environmental exposure assessment shall be carried out in the dossier, e.g. by applying the ESD of PT12.

PT6 is the most appropriate for biocidal products used in the storage of other raw materials in paper mill (e.g. starch before its cooking) and prior to the supply of raw materials to a paper mill (e.g. during transport). As already stated under point 2.5.8.2.1, preservation of paper itself or other final products belongs to PT9.

Since there are different scenarios for using these substances, the selection of the most suitable product type for active substances should be considered on case-by-case basis in order to find the most relevant scenario for the risk assessment. As a general rule, biocidal products used at the wet-end of a paper machine would be regarded as PT 12, whilst those used at the dry-end would be regarded as PT 6 (2.5.8.2.1).

2.5.8. PT 14 - Rodenticides

2.5.8.1. Baits containing plaster ($CaSO_4$ x $2H_2O$)

Question: A company intends to place a rodenticide on the market, which contains plaster ($CaSO_4$ x $2H_2O$) as an active substance. According to the company, the rodent eats the bait, which contains sugar and cocoa as additives. After swallowing the preparation, the plaster hardens within the stomach of the rodent with the effect that the animal will die of thirst and starvation. The company states that the product acts by physical means, because neither a chemical nor a biological mode of act can be seen during the process of death that is directly caused by the product itself. Is the product within the scope of the BPD?

Answer *(agreed in June 2003)*: In line with the answers on rodenticides containing celluloses (see 2.1.21.1), the product is deemed to be within the scope of the BPD. With regard to this type of products, it should be recalled that according to Article 5(1)(b) of the BPD, only products which do not induce unnecessary suffering and pain for vertebrates can be authorised.

2.5.8.2. Grains containing a second generation anticoagulant as well as an insect growth regulator

Question: A company intends to place on the market grains, containing a second generation anticoagulant as an active substance, as well as an insect growth regulator, which is incorporated into the product, so that grains will not be damaged by insects. Is the product falling within the scope of PT14, 18 or both?

Answer *(agreed in April 2006)*: Only PT 14. The product is sold with the claim of killing rodents, and that is achieved by the second generation anticoagulant, alone. It is not sold as, and could not possibly be efficacious against insects. It is not sold with the claim of *protecting crops from insects* using the insect growth regulator either.

The grain is the delivery system for the second generation anticoagulant (which is the active substance) against rodents (which are the harmful organisms). The insect growth regulator only protects the delivery system (treated article). The product therefore falls under the scope of PT 14 only.

In the case of grains containing an insect growth regulator alone to protect crops from insects and that are only sold to be used for agricultural purposes, the insect growth regulator itself is an agricultural pesticidal active substance and will require an authorisation in accordance with the provisions of Directive 91/414/EEC; only here it can be regarded as a ‘protecting substance/product’.

2.5.9. PT 19 – Repellents and attractants

2.5.9.1. Repellents against hares, rabbits, dogs and cats

Fertiliser containing guano is used to repel hares and rabbits from e.g. graveyards. Another product, rubber latex, is used to repel cats and dogs in children's playgrounds. A further product contains a synthetic substance similar to musk of skunk and is used to repel cats and dogs. Are these products within the scope of the BPD?

Answer (*agreed in June 2003*): The products are either within the scope of the BPD or the Plant Protection Products Directive (PPPD). According to the Guidance Document on the borderline between Plant Protection Products and Biocides, products used in plant growing areas to protect plants, are covered by the PPPD, which clearly applies to repellents against rabbits and hares, including for protection of graveyards. Product used to repel cats and dogs are not within the scope of PPPD, in particular if they are intended to be used in playground areas. Hence, they are biocides.

2.5.9.2. Sticky traps containing attractants

Question: There are sticky glue traps containing insect pheromones to decimate harmful insects. Other sticky traps contain food such as jam, honey, sugar, apple juice, caramel or banana flavour as attractants. There are also sticky traps, which do not contain attractants. Are these products within the scope of the BPD?

Answer (*modified in June 2004***)**: The description in Annex V of PT 19 (Repellents and attractants) is the following: 'Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.' It is not said in these definitions that the product has to be lethal for the target organism. It is enough that the product exerts some kind of controlling effect and that the purpose of the use is to control harmful organisms. Thus, products containing attractants/repellents are within the scope of the BPD.

According to Article 1(2)(r) of the BPD, products used for the protection of plants or plant products are excluded from the BPD. Food and feedstuffs are not generally excluded, as no relevant Directive is mentioned in that Article of the BPD. When they are used in attractants and repellents, the intention is not to feed but to control the effects of harmful organisms. In a pragmatic approach, food and feedstuffs used as co-formulants in biocidal products could be considered as substances of no concern, whereas, when they are used as active substances they will have to be evaluated taking into account waiving possibilities as referred to in Article 8(5) of the BPD[28]. It states that "information, which is not necessary owing to the nature of the biocidal product or of its

[28] The case of insect attractants and repellents that are plant extracts or used as food ingredients was discussed at the 2nd Meeting of the Working Group on Essential and Other Specific Categories of Biocides in March 2004. The Group encouraged interested companies to prepare concrete proposals on which specific studies mentioned in Annex IIA or IIIA to the BPD could be waived and on what grounds. This could then be submitted to the Working Group on Testing Strategies and become a Technical Notes for Guidance. If necessary, it could be adopted as a set of reduced data requirements on the basis of Article 29 of the Directive.

proposed uses need not be supplied. The same applies where it is not scientifically possible to supply the information."

Sticky traps without attractants are not covered by the BPD as the controlling effect is not by chemical or biological means.

2.5.9.3.Traps containing pheromones as attractants and other active substances

Question 1: Tricosene is the main component of the fly sex pheromone. It is applied in a sugar bait together with an insecticide. The fly is attracted to the bait by tricosene, it will eat from it and will die. The fly bait is a product in type 18, while the substance tricosene is an attractant. Should the product containing tricosene be classified in type 18 or 19?

Tricosene is also applied in an electrocution trap. Tricosene attracts and the electrocution kills the fly.

Should the product containing tricosene in this case be classified in type 18 or 19?

Answer: The first product contains tricosene as an attractant and a substance that is an insecticide. The final product is an insecticide and hence in PT 18. The same active substance may be used in products belonging to different product types to e.g. improve the efficacy, but it is the substance that in the end combats the harmful organism that decides in which product type the product should be classified.

In the second example tricosene is an attractant in a product (a trap that uses non-chemical and non-biological means to kill the insect (electrocution)). Therefore the product is in PT 19.

Question 2: A product for use in traps contains the components sugar, apple juice, caramel flavour, acetic acid and tricosene. Acetic acid is used to repel bees and bumblebees, and, according to the producer, tricosene is used to attract wasps. The product is on the market as a concentrate, which must be diluted with water before use. The producer states that the wasps are lured to the trap and drowned in the solution. Is the product a biocidal product within the scope of the BPD?

Answer: Sugar and apple juice are foodstuffs and, as they are used as co-formulants, can be considered as substances of no concern. Tricosene is a pheromone, which is assigned to product-type 19 and thus a biocidal active substance. However, it is doubtful that tricosene would actually attract wasps – it is an attractant for flies. Acetic acid is used in this product as a repellent for bees and bumblebees, which are not considered as harmful. That means that acetic acid is not used in the product as a biocidal active substance to repel harmful organisms. There is no information about caramel flavour. This would be needed to clarify whether or not it is covered by the BPD.

The formulated product is covered by the BPD and, as the harmful organisms (most likely flies and not wasps as claimed by the producer) are killed through drowning (not a chemical or biological effect), the product would be in PT 19.

2.5.9.4.Pheromones used in animal housings combined with insecticides

Question: A company wishes to supply a pheromone product as a spray-on formulation for use as an attractant on target devices in animal housings. The target device will be treated with a conventional killing insecticide and the purpose of the pheromone is to

improve the efficacy of the latter by attracting and encouraging target pests to land on the target. Thus the pheromone has no pesticidal activity as it simply improves the effectiveness of the insecticide which would be present anyway. As an alternative, the same pheromone could be supplied pre-sprayed onto a target device onto which the user will spray a conventional killing insecticide. Again, the pheromone component has no insecticidal properties of any kind. It is the conventional insecticide which has the pesticidal properties and the pheromone just enhances its efficacy.

In neither case would the company supply nor recommend the insecticide but would expect the user to choose an insecticide approved for the purpose of controlling the relevant pest in animal houses. Does the BPD apply to the formulated pheromone as described above?

Answer *(agreed in June 2004):* Products containing attractants/repellents, like pheromones, are within the scope of the BPD and a final formulation placed on the market containing only pheromones as active substances should be regarded as PT 19. A pheromone, used as an attractant, can be combined with an insecticide in a final formulation which is placed on the market. In that case, the product (attractant + insecticide) belong to PT 18 (insecticides). The same pheromone could be used also as an active substance in products belonging to different product types to e.g. improve the efficacy, but it is the substance that in the end has the ultimate controlling action on the harmful organism that decides in which product type the product should be classified (see also 2.5.9.3).

2.5.9.5.Traps for monitoring purposes

Question: Traps, which contain attractants, are sometimes used for insect monitoring purposes only. Are they covered by the BPD?

Answer: Traps containing attractants, which are used for insect monitoring only, are not within the scope of the Directive according to the definition of a biocidal product.

Additional question: In the framework of the e-Consultation group, the question was raised to further clarify the conditions under which traps used for monitoring purposes are not considered biocidal products and are, therefore, outside the scope of Directive 98/8/EC (hereafter "the Biocides Directive). These traps shall be differentiated from traps which are considered biocidal products and are, thus, covered by the Biocides Directive.

Additional answer (agreed in November 2007): Monitoring traps are used in order to assess the necessity and the success of measures taken with regard to pest management. The word 'monitoring' in this context refers to all kinds of systematic observation or surveillance or recording of a process with the aid of technical devices or which other observation systems.

Monitoring traps emit specific pheromones as attractants for particular pest species. As they are not intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism, they are deemed not to fulfil the definition of a biocidal product as laid down in Article (1)(a) of the Biocides Directive. This means that monitoring traps used to assess the necessity and the success of pest management measures must be considered outside the scope of the Biocides Directive.

Such conclusion is in conformity with the first answer given above. In this case, traps used for insect monitoring purposes were held to fall outside the scope of the Directive.

Furthermore, it should be noted that the wording and graphical elements on the label of monitoring traps shall be such as not to mislead the consumer or make him believe that the trap is a biocidal product. Thus, biocidal claims like "reduces, eliminates, kills or controls" harmful organisms or graphical elements like "crossed out insects or dead insects" must not be used on the label of monitoring traps.

It would also contribute to the ability of the general public to differentiate between monitoring traps and traps that attract harmful organisms to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on them if monitoring traps clearly identify their purpose on the label by using the word "monitor" (or an adequate translation of the term) as part of the product's name (e.g. monitoring trap, food moth monitor trap).

Finally, it should be recalled that traps intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on harmful organisms will be principally considered biocidal products, unless excluded on other grounds from the scope of the Biocides Directive.

2.5.9.6.CO_2 as an attractant

Question 5: A mosquito control device contains the insect attractant substance octenol. To improve the attractant effect propane or butane are burnt to emit carbon dioxide. Is it required to submit data for carbon dioxide to be used as an attractant?

Answer (*agreed in June 2003*): It seems that propane and butane in this case are precursors for the active substance carbon dioxide, which is considered to attract mosquitos. Octenol is used in addition for the same purpose. If there is no killing effect or if the killing effect is exerted by non-chemical/non-biological means this product should be in PT 19, as the attractants are then the only active substances according to the BPD. Both attractants, CO_2 and octenol need to be included in Annex I or IA before such a product can be authorised. If relevant for the risk assessments, data are also required for the precursors. Waiving possibilities should be taken into account.

2.5.9.7.Pet training attractant

Question: A company has asked whether a product used to train a pet/companion animal (e.g. puppy/kitten) to urinate/defecate in acceptable areas would come under the scope of the BPD.

The company state that the product is sprayed onto the area chosen by the pet owner and the animal is attracted to where it has been sprayed and then urinates/defecates in that spot.

Answer (*agreed in November 2007*): The definition for PT 19: Repellents and Attractants is a product: *"used to control, harmful organisms by repelling or attracting"…….*

The definition of a harmful organism, in Article 2 1f of the Directive, is …. *"any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment."*

In the case presented, we consider the 'pet' (the urine/faeces it produces) to be a '*harmful organism'*. Although the pet in itself is not *"an unwanted presence"* its urine/faeces could be considered as having a *"detrimental effect"* on *"the environment"* e.g. the house the human uses. It is therefore considered that this product falls under the scope of the BPD and would be included in PT 19: Repellent/attractant.

2.6. Specific groups of active substances

2.6.1. Acids and bases

2.6.1.1. General questions

Question 1: Are sodium/potassium hydroxide in disinfectants containing sodium hypochlorite in all cases to be considered as active antimicrobial agents?

Question 2: Products for cleaning purposes sometimes have desired anti-microbial properties arising from their low or high pH, e.g. containing lactic acid, citric acid, sodium and potassium hydroxide. Are they to be regarded as biocidal products?

Question 3: Granulated glass, consisting of the oxides of silicon, phosphorus, sodium and calcium, is used to adjust the pH value of solutions for technical reasons. The effect of the substance is to increase the pH to a value between 9 and 12 by an ion exchange mechanism between the glass and the surrounding environment. At a pH value of 9 - 12 there are also bacteriostatic properties.

Question 4: Can acids or bases become basic substances in the sense of the BPD?

Answers: Although high/low pH values give products anti-microbial properties, not all acids and bases have to be considered as active substances as long as they are not placed on the market for biocidal purposes and are not labelled as such. For example, if the purpose is to control the pH-value of a solution or to participate in a chemical reaction, etc., the acids and bases involved are not regarded as biocidal active substances.

The Commission and the Member States have agreed[29] that for sodium hypochlorite based disinfectants with low concentrations of hydroxide, the hydroxide should be considered as an additive to stabilise sodium hypochlorite. However, in disinfectants with hydroxides in relatively high concentrations (0.5-1% in the ready for use dilution), which are used for control of specific organisms, the main function of the hydroxide is to disinfect and it therefore has a biocidal function. A borderline for distinction could be a concentration of 0.1 m or pH > 13.

The same applies to solutions with other anti-microbial agents, such as quaternary ammonium salts. If the concentration of hydroxide is low, they should be considered as additives with primary cleaning functions, whereas if their concentration is high (cut off 0.1 m or pH > 13), they should be considered primarily as active anti-microbial agent in the biocidal products.

Sodium/potassium hydroxide and many of the other acids or bases certainly qualify for being potential basic substances, as large quantities are used in industrial applications

[29] For further guidance see also document '**Mode of action and other issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

and only small volumes in biocides. However, if they are included in Annex IB, they cannot be directly marketed for a biocidal use.

2.6.2. Naturally occurring products, their extracts and essential oils

2.6.2.1. Cedarwood oil, Lavender oil and other essential oils

Question: Cedarwood oil is used for the control of textile pests such as the cloth moth (Tineola bisselliella). The substance expels existing and repels arriving moths, while moth larvae are controlled as the cedarwood oil acts as a feeding depressant. Attractants and repellents are not applied directly on human or animal skin.

Cedarwood oil is extracted from species of cedar trees. Cedarwood oil products are generally marketed as mixtures of defined extracts of cedarwood oil (active substance). The products are usually sold in small dispensers attached to a carton card with an integrated hanger. Small amounts of the cedarwood oil are constantly released into the air, thus providing protection against the moths. The product is placed in the wardrobe where it is active over a three-month period.

Cedarwood oil is a general constituent of lotions and other products for use directly on human skin. It is listed as a food additive by the Food and Drug Administration in USA. In Europe, like in the USA, cedarwood oil is a standard constituent of cosmetic products.

Like cedarwood oil, lavender oil is used for the control of textile pests. In USA it is a constituent in cosmetic products and is also used as a food additive. Lavender oil products are formulated, packed and used in a similar way to cedarwood oil products.

Clove oil and citronella oil are used in powder form for bio-waste containers as they have repellent effect on flies like houseflies or bluebottles. From company information clove oil is also a slight disinfectant agent that inhibits the formation of mould and bacteria on the waste.

Are these products under the BPD and if so, which data can be waived?

Answer: Products having only a repellent activity without killing effects are fully in line with the definition of Biocidal Products and therefore they should be regarded as biocidal products (PT19). Examples are invertebrates such as fleas or mosquitos, vertebrates such as birds, cats and dogs. Furthermore, products containing such repellents, for example collars, neckties and ear-marks are covered.

In principle, the arguments that an active substance is a natural product or “extract” or that the substance is used in other products (cosmetics, food) do not automatically justify a reduction of the data requirements. Waiving of data is only possible if a test is technically not feasible or is unnecessary for scientific reasons and if these reasons are substantiated. Whether some of the data required for the submission of the dossier can be waived should be discussed as early as possible with the competent authority in the designated Rapporteur Member State. Further guidance can also be found in the Technical Notes for Guidance on Data Requirements at: http://ecb.jrc.it/biocides/

2.6.2.2. Cedar wood, herbs, aromatic substances etc.

Question: Are the following products within the scope of the BPD:

1) Small pieces of cedar wood to protect clothes (textiles) against insects (moths) in wardrobes

2a) Mixed herbs contained in a pad to be used against moths in wardrobes

2b) Lavender contained in a pad to be used against moths in wardrobes

3) Products containing aromatic substances put on the market with a biocidal claim for a "side effect" to be effective against insects as a repellent:

4) Soft soap in form of a spray to be used only against insects – without claiming any other effect such as cleaning or disinfectant functions

Answers:

1) If the company responsible for placing this product on the market, considers cedar wood to be effective against moths and places it on the market as a biocidal product, indicating that it is effective, it is considered to be a biocidal product (PT 18 or 19). Volatile compounds of cedar wood should be considered as the active substances.

2a) If the company responsible for placing this product on the market considers the mixed herbs to be effective against moths and places the product on the market as a biocidal product, indicating that it is effective, it is considered to be a biocidal product (PT 18 or 19). Volatile compounds in the herbs contained in the pad should be considered as the active substances.

2b) If the company responsible for placing this product on the market considers lavender pads to be effective against moths and places the product on the market as a biocidal product, indicating that it is effective, it is considered to be a biocidal product (PT 18 or 19). Volatile compounds in lavender should be considered as the active substances.

3) Once the biocidal effect is there and expressed in a claim, such products are biocidal products (PT 19).

4) This is a biocidal product, provided the mode of action includes action by chemical or biological means, as the only effect claimed is to protect against insects.

2.6.2.3. Essential oils in detergents

Question: A formulator produces substances based on natural essential oils, claiming that they are free of toxicity and present no hazards for the environment. The formulator claims that they are not bactericides, fungicides or disinfectants in accordance with French standards (AFNOR norms) but they have nevertheless bacteriostatic and fungistatic effects.

Are cleaning products containing these substances, which are not considered to be disinfectants but have bacteriostatic or fungistatic effects, subject to the BPD?

Answer: If the products are placed on the market without any biocidal intent, then in principle, they are not subject to the BPD. However, the concentration of the substance with the bacteriostatic or fungistatic effects should also be taken into consideration. If the concentration is high, then the action may primarily be biocidal and the products are subject to the BPD. See also the answer in 2.1.1.

Additionally, test data would be required to substantiate the claim that the products are not toxic and present no hazard to the environment.

2.6.2.4. Essential oils in aromatherapy

Question: Does the BPD affect the production or use of essential oils in aromatherapy?

Answer (*agreed at 28th CA meeting*): The BPD concerns the placing on the market and use of biocidal products, which are defined in Article 2 of the BPD. If the producer of essential oils makes a claim that products containing the oils have biocidal effects, the oils are covered by the BPD and its obligations would have to be fulfilled. Non-biocidal uses of the oils would not have to fulfil the obligations under the BPD. Aromatherapy would (probably) be a non-biocidal use of essential oils and hence would not be covered by the BPD.

2.6.2.5.Geraniol and Citronella oils NEW

Question: Geraniol is a constituent of several essential oil, and for instance, of citronella oils. Citronella oils are obtained from the steam distillation of fresh or partly dried grasses of Cymbopogon spp.: C. nardus (L.) Rendle (Sri Lankan type from Sri Lanka) and C. winterianus Jowitt (Java type from S.E. Asia, India, China, Central America & Indonesia). They contain respectively 20.9% m/m and 23.2%m/m of geraniol (source : http://www.hc-sc.gc.ca/fn-an/securit/facts-faits/citron/citronella_oil_summary-resume_essence%20de%20citronnelle_03_e.html).

Geraniol, CAS n°106-24-1, has been identified and notified for PT18 and 19.

Citronella oil CAS n°8000-29-1, Cymbopogon winterianus extract CAS n°91771-61-8 and Cymbopogon nardus extract CAS n°89998-15-2 are only identified, but not notifed.

A company wants to put on the market a product that contains citronella oil, and not pure geraniol, and claim that geraniol is the active substance. Can this product be put on the market?

Answer (*agreed at 28th CA meeting*): Essential oils are UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials), and in our case, citronella oils are multi-constituent substances. According to RIP 3.10 used in Reach regulation, also used in the BPD for technical equivalence, a substance is considered as *"A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition*". Therefore, a citronella oil fits the definition of a substance.

Concerning essential oils, the whole mixture of all constituents comprising an extract / oil is regarded as the active substance as it is not possible to distinguish between individual modes of action assigned to each single constituent. There may be cases where there would be one main constituent in the extract / oil, but nevertheless the main constituent does not cover the substance identity. Therefore, citronella oil can be considered as an active substance in its whole, and not only geraniol.

In consequence, looking at the nature of citronella oil and the definition of what is a substance, the repellant products containing only citronella oil can't be put on the market

since, even if the active substance claimed is a single constituent of the essential oil, in this case geraniol. Citronella oil shall be included into Annex I or IA of directive 98/8/EC. If a repellant product contains citronella oil as well as other notified active substance(s), the company shall be able to show that citronella oil is not an active substance with suitable efficacy tests.

2.6.3. Food and feed

2.6.3.1.Cayenne pepper / sugar / water as repellents

Question: A company produces a product containing cayenne pepper, sugar and water to be used against martens. The product is sprayed on brake pipes and cooling tubes of cars. If an animal bites into or licks a treated part of the car the taste of the product will discourage further biting.

Is this product within the scope of the BPD?

Answer (*agreed in January 2003*): The BPD states in Article 1(2) a number of Directives, which apply to products that are excluded from the BPD. Directives on food additives, hygiene in egg production, fishery products etc. are included in this list, but there is no mention of any legislation on food in general. Furthermore, when food and feed are used in attractants or repellents the intention is not to feed animals but to control the effects of harmful organisms or animals. Therefore it seems not possible to exclude these products in general from the scope of the BPD.

In a pragmatic approach food and feed used as co-formulants in biocidal products could be considered as substances of no concern. However, food and feed used as active substance in biocidal products would have to be evaluated taking into account waiving possibilities as referred to in article 8 (5) of the Directive.

In this case, martens, which lick or bite on the treated equipment, will be repelled from the car. A "long distance effect" is not required for a product to be classified as a repellent. Thus, the product would fall under PT 19, Attractants/Repellents[30].

2.6.3.2.Garlic oil as repellent:

Question: A company is marketing a repellent for deer and martens consisting of polyester sticks containing garlic oil. This dispenser is placed near streets in order to keep deer from crossing the streets or under the bonnets of cars in order to keep martens away. Should this dispenser containing garlic oil be regarded as a biocidal product?

Answer (*agreed in June 2003*): This product seems to be similar to the martens repelling product discussed above. The garlic oil contains the active substances, which in this case act as biocides by repelling certain animals. The product is thus within the scope of the BPD and data should be submitted accordingly. Waiving possibilities should be taken into account.

2.6.4. Lignin

Question: Lignin is a naturally occurring substance constituting 10 to 40% of most plant materials. It is non toxic, but has some interesting biological activity if in contact with

[30] For further examples, see also 2.1.2.

micro-organisms. Lignin can be recovered in many processes but mostly in the pulp industry as waste. Lignin is also special as there is no precise molecular formula defining it, but only a structural formula composed of three basic monomers that can be polymerised randomly. Lignin can vary quite a lot by molecular weight and functional groups that are both influenced by the production process. A consortium has proposed a research project (eventually accepted by the EC), for developing directives and recommendations at European level for improving the commercial utilisation of lignin.

Does lignin have to be notified under the BPD?

Could lignin be considered as a low-risk active substance or as a basic substance? And what would this mean for the actions to be taken?

How is the procedure, in case of naturally occurring products, for determining the definition of the substance that would be put on Annex IA? A proposed definition could be:
A natural polymer formed by a back bone of a phenylpropane polymer polymerised by ether and/or by ester bonds and/or by carbon-carbon bonds and containing any of the typical basic functionalities which are phenolic hydroxyl, aliphatic hydroxyl, carboxyl, methoxy and carbonyl, provided that such polymer is extracted from plant material by organic solvents and/or water in acidic or alkaline conditions and/or under the use of other additives and/or modified by subsequent chemical or biochemical reactions, and provided that the resulting organic polymer does not contain more than 1% on weight of measurable matter that is neither of plant origin, nor from degradation of the natural lignin molecules, nor from water, nor from air, nor one of the above mentioned typical basic functionalities.

Answer: There is indeed no unique molecular formula or definition of lignin and there are numbers of records in EINECS.

Based on the description of the thematic network project, the biocidal uses of lignin are rather new and necessitate further research. Current marketing for such purposes seems to be very limited (if at all existing). For notification under Regulation 1896/2000 there is a need to provide proof of being on the market before 14 May 2000 by providing ‘an invoice, composition of a product and/or a label’.

If lignin is considered a new active substance, an application for inclusion into Annexes I or IA or IB of the Directive (and/or for provisional authorisation of a biocidal product containing it) or for Research and Development purposes can be submitted at any point in time, when a complete dossier on the active substance and a biocidal product containing it is available. The toxicological profile of the substance will then determine whether it can be included into Annex I or IA (cf. Article 10(1) of Directive 98/8).

There is no defined procedure yet developed for determining the definition and listing of products of natural origin in Annex IA (nor in Annex I). For this specific case, further discussions and development of appropriate procedures will certainly be necessary, and the proposals from the company could certainly be a basis for discussions among experts of the Member States.

The same applies to the question on whether lignin could be considered as a basic substance. The procedures to follow are very similar to those for active substances; an application needs to be submitted for an inclusion of lignin in Annex IB and the required dossier has to be provided, which is not fundamentally different from the dossier for an

active substance[31]. According to the definitions of Article 2, only substances that have some minor use as biocide but are not directly marketed for biocidal uses (i.e. having no claim in this sense) can be included on Annex IB.

3. TREATED ARTICLES

3.1. Treated articles and import of such articles

Question 1: A footwear product to be placed on the market in the EU contains a biocidal active substance. Does the product have to be authorised under the BPD?

Question 2: Several companies from the US that sell products in Europe want to determine how the EC regulates "treated articles" under the BPD. Their products contain preservatives to keep bacteria or other pests from degrading or deteriorating the article. In the U.S., although the biocide that is used in the article must be registered at EPA (as in the EC), the article is not required to be registered under the U.S. pesticide law (FIFRA), as it is exempted under the treated article exemption (40 C.F.R. Section 152.25(a)). Under this regulation, as long as the producer of an article uses a registered biocide and restricts its claims to protecting the article itself (as opposed to controlling pests outside the article), then no registration is required.

According to their understanding the Biocidal Products Directive does not contain a similar explicit rule (although the active substance, such as the preservative, obviously must be authorised). Are treated articles not regulated in the EU under the Directive?

Answer: When an article has been treated with a biocidal active substance with the intention to control organisms harmful to the treated article/material itself (on the surface or inside), then the treated article shall not be considered as a biocidal product (Internal effect). Examples on such articles might be treated materials like wood, leather, and most water based paints. However, the active substance that (by itself or in a formulation) that has been used to treat the article is a biocidal product requiring authorisation. Treated articles imported from non-EU countries are not currently covered by the BPD.

The combination of an article and an active substance, if the active substance is placed on the market as an inseparable ingredient of the article, has to comply with the requirements of the Directive if it is intended[32] that the biocidal active substance is released from the treated article to control harmful organisms outside the treated article (external effect) or if it is intended to control only organisms that are not harmful to the treated article itself. In such cases, the article has the function of a delivery system and shall be considered as a biocidal product that must be authorised[33]. Examples of such delivery systems are:

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[31] For further guidance please refer to chapter 5.4 of the Technical Notes for Guidance on Data Requirements, available at http://ecb.jrc.it/biocides

[32] It was suggested to use the terms 'designed to' and make reference to a claim by the manufacturer regarding a biocidal function. However, the definition of a biocidal product in Directive 98/8/EC does not necessitate such a claim to be made. Although it is reasonable to expect that an intended biocidal action would be reflected in a relevant claim on the label, there could be cases where such a claim would not be made. The current wording reflects the definition.

[33] Sweden does not agree with this view as it considers that the definitions of the Directive do not allow for such an interpretation. In Sweden's opinion, treated articles are only biocidal products if the primary function is biocidal. This would apply only to the 2nd example in the list. The other examples should be

1. Mosquito nets containing insect repellents

2. Insecticidal strips treated with insecticides

3. Mattress covers that are labelled as anti mite for use in prevention of the action of house mites outside the cover (i.e. within the mattress)

4. Impregnated tissues with "antibacterial" properties (if not regarded as medicinal products, e.g. for certain applications in hospitals)

5. Antibacterial lavatory seats where the active substance is released during use.

6. Sleeping bag treated with an insect repellent.

7. Socks treated with a biocidal active substance intended to have a biocidal action on the foot.

8. Treated textiles to be used for pets that release substances with a lethal effect on fleas and flea eggs[34]

When the article has been treated with the biocidal active substance with the intention to control organisms harmful to the treated article/material itself (on the surface or inside), then the treated article shall not be considered as a biocidal product (Internal effect). Examples on such articles might be treated materials like wood, leather, and most water based paints. However, the active substance that (by itself or in a formulation) that has been used to treat the article is a biocidal product requiring authorisation.

Question 3: If treated articles imported from non-EU countries, are not currently covered by the BPD, does this mean that active substances used to treat articles manufactured in the U.S. for import to the EU must also be listed as active substances (authorized for use as a preservative) in the EU? Or does this mean that any active substance, properly applied in the U.S., which is contained in a treated article imported to the EU, is not regulated by the BPD as long as claims are restricted to protecting the article itself?

Answer: The latter interpretation is correct.

3.2. Tooth brushes, nappies and dummies

Question: A company places tooth brushes, nappies and dummies on the market, which contain nano-particles of silver in order to prevent micro-organisms from growing on their surface. Are these products within the scope of the BPD?

Answer (*agreed in June 2003*)**:** According to the relevant guidance document, the combination of an article and an active substance, if the active substance is placed on the market as an inseparable ingredient of a product, shall be regarded as being under the scope of the Directive if it is intended that the biocidal active substance is released from

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dealt with during the authorisation of the biocidal product used to impregnate the articles, from which the active substance will be released. For further guidance see also document '**Guidance on treated material/articles and some other scope issues**' available at: http://europa.eu.int/comm/environment/biocides/pdf/definitions.pdf

[34] The competent authorities of the Veterinary Medicinal Products Directive have recently decided that such products are not within the scope of that Directive

the treated article to control harmful organisms outside the treated article (external effect) or if it is intended to only control organisms that are not harmful to the treated article itself. When the combination of the article with the biocidal active substance is intended to control organisms harmful to the treated article/material itself (on the surface or outside) then the article shall not be considered as a biocidal product (internal effect).[35]

In this case, although there is most probably only very limited release of the active substance and the intended control effect is merely on the surface of the treated product, it is obvious that the intended effect of the biocidal substance is not to protect the articles (tooth brushes, nappies, dummies), but humans, i.e. outside the treated article. Hence the treated articles are biocidal products.

3.3. Boots

Question: A certain brand of safety boots has an insole with antibacterial activity and a claim of "Hygienic protection". The insole is an integral part of the boot. What is the biocidal product?

Answer (*agreed in June 2003*)**:** The product, which is used to give the insole antibacterial properties, is a biocidal product. If this product is intended to be released from the insole to exert its activity outside the insole, then also the insole is within the scope of the BPD. If the insole is an integral part of the boot and there is a biocidal claim of the boots, then the boots are within the scope.

3.4. Antibacterial garbage bags

Question: A company wishes to put on the market garbage bags containing a biocidal active substance. The company is arguing that as bacteria can settle on garbage bags which are used for disposing waste, consumers may come into contact with the bacteria when handling the filled bags. It also claims that reproduction of bacteria can be significantly inhibited by providing the garbage bags with an antibacterial finish. The biocidal active substance is added to the polymer during extrusion and the company claims that this treatment provides long-lasting antibacterial protection. The question is, whether this kind of garbage bags should be regarded as biocidal products even if the active substance is added only to prevent bacterial growth on the surface of the bag.

Answer: Although the treated garbage bag is a product where the intended control effect is on the surface of the treated article only and the active substance is not intentionally released for effects outside, it is obvious that the intended effect of the biocidal substance is not to protect the garbage bag, but humans, i.e. outside the treated article. The treated bags are therefore considered to be within the scope of the BPD.

3.5. Mould-proof sealant

Question: A sealant, with less than 0,1 % of an active substance is used for special applications in wet areas like kitchens, bathrooms. The substance prevents the growth of mould on the sealant.

There is no special claim that the sealant kills or controls fungi.

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[35] For further guidance see also document '**Guidance on treated material/articles and some other scope issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

The package of the sealant has only an indication that the sealant is specially developed for wet areas.

1) Has the sealant to be considered as biocide or not?

2) Are indications as mould proof allowed to be on the package in case the sealant is not a biocide?

Answer *(agreed in December2003)*: The sealant itself is not a biocide and should be considered as a treated article: the sealant is not a delivery system product because the biocidal product is added to preserve the sealant and not to exert a biocidal action outside the sealant.

The product used to treat the sealant should be considered as PT 7 if it is used in indoor areas, PT 10 seems to be more relevant for outdoor areas (no indoor exposition was taken into account in the ESD).

The claims on the packaging of a treated article are not regulated by Directive 98/8/EC. For that issue, more general legislation on consumers' protection (e.g. misleading advertising) would probably apply.

3.6. Preservatives for building materials

Question: To which product-type 7, 9 or 10 belong biocidal active substances which are used for the protection of building materials in the sanitary and outdoor section as

- ceramic tiles adhesives
- plasters
- silicone sealing compounds
- putty
- knifing filler/surface finishing compounds
- mortar ?

Answer *(agreed in June 2004):* According to the scope of the Emission Scenario Document (ESD) on masonry preservatives (PT10), biocidal products covered by this product type are products for the preservation (to protect or/and to cure) of mortar, concrete, concrete additives, baked clay, slate and other building materials (as plaster).

There are biocides which are added at low concentration to other additives for mortar or concrete. These biocides are used to protect the additives themselves and not building materials. These biocides are covered by PT 6 “in-can preservatives” but their releases to the environment can also be performed according to the ESD for PT10.

Moreover, there are also biocides added to paint, mortar or roughcast, but also silicone sealing compounds, putty and knifing filler/surface finishing compounds could be included, which are used on buildings to protect both product and building against mosses, lichen, algae… These biocides belong to PT 7 “film preservatives” but to estimate exposure the ESD for PT10 can be used as well.

The product used to treat the sealant should be considered as PT 7 if it is used in indoor areas, PT 10 seems to be more relevant for outdoor areas (no indoor exposition was taken into account in the ESD on PT10) (see also 3.5).

A similar approach could be used for the different building materials according to the scope of the ESD for PT10 as described before.

4. SIMPLIFIED PROCEDURES

4.1. Basic substances

4.1.1. Iodine

Question: A company produces a range of finished products containing as an active substance a biocidal polymer, in which iodine crystals are fused. Iodine is then released slowly. The iodine is only released by contact with micro-organisms. The biocidal polymer is used in a range of products including air and water filtration, paints and coatings and surface disinfection sprays. In each case claims will be made of anti-microbial activity for the products.

Is the pure iodine or the iodine polymer the active substance? Is the iodine polymer or the end product the biocidal product under the definitions given in the BPD?

Could iodine used as a disinfectant be classified as a basic substance?

Answer: From the description of the action of the range of products, they fall within the scope of the BPD ("claims will be made of anti-microbial activity for the products").

The BPD distinguishes between 'active substance' and 'biocidal product'. The active substance is iodine, and the formulated product is, in all cases described, the polymer. The product for which authorisation would be required could, however, be the paint / water filter / air filter. For this the authorities would have to be consulted.

If the disinfectant products containing iodine are supplied with biocidal claims, then iodine does not comply with the definition of a basic substance, as it is required that basic substances are not directly marketed for biocidal use.

4.1.2. n-Propanol

Question: Without providing any specific information on specific uses, a company would like to know whether n-Propanol could be a basic substance included in Annex IB?

Answer: From the information provided, it is not clear whether n-propanol is an active substance or a co-formulant in a product. If it is an active substance, see the previous answer in the second paragraph of 2.1.6.1.

4.1.3. Silica gel

Question: Is silica gel used as an insecticide within the scope of the BPD and if so, is it a basic substance?

Answer (*updated in December 2005*): *Silica gel* (either hydrophilic or hydrophobic) acts through absorption of the lipid layer covering insects' chitin protection, which then leads to desiccation and death of the target organism. Consequently, by destructing the natural water barrier, the waxy layer of the cuticle and hence disrupting the functioning of the water preservation mechanism, silica interferes with physiological processes, and the substance is within the scope of the Directive. Due to the nature of the substance justified

waiving of data may be possible. The BPD mentions silica gel as a potential basic substance[36].

4.2. Frame formulation

Question: Does the BPD have a repackaging provision or subregistration provision? In the U.S., a company may receive a registration to repackage a product (without changing the product) with its own label that allows the company to add its name to the product label. In other cases, a company may "subregister" another company's product by selling it with its own label on the product. In both cases the second company may only change the name or package on the product, not the composition of the product itself. After reviewing the BPD the company has not seen a provision that addresses these issues. However, could this be covered by the "frame formulation" provision?

Answer: The concept of frame formulations is a tool in the Directive for such "subregistrations" of repacked products; a letter of access would be another possibility. Such a letter would also be necessary when the concept of frame formulation is to be used. Some guidance on this procedure is given in the Technical Notes for Guidance on data requirements[37] and more is given in the Technical Notes for Guidance on product evaluation. As the authorisation or registration of products is a Member State responsibility, the Competent Authorities in the Member States should be consulted and may be in the position to give further advice on individual cases.

Certain issues, like fees charged for this type of "subregistrations" will, in any case, be specific to the country registering the product.

5. OTHER LEGAL AND ADMINISTRATIVE ISSUES

5.1. Ethanol / Joint notification

Question: A consortium preparing notification(s) on ethanol as a basic substance asked the following questions:

1. Do all producers have to be listed or can a consultant act as a consortium facilitator?

2. Does every known producer of ethanol have to be listed in the dossier even if they have not participated in the notification?

3. Do drink producers have to be listed?

4. Is it necessary for ethanol/basic substances to list the production sites?

5. Is the identity of recipients necessary for ethanol/basic substances?

6. Are accepted residual levels necessary for ethanol/basic substances? Ethanol is a substance naturally produced in the body. Therefore this type of information is impossible to quantify.

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[36] For further guidance see also document '**Mode of action and other issues**' available at: http://europa.eu.int/comm/environment/biocides/index.htm

[37] Available at: http://ecb.jrc.it/biocides

7. How should information on denatured ethanol grades be handled? There are many hundreds of grades used in Europe, which come and go according to C&E requirements. Can a 'frame formulation' be proposed?

Answer: There is specific guidance for notification of basic substances in Annex II of Regulation 1896/2000, which is available at http://ecb.jrc.it/biocides.

1. All producers have to be listed. Concerning the quantities and market shares see the recommendations for notifiers at http://ecb.jrc.it/biocides.

2. No.

3. No.

4. No.

5. No.

6. No. This is the answer whether or not it is “naturally produced in the body”.

7. The notification/full dossier has to contain the required information and e.g. concentration ranges and the denaturation agents should be given.

5.2. Product authorised for two product types (PT2 and 18)

Question: A company intends to place a product on the market with acaricidal (PT 18) and bactericidal (PT 2) properties. It is very likely that the product contains different active substances with acaricidal and bactericidal activity, respectively.

Can one biocidal product be authorised under two product types? If so, should all active substances be included into Annex I (or IA) for both product types?

Answer *(agreed in June 2004):* The Directive does not exclude that a product is authorised for two product types. Obviously the conditions for authorisation (acceptability of risks due to the presence of several active substances and possibly other substances of concern - and efficacy for all intended effects) must be fulfilled. Also, this must be very clear from the label and use instructions.

It will probably not be possible to include all active substances into Annex I (or IA) for all PT's in question, as it will not be possible to demonstrate efficacy for the different active substances in PT 2 and in PT 18. The substances should be included only for the effects that they actually have. Only for the finished product containing both of them, will it then be possible to demonstrate efficacy for both uses. When authorising such combined products, competent authorities must of course verify that the active substances contained are included in Annex I or IA for the relevant PT's.

5.3. Permanent office

Question: According to Article 8 (1), last sentence of the BPD, applicants for an authorisation or registration of a biocidal product are required to have a permanent office within the Community.

1) Could a merely 'administrative' permanent office be regarded as a 'permanent office' if such an office has at least one person employed a tax identification number for the office representative and a permanent postal address?

2) Could a company with a regular permanent office within the Community apply on behalf of a company, which has no permanent office within the Community in a way that the company with no permanent office will be the person responsible for the first placing on the market of a biocidal product within the Community, and the holder of the authorisation/registration, once it is issued?

Answer *(agreed in June 2003)*:

1) An administrative office as described in the question fulfils the requirements.

2) Only a company which has a permanent office within the Community can become a holder of an authorisation/registration and has, thus, the legal responsibility. Of course, this can be a company applying for authorisation of a product that is actually produced by a company with no permanent office within the Community. In all cases, the applicant is the one who will be the holder of the authorisation and he must have a permanent office within the Community.

6. DATA REQUIREMENTS / WAIVING

6.1. Use of Literature data

Question: Can literature data be acceptable for use in notification? Will it be acceptable to use study information from an EPA Re-Registration Eligibility Document (RED) for substances regulated under FIFRA? These summary documents are in the public domain even though the reports referred to in the RED are not.

Answer: After discussions held between experts from the Member States and the Commission services it is agreed that in principle literature data may be used under the following conditions:

- For the purposes of notification literature data may be used if they comply with the rules of article 8 of Directive 98/8/EC.

- Furthermore, the identity, purity and the impurities of the substance have to be defined in the publication and to be comparable with the notified substance.

- The test must have been conducted according to international guidelines (e.g. EU or OECD) and GLP is also an important issue. Deviations should be justified (cf Art. 8 (8) and (9) of Directive 98/8/EC).

- The reporting of the study should allow evaluation of the quality of the study.

The problem concerning the declaration in item 7 of annex II of Regulation 1896/2000 (EC) could be solved by arguing that test data of adequate quality are publicly available, and that the repetition of tests should be avoided to protect laboratory animals.

The acceptance of literature data in a notification neither predetermines the verification of the complete dossier nor the acceptance of the tests summarised in the notification.

The final decision will be taken by the Rapporteur Member State after consultation with the other Member States and the Commission.

6.2. Impure active substances and concentrates/solutions

Question: The technical grade powder of an active substance is 95%. A liquid concentrate of the active substance (premix 2,5%) is placed on the market and it is then used to formulate a final rodenticide. The final product to be sold to the general public contains very small quantities of the active substance, usually 0.0005% for baits. Which is the right product to submit information on as active substance, the technical active substance (95%), the liquid concentrate or both?

Answer *(agreed in June 2003)*: The definition of an active substance in the Biocidal Directive refers to the definition of a 'substance' in Directive 67/548/EEC. In this Directive 'substance' means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but **excluding any solvent which may be separated without effecting the stability of the substance or changing its composition**. From a legal point of view, the 'premix' is not a substance but a mixture produced to improve the further handling of the active substance.

The Technical Notes for Guidance on Data Requirements, chapter 1.3, paragraph 5, state that, as a general rule, tests on the active substance should be carried out on the substance as it is to be supplied for formulation of the product for which the approval is applied. However, according to the definition above it is the 95 % concentrate that should be tested provided that the solvent may be separated without affecting the stability of the substance or changing its composition. If relevant, the solvent in the 2.5 % 'premix' should still be taken into account in the risk assessments.

6.3. Data on residues for PT 8 and PT 14

Question:

Is it required to have in the dossier information about residues in soil and in foodstuff (TNsG on data requirements, chapter 3A point 6.14 and 6.15) for PT 8 and 14 for the evaluation in view of Annex I inclusion?

Is information on residues for human exposure (appendix 4.2 point 2.10.1) required when there is marketing for the general public? Must the laboratories and operators who carry out tests be qualified?

Answer *(agreed in June 2004):* Without precise knowledge of the substances(s) concerned and the intended applications it is not possible to answer these questions in an absolute way. Only the Rapporteur Member State can make the necessary detailed judgement.

In principle, the TNsG on data requirements provide guidance on how to deal with residues and specify in some cases which data should be required:

Chapter 2 (core data) does not require residue data specifically, except in the 'analytical methods chapter' in which analytical methods for identifying the residues are required. *Analytical methods in all relevant environmental media including recovery rates and the limits of determination for the active substance, and for residues thereof, and where*

relevant in/on soil, air, water and animal and human body fluids and tissues. However, concerning efficacy data, for PT 14, *residue data in target organisms concerning the active substance and including toxicologically relevant metabolites would be needed in order to assess the risks to predators.*

However, for some specific mandatory tests, where residues are found in the food chain, waiving is not possible (example: subchronic toxicity). For environment, for example, data on residues in tissues of aquatic organisms should be estimated (complementary experiment in the bio-concentration test).

Chapter 2.5 gives the 'obligatory additional data' for all product types, and for PT 8 and 14, residue data are not included. However, chapter 2.5 should only used as a rough guide. It should always be used in conjunction with the Emission Scenario Guidance documents and the more detailed Technical Guidance on Risk Assessment. Expert discussion and assessment has subsequently updated and superseded some of the advice given in this chapter, which will in the fullness of time be updated. Until such a time it is advisable to always check with the appropriate Rapporteur Member States before committing resources to data requirements.

Chapter 3 (additional data) contains requirements for information on residues where food and feedstuff contact is possible. Specific information on analytical method for residues is required *if the active substance or the material treated with it is to be used in a manner which may cause contact with food or feedstuffs (e.g. when used for disinfection in food production or transportation, in the food processing industry or catering services), or intended to be placed on, in or near soils in agricultural or horticultural use. This may be the case for product types 1, 2, 3, 6, 8, 14 and 18.* Furthermore, in the case of contact with food, Directive 89/109/EEC is relevant.

Data on residues should be provided *if the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored.* Specific toxicological and metabolic studies for food and feedingstuffs shall be required in accordance with paragraphs 6.15.1-6.15.5.

The list of the product types for which this data shall be required is not exhaustive. The need for additional data will be decided on a case-by-case basis according to expert judgement. In PT 14, for *products to be used in places where the contamination of food or feeding stuffs is possible, or near soils in agricultural or horticultural use* all or some of the listed tests may be relevant.

If the proposed use excludes or does not mention food and feedstuff contact/migration the information is not necessary. However the information may have to be submitted later if a product is used in this way. Member States will require these data at that point. If the product dossier(s) do(es) not relate to representative uses where such contact is likely, then data is not needed for inclusion into Annex I.

For the environment, information related to the fate and behaviour of the active substance and its degradation products are needed in order to assess environmental exposure.

The data and information provided should be sufficient to permit the residue of concern, and to which non-target species are or may be exposed, to be defined. The testing strategy for the fate and behaviour of an active substance in the environment and the

testing strategy on biodegradation of the active substances are outlined in the data requirements. The testing strategy will ultimately depend on the degradation characteristics of the substance (chapters 7.2 and 7.5 are dedicated to soil compartment). If the substance degrades well, and no toxicologically relevant metabolites and/or degradation products are formed, data may not be required. For wood preservatives 'non-degradable' characteristics would be expected but the exact data requirements are 'substance-by-substance'. The data requirements are essentially exposure driven, so a description of the proposed use of the substance is needed, as well as the degradation characteristics.

Further residue data could be required on a case-by-case basis according to expert judgement, but no further guidance could be written in the TNsG. If the proposed uses include use by the general public then an evaluation of consumer exposure must take place. Details for the exposure assessment can be extracted from the 'typical product' as described in the product dossier. For wood preservatives the OECD has developed a guidance document for estimating the human and environmental exposure. The document outlines the exposure estimates needed for different situations. The general guidance for human exposure to wood preservatives should be followed and some data/estimates are needed, for human exposure. If the dossier fails to give human exposure data it is most likely incomplete.

Concerning laboratories and operators, there is a general requirement in the TNsG that the submitted studies must be performed according to GLP (with certain exceptions - e.g. exposure or efficacy data) and this sets some quality assurance requirements for the laboratories performing tests for a dossier (see chapter 6).

7. ANNEXES

7.1. Tables with examples of borderline cases

For general guidance on a number of borderline questions please refer to the guidance documents available at http://europa.eu.int/comm/environment/biocides/index.htm.

7.1.1. Biocidal products

The following examples are extracted from the documents and / or have been discussed at Scope Group meetings:

Hand disinfectants, disinfectant soap, antiseptic soap, antibacterial or antimicrobial soap, antibacterial or antimicrobial cleaning gel, antibacterial or antimicrobial cleaning solution	**Human hygiene biocidal products (PT 1)** If used e.g. to avoid cross contamination in the food industry
Fresh-up towels with a general disinfecting claim	**Human hygiene biocidal products (PT 1)**
Detergents and cleaning products (auxiliary aids for washing processes like fabric conditioners are included) intended to have a biocidal activity (reliably controlling micro-organisms like fungi and bacteria)	**Human hygiene biocidal products (PT 1)**
Disinfectant mouth solution, antiseptic mouth solution (no medicinal claims)	**Human hygiene biocidal products (PT 1)**

Disinfecting detergents (e.g. to be used in households and other premises on surfaces and utensils, dishwashing products intended to have a biocidal effect)	**Private area and public health area disinfectants and other biocidal products (PT 2)**
Toilet cleaners containing limescale remover when intended to have a biocidal effect	**Private area and public health area disinfectants and other biocidal products (PT 2)**
Sanitary products (toilet bars included) and other toilet products used in toilets with an active substance or substances exerting a biocidal activity (e.g. killing or preventing the growth of micro-organisms).	**Private area and public health area disinfectants and other biocidal products (PT 2)**
General disinfectants used on animals (e.g. iodine solutions for disinfection of navels after birth)	**Veterinary hygiene biocidal products (PT 3)**
General disinfectants used in footbaths for animals for prevention of cross contamination	**Veterinary hygiene biocidal products (PT 3)**
Disinfectants used in areas in which animals are housed, kept or transported	**Veterinary hygiene biocidal products (PT 3)**
Products for the control of external parasites of fish, used by adding the products to the water where fish swim and no medicinal claim	**Veterinary hygiene biocidal products (PT 3)**
Hygiene protection for textiles in contact with human skin	**Fibre, leather, rubber and polymerised materials preservatives (PT 9)**
Anti-microbial finish for textiles in contact with human skin and anti-microbial treatment of PUR-coated textiles	**Fibre, leather, rubber and polymerised materials preservatives (PT 9)**
Mildew–proof and rot-proof finish for textiles	**Fibre, leather, rubber and polymerised materials preservatives (PT 9)**
Products which contain repellents for example collars, neckties, ears marks, without any lethal effect	**Repellents and attractants (PT 19)**
Repellents (without any lethal effect and without medicinal claim) that are directly applied to human and animal skin	**Repellents and attractants (PT 19)**
Products intended to kill flies on horses by direct application on the horses' skin without medicinal claim.	**Insecticides (PT 18)**
Mite repellents (without any lethal effect) to be used on human skin	**Repellents and attractants (PT 19)**
Mosquito nets containing insect repellents	**Repellents and attractants (PT 19)**
Sleeping bag treated with an insect repellent	**Repellents and attractants (PT 19)**
Anti fleas collar	**Repellents and attractants (PT 19)**
Repellent cream, gel, stick, lotion with a UV filter	**Repellents and attractants (PT 19)**
Repellent cream, gel, stick, lotion to be put on the skin or on the pillow	**Repellents and attractants (PT 19)**

Further examples with relevant explanations can also be found in Guidance document Doc-Biocides-2002/04, available at: http://europa.eu.int/comm/environment/biocides/index.htm.

7.1.2. Not Biocidal products (i.e. covered by another Directive or not acting by chemical or biological means)

The following examples are extracted from the documents and / or have been discussed at Scope Group meetings:

Products containing active substances with lethal effects on external parasites to be used on human beings or animals with medicinal claim.	**Human or Veterinary medicinal product**
Antidandruff shampoo	**Cosmetic Product**
Anti-lice shampoo	**Human Medicinal Product**
Paste to protect against doves (making the surface to be protected elastic, which birds dislike).	The dove paste acts by physical means and is **not covered by the Biocides Directive**