

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

Note on Issues and Policy Options

Prepared for European Commission
Directorate General Environment

RPA

**In association with Hydrotox GmbH
and Milieu Ltd**

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Impact of the Revision of Directive 98/8/EC concerning the Placing of Biocidal products on the Market

Note on Issues and Policy Options – February 2008

prepared for

European Commission – Directorate General Environment

by

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1. INTRODUCTION

1.1 Objective of the Note

1.1.1 Overall Objective

The objective of this note is to present different policy options for the main areas for revision of Directive 98/8/EC (the BPD) that have been identified by the Commission, based on previous studies analysing the impacts of the BPD and the main problem areas. This note aims to describe the issues to be addressed and to set out clearly and coherently formulated policy options, which will provide the focus for the remainder of the study.

1.1.2 Policy Options to be Evaluated

The policy options to be evaluated address five main issues, identified by the Commission:

- the scope of the BPD;
- product authorisation;
- data sharing;
- data requirements;
- fees charged by Member States for carrying out the procedures of the BPD; and
- incorporation of provisions regarding biocides use.

For each of these issues, a range of policy options is evaluated, including in each case the ‘no action’ option, which will include minor corrections which the Commission may make to the BPD to clarify and make the current BPD work more smoothly.

1.1.3 Impacts to be Assessed

For each of the policy options identified, the assessment addresses the impacts on a range of stakeholders, and on the environment. These impacts include:

- Impacts on **industry**: economic impacts, including competitiveness and competition, administrative burden; particularly impacts on SMEs;
- Impacts on **public authorities**: economic impacts, administrative burden;
- Impacts on **product availability**: ability to combat harmful organisms, investment in safer products and innovation;
- **Social** impacts: public health and safety, employment;
- **Environmental** impacts.

The focus of the impact assessment is on major, feasible, policy options. It excludes both minor corrections and clarifications to the text and options which have been discounted by the Commission (e.g. repealing the BPD and instead incorporating controls over biocides under the PPP or REACH) as well as changes already envisaged by the

Commission (e.g. exclusion of food and feed attractants from the scope of the BPD, replacing the BPD by a Regulation).

1.2 Organisation of the Policy Options Note

In sections 2 to 7 of this note, each problem area identified by the Commission is discussed in turn, with the discussion including:

- a description of the problem and the aim and objectives to be achieved through revision of the BPD;
- a list of the options identified and options discarded at this stage;
- description of the policy options identified; and
- a comparative table setting out a preliminary assessment of the advantages and disadvantages of each option for the stakeholders affected.

Section 8 of the note summarises the policy options that we propose should be the focus of the remainder of the study. The remaining sections of the note then set out the process that will be used to assess the options identified. Section 9 identifies key sectors for assessment and section 10 outlines a consultation work plan.

2. SCOPE OF THE DIRECTIVE

2.1 The Problem

During the review of the impacts of the implementation of the BPD, several concerns associated with the current scope of the BPD were identified. Some of these problems are due to changes in EC law since the entry into force of the BPD. In particular, the list of legislation mentioned as exemptions from the scope in Article 1(2) of the BPD needs to be adapted and updated. Other changes affect specific active substances that may be either covered by several EC acts or not covered by any instruments.

The following issues related to the scope of the BPD have been identified by the Commission:

- 1) **Borderline issues:** these refer to products for which it is unclear whether they should come within the scope of the BPD or other Directives or Regulations. The Commission has issued a number of guidance documents clarifying some of these borderline issues (e.g. plant protection products, medicinal product for human use and veterinary medicinal products, cosmetics, in-situ generated biocides, food and feed additives, medical devices, detergents). These guidance documents are not legally binding and the revision of the Directive could provide an opportunity to incorporate some of the agreements reached regarding certain borderline cases. New issues may also have arisen due to new developments in EC law (e.g. REACH and changes in food law) that could also be taken into account.
- 2) A specific borderline issue concerns groups of substances not currently regulated by any EC instrument and which could qualify as biocidal products ('limbo products'): this is the case for "food processing aids". "Food processing aids" are used for the disinfection of food of animal or plant origin (e.g. decontamination of animal carcasses, decontamination of salads). These are defined by Directive 89/107/EEC to differentiate them from food additives and thus are not subject to any evaluation, since they are not currently considered biocides either. Other types of limbo products may include certain biocides used in food contact materials.
- 3) Treated articles with internal effect are not covered by the BPD. Thus, articles or materials treated with a biocidal product in order to protect the article itself fall outside the scope of the BPD and need no authorisation to be placed on the EU market. As a consequence, nothing in the current BPD prevents in principle the import into the EU of articles/materials treated with biocides not authorised or even banned in the EU. Apart from consumer protection issues, this loophole places EU producers at a disadvantage and may lead to circumvention of the Directive.
- 4) Administrative costs associated with the number of product types. Member States and industry have complained about the resources needed to deal with the evaluation of a large number of active substances/product-type combinations and subsequent product authorisations.

Different regulatory options could be envisaged to overcome these problems. Section 2.2 introduces and outlines these options.

2.2 Options

2.2.1 No Action

Under this option, no major action is foreseen; only necessary changes would be made to update the Directive. Articles 1 and 2 of the BPD would be adapted to developments in the legislation covered.

2.2.2 Extend Scope to Cover ‘Limbo’ Products

This would consist of the extension of the scope of the BPD to cover "limbo products", which are not yet covered by the BPD or other Directives.

The Commission has identified food processing aids as a potential “limbo product”. If a substance used in food processing remains in food, it is considered a food additive and regulated as such. Currently, processing aids are defined in the first footnote of Directive 89/107/EEC as any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product. However, Article 1(3)(a) states that Directive 89/107/EEC shall not apply to processing aids..

Processing aids are removed from the food after they have fulfilled their technological purpose. However, traces of processing aids may remain in food as long as they do not present any health risk and do not have any technological effects on the finished product. Directive 89/107/EEC does not further define the conditions under which processing aids present a health risk or have technological effects on the finished product.

Article 1(2)(i) of the BPD excludes from its scope products that are *defined or within the scope* of Directive 89/107/EEC. Read in conjunction with the text of Directive 89/107/EEC, this means that processing aids fall neither within the scope of Directive 89/107/EEC nor the BPD. As a consequence, substances used as processing aids are not subject to any evaluation of their effects on the environment at EU level.

It should be further noted that processing aids used on food of animal origin are covered by Regulation (EC) No 853/2004. This Regulation prohibits the use of any substance other than potable water to remove surface contamination from products of animal origin unless such a substance has first been approved by a comitology procedure. However, compared with the BPD, the approval procedure under Regulation (EC) No 853/2004 does not adequately address environmental concerns. In addition, Regulation (EC) No

853/2004 does not apply to processing aids used on food of plant origin. This leaves it to the discretion of the Member States whether they take any action to evaluate the human health and environmental concerns that they might present.

As certain processing aids can have biocidal effects and fulfil the definition of a biocidal product, it may be logical that they should come within the scope of the BPD. An extension of the scope of the BPD to cover processing aids would ensure that any risks posed by these substances to the environment and human health are identified, examined and, if necessary, addressed through risk mitigation measures. There are two ways in which this could be achieved:

- Amending Article 1 (2): “*This 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 the following instruments for the purposes of these Directives...*” and/or
- Amending Annex V of the BPD: Product-type 20: Preservatives for food or feedstocks. Products used for the preservation of food or feedstocks by the control of harmful organisms *and processing aids*.

Two particular concerns have arisen in relation to food processing aids. The first concerns import of chicken carcasses treated with biocidal substances which are not approved for use on the EU market. The second concerns the practice of washing vegetables, particularly salad vegetables for packaging, in biocidal substances such as chlorine.

Other examples of ‘limbo’ products include biocides used in food contact materials, which are currently excluded from the scope of the BPD. Points of concern include their environmental impact, efficacy, use in consumer products and antimicrobial resistance. The impacts of their inclusion within the scope of the BPD will also be assessed.

2.2.3 Extend Scope to Cover Treated Articles

This option would enable the BPD to cover treated articles. This option is based on the option recommended in the study on treated articles¹. This option would address the most significant treated articles identified in the study. Articles treated with in-can and film preservatives (PT 6 and 7), wood preservatives (PT 8), fibre, leather, rubber and polymerised materials preservatives (PT 9) are of special concern.

The approach would consist of the adoption of a general obligation that only articles and materials treated with substances included in Annexes I, IA or IB could be placed on the market. Two possibilities are then available depending on whether the substance has already been assessed and is included in Annex I, IA or IB but not for that particular use; or whether the substance has not been assessed at all.

1 Milieu Ltd and DHI: Study on the impacts of possible measures to manage articles or materials treated with biocides – in particular when imported (No 07-0402/2005/414388/MAR/B4) http://forum.europa.eu.int/Public/irc/env/bio_reports/library?l=/treated_articles/

If the **active substance has already been assessed** and included in Annex I, IA or IB, but either not for that particular use, or where releases of the substances from treated articles are significantly different from those taken into account during the risk assessment, it may be possible to establish a “*simplified*” procedure. This would be a proportionate solution, since much of the data would already be available and it would be more a matter of extending the scope of the inclusion of the substance in Annex I, IA or IB. The provisions regarding data protection and access to data under the BPD would apply in any case.

Such a simplified procedure would apply to active substances where a full assessment under the BPD has been carried out for at least one specific use. Any new uses of the substance as a biocidal product would have to undergo a full assessment, if the exposure situations are different from those included in the risk assessment. However, inclusion in Annex I, IA or IB implies that a set of data on toxicological, metabolic studies and ecotoxicological studies required for the risk assessment exists. In order to carry out a new risk assessment, the new exposure scenario would have to be described and related to the existing hazard assessment. The adequacy of the available set of data on hazard to human health and the environment to carry out the risk assessment for the new exposure and possibly new exposure routes would have to be evaluated. Based on the exposure assessment, a supplemental risk assessment would then be carried out in order to complete the existing risk assessment. Compulsory data sharing (see section 4 below) might be necessary.

The simplified procedure for new uses of a substance included in Annex I, IA or IB should thus consist of submission of the exposure assessment and the supplemental risk assessment with a reference to the existing registration.

If the **substance has not been previously assessed** in the EU, a simplified procedure does not seem an adequate solution, in order to maintain the high level of protection of human health and the environment introduced by the BPD. In order to place all economic operators on equal footing in the EU market, and ensure that the substances do not pose unacceptable risks for human health and the environment, a full assessment as provided by the BPD could be required.

The practical aspects of this option will be assessed.

To facilitate enforcement and to enable informed choices by consumers, labelling requirements for all or the most relevant treated articles are recommended. (Quality labels are already in place for several PT, e.g. ecolabels, national labels of industrial organisation. For example, Sweden has a system for labelling treated wood). Such labelling could follow a procedure similar to Article 15 of Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food:

- indication “treated with approved biocide’ or symbol;
- if necessary, special instructions to be observed for safe and appropriate use;
- name or trade name and address of manufacturer, processor, or seller responsible for placing the product on the market;

- traceability is also important in order to ensure at all stages the control, the recall of defective products, consumer information and identification of the person to be held liable;
- further labelling might include indication of the active substance used and instructions for disposal (e.g. of treated wood).

A contact point for stakeholders to report non-conforming products was also recommended.

2.2.4 Extend the Scope to Cover both Limbo Products and Treated Articles

This option combines the two previous options.

2.2.5 Reduce the Number of Product Types

The Commission, competent authorities and stakeholders have raised concerns that the number of product types (PT), and the fact that there are variations in exposure patterns and hence risks within product types, has added to the complexity of the BPD. However, to date no concrete proposals on potential PT combinations have been made.

The main impact of the current system of product types is on active substances. The study of the impacts of implementation of the BPD showed that individual active substances may be used in a number of different PT, requiring preparation of separate dossiers and, in many cases, payment of additional fees for each PT. This has resulted in manufacturers limiting the number of PT for which an active substance is supported, focusing their efforts on PT which are the largest and/or most profitable markets. Reducing the number of PT could reduce the number of dossiers submitted and the number of fees payable. However, it is also likely to result in lengthier and more complex dossiers, with no reduction in data costs for industry or the costs of evaluation for competent authorities, since the same information will be needed to assess the impacts on human health and the environment.

In addition, by the time the BPD is amended, the review programme will be largely complete so that the impacts of reducing the number of PT will be limited. Changing the PT once most substances have been through the review programme could also lead to confusion and, depending on the changes made, could mean that accepted dossiers have not necessarily addressed all the risks relevant to the (new) PT. The impact of a reduction in the number of PT is likely to be much less at the product authorisation stage. An initial review of the German biocidal products register indicated that less than 1% of products were notified for more than one PT.

For these reasons, we propose to undertake a two-stage review of the potential impacts of reducing the number of PT:

- We will first examine national product registers to determine whether changes in the number of PT are likely to have a significant effect at the product authorisation level. We will identify the number of products notified for more than one PT and evaluate

the potential reduction in the administrative burden that would result from reducing the number of PT;

- If this analysis indicates that the reduction in the administrative burden could be significant, we will then examine what combination of PT could result in the greatest reduction in administrative burden.

There are a number of ways in which PT could be combined. The PT combinations identified in the German biocidal product register from 2006 were PT 18 and 9, PT 1 and 2, PT 5 and 12, PT 6 and 7 and PT 7 and 8.

Other proposals could also be envisaged. For example:

- Combine PT 2 and PT 4: these are disinfectants which have a similar use pattern.
- Combine PT 6, 7, 9 and 10 (preservatives).
- Combine PT 11 and 16: the only application of molluscicides outside the Plant Protection Products Directive (Directive 91/414/EEC) is in the field of cooling water treatment. For this reason, no active substance was supported for PT 16.
- Combine PT 15, 17, and 23: all relate to vertebrates. Note that PT 15, 17 and 23 are not permitted in Germany.

The exclusion of food preservatives (PT 20) from the scope will also be assessed in this option.

2.3 Preliminary Assessment of Advantages and Disadvantages

Stakeholders	Option				
	1. No action (minor updating)	2. Include limbo products	3. Include treated articles	4. Include limbo products and treated articles	5. Reduce number of PT
EU industry	<i>Advantages:</i> Clearer and more harmonised regulatory regime and thus fewer resources required to provide advice on whether products need to be authorised	<i>Advantages:</i> Clearer and more harmonised regulatory regime	<i>Advantages:</i> Harmonisation of rules Level playing field with third countries manufacturers	<i>Advantages:</i> Combined advantages of 2 and 3	<i>Advantages:</i> Possibly lower fees from smaller number of products to be authorised Possibly lower fees for submitting new substance dossiers
	<i>Disadvantages</i> No substantial economic savings: products will still need authorisation	<i>Disadvantages</i> Costs to manufacturers for support and authorisation of substances and products not currently covered by the BPD.	<i>Disadvantages</i> Costs of labelling (if not using a label already) Importers of manufactured products may have to shift to other suppliers and lose market (or face increased costs)	<i>Disadvantages</i> Combined disadvantages of 2 and 3	<i>Disadvantages</i> Unequal treatment of those that have supported substances now falling outside of the scope of the BPD and thus loss of investment
Administration (implementation and enforcement)	<i>Advantages</i> Clearer and more harmonised regulatory framework and thus less time spent on questions to the Commission and discussion of borderline issues	<i>Advantages</i> Clearer and more harmonised regulatory regime	<i>Advantages</i> Combined enforcement with other compulsory labelling/chemicals products rules Categories of product requiring enforcement clearly defined	<i>Advantages</i> Combined advantages of 2 and 3	<i>Advantages</i> Possibly reduced confusion and administrative requirements for product authorisation
	<i>Disadvantages</i> Not a significant reduction in administrative burden, since no major change in product authorisation	<i>Disadvantages</i> Increased administrative burden due to new product authorisations	<i>Disadvantages</i> Some costs related to training and improvement in customs controls	<i>Disadvantages</i> Combined disadvantages of 2 and 3	<i>Disadvantages</i> Loss of revenue from product authorisation fees
Consumers, health & environmental protection	<i>Advantages</i> Limited – possibly better information due to clearer regulatory framework and increased harmonisation?	<i>Advantages</i> [depending on substances covered] Environmental benefits (greater safety of released substances) Potential increase in consumer protection (more substances)	<i>Advantages</i> Ability to make informed choices Improved safety of articles and materials on the EU market Risks related to substances in articles reduced	<i>Advantages</i> Combined advantages of 2 and 3	<i>Advantages</i> None, except possibly lower prices

Stakeholders	Option				
	1. No action (minor updating)	2. Include limbo products	3. Include treated articles	4. Include limbo products and treated articles	5. Reduce number of PT
		controlled)			
	<i>Disadvantages</i> n/a	<i>Disadvantages</i> These benefits may be negligible?	<i>Disadvantages</i> Possibly increased prices	<i>Disadvantages</i> Combined disadvantages of 2 and 3	<i>Disadvantages</i> Risk of less safe products or increased risk of misuse
Social impacts	<i>Advantages:</i> n/a	<i>Advantages:</i> Increased safety of workers (users of products covered)	<i>Advantages:</i> Improved health and safety (import of safer intermediate goods)	<i>Advantages:</i> Combined advantages of 2 and 3	<i>Advantages</i> Costs savings may lead to greater investment in innovation and increased employment in SMEs
	<i>Disadvantages</i> n/a	<i>Disadvantages</i> New products covered may increase costs on SMEs and lead to loss of jobs	<i>Disadvantages</i> n/a	<i>Disadvantages</i> Combined disadvantages from 2 and 3	<i>Disadvantages</i> n/a
Product availability	<i>Advantages</i> n/a	<i>Advantages</i> n/a	<i>Advantages</i> May possibly lead to additional substances being supported and thus more products available on the market	<i>Advantages</i> Combined advantages of 2 and 3	<i>Advantages</i> More products on the market due to savings in costs
	<i>Disadvantages</i> n/a	<i>Disadvantage</i> May reduce the number of products, due to costs of authorisation	<i>Disadvantages</i> n/a	<i>Disadvantages</i> Combined disadvantages of 2 and 3	<i>Disadvantages</i> n/a

Table 2.1: Preliminary Assessment of Advantages and Disadvantages to Stakeholders of Options Relating to Scope					
Stakeholders	Option				
	1. No action (minor updating)	2. Include limbo products	3. Include treated articles	4. Include limbo products and treated articles	5. Reduce number of PT
Others (trade, internal market, transparency)	<i>Advantages</i> Improved circulation of goods, including imports, through better and more transparent regulatory regime	<i>Advantages</i> Increased harmonisation, thus facilitating circulation of products	<i>Advantages</i> Harmonisation of rules	<i>Advantages</i> Combined advantages of 2 and 3	<i>Advantages</i> May increase trade from third countries due to reduced requirements for product authorisation
	<i>Disadvantages</i> n/a	<i>Disadvantage</i> If these products were not covered by EC law or national law, it may delay free movement of goods due to the need to get a product authorised in all MS.	<i>Disadvantages</i> Third country manufacturers: additional costs for shifting substances and compliance with the BPD unless already done because of compliance with legislation of other countries (e.g. US) Cost of notification of non registered substances Cost of labelling	<i>Disadvantages</i> Combined disadvantages of 2 and 3	<i>Disadvantages</i> n/a

3. PRODUCT AUTHORISATION

3.1 The Problem

Articles 3 to 8 of the BPD describe the procedure and conditions of authorisation, which are a precondition to the placing on the market of biocidal products. An effective authorisation system is important for monitoring and enforcement of the market for biocidal products and was in place in several countries before the entry into force of the BPD. In those Member States, fewer biocidal products were placed on the market than in countries that only had a registration procedure or had no such requirements for biocidal products².

Complexity of the system

The product authorisation system is complex and could be further clarified. The study on the impacts of implementation of the BPD indicated that technical guidance was needed (e.g. on analytical methods, identity, technical equivalence, kind of exposure scenario to be applied). Some authorities also requested guidance concerning product authorisation, frame formulations and mutual recognition.

Mutual recognition

Mutual recognition is widely accepted by stakeholders and is seen as the major benefit of the BPD by industry, by facilitating the movement of goods within the internal market. However, in the previous study, all stakeholders expressed concern regarding the effective and homogenous application of mutual recognition procedures in all Member States. In particular, some Member States may find difficult to trust the assessment of other Member States and all Member States would have to apply the same principles to judge the completeness and the substance of a dossier.

The practical implementation of mutual recognition may pose some problems because national rules and different data requirements would still be applied to product authorisation and registration (in the case of low-risk products). This may result in a requirement for additional tests (e.g. in relation to efficacy testing) for mutual recognition due to different national approaches. This is directly linked to concerns regarding the level of protection on the national market. Mutual recognition may, according to some national authorities, increase the number of biocidal products on the market, with products formerly not approved, or with restricted use, introduced onto national markets. By contrast, some stakeholders considered Article 4 of the BPD as too wide, since it would allow Member States to impose conditions on placing biocidal products on the market.

Moreover, although mutual recognition of product authorisations and registrations may

2 Only some of the national systems pre-dating the BPD required authorisation of biocidal products. Other national systems only required registration of biocidal products. Finally, in some countries no specific requirements for biocidal products were in place.

save time and resources, difficulties may arise due to unclear rules. For instance, mutual recognition is not applied to provisionally authorised new active substances and Member States' authorities have different approaches in cases where a biocidal product contains a second active substance currently being evaluated.

Many manufacturers of biocidal products are also manufacturers of plant protection products. Negative past experience with the mutual recognition mechanisms under the Plant Protection Products Directive are the basis of stakeholders' concerns regarding the effectiveness of mutual recognition within the BPD in ensuring free movement of biocidal products within the EU. Amendment of the BPD could therefore provide for a faster and more effective mechanism, facilitating free movement of biocidal products within the EU.

3.2 Options

3.2.1 No action

The current system, with the evaluation of active substances at Community level and subsequent authorisation of products (or registration in the case of low-risk products) containing the approved substances at national level (two-tier system), would be maintained.

However, effort could be made to facilitate the mutual recognition of authorisations through informal discussions. One possibility could be to discuss general issues of mutual recognition informally, through e.g., workshops. The outcome of these discussions could be a guidance document on mutual recognition.

Guidelines on refusal of mutual recognition would be particularly important. For example, these could include guidelines to define the basis to justify a refusal; guidelines to identify situations and PT for which climatic conditions could be considered as a justification to refuse (e.g. pest control, drinking water disinfectant).

Another possibility could be to hold informal discussion on mutual recognition of a specific product that could be considered problematic. This product could be brought to the attention of other Member States in the Standing Committee and specific concerns could be dealt within the Committee.

3.2.2 Baseline Plus

Under this option, product authorisations (and registrations for low risk products) are still issued at national level but mutual recognition and conflict resolution provisions are strengthened. This option will also require clarification of the elements of current mechanism (e.g. some or all of the aspects of the 'no action' option outlined above).

Mutual recognition of authorisations or registrations would be initiated by a Member State when that Member State receives an application for authorisation (or registration)

of a product already authorised (or registered) in another Member State. Member States could also decide to authorise (or register) the placing on their market of a product, even if no application was made by a company, if they consider that there is a need for that product on their territory. The mechanism to reinforce mutual recognition could be the adoption of a decentralised authorisation procedure (which could be considered as a kind of simultaneous mutual recognition or authorisation of a product simultaneously in different Member States).

There are two options for strengthening the system of mutual recognition:

- adopting an approach similar to the decentralised procedure to approve medicinal and veterinary medicinal products under Directives 2001/82/EC and 2001/83/EC; or
- following the example of the proposed Plant Protection Products Regulation.

Decentralised Procedure under Directives 2001/82/EC on medicinal products and 2001/83/EC on veterinary products

Under both of these Directives, when an applicant wants to market a product in more than one Member State, he submits an application based on an identical dossier in all these Member States. The applicant requests one of the Member States to be the “reference Member State” in charge of preparing the assessment report. If the product has already received a marketing authorisation in the reference Member State, the reference Member State has 90 days to approve or update the assessment report; in other cases, the reference Member State has 120 days to prepare a draft assessment report, draft product characteristics and draft leaflet.

The assessment report, together with a summary of the product characteristics, labelling and packaging leaflet is sent to the other Member States concerned and to the applicant. The concerned Member States have 90 days from receipt of the documents to approve the assessment report and inform the reference Member State accordingly. The reference Member State records the agreement of all parties, closes the procedure and informs the applicant. Within 30 days after acknowledgment of the agreement, each Member State in which an application has been submitted is to adopt a decision in conformity with the approved assessment report.

A coordination group is set up for any question regarding the marketing authorisation, i.e. when a Member State cannot approve the assessment report, product characteristics, labelling and leaflet on the grounds of potential serious risks to public health, or in the case of veterinary medicinal products, serious risk to human or animal health or the environment. The Member State questioning the authorisation gives detailed explanation of the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. Within the coordination group, the Member States concerned are to use their best endeavours to reach an agreement on the action taken. If no agreement is reached, the matter is referred to the Committee for Medicinal Products for Human Use. This Committee acts as a conflict resolution mechanism in the mutual recognition procedure or when two or more applications have been made for marketing

authorisation and Member States have adopted divergent decisions. A marketing authorisation can also be referred to directly to the Committee in specific cases where the interest of the EC is involved.

Finally, to promote harmonisation of authorisations, Member States forward each year to the coordination group a list of the products for which a harmonised summary of product characteristics is drawn up. This list is forwarded to the Commission. This serves the Commission or the Member State to identify products that may be referred to the Committee (e.g. because of divergent authorisations, Community interest and so on).

A similar system could apply for the BP authorisation. The Commission would need to develop guidelines defining a potential serious risk for human or animal health or the environment. The main shortcoming of the adoption of this procedure in the area of Biocides is that there is currently no neutral or coordination entity, the equivalent of the EMEA³. The EMEA acts as secretariat for mutual recognition and to the conflict resolution procedure. It also summarises the Committee's opinion and gives opinion that then serve as a basis for the final decision adopted by the Commission in committee. However, the EMEA's coordinating tasks could be assumed by the reference Member State during the mutual recognition procedure and by the Member State rapporteur during the conflict resolution procedure, or taken on by an existing or new body.

This procedure may ease the authorisation of products simultaneously (or very close in time) in different Member States. The costs of dossier examination could be distributed among the Member States in which the applicant intends to market the product. Fees to be paid by the applicant could be significantly reduced as a consequence, so that the applicant only needs to pay once in order to market a product in several Member States. The reference Member State is in charge of distributing information to the concerned Member States and thus the applicant may save on administrative costs. However, if one of the concerned Member States does not agree with the reference Member State opinion, before going into the conflict resolution Committee, the coordination group will try to reach an agreement. This step may delay authorisation of the product and thus its placing on the market.

Example of the Proposed Plant Protection Products Regulation

Under the proposed revision of the Plant Protection Products Directive (version agreed by the Council on June 2007), the Community has been divided into climatic zones. Any person who wishes to place a plant protection product on the market submits an application in each Member State where the plant protection product is intended to be placed. The application includes *inter alia* a list of intended uses in the zones and the Member States where the application has made or intends to make an application and a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned. In the case of an application for use in greenhouses or as post-harvest treatment, or for treatment in empty storage rooms only, one Member State shall be proposed to evaluate the application in all zones. The application shall be examined

3 Refusals of mutual recognition are dealt at the Commission via voting of the Standing Committee (Article 4 of the BPD)

by the Member State proposed by the applicant unless another member State agrees to examine it. If the application is for several zones, the Member State in each zone in charge of evaluating the application shall agree on the evaluation of data which are unrelated to the environmental and agricultural conditions. As climatic zones are much less important in the context of biocides, this approach does not provide a viable model for the BPD.

However, some aspects of the approach of the proposed Plant Protection Products Regulation may still be relevant. In particular, the holder of an authorisation can also apply for mutual recognition for the same plant protection product and for the same use in another Member State/s. In the case of refusal, the decision is submitted to the Commission and decided by the Standing Committee.

Both examples show how problems with mutual recognition have led to decentralised product authorisation, with a mechanism to ensure coordination amongst Member States where a product is intended to be placed. Under these mechanisms, the person wanting to market a product in several Member States could submit an application based on the same dossier and including a proposal for a reference Member State. The applicant may choose a Member State where the product was already authorised, in which case the Member State will have to update the assessment report. If the product was not previously authorised in that Member State, the Member State will have to prepare a draft assessment. The other Member States in which an application has been submitted refrain from examining the dossier.

The evaluation of the dossier is normally based on common principles or criteria. The other concerned MS are to adopt a decision based on the evaluation carried out by the reference Member State although they can make some changes in the labelling or adopt further risk reduction measures based on the conditions in the particular country. These measures are not meant to delay the product authorisation. Regardless on whether there is a formal coordination group, the reference Member State and the concerned Member States cooperate and exchange information. These procedures help Member States to share the burden of evaluation, which in its turn may lead to a reduction in the fees to be charged to the applicant for the product authorisation.

The advantage of the approach under the proposed Plant Protection Products Regulation is that the negotiation within the coordination group in the case of disagreement (as required under Directives 2001/82/EC and 2001/83/EC) is avoided. This may accelerate the authorisation. However, the rules are not finally decided and some areas remain unclear.

This decentralised authorisation could be a complement to the common register of biocidal products within the EC foreseen in the BPD. The common register could attribute one authorisation number to each biocidal product, product characteristic and label (as in the Medicinal Products Directive). When a Member States authorises a biocidal product, the authorisation or registration (in the case of low-risk biocidal products) number is included on a database. The database would serve as way of identifying products authorised in several MS and whether there are divergent authorisations and so on. This register would also allow Member States to consider the

authorisation of a biocidal product, even if no application has been submitted.

3.2.3 Single Community Authorisation

Under this option, a biocidal product authorised or registered (in the case of low-risk biocidal products) in one Member State could be placed on the EU market freely, without need for any further administrative procedures, other than complying with labelling rules. This would reduce the administrative burden for industry and authorities, while ensuring the protection of consumers' health. The procedure would be similar to that adopted for parallel imports.

The company intending to market the biocidal product in another Member State would have to notify the Competent Authority of its intention to market the product. This would be accompanied by information proving that the product is identical or equivalent to a product already authorised in another Member State. The Competent Authority would need to authorise the product label, which implies that the company will have to submit a label and packaging proposal and safety data sheet. This will ensure that the distributed product complies with labelling requirements (e.g. language). Other risk reduction measures to be included in the label could be considered by the Member State, given the specific conditions applicable in that Member State.

The system could be completed by a clause stating that Member States may object to authorisation within a certain time period. The conditions for refusal could be described in a detailed and clear way in the revised act. Refusals could be notified to the Commission and dealt with within the Standing Committee.

Although this is a rapid mechanism for authorisation of products and is in line with basic Community law regarding free movement of products, it would require changes to the basic structure of the current BPD. This would probably only be justifiable if there were significant potential benefits and if adequate safeguards were provided to the Member States.

3.2.4 Centralised authorisation

This would consist of a centralised procedure for product authorisation, carried out either by a central agency or modelled on the current procedure for the assessment of active substances.

As no central agency exists under the current BPD, either a new agency would have to be created or the role taken on by an existing agency set up under other Community legislation. If modelled on the system for evaluation of human and veterinary medicines, the system would also allow a company to opt for product authorised at national level (decentralised procedure) and additionally ask for mutual recognition in different countries (as above). The agency would examine the dossier submitted by the applicant and formulate an opinion. The agency's opinion would serve as the basis for the Commission to adopt a decision on the authorisation of the product within the

Community, assisted by the Standing Committee. This system ensures a harmonised approach to product authorisation with the potential for the Commission, assisted by the Standing Committee, to overrule the decision of the agency.

Alternatively, the centralised procedure could be modelled on the current procedure for the assessment of active substances, with one Rapporteur Member State, a peer review at Community level and an authorisation, valid in the 27 EU Member States, granted by the Commission. The system would be similar to the authorisation mechanisms under REACH for substances of very high concern. Under this procedure, the Rapporteur Member State, which could be proposed by the applicant or decided within Comitology (e.g. one Member State could volunteer), will carry out the dossier evaluation. The results will be presented for peer review at Community level and finally the decision on authorisation will be taken on the basis of the evaluation by the Commission, assisted by the Standing Committee. The authorisation would be valid for all Member States, although additional risk reduction measures could be taken by a specific Member State to take account of specific characteristics or conditions.

The mechanism could be completed by a safeguard clause allowing a Member States to refuse the authorisation, given the specific conditions in the Member States concerned. The basis for refusal could be limited to environmental and health concerns and the Member States would have to provide justification. The Member State refusal would be examined by the Commission, which would carry out Article 95(4)-(6) test to consider whether the Member State position is justified and proportional or whether additional risk mitigation measures less restrictive of free movement could be adopted. Article 95(4) would be used in cases where a Member State wishes to maintain a prohibition to place on the market certain biocidal products (e.g., certain products currently banned in a given Member State). Article 95(5) would be used in cases where a Member State does not agree with the authorisation and wishes to ban an authorised product (introduce a new restriction). The application of Article 95(5) test is much stricter since the Member State would have to prove that the national conditions clearly defer from the rest of the Community.

Although this option would also ensure a harmonised approach to product authorisation, while allowing for safeguard clauses, it may lead to delays similar to those experienced in the approval of active substances. There is risk that discussions already held during the active substance evaluation will be repeated during the product authorisation. In addition, Member States may not accept a system which so reduces their flexibility to take account of their specific conditions.

A further option may be to identify the product types for which it is likely that mutual recognition may be difficult and to submit them to a centralised procedure (see Option 2 above). Alternatively, the centralised procedure could be used for categories of products for which a general common agreement exists (e.g. industrial products). The system under REACH also foresees a mechanism to ensure the quality of dossier evaluation. Basically, the Member State rapporteur is paid to carry out the assessment from the budget of the ECHA. This mechanism would probably be difficult to adopt for biocides, though, unless an existing agency is given competence for biocidal product authorisation or a new agency is created.

3.3 Preliminary Assessment of Advantages and Disadvantages

Stakeholders	Option			
	1. No action (minor updating)	2. Baseline plus	3. Single Community authorisation	4. Centralised authorisation
EU industry	<i>Advantages:</i> Clarification would assist harmonisation, especially regarding mutual recognition. Improved guidance	<i>Advantages:</i> Strengthen and facilitate product authorisation in several Member States at the same time or close in time (reducing risks of refusals) Reduce financial burden for companies if costs distributed among MS	<i>Advantages:</i> Ensure free circulation of goods and alleviate administrative and financial burden for companies	<i>Advantages:</i> Ensure free circulation of goods by harmonisation of requirements and procedure
	<i>Disadvantages</i> Uncertainties remain	<i>Disadvantages</i> Flexibility left to MS to apply the system- uncertainty- A MS may not follow the reference MS opinion leading to possible delay of authorisation or that a product is not authorised in that MS	<i>Disadvantages</i> Potentially higher fees in the MS where first authorisation takes place	<i>Disadvantages</i> Significant costs of establishing a new Agency Potential for significant delays if there is no Agency

Stakeholders	Option			
	1. No action (minor updating)	2. Baseline plus	3. Single Community authorisation	4. Centralised authorisation
Administration (implementation and enforcement)	<i>Advantages</i> No changes in the legislation to implement Workshop to clarify the positions	<i>Advantages</i> Potential to share the burden of evaluation More harmonised approach and less risk of divergences – better information exchange Possibility to initiate mutual recognition and to authorise a product without application	<i>Advantages</i> Less work if not the first MS where the product is placed	<i>Advantages</i> A new Agency would reduce the workload of MS Even if no Agency, the evaluation work could be allocated to MS who have the capacity
	<i>Disadvantages</i> Uncertainty on the utilisation of Article 4(4)	<i>Disadvantages</i> May make it more difficult for MS to justify refusal of applications and thus less flexibility (decision will depend on reference MS assessment)	<i>Disadvantages</i> Control over assessment lies with another Member State with limited grounds for refusal (less flexibility) May require preparation of a more complete evaluation dossier, with justification for granting authorisation	<i>Disadvantages</i> Absence of control over assessment and on the type of biocidal product on the national market Loss of revenues from fees A central agency would require significant financial resources and experienced staff
Consumers, health & environmental protection	<i>Advantages</i> No changes	<i>Advantages</i> Facilitate placing on the market of safer products	<i>Advantages</i> Labelling rules are maintained	<i>Advantages</i> Guarantee of harmonised requirements, leading to more reliable assessment Facilitate placing on the market of safer products, hence better offer
	<i>Disadvantages</i> No changes	<i>Disadvantages</i> n/a	<i>Disadvantages</i> Less potential for more stringent controls over authorisations in certain MS leading, to less safe product	<i>Disadvantages</i> Higher national protection levels might be abandoned.

Table 3.2: Preliminary Assessment of Advantages and Disadvantages to Stakeholders of Options Relating to Product Authorisation

Stakeholders	Option			
	1. No action (minor updating)	2. Baseline plus	3. Single Community authorisation	4. Centralised authorisation
Social impacts	<i>Advantages:</i> None	<i>Advantages:</i> Improved mutual recognition would expand markets and potentially support more employment	<i>Advantages:</i> Improved mutual recognition would expand markets and potentially support more employment	<i>Advantages:</i> Improved mutual recognition would expand markets and potentially support more employment New Agency could create jobs
	<i>Disadvantages</i> None	<i>Disadvantages</i>	<i>Disadvantages</i> Fewer staff needed by companies for authorisation procedures	<i>Disadvantages</i> Fewer staff needed in national authorities
Product availability	<i>Advantages</i> No change	<i>Advantages</i> Facilitate distribution of products on the EU market: more products available	<i>Advantages</i> Facilitate distribution of products on the EU market: more products available	<i>Advantages</i> Facilitate distribution of products on the EU Market: more products available
	<i>Disadvantages</i> No change	<i>Disadvantage</i> No change	<i>Disadvantage</i> No change	<i>Disadvantages</i> No change
Others (trade, internal market, transparency...)	<i>Advantages</i> Guidance would improve transparency	<i>Advantages</i> Improved internal market due to mutual recognition; stimulate competition and reduce the risks of protectionism	<i>Advantages</i> Functioning of internal market without barriers Increased transparency Reduced risks of protectionism	<i>Advantages</i> Functioning of internal market without barriers Increased transparency Reduced risks of protectionism
	<i>Disadvantages</i> n/a	<i>Disadvantage</i> n/a	<i>Disadvantage</i> n/a	<i>Disadvantages</i> n/a

4. DATA SHARING

4.1 The Problem

Article 12 of the BPD provides for the “use of data held by competent authorities for other applicants”, i.e. for second or subsequent applicants. Article 13 sets out rules for cooperation in the use of data for second and subsequent applications for authorisation. However, Article 19 of the BPD notes that competent authorities should take account of the fact that some information may be confidential. Article 13 also allows Member States to introduce national measures obliging the applicant and holders of former authorisations located within their territory to share the data, with a view to avoiding duplicate testing on vertebrate animals for establishing a reasonable balance of the interests of the parties concerned.

The study on the impacts of implementation of the BPD indicated that there is considerable uncertainty about the rules for data sharing and that this has given rise to problems for industry and competent authorities.

In relation to **active substances**, data sharing aims to avoid the submission to the authorities of multiple dossiers, containing newly re-generated data, for the same active substance. Multiple submissions with newly generated data, and thus duplication of the evaluation, may complicate the process and lead to conflicting conclusions. It also raises the risk of duplication of testing with vertebrate animals, which is contrary to the goal of the BPD. It has therefore been proposed to revise the conclusions of the Note for Guidance and to agree that, in cases where multiple dossiers are received and accepted as complete for one particular substance, the Rapporteur Member State should prepare a single Competent Authority report.⁴

To limit the risk of restrictions on new companies entering the market, and to alleviate the administrative burden and costs of the procedure, consortia may be formed. This can be especially beneficial for SMEs, which can often not bear the costs of a procedure by themselves. However, multinational companies are seen as having little interest in forming consortia, since they are often the owners of the required data. Besides, the organisation of data sharing and protection (among competitors) may also increase costs. This makes it very difficult for SMEs to have access to information. Refusing to form consortia may also be a legal way to obtain a monopoly position within the EU.

The provisions on data protection in Article 12 of BPD state that the second or subsequent applicant needs a “letter of access” from the first applicant, who owns the data, to use their data when the data protection periods have not expired. The refusal of this letter may be a tool for the data owner to keep competitors out of the market.

4 CA-March07-Doc.6.6: Evaluation of multiple dossiers submitted under the review programme for the inclusion in Annex I or IA to Directive 98/8/EC of the same active substance.

Further problems related to data sharing may appear in relation to **biocidal products**, although duplication of animal testing is less likely to be an issue. Most animal test data are required to evaluate an active substance and not the product. At the product authorisation level, the animal test data needed would in most cases be limited to efficacy data and it is unlikely that sharing data from tests with a specific biocidal product would be feasible. The issue of data sharing will most likely arise in relation to references in product authorisation dossiers to animal tests on an active substance. There was concern amongst stakeholders in the study on the impacts of implementation of the BPD that manufacturers of active substances who were also biocidal product manufacturers could refuse letters of access to competing product manufacturers, thus ensuring a monopoly. A second concern is the potential problems in obtaining a letter of access for a second or subsequent applicant for the same or equivalent biocidal product.

The limitation of data access is a delicate issue, since it could be used, by large companies especially, to restrict new entrants to the market. However, unclear rules on requirement to share data may benefit “free-riders” on the market (using data of other companies without sharing the costs). On the one hand, data protection is necessary to ensure that data owners benefit from their investment and receive fair and transparent cost compensations from second applicants within certain data protection periods. The failure of data sharing, on the other hand, may lead to the need to repeat animal tests in contradiction to one of the principles of the BPD.

Issues exclusively related to sharing of data on substances may not be relevant in the context of the future revision of the BPD, since most of the substances would already have been evaluated at Community level. Although improved data sharing procedures could be important for future new active substances, new rules on data sharing might be opposed by companies that have already submitted dossiers under the current rules, thus investing resources to carry out tests. For this reason, the impacts of new data sharing requirements at the product authorisation level are likely to be more significant. However, this analysis may be more difficult since there is as yet no experience in the application of the BPD in this area.

4.2 Options

4.2.1 No action and clarification

Under this option, the current system of only *encouraging* data sharing at the product stage would be maintained. However, the wording would be improved in order to clarify the requirements and further encourage data sharing. The wording changes could draw upon the REACH model. A guidance document on data sharing could also be developed.

In addition, Article 13 (see section 4.1) might be expanded to non-EU second applicants, following the proposed Plant Protection Products Regulation, where Member States can enforce sharing of studies with vertebrates (Article 59). The obligation of prospective applicants to contact the Competent Authorities before carrying out tests (Article 58) might also avoid duplication of animal tests.

4.2.2 Mandatory Sharing of Vertebrate Animal Test Data at Product Authorisation Stage

Under this option, sharing of (together with compensation for) vertebrate animal test data would be mandatory at the *product authorisation* level. A provision in the text of the Directive could clearly state that studies involving vertebrate animals should not be repeated.

A company requesting a product authorisation would be required to inquire from the authorities whether an authorisation has already been submitted for a product containing the same active substance. If the proposal for a Plant Protection Products Regulation is followed, the applicant should at the same time submit all data regarding the identity and composition of the product he intends to put on the market, to allow the authorities to judge the seriousness of the application.

Applying REACH model, if a dossier for the same or equivalent product, or a product containing the same active substance, had been submitted less than 12 years earlier, the authorities would inform the applicant of the names and addresses of the company which carried out the previous study. To ensure that sharing works properly, a system could be set up to ensure that all the information needed is accessible, such as a centralised inventory of studies. The Member State competent authorities could also be required to provide, for each product, a list of the tests and study reports concerning this product, and the substance contained in the product, necessary for first authorisation or amendment of an authorisation. The Member States or the Commission could also provide the list of tests and reports for which the applicant claimed data protection, as in the proposal for a Plant Protection Products Regulation.

Where a study has been carried out on the substance contained in the product less than 12 years earlier, the applicant would be required, in the case of information involving tests on vertebrate animals, to request from the previous company the information he needs in order to make the application for authorisation. The “old” applicant would then have to share his data with the “new” one. This obligation could be compensated for by sharing of costs, for instance on an equal basis, as in REACH. A clause on conflict resolution by arbitration could also be added. The provision could indicate that the “new” and the “old” applicants shall “make every effort to reach an agreement” on the sharing of the information requested by the potential applicant(s), or the issue may be submitted to arbitration. They shall also “make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way”. Here again, guidance on cost sharing could be based on the model of REACH.

If there is a failure to reach an agreement, the potential applicant(s) would inform the authorities, which would have the ability to give them authorisation to use the data (this would, of course, be subject to the possibility of appeal).

4.2.3 Mandatory Sharing of Vertebrate Animal Test Data at the Product Authorisation Stage and Active Substance Approval Stage

Under this option, the obligation to share data would be expanded to cover active

substances as well as the product authorisation stage. A version of the REACH model, as described above, would be used. It would include the requirement to share data from previous studies, the centralised inventory of studies, and a provision would forbid the repetition of studies involving vertebrate animals. A system of cost sharing (or compensation) would be set, as well as mandatory recourse to arbitration for the resolution of conflicts.

The Commission has suggested that an exception might be proposed for new active substances, where for the first 10 years (out of 15) of data protection, vertebrate animal test data sharing would be voluntary and not compulsory. The Commission indicates that this could stimulate innovation and encourage companies to invest in the development of better and safer chemicals. Existing active substances withdrawn from the Review Programme and introduced again in accordance with Article 11 of the Directive would be excluded from these benefits. Providing such an exception for new substances, though, would limit the additional impacts of this option, compared with Option 2. It is notable that REACH does not differentiate between new and existing substances in relation to data sharing, although there are different arrangements for non phase-in and phase-in substances.

4.3 Preliminary Assessment of Advantages and Disadvantages

Stakeholders	Options		
	1. No action	2. Mandatory data sharing (product authorisation)	3. Mandatory data sharing (product and active substance, with exemption for new active substances)
EU industry	<i>Advantages:</i> Less uncertainty due to clarifications and guidance	<i>Advantages:</i> Improved data sharing Reduced testing costs Sharing of data compensated Possibility of arbitration in case of conflict - minor involvement of authorities and quick settlement of problems	<i>Advantages:</i> Improved data sharing Reduced testing costs Sharing of data compensated Possibility of arbitration in case of conflict - minor involvement of authorities and quick settlement of problems
	<i>Disadvantages</i> No guarantee that data will be shared more effectively Risk of free-riders on the market remains Risk of use of data protection to provide an obstacle to new market entrants remains	<i>Disadvantages</i> Loss of know how and possibly market share to companies that have invested in testing	<i>Disadvantages</i> Loss of know how and possibly market share to companies that have invested in testing

Stakeholders	Options		
	1. No action	2. Mandatory data sharing (product authorisation)	3. Mandatory data sharing (product and active substance, with exemption for new active substances)
Administration (implementation and enforcement)	<i>Advantages</i> Easier interpretation of EC legislation due to clarification and guidance No major changes, i.e. to for implementation and enforcement	<i>Advantages</i> Possibility of arbitration in case of conflict - minor involvement of authorities and quick settlement of problems	<i>Advantages</i> Possibility of arbitration in case of conflict - minor involvement of authorities and quick settlement of problems Risk of multiple of dossiers for the same substance fully addressed
	<i>Disadvantages</i> Risk of multiplication of dossiers for a same substance not fully addressed	<i>Disadvantages</i> Additional administrative burden	<i>Disadvantages</i> Additional administrative burden
Consumers, health & environmental protection	<i>Advantages</i> n/a	<i>Advantages</i> Risk of duplication vertebrate animal testing addressed	<i>Advantages</i> Risk of duplication vertebrate animal testing addressed Data sharing is not an obstacle to new submissions, which may encourage safer substances onto the market
	<i>Disadvantages</i> Risk of duplication of testing with vertebrate animals not fully addressed	<i>Disadvantages</i> Data sharing may still be an obstacle and some tests may need to be repeated	<i>Disadvantages</i> n/a
Social impacts	<i>Advantages:</i> No change	<i>Advantages:</i> Reduced costs for industry, possibility for cost sharing	<i>Advantages:</i> Less costs for industry, possibility for cost sharing
	<i>Disadvantages</i> No change	<i>Disadvantages</i> n/a	<i>Disadvantages</i> n/a
Product availability	<i>Advantages</i> No change	<i>Advantages</i> Potentially more products on the market due to improved data sharing rules and thus less barriers for new entrants	<i>Advantages</i> More products on the market through entrance facilitation
	<i>Disadvantages</i> No change	<i>Disadvantage</i> n/a	<i>Disadvantages</i> n/a
Others (trade, internal market, transparency)	<i>Advantages</i> Improved transparency through wording changes and guidance	<i>Advantages</i> Improved transparency and internal market	<i>Advantages</i> Improved internal market
	<i>Disadvantages</i> n/a	<i>Disadvantage</i> n/a	<i>Disadvantages</i> n/a

5. DATA REQUIREMENTS

5.1 The Problem

Article 8 of the BPD, as well as Annex II B and III B, indicates in detail the data that should be provided by the applicant for the authorisation of a biocidal product. For each active substance in the biocidal product, the applicant must provide a dossier or a letter of access satisfying the requirements set out in Annex IIA and Annex IIIA.

The study on the impacts of implementation of the BPD indicated that the burden of data requirements for **active substance** dossier preparation is a major issue for companies that intend to support active substances. The cost of performing all studies required can be extremely high⁵ and the active substances would need to be marketed over a long time period to recover the costs. That has led the industry to focus more on supporting existing actives than on the development of new substances. However, although data requirements for active substances are quite demanding, they may also be necessary to ensure the safety of the substance.

To reduce this administrative burden, the waiving of data requirements, and in some cases reduced data requirements (e.g. pheromones), has been introduced. However, with some exceptions (e.g. rodenticides), there is no clear guidance on waiving of data requirements and communication on waiving between national authorities, as well as between national authorities and industry, has proved to be problematic. This is a crucial issue, since waiving of data needs to be decided in an early stage of the process to avoid failing the completeness check. In the previous study there was particular uncertainty concerning whether or not core data can be waived, but it seems that there is broad acceptance among Member States that in principle core data can be waived. The same question applies to very low exposure (both to man and the environment) products. Finally, many biocidal active substances are also covered by and assessed under other EC legislation, sometimes on the basis of less data. These assessments could be taken into account by the BPD to reduce data requirements.

As in the case of data sharing, however, issues exclusively related to data requirements on active substances may be of limited relevance in the context of the future revision of the BPD, since most of the existing active substances would already have been evaluated at Community level. Although changes might encourage the development of new active substances, new rules with reduced requirements might be strongly opposed by companies that have already invested to support substances under the current rules.

In relation to **biocidal products**, there are provisions for less onerous requirements, in the form of registration rather than authorisation, for low risk products containing active substances included in Annex IA. The previous study indicated that only a few low-risk substances are likely to be supported by industry, as the data requirements are considered

⁵ According to the last BPD study, from scratch, up to between 3-5 million EUR

too high, and therefore this option will only be of limited relevance in practice⁶. Therefore, some formulators focused more on waiving of data requirements for active substances they consider low-risk than on simplified procedures for biocidal product registration.

As in the case of active substances, some biocidal products might already be authorised under other EC law and data used for this authorisation could be accepted under the BPD. Examples include plant protection products or certain products authorised under the medicinal products and veterinary medicinal products Directives.

5.2 Options

The three options proposed below focus on a simplification of data requirements. However, in some options, changes to data requirements will affect mostly active substances and will therefore only have an impact on new substances that could be placed on the EC market.

5.2.1 No Action or Minor Changes (Clarification)

This option retains existing provisions and the current system. Wording changes could be introduced in order to clarify and make operational the waiving options already in place. Another option would be to prepare detailed appropriate guidance in the form of Notes for Guidance, published in the Official Journal.

Under this option, Member States would still have discretion as to the waiving of data. However, under the first sub-option, the wording of the Directive would be made more precise, to clarify the concept of waiving in order to avoid obstacles linked to the existing uncertainties.

Under the second sub-option, more guidance would be provided as to data requirements in general, and to waiving of data in particular. This would ensure harmonisation of data requirements amongst national authorities. One possibility is to update the TNsG on data requirements and waiving possibilities. In addition, as was highlighted in the previous study, Annex XI of REACH may be relevant to applicants for Annex I inclusion, as well as for product authorisation, and could be included in some form in the BPD. Other forms of guidance may be provided through workshops, or during the peer review process.

In addition, more guidance on the possibility to use existing information, such as studies and tests conducted in the past, public domain data, or non-test data from *in vitro* models or data validated in other countries (e.g. the USA) could be considered. This is similar to REACH, which also provides guidance on how to evaluate the validity and reliability of the information.

6 However, one such substance, CO₂, has already been included in this Annex

5.2.2 Revised Requirements for Low-Risk Substances

The key issue in revising requirements for low-risk substances is to define such substances. This may prove difficult as, while various substances could be potentially considered low risk, in fact risk always depends on the product formulation, exposure and use conditions, which are difficult to assess at the specific substance level alone.

The US EPA, distinguishes between conventional pesticide active substances (generally synthetic manufactured) and biological pesticides (microbial pesticides, plant extracts, pheromones and attractants). Following an approach similar to the BPD, it exempts from data requirements certain minimum risk pesticide products containing only active and inert ingredients which have been listed in Appendix A and 4A. Currently around 30 minimum risk active substances have been identified under section 25 (b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), among them several natural occurring substances like cedar oil, Citronella and Citronella oil, Geraniol, all of which are covered by the BPD.⁷

The identification of low toxicity pesticide chemicals (actives and inert) follows a tiered approach and is conducted by the Office of Pesticide Programs:

- Tier 1 uses existing information only, no additional studies are required. It covers chemicals with a long history of safe usage for which available knowledge demonstrates lack of toxicity (1a), which is confirmed by Structure-Activity-Relationship (SAR) assessments (1b).
- Within Tier 2, the submission of a limited data set is required and a hazard assessment is carried out by considering all the results, SAR assessment and existing information.
- For substances known or suspected of having significant toxicity, a complete data package is required, similar to the approach for active ingredients in conventional pesticides (Tier 3)⁸.

The Commission's proposal for a new Plant Protection Products Regulation (2006/0136 [COD]) contains separate paragraphs relating to "low-risk" and "basic" substances. The proposal considers as low risk substances those that are not carcinogenic, mutagenic, toxic for reproduction, sensitising, persistent or endocrine disrupters and which have low toxicity (Article 22 of the proposal). Article 22 extends the period of approval to 15 years for low risk active substances (instead of 10 year for conventional active substances). Article 23 provides a definition for basic substances and extends the period of their approval for an unlimited time.

7 US Environmental Protection Agency, Office of Pesticide Programs, Minimum Risk Pesticides Exempted under FIFRA Section 25(b) Clarification of Issues. Pesticide Registration (PR) Notice 2000-6, May 7, 2000 http://www.epa.gov/PR_Notices/pr2000-6.pdf

8 The office of pesticide programs guidance document on methodology for determining the data needed and the types of assessments necessary to make FFDCA section 408 safety determinations for lower toxicity pesticides. Chemicals office of pesticide programs. U.S. EPA, June 7, 2002 http://www.epa.gov/oppfead1/cb/csb_page/updates/lowertox.pdf

Low toxicity could also be included in the revised BPD to identify low risk substances. However, the proposal for a new Plant Protection Product Regulation does not contain a definition of low risk substances and there are no proposals for reduced data requirements. (These will be defined in a future Regulation on Data Requirements for Active Substances and for Plant Protection Products.)

The draft guidance document⁹ on data requirements for some PPP based on plant extracts, the inclusion into the “GRAS” list (“Generally Recognized As Safe” list for food additives in US and Australia)¹⁰ and the OECD guidance for registration requirements for Pheromones and other Semiochemicals¹¹ could serve as a starting point for the definition and/or reduced data requirements for potential low risk substances. The GRAS list contains substances intentionally added to food (food additives) which have been reviewed and approved according to the Federal Food, Drug, and Cosmetic Act by the Food and Drug Administration (FDA). It is clearly stated that the evaluation does not allow determination of the safety for all uses.

The system could be compared to the current EU procedure for food additives, which also have to be approved by the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)¹². In the previous study, the re-establishment of the Working Group on essential and other specific categories of active substances was proposed by some competent authorities, in order to adequately address issues such as low risk active substances.¹³

In addition, other substances could be identified based on expert judgment or available information (such as in Annex IV or V of REACH). For these substances, a simple notification of placing on the market would suffice. Only basic information on the identity of the substance, information about the producer and the person responsible for placing it on the market, the use pattern etc. would be required. Competent Authorities could have the option to demand further information, if this proves necessary.

There are a number of precedents for this. For example, in relation to homeopathic products, clinical trials data are not required if the active substances in the product have been in well-established medicinal use within the Community for at least 10 years with recognised efficacy and an acceptable level of data. The trials are replaced by scientific literature. Such an exemption could be introduced into the BPD.

9 SANCO/10472/2004 http://ec.europa.eu/food/plant/protection/evaluation/plant_extracts.pdf

10 <http://www.cfsan.fda.gov/~dms/grasguid.html>

11 OECD SERIES ON PESTICIDES Number 12 Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control
<http://www.oecd.org/dataoecd/44/31/33650707.PDF>,

OECD Guidance for Industry Data Submissions for Pheromones and other Semiochemicals and their Active Substances <http://www.oecd.org/dataoecd/5/44/31919832.pdf>

12 <http://www.rdg.ac.uk/foodlaw/additive.htm>

13 Revised Working Paper EFFECTS OF DIRECTIVE 98/8/EC ON ESSENTIAL AND OTHER SPECIFIC CATEGORIES OF ACTIVE SUBSTANCES ANALYSIS OF THE PROBLEMS AND POSSIBLE SOLUTIONS 8.03.2004

The development of low-risk substances could also be encouraged by means other than reduced data requirements, for example prolongation of their period of approval (as in the proposed revision of the Plant Protection Products Directive) or by reduced fees (as in the example of registration of biological control products in Canada¹⁴). Emergency mechanisms could be introduced to require withdrawal of substances on the basis of new scientific information suggesting that the substance may pose unacceptable risks.

Products which contain low-risk active substances, listed in Annex IA, are registered and not authorised. There are reduced requirements for testing data; only information on identity, intended uses, efficacy, analytical methods and classification/labelling need to be submitted. Introducing more specific criteria for low-risk substances, and reducing the data requirements for these, could make the registration procedure for products operable. By encouraging manufacturers to support more substances for inclusion in Annex IA, reduced data requirements for low risk substances, as discussed above, could therefore reduce the data requirements for products containing these substances.

5.2.3 Rewording Provisions Concerning Data Waiving and the Use of Existing Information

There are a number of ways in which the data requirements of the BPD could be strengthened, to minimise animal testing and to reduce costs as far as possible. These include:

- strengthening of provisions on **waiving**;
- clarifying the use of **existing information**; and
- the system could be completed by the introduction of a **common procedure to challenge requests** from authorities for extra data, that were not necessarily required to establish risk, but which could give rise to excessive cost.

Data Waiving

One of the key methods is the strengthening of the data waiving provisions in the BPD. This could be done by introducing a clear policy objective (testing on vertebrate animals only as last resort) and extending the possibility of data waiver. Data could be waived on the same grounds as stated in REACH: scientifically not necessary, technically not possible and substance-tailored exposure-driven testing. REACH has defined waiving possibilities for higher tier animal tests such as sub-chronic toxicity, long-term repeated toxicity, carcinogenicity and reprotoxicity, which are part of the common core data set for biocidal active substances.

Parts of Annex XI of REACH could be included within the BPD in order to provide further guidance and to oblige competent authorities to provide justification when a

14 <http://www.rebeca-net.de/downloads/Regulation%20of%20microbials%20semiochemicals%20botanicals.pdf>

waiver request is denied. In addition, non-testing data obtained through (Q)SARs, read-across, human historical data, category approaches, etc. should be accepted, where possible, and the use of these methods actively promoted. The US tiered approach on data requirements could also be considered as a model.

It would be also possible to revisit the concept of core data and additional data. The core data set described in Annex II of the BPD does not distinguish between PT while the additional data set of Annex III is considered being PT dependent. Chapter 2.5 and 3 of the TNGs on data requirements give PT-specific additional data sets for active substances and biocidal products. Although in principle core data can also be waived, they are often considered as a minimum data set. Thus, moving some core data to the additional data could encourage waiving. For substances whose core data show no or low risks, no further data might be requested, whereas for other substances, additional data could be required. In this case, the core data package would have to be revisited to identify possibilities for reducing data requirements.

Furthermore, data requirements would be waived if *in vitro* testing shows that further *in vivo* tests are not necessary for CMR properties (although this is not expected to have a major effect). Examples of conditional waiving possibilities exist for dermal acute toxicity, metabolism studies in mammals, short term repeated dose (28 day), subchronic toxicity 90 day, and chronic toxicity (two species). However there is no *in vitro* test which determines the waiving of these studies. Waving of *in vivo* mutagenicity is only possible for mutagenicity studies, if negative results are determined by *in vitro* tests. Carcinogenicity studies can also be waived if no adverse effects have been determined in mutagenicity and repeated dose studies

It might also be possible to link data requirements to PT. This would mean that PT associated with use patterns which involve only reduced exposure, etc. would benefit from reduced data requirements. This would allow systematic data waiving or a tiered approach in determining the data set, according to the use pattern, linked to the specific PT. The possibility of the competent authorities to ask for additional information, if appropriate, could be retained.

Linking data requirements to PT was considered in the Draft Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC. The draft Guidance is based on the OECD Monograph 12 (OECD ENV/JM/MONO(2001)12), the UK document (TMIII04GEN-ITEM1B-UKCOMMENTS-IBMA AND TSGE.DOC) and on comments received from other Member States. There is further guidance for rodenticides only¹⁵; the subchronic toxicity study (90-days), chronic toxicity, carcinogenicity with rodents, teratogenicity study in the second species (normally in rats) and two-generation reproduction (fertility) toxicity study can potentially be waived.

15 REFINED WAIVING CONCEPT FOR RODENTICIDES Addendum to the TNGs on Data Requirements, Chapter 1.4 (Guidance on non-submission of data)

Use of Existing Information

The use of existing information could be strengthened by including a clause in the BPD stating that, where available and appropriate, an assessment carried out under other Community legislation (e.g. risk assessments completed under Regulation (EEC) No 793/93, cosmetics, food additives, feed additives, active substances for plant protection products) shall be taken into account in the development of, and reflected in, the risk assessment. Guidance on the use of existing data has also been prepared for REACH.¹⁶ The US EPA guidance document on safety determinations for lower toxicity pesticide chemicals also contains examples of useful information sources (see footnote 8).

Some existing data can be used without the need to obtain a letter of access, for example the existing classification according to Directive 67/548/EEC (and in future the Globally Harmonised System of Classification and Labelling of Chemicals). This will be an advantage for users of data, but a potential disadvantage to data-holders.

In some cases, it may be appropriate to exclude from the BPD products which are subject to existing Community legislation. For example in PT20, most uses appear to be covered by other EC legislation, such as Directive 89/107/EEC concerning food additives, Directive 88/388/EEC relating to flavourings for use in foodstuffs and Directive 95/2/EC on food additives other than colours and sweeteners. While the Manual of Decisions¹⁷ gives several examples of borderline cases not belonging to PT20, there is no example of a typical PT 20 product.

In addition, **data requirements for product authorisation** could be reduced where the product has already been authorised under other Community legislation (with similar exposure scenarios and analysis of risks), provided it contains a substance listed in Annex I, IA or IB. This would apply particularly to plant protection products or to certain products authorised under the medicinal products and veterinary medicinal products legislation. The information to be provided would only cover aspects not assessed under these other pieces of legislation, for example environmental impacts.

5.3 Preliminary Assessment of Advantages and Disadvantages

Stakeholders	Options		
	1. No action or minor changes (clarifications)	2. Reformulated requirements for low risk substances	3. Data waiving and use of existing information
EU industry	<i>Advantages:</i> Reduced uncertainty through clarification of data requirements, more guidance available	<i>Advantages:</i> Reduced costs for manufacturers of low-risk substances and products containing them	<i>Advantages:</i> Improved flexibility, differences in substance risks better addressed Reduced costs for

16 Guidance Document to Industry on the Information for REACH: Part 1- General Issues (RIP 3.3)

17 <http://ec.europa.eu/environment/biocides/pdf/mod.pdf>

Table 5.1: Preliminary Assessment of Advantages and Disadvantages to Stakeholders of Options Relating to Data Requirements			
Stakeholders	Options		
	1. No action or minor changes (clarifications)	2. Reformulated requirements for low risk substances	3. Data waiving and use of existing information
	Improved flexibility: waiving option would be made operational Harmonisation of data requirements amongst national authorities		manufacturers of products authorised under other pieces of EC law
	<i>Disadvantages</i> Continued discretion of MS as to waiving of data	<i>Disadvantages</i> Difficulties may remain over definition of low-risk substances	<i>Disadvantages</i> More complex system of data requirements to understand
Administration (implementation and enforcement)	<i>Advantages</i> Reduced uncertainty through clarification of data requirements, more guidance Discretion of MS as to waiving of data continues	<i>Advantages</i> More active substances available for Annex IA inclusion	<i>Advantages</i> More targeted evaluation Less data to be assessed
	<i>Disadvantages</i> Harmonisation of data requirements leading to less control over requirements specific to one MS Justification of waiving decisions might increase workload	<i>Disadvantages</i> Would require agreement amongst MS on the definition of low-risk substances	<i>Disadvantages</i> More limited control over evaluation, which may increase risk of putting dangerous product on the market Could need more coordination among competent authorities within a MS to share information
Consumers, health & environmental protection	<i>Advantages</i> Improved harmonisation of data requirements amongst MS for equal quality between evaluation in different countries	<i>Advantages</i> Reduced animal testing Use of low risk products might replace known high risk products	<i>Advantages</i> reduced animal testing
	<i>Disadvantages</i> Failure to support potentially low-risk substances not addressed	<i>Disadvantages</i> More limited control over evaluation, which may increase risk of putting dangerous product on the market	<i>Disadvantages</i> More limited control over evaluation, which may increase risk of putting dangerous product on the market
Social impacts	<i>Advantages:</i> No change	<i>Advantages:</i> Reduced data cost for industry may encourage more products onto the market with potential employment benefits Substitution of higher risk products might lead to improvement of health of professional users	<i>Advantages:</i> Reduced data cost for industry may encourage more products onto the market with potential employment benefits Substitution of higher risk products might lead to improvement of health of professional users
	<i>Disadvantages</i> No change	<i>Disadvantages</i> Unknown risks of “low risk products” might not become apparent and are not assessed.	<i>Disadvantages</i> Unknown risks of substances where requirements are waived might not become apparent and are not assessed.
Product	<i>Advantages</i>	<i>Advantages</i>	<i>Advantages</i>

Table 5.1: Preliminary Assessment of Advantages and Disadvantages to Stakeholders of Options Relating to Data Requirements			
Stakeholders	Options		
	1. No action or minor changes (clarifications)	2. Reformulated requirements for low risk substances	3. Data waiving and use of existing information
availability	No change	Facilitate support of more substances by industry - more products available	Facilitate support of more substances by industry - more products available
	<i>Disadvantages</i> No change	<i>Disadvantage</i> Potential low quality products remain on the market.	<i>Disadvantages</i> Potential low quality products remain on the market.
Others (trade, internal market, transparency)	<i>Advantages</i> Increased transparency	<i>Advantages</i> Increased transparency	<i>Advantages</i> Increased transparency
	<i>Disadvantages</i> Loss of potential low risk active substances and products not addressed	<i>Disadvantage</i> n/a	<i>Disadvantages</i> n/a

6. FEES CHARGED BY MEMBER STATES

6.1 The Problem

Article 25 of BPD states that “Member States shall establish systems obliging those having placed or seeking to place biocidal products on the market and those supporting entries for active substances on Annex I to pay charges, corresponding as far as possible to their costs in carrying out all the different procedures associated with the provisions of this Directive”. Two types of fees shall be distinguished: those related to the evaluation of active substances and those related to the evaluation of biocidal products.

There are differences in the practice in relation to fees from one Member State to another. Several problems were identified in the previous study as causing a problem to competent authorities or industry.

Varying and high fees

Fees charged for the evaluation of active substances vary from €50,000 to €300,000 per substance. The fees payable to the Member States may account for a significant portion of the total cost of supporting an active substance for companies (from 5% to 75%). The highest fee paid by companies responding to the previous study was €900,000 to €1 million, for a single active substance in 13 product types. The lowest was €82,000, for an active substance within a single product type. Industry stakeholders responding to the previous study indicated that the high level of fees, as part of the overall high costs of supporting active substances, acted as a disincentive to the development of new, and potentially safer, active substances. However, some Member States indicated that the level of fees was not sufficient to cover the costs they incurred.

The fact that fees for active substances differ between Member States raises the risk of market distortions, with the industry preferring to submit dossiers in countries applying lower fees, leading potentially to an overload of work for those countries and a loss of revenue for the more expensive Member States. In practice, however, the previous study showed that the level of fees is only one factor in industry’s choice of which Member State to submit a dossier.

The issue of fees for active substances may not be a major issue for the future revision of the BPD, since most of the substances should already have been evaluated at Community level. However, it may be important for future new active substances or for “old biocides” withdrawn from the Review Programme the re-introduced as “new” active substances.

Proposed fees for the authorisation of biocidal products range from €1,000 to €70,000 per biocidal product.¹⁸ There are also differences in the proposed fees for mutual recognition

18 These data were obtained from the previous BPD study, based on a document on fees levied in MS which was distributed at the 21st competent authorities meeting. They are the fees levied by the Member States,

of biocidal products, which range from €633 in Poland to €25,000 in Germany. In the Swedish authorisation procedure for biocidal products, additional fees have been set for each active substance previously not on the national market in an authorised pesticide.

As no biocidal products have yet been authorised under the BPD, the impact of fees on the authorisation process is harder to determine. It may be possible that the level of fees in “expensive” Member States may hinder the mutual recognition process. High mutual recognition fees could act as a disincentive to market a product in a given Member State, and could potentially be used as a way of protecting national products or ensuring that only products assessed in that Member States will be authorised.

Conditions for the payment of fees

Competent Authorities as well as industry indicated that the conditions applicable to payment of fees remain unclear. One aspect of uncertainty related to the method for setting fees. The Directive indicates that the costs shall correspond to the costs of the Member State “in carrying out all the different procedures associated with the [...] Directive”. However, there are divergences as to the interpretation of the scope of the words “all the different procedures”. Industry believes that fees should cover only the costs of dossier evaluation, authorisation or registration and some Member States levy fees based on the actual time spent on the evaluation process. However, some Member States’ authorities refer to the text of the Directive to justify that the fees should cover all the work required under the Directive, and not only the work carried out on an individual application. These differences in interpretation may hinder the objective of the BPD to harmonise the market.

Another aspect is the fee structure. In some cases, the same fee is charged for an active substance for the first product type and for all subsequent product types, while some Member States reduce the fees for the second and subsequent product type in which an active substance is used.

Another issue is the disparity between Member States as to when fees have to be paid. Some Member States require the full amount to be paid in advance, when the dossier is submitted, and reject dossiers if the fee is not received in time. Others require a smaller amount to be paid initially, to cover the costs of the completeness check, with the full fee when the evaluation starts. Where fees are paid in full when the dossier is submitted, there are no common rules on whether fees have to be paid back, e.g., if the dossier does not pass the completeness check and is not evaluated.

6.2 Options

The options set out below relate to the current system of evaluation of dossiers by

Norway and Iceland for the evaluation of existing active substances within the framework of the Biocides Directive. Meanwhile, considerable changes to the fees levied in MS have been indicated. Data on the actual fees levied will need to be obtained from MS.

Member States. If the options for decentralised or centralised product authorisation set out in section 3, or the tiered data requirements set out in section 5, were adopted, this would clearly have implications for the fee scale and structure.

6.2.1 No Action but Increased Transparency

One of the possibilities to address the problems identified above is to retain the current system, with fees and conditions set at Member State level, but to increase transparency.

As the levels of fees are already published, the main change would be to clarify the conditions for payment of fees. This would cover, for example, the timing of payment (whether the full fee had to be paid in advance and whether it would be returned if the dossier proved to be incomplete), the fees levied for the second and subsequent product type for an active substance dossier and whether product authorisation fees differed between products previously approved in a Member State and those being placed on the market for the first time.

The publication of the fee structures in this way would be mandatory, in order to guarantee equal access to information to companies. This would enable companies to compare fees amongst Member States, which may eventually lead to a reduction of the differences in fees amongst Member States.

6.2.2 Harmonised Fee Structure

A further step in addressing the disparity in fees between Member States would be the harmonisation of fee structures between Member States. Member States would remain free to set the level of fees, but the structure of fees would be mandatory.

Reduced fees for multiple submissions

As noted above, most Member States charge a separate fee for each product type for which an active substance dossier is submitted. Some countries charge the same amount for each product type, independently of the number of product types; others charge more for the first product type and less for a subsequent one. As the active substance is the same for each product type, it seems reasonable that less work is required to review subsequent dossiers than the first dossier. Under this option, the full fee would be charged for the first product type only, with a reduced fee for all subsequent product types for the same active substance.

For products, similarly, when a product is authorised for multiple PT¹⁹ only one fee or a fee for the first PT and decreasing for all subsequent product types could be foreseen, since the active substance is the same. It might also be envisaged to set lower fees for simplified or "accelerated" reviews of similar authorisation cases, such as re-authorisation, mutual recognition and minor changes in composition, as well as for low-risk products.

19 Examples might include surface disinfectants used in PT 2 and PT3 or biocidal products used in lower quantities as a repellent and in higher quantities as insecticide.

Variation in Fees by Product Type

Varying fees by PT could be introduced if different data requirements for different PT were adopted (see section 5.2.3), to reflect the level of analysis needed. For example, the fee structure in France includes discounts on product authorisation fees where:

- the evaluation of the eco-toxicological dangers of the product can be done by calculation;
- when an assessment of the product has already been carried out; or
- when the nature of the product indicates that the risks are significantly lower.

Additional fees can also be charged, when further analysis is required.

Variation of fees by PT could also be used to encourage the development of products, or active substances, that are low risk or where there is a shortage of products/substances on the market. For example, Belgium plans to offer a discount on authorisation fees for a biocidal product if it is essential for the protection of human health or the environment.

Installment system

One option to address industry concerns about the high level of fees might be to suggest an installment system for payment, to spread the costs for industry over the period of the evaluation procedure. This might consist of charging part of the fee at the beginning and part at the end of the process (for instance, half of the fees at the beginning and half at the end of a dossier evaluation). Where Competent Authorities have time recording systems for the actual work undertaken to carry out an evaluation, separate fees could be charged for the completeness check (to be paid on submission of the dossier) and the remaining work (perhaps with part payable on commencement of the work and the remainder when it is complete). However, as only a few Competent Authorities currently record the time spent in this way, it would be difficult to apply this approach across the EU.

It could also be specified, in the case of active substances, that any fees already paid should be returned to the company when the dossier could not be finalised, e.g. in case it has not passed the completeness check and was not evaluated. This could apply after a given number of days.

6.2.3 Centralised Fee System

The third option would be to set standard fees at EU level. This would be most feasible under a central system of product authorisation (see section 3.2.4). It could potentially be achieved, though, either by specifying the fees to be charged by Member States or by levying the fees centrally and refunding Member States for the actual work they have carried out.

Setting a lower and an upper range for the fees to be charged by Member States would limit the disparities between the Member States and thus the potential for a distortion of competition between cheaper and more expensive countries for each procedure. The

level of fees set would need to take account of the actual costs of competent authorities; in the previous study, a number of competent authorities indicated that current fee levels did not fully cover their costs. The economic differences among the 27 Member States may make it difficult to identify appropriate harmonised fee levels.

Centralised levying of fees could be applied through provisions on fees similar to those envisaged by REACH (point 100). This indicates that a Commission Regulation will specify the structure and amounts of fees, including the circumstances under which a proportion of the fees will be transferred to the relevant Member State. A first draft of the Commission Regulation on the fees and charges payable to the European Chemicals Agency is currently being discussed.²⁰

Under such a centralised system, the level of fees repaid to Member States could be related to the actual work required. On the UK model, the fees would be calculated on the basis of the actual work done by the Member State competent authorities. This would, of course, require a comprehensive system of recording the time spent on various activities, to make sure that the final fee represents the cost of the work actually undertaken. On this basis, if more time is spent on an evaluation, a further fee could be charged to cover the work. Equally, if less time is spent on an evaluation, the calculated difference could be refunded. There could be standard prices for the completeness check and generally fees could take account of the effort of industry to prepare the dossier (where more effort has been made to ensure a high quality dossier, the fees would be less). The fees could also take account of the number of product types, with a fixed amount for the first product type, and then a fraction of that amount for each subsequent product type.

6.2.4 Specific Provisions for SMEs

Reduced fees could also apply to SMEs, again using the model of REACH, as high fees are more often an obstacle for SMEs to support substances or to keep their products on the market. This could take the form of a fixed discount on the standard fee, potentially with additional reductions for micro enterprises. This is likely to be problematic for certain Member States, which are legally obliged to cover the full costs of their activities from industry. One alternative would be to introduce an obligation for annual fees and give reductions to SMEs in that context.

SMEs could also have the possibility to pay in instalments, as discussed in section 6.2.3.

In both cases, this option would be easier to apply under a centralised fee system but could also be included within a harmonised fee system

6.3 Preliminary Assessment of Advantages and Disadvantages

In the previous study, several companies called for harmonisation of fees across the EU.

20 <http://www.reach-forum.eu/docs/regulations/EU/ECHA/charges/REACH-Fees.html>

It was argued that harmonisation would help achieve a common market, and that the rationalisation would reduce the unintended consequence of biocidal products being removed from the market purely on registration cost grounds.

Table 5.1 sets out a preliminary assessment of the advantages and disadvantages of the different options on fees set out above.

Stakeholders	Options			
	1. No action but increased transparency	2. Harmonised fee structure	3. Centralised fee system	4. Specific provisions for SMEs
EU industry	<i>Advantages:</i> Publication would facilitate budget planning for companies Publication may reduce differences between MS due to open comparison	<i>Advantages:</i> Rationalised approach; greater predictability of fees	<i>Advantages:</i> Less disparity between MS; less risk of distortion of competition	<i>Advantages:</i> Reduced fees adapted to SMEs (and/or payment by instalment)
	<i>Disadvantages</i> High fees still a problem, especially for SMEs	<i>Disadvantages</i> Risk of discrepancies between Member State not removed Fees might still be considered as too high for supporting active substance or products	<i>Disadvantages</i> Less flexibility in selecting a cheaper country	<i>Disadvantages</i> Higher financial burden on big companies through discounts for SMEs
Administration (implementation and enforcement)	<i>Advantages</i> Clearer information may enable more effective budget planning by CAs	<i>Advantages</i> Clearer information may enable more effective budget planning by CAs Clarity over fees to be charged so fewer objections from companies	<i>Advantages</i> Linking of workload to CA capacity possible	<i>Advantages</i> Needs of SMEs can better be addressed by CAs
	<i>Disadvantages</i> Potential loss of revenue for expensive MS as companies switch to cheaper MS	<i>Disadvantages</i> Less flexibility Different costs of national staff might not be addressed adequately.	<i>Disadvantages</i> Very little margin of manoeuvre Reduced revenues	<i>Disadvantages</i> Impact of cost discounts for SMEs on overall costs unclear
Consumers, health & environmental protection	<i>Advantages</i> No change	<i>Advantages</i> More (safe) products on the market if fees reduce	<i>Advantages</i> More (safe) products on the market if fees reduce	<i>Advantages</i> More (safe) products on the market due to lower fees for SMEs
	<i>Disadvantages</i> No change	<i>Disadvantages</i> n/a	<i>Disadvantages</i> n/a	<i>Disadvantages</i> n/a
Social impacts	<i>Advantages:</i> No major change	<i>Advantages:</i> No major impacts	<i>Advantages:</i> No major impacts	<i>Advantages:</i> Procedure less costly for SMEs helping them to stay on the market
	<i>Disadvantages</i>	<i>Disadvantages</i>	<i>Disadvantages</i>	<i>Disadvantages</i>

Table 5.1: Preliminary Assessment of Advantages and Disadvantages of Options related to Fees				
Stakeholders	Options			
	1. No action but increased transparency	2. Harmonised fee structure	3. Centralised fee system	4. Specific provisions for SMEs
	No major change	No major impacts	No major impacts	
Product availability	<i>Advantages</i> No major change	<i>Advantages</i> Potentially improved competition, more safe products on the market	<i>Advantages</i> Potentially improved competition, more safe products on the market	<i>Advantages</i> More (safe) products on the market due to lower fees for SMEs
	<i>Disadvantages</i> No major change	<i>Disadvantage</i> n/a	<i>Disadvantages</i> n/a	<i>Disadvantages</i> n/a
Others (trade, internal market, transparency)	<i>Advantages</i> Increased transparency	<i>Advantages</i> Internal market improved Increased transparency	<i>Advantages</i> Internal market improved Increased transparency	<i>Advantages</i> SMEs able to compete better with larger companies
	<i>Disadvantages</i> No major change	<i>Disadvantage</i> n/a	<i>Disadvantages</i> n/a	<i>Disadvantages</i> Potential market distortions in favour of SMEs

7. BIOCIDES USE

7.1 The Problem

Pesticides, including biocides, have been regulated for a long time. However, unwanted amounts of certain pesticides can still be found in the environment, and residues exceeding regulatory limits still occur in agricultural product. Therefore, the European Parliament and the Council have decided to address this impact through a long term action programme, which includes the development of a Thematic Strategy on the Sustainable Use of Pesticides (the pesticides Thematic Strategy), to be implemented through a Directive on Sustainable Use of Pesticide. The pesticides Thematic Strategy covers the product life-cycle, following the FAO approach and the Strategic Approach to International Chemical Management (SAICM) of covering chemicals from cradle to grave.

The lack of specific provisions regarding the use of biocidal products has been identified by various stakeholders as a shortcoming of the current legislation. This is especially important given that, according to PAN Europe, a significant percentage (62%) of biocidal products is used by non professionals, with no possibility to monitor and enforce proper use. The pesticides Thematic Strategy aims to reduce the risks linked to products, through awareness raising, strengthening of enforcement measures and targeted protection.

Although the pesticides Thematic Strategy mainly focuses on pesticides, the European Parliament has indicated that comparable measures should be considered for biocides. These measures could be incorporated into the pesticides Thematic Strategy. This possibility was considered positively in the impact assessment study carried out on the pesticides Thematic Strategy. The pesticides Thematic Strategy foresees national action plans on pesticides use as the major implementation tool to achieve the objectives of the Thematic Strategy. Several countries already have such plans, covering both pesticides and biocides. In particular, Belgium has set out a Program for Reduction of Pesticides and Biocides in order to manage risks and control the use of pesticides and biocides, with targeted objectives for the reduction of risk. In Germany, the legislation transposing the BPD includes provisions on the safe use of biocidal products and good practices.

7.2 Options

Action to ensure the safe use of biocides could be achieved through three options: some biocides could be included in the future Directive on Sustainable Use of Pesticides, the BPD could include provisions on safe use, or an independent framework on the safe use of biocides could be created.

The Commission requested that this study should consider policy options on safe use of biocides to the extent possible, within the available time and budget. As the safe use of biocides is a new and very complex field, the consultants propose not to consider this

issue in detail. It is planned to address the issue briefly through the consultation process (see section 10) and to provide a note on options for the sustainable use of biocides, without attempting to quantify the impacts.

7.2.1 No Action

Under this option, no action would be taken at EU level to address the issue of use of biocides. It will be possible for the authorisation of biocidal products at Member State level to provide clear conditions for the safe and sustainable use of biocides. It should be noted that Article 5 (3-4) of the BPD already allows Competent Authorities to link the authorisation of a biocidal product to conditions relating to marketing and use necessary to protect the health of distributors, users, workers and consumers or animal health or the environment. However, this may give rise to problems for mutual recognition.

7.2.2 Include Some Biocides within the Pesticides Thematic Strategy

The European Parliament has proposed to include biocidal products used for pest control purposes (PT 14-19) into the scope of the pesticides Thematic Strategy, as they pose similar risks to human health and the environment. While practical aspects of rodent control for plant protection (plant protection use) and public health (biocidal use - PT 14), or the use of fumigation agents for pest control in plant stockrooms (plant protection use) or foodstuff processing industry (biocidal use – PT 4), are very similar there are also considerable differences in application fields (e.g. spraying application for cockroach control in kitchens). However, the other main groups of biocides (disinfectants, preservatives, others) do not really overlap with plant protection products and so would not be addressed by this option.

7.2.3 Include Provisions on Biocides Use into the BDP

The pesticides Thematic Strategy will establish a Directive on the Sustainable Use of Pesticides; to date, there is no indication that the revision of Plant Protection Products Directive (Directive 91/414/EEC) into a Regulation will include sustainable use. The inclusion of any provisions for safe use of biocidal products in the BPD would necessarily remain very unspecific, considering the very broad and diverse applications fields of biocidal products.

7.2.4 Develop a Specific Framework on Sustainable Use of Biocides

During the stakeholder consultation for the study on the impacts of the implementation of the BPD, some stakeholders suggested that a directive on the sustainable use of biocides (with the objective of reducing the use and the risks of biocides) could be considered.

Several provisions foreseen within the pesticides Thematic Strategy could also provide a starting point for developing measures on sustainable use of biocides:

- improvement of awareness and training of professional users and distributors;
- certification of professional users;

- protection of non-professional users (e.g. by distribution or use restrictions);
- collection of packaging and unused (obsolete) products;
- systematic data collection on biocides sales and use;
- establishment of National Plans to reduce hazards, risks including the involvement of stakeholders; and
- inspection of application equipment

The focus of these provisions lies in supply of information, training and the establishment of National Action Plans for sustainable use. This means that the key elements will be implemented by Member States, some of which already have established or are planning risk reduction measures not only for plant protection products but also for biocidal products.

Potentially, the availability of certain biocidal products to non specialised consumers might also be discussed within a new framework for the sustainable use of biocides. In certain Member States, such as Denmark, rodent control is limited to specialised pest control workers and rodenticides are not allowed to be sold to consumers. In Germany, there is a discussion among hygienists as to whether household disinfectants applied by consumers are useful at all. The limitation of use of certain biocides to professional users might become an issue, similar to the prohibition of aerial spraying proposed within the pesticides Thematic Strategy. Therefore the development of national plans of safe use of biocides might have impacts on product authorisation and mutual recognition.

7.3 Preliminary Assessment of Advantages and Disadvantages

Stakeholders	Options		
	1. Include biocides into PPP framework	2. Include provisions on use into the BPD	3. Develop specific framework legislation on biocides
EU industry	<i>Advantages:</i> No major changes	<i>Advantages:</i> No major changes	<i>Advantages:</i> All measures proposed can be discussed in details with all stakeholders
	<i>Disadvantages:</i> No major changes but potentially some costs associated with training of professional users	<i>Disadvantages:</i> No major changes but potentially some costs associated with training of professional users	<i>Disadvantages:</i> Contribution to developing the framework takes time and effort.
Administration (implementation and enforcement)	<i>Advantages:</i> Would strengthen the development of national plans for safe use of all pest control agents	<i>Advantages:</i> Would strengthen the development of national plans for safe use of all biocidal products	<i>Advantages:</i> All measures proposed can be discussed in details with all stakeholders
	<i>Disadvantages:</i> No major changes; measures could easily be included in national strategies on safe use of pesticides	<i>Disadvantages:</i> Experienced staff needed to develop measures on safe use of all biocidal products	<i>Disadvantages:</i> Experienced staff needed to develop the framework and later on the national plans

Table 5.1: Preliminary Assessment of Advantages and Disadvantages of Options related to Biocides Use			
Stakeholders	Options		
	1. Include biocides into PPP framework	2. Include provisions on use into the BPD	3. Develop specific framework legislation on biocides
Consumers, health & environmental protection	<i>Advantages</i> Measures on safe use of pest control biocidal products would become effective at the same time as measures on safe use of PPP	<i>Advantages</i> All PTs considered	<i>Advantage</i> All PTs considered. Specific requirements for certain applications can be developed
	<i>Disadvantages</i> Other PTs such as household disinfectants not covered	<i>Disadvantages</i> General statements on safe use may not be detailed enough	<i>Disadvantages</i> Long range process which delays measures becoming effective
Social impacts	<i>Advantages:</i> Reduction of risks to health of professional pest control workers	<i>Advantages:</i> Reduction of risks to health of professional pest control workers	<i>Advantages:</i> Reduction of risks to health of professional pest control workers
	<i>Disadvantages</i> none	<i>Disadvantages</i> None	<i>Disadvantages</i> Time and effort needed for the establishment of the framework
Product availability	<i>Advantages</i> Certain biocidal products might be excluded from consumer use	<i>Advantages</i> Certain biocidal products might be excluded from consumer use	<i>Advantages</i> Certain biocidal products might be excluded from consumer use
	<i>Disadvantages</i> none	<i>Disadvantage</i> none	<i>Disadvantages</i> none
Others (trade, internal market, transparency)	<i>Advantages</i> No major changes	<i>Advantages</i> No major changes	<i>Advantages</i> No major changes
	<i>Disadvantages</i> Specific measures on safe use at MS level might hinder mutual recognition of product authorisation	<i>Disadvantage</i> Specific measures on safe use at MS level might hinder mutual recognition of product authorisation	<i>Disadvantages</i> Specific measures on safe use at MS level might hinder mutual recognition of product authorisation

8. SUMMARY OF OPTIONS TO BE ASSESSED

Table 8.1 summarises the options to be assessed during the study.

Table 8.1: Summary of Options to be Assessed	
Scope	No change: only necessary amendments to update the BPD
	Extend scope to include limbo products: food processing aids, food contact materials, plus any others identified during the study
	Extend scope to include treated articles: based on the option recommended in the previous study on treated articles
	Extend scope to cover both limbo products and treated articles
	Reduce the number of product types
Product authorisation	No action: guidance and other measures to encourage mutual recognition
	Baseline plus: strengthen mutual recognition based on the decentralised procedure of Directives 2001/82/EC and 2001/83/EC
	Single community authorisation: free circulation of products authorised in one MS
	Centralised authorisation: by a central Agency or modelled on the existing procedure for active substances
Data sharing	No action: only encourage data sharing
	Mandatory sharing of vertebrate animal test data at product authorisation stage
	Mandatory sharing of vertebrate animal test data at product authorisation and active substances stages, with an exemption for new substances
Data requirements	No action: minor clarifications only or additional guidance
	Reformulating the system for low risk substances
	Rewording provisions concerning data waiving and the use of existing information
Fees	No action: increased transparency
	Harmonised structure: reduced fees for multiple submissions, varying fees by product type, payment by instalments
	Centralised fees: specified range of fees for MS to levy or centralised charging with reimbursement of MS
	Specific provisions for SMEs: discounts, payment by instalments
Use (qualitative assessment only)	No action
	Include some biocides within pesticides strategy (European Parliament proposal)
	Include provisions on biocides use within BPD
	Develop a specific framework on biocides use

9. SELECTION OF KEY SECTORS FOR ASSESSMENT

9.1 Introduction

From the previous studies on the impacts of the BPD and on treated articles, we hold information from a wide range of sectors manufacturing, formulating and using biocidal products. We will use this information to evaluate the impacts of the proposed options across these sectors, as far as possible.

However, there are gaps relating to both baseline data and the potential response of stakeholders to the changes included in the policy options. Given the wide and divergent scope of the BPD, with 23 different PT and a wide variety of areas of use (from households to general industrial and highly specialised professional use), it may not be possible to gather sufficient data to analyse the impacts of the identified policy options in detail on all potential stakeholders. If this proves to be the case, we will focus our analysis on representative sectors and groups.

This approach was adopted in the previous studies. Three specific treated articles and materials were selected for detailed evaluation in the study on treated articles: fungi-resistant paint (PT 7); treated wood (PT 8) and tanned leather (PT 9). The selection was based on the size of the markets for different treated articles and materials, the potential for imports and the quantity of biocides used. While the analytical overview of the study on impacts of implementation of the BPD covered all product types, only PT 8, 14, 16, 18, 19 and 21 were considered in the case studies, as only dossiers for these product types had been submitted before the study began. It is notable that, in both studies, there were relatively few differences in impacts between the sectors; other than in a few, very specific cases, the same issues and concerns applied across the sectors studied. This should make extrapolation of findings from the selected sectors simpler.

The sectors and groups to be selected should cover two main types of criteria:

- they should be sufficiently **representative** of the biocidal products market as a whole to permit extrapolation of the findings of the analysis;
- they should include stakeholders affected by each of the **policy options** identified.

Each of these criteria is discussed further below. We then make an initial suggestion of sectors for detailed study. However, we would like to retain some flexibility in this selection, as further investigation may indicate that the characteristics of the selected sectors differ from our current perceptions, and/or that other sectors may provide a better basis for examining the impacts of the policy options.

9.2 Representativeness

The Technical Specification indicates that the selected key stakeholders they should cover as a minimum:

- each of the main types of biocidal product (disinfectants, preservatives, pest control, others);
- both existing and new substances;
- the full supply chain (active substance manufacturers and importers, biocidal product formulators, manufacturers of treated articles, distributors and retailers, end users);
- different company sizes (small, medium and large); and
- a range of different Member States.

The technical specification identifies four sub-criteria for selecting key stakeholders:

- ***the availability of data***: most data will be available for the sectors that were the focus of in the previous two studies, but in the course of these studies we also gathered general information on the biocidal product industry;
- ***representativeness of the relevant ‘market chain’***: the study on treated articles found that the market chain is extremely complex and varies from product type to product type. However, by ensuring that the sectors selected cover products for professional and for consumer use, those used directly and those incorporated into articles, and products with both wide and narrow ranges of uses, it should be possible to cover the range of market chains;
- ***representativeness of the size of industries***: there are two aspects to the question of size. One is the size of the companies participating in the sector, in particular the proportion small companies. The previous studies indicated that SMEs play a significant role in most sectors of the biocides market. The other aspect is the proportion of the total biocides market accounted for by the sector in question. Obviously, large sectors will represent a higher proportion of the market than small sectors. However, niche sectors may have particular concerns, which should not be ignored in the analysis; and
- ***possibilities for meaningful extrapolation to related sectors***: where the characteristics of a particular sector, e.g. the numbers and sizes of manufacturers and/or formulators within a sector are similar to that of the market as a whole, this may make extrapolation of the results to related sectors more straightforward, allowing for a more robust analysis of impacts. By addressing the criteria outlined above, we believe that this criterion will be met.

Table 9.1 below provides an analysis of the product types covered by the BPD against the representativeness criteria.

Table 9.1: Assessment of Product Types Against Representativeness Criteria							
PT	Criteria						
	Data Availability		Market Chain		Size		Dossiers submitted for new active substances ²¹
	Study on BPD impacts – case studies	Treated articles study	Wide range of uses	Narrow range of uses	Small and large companies	Large share of total biocidal products market	
Disinfectants							
1				√	√		√
2			√		√	√	√
3			√		√	√	√
4				√	√		√
5				√	√	√	√
Preservatives							
6		√	√		√	√	
7		√	√		√	√	
8	√	√		√	√	√	√
9		√	√		√		
10				√	√		
11				√	√		
12			√		√		√
13				√	√		
Pest Control							
14	√			√	√		
15				√	√		
16	√			√	√		
17				√	√		
18	√		√		√		√
19			√		√		
Others							
20				√	√		
21	√			√	√	√	√
22				√	√		
23				√	√		

Although some of the policy options outlined in sections 2 – 7 of this report will affect a wide range of sectors, others will be more specific in their impacts. Table 9.2 indicates which of the policy options will have a more specific affect, and the product types/sectors that will be most affected.

21 CA-Nov07-Doc.9.1: Active chlorine PT1; sodium N-chlorobenzenesulphonamide PT 2, 3, and 5; silver nitrate PT 2, 3, 4, and 5, Thiacloprid, PT8, Carboquat-DDA Carbonat PT8; Acrolein PT12, Inoxacarb PT18, Tralopyril PT21

Table 9.2: Sectors Affected by Different Policy Options		
Policy option	Sector characteristics affecting impacts	Product type (examples)
Scope		
No change	Currently covered by BPD	All
Include limbo products	Producers and users of	n/a
Include treated articles	Articles treated for internal effect	6,7,8,9 [sub-sectors identified as most significant in articles study]
Include limbo products and treated articles	(as above)	(as above)
Exempt certain PT and substance classes	Exempted PT REACH Annex IV substances	1, 20 6, 14, 15, 18, 19, 20 ¹⁰
Product authorisation		
No action	Sectors currently subject to national authorisation in one or more MS (mutual recognition will reduce market barriers)	All (except 17) are covered by at least one
Baseline plus	Sectors placing products on the market in more than one MS	All
Single community authorisation	Sectors placing products on the market in more than one MS	All
Centralised authorisation	Sectors placing products on the market in more than one MS	All
Data sharing		
No action	Sectors where new substance dossiers have been submitted Sectors where new substance dossiers have been withdrawn	1, 2, 3, 4, 5, 8, 12, 18, 21 14 (Cholecalciferol), 18 (Metofluthrin)
Mandatory sharing of animal data – product authorisation	Sectors where active substance manufacturers are also formulators	All?
Mandatory sharing of all data – with exemption for new substances	Sectors where active substance manufacturers are also formulators New substances with multiple manufacturers	All? None anticipated
Data requirements		
No action	All	All
Tiered approach - substances	Sectors where a high proportion of active substances were not supported	2, 8, 16, 18, 19, 21
Reduced data – products	Sectors with a high proportion of products already regulated	1, 3, 14 -19, 23
Remove efficacy requirement	All	All
Fees		
No action	All	All
Harmonised structure	All	All
Centralised fees	All	All
Specific provisions for SMEs	Sectors with a high proportion of SMEs	All
Use		
No action	All	All
Include some biocides in pesticides strategy	Pesticides	14 -19, 23
Include provisions on use in BPD	All	All
Develop biocides strategy	All	All

9.3 Selected Sectors

Table 9.3 combines information on the impacts of policy options with the table on representativeness (because the issue of new substances is included in the assessment of policy options, this column from Table 9.1 is not repeated). The product types within each major group which meet the widest range of criteria are highlighted.

Table 9.3: Assessment of Product Types Against All Criteria							
PT	Criteria						
	Data Availability		Market Chain		Size		Impacted by specific policy options
	Study on BPD impacts – responses from full product chain	Treated articles study	Wide range of uses	Narrow range of uses	Small and large companies	Large share of total biocidal products market	
Disinfectants							
1			√		√		√
2			√		√	√	
3				√	√		
4				√	√		
5			√?		√	√	
Preservatives							
6		√	√		√	√	√
7		√	√		√	√	√
8	√	√		√	√	√	√√√
9		√	√		√		√
10				√	√		√
11				√	√		
12			√		√		√
13				√	√		
Pest Control							
14	√			√	√		√√
15				√	√		√
16	√			√	√		√√
17				√	√		√
18	√		√		√		√√√
19			√		√		√√√√√
Others							
20				√	√		√
21				√	√		√
22	√			√	√		
23			√?		√		

Based on the assessment in Table 9.3, our initial recommendation is that the following sectors are selected for more detailed study:

Disinfectants:

- **Private and public health area disinfectants (PT 2):** this is the most important sector in terms of volume, diversity of applications and also covers the private, public and industrial sectors;
- **Veterinary hygiene products (PT 3):** this will enable us to address the borderline with

veterinary medicines.

Preservatives

- **Wood preservatives** (PT8): wood preservatives were addressed in the study on treated articles, and we suggest that the work on the policy option to include treated articles covers the same sectors as the previous study. This is also a sector with a high market share and accounts for a large proportion of the total biocides market. However, experience with this sector may not be readily transferable to other sectors. We will therefore consider whether sufficient data are available on **in-can preservatives**, which also have a major market share and were covered by the study on treated articles.

Pest control

- **Repellents/attractants** (PT 19): although these products account for only a small proportion of market share, the product type has experienced a high proportion of active substance withdrawal and could be useful for assessing the impacts of policy options on scope and data requirements.

Others

- **Preservatives for food and feedstocks** (PT 20): this may enable us to address the issue of 'limbo' products in the form of food processing aids.
- **Antifouling products** (PT 21): this PT has suffered the largest percentage withdrawal of active substances. Although no users from this sector responded to the study on impacts of the BPD, the team has a range of useful contacts with the sector to assist in gathering additional data, if necessary.
- We recommend that **embalming fluids** (PT 22) are **not** the subject of further study. This sector has demonstrated a high level of concern about the impacts of the BPD. However, we believe that many of these concerns are unfounded and, because of its particular features, experience from this sector would not be readily transferable to other sectors.

10. PRELIMINARY CONSULTATION PLAN

10.1 Objectives of Consultation

The focus of consultation will be on:

- filling gaps in the data on the impacts of the baseline (the current BPD), particularly views on the impacts of the provisions that have not yet been implemented;
- validation of the issues and options identified in this report;
- confirming the likely responses of stakeholders to each of the policy options; and
- obtaining more detailed data on the impacts (costs and benefits) of these responses.

10.2 Consultation for Assessment

The main focus of consultation will be on obtaining the information needed to complete the detailed analysis. The approach to consultation will be tailored to the particular characteristics of the stakeholder supply chain, the nature of the policy options affecting that supply chain and the information available from our previous studies.

We have prepared an initial list of the data required to assess the impacts of the policy options set out in this note and compared this to available data, in order to identify the gaps. We will develop this analysis further through a more detailed review of available data, to fill the gaps as far as possible. Once this has been completed, we will determine what further steps are necessary. This may include:

- additional literature searches (though we are confident that we are aware of most of the available data, from our previous studies);
- contact with respondents to the previous studies from the key stakeholder sectors, where relevant, to request additional data (using short individual or tailored questionnaires, email or telephone discussions), 18 companies that participated in the study on impacts of implementation of the BPD have already indicated their willingness to contribute to this study;
- contact with industry associations in the key sectors or parts of the supply chain where there are no relevant previous respondents and/or previous respondents do not hold the necessary data. This will include stakeholders suggested by the Commission. Where possible, data will be gathered directly from the association. If this is not possible, associations will be requested to suggest individual companies who could provide data. This is most likely to be necessary in the case of users of biocidal products, who were not well represented in responses to the study on the impacts of implementation of the BPD.

We do not plan to use a standard questionnaire for data gathering purposes; instead, contact with stakeholders will focus on the specific information that we require for the analysis. However, we will ask a number of standard consultation questions in each case, focusing on how the stakeholders are likely to respond to the proposed policy options.

10.3 Consultation with Other Stakeholders

In addition to data gathering and consultation with the key stakeholder groups, we propose to hold more general consultation with a smaller group of representative stakeholders. The focus of the consultation will be on the likely response of the stakeholders to the proposed policy options, to add to the robustness of the assessment of impacts. The consultation approach is likely to take the form of a list of discussion points to be sent in advance to the selected stakeholders, followed by telephone (or face-to-face) discussion once the stakeholder has had time to prepare.

The selected stakeholders will include a balance of different groups, including:

- up to three NGOs representing environmental, public health and pest control interests. These might include, for example, PAN Europe, the Health and Environmental Alliance (HEAL), the International Water Association and Confederation of European Pest Control Associations;
- industry (up to three SMEs and three large companies from sectors not included in the key stakeholders); and
- up to three Member States; we will focus on those that are keen to contribute and have given thought to the ways in which the BPD could be developed. They are likely to be drawn from Germany, Sweden, Finland and Austria and the UK often has a very practical view on these issues.

The consultation with other stakeholders will take place after the initial consultation for data gathering and will be designed to check that the findings from the key stakeholder consultation are sufficiently representative to allow for extrapolation to the biocidal products sector as a whole. Thus the participants, and the specific points for discussion, will be identified once initial consultation is complete.