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Subject:	Commission staff working paper accompanying the proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products - Impact assessment

Delegations will find attached Commission document SEC (2009) 773.

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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the placing on the market and use of biocidal products

IMPACT ASSESSMENT

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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the placing on the market and use of biocidal products

IMPACT ASSESSMENT

Lead DG:	DG ENV
Other involved services	DG's ENTR, SANCO, AGRI, JRC, RELEX, TRADE, COMP, MARKT, SJ, SG.
Agenda planning:	2008/ENV/003

The report commits only the Commission's services involved in the preparation and the text is prepared as a basis for comment and does not prejudice the final form of any decision to be taken by the Commission

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Executive summary

Directive 98/8/EC (the Directive) seeks to harmonise the placing of biocidal products on the market whilst guaranteeing a high level of protection for humans, animals and the environment.

Although the Directive has been successful in removing a number of undesirable products from the EU market, and in bringing structure to an area that was regulated in a fragmented way in the Member States, during the first eight years of the implementation of the Directive, several problems have been identified. These include the slow progress in the active substance Review Programme, the high level of withdrawal of certain active substances[1] and products and the lack of incentives for the development of new active substances.

The main reasons for these consequences are:

– the loopholes and the lack of clarity relating to the scope of the Directive;

– the extensive data requirements for dossier preparation leading to high costs;

– the low attractiveness of simplified procedures for low-risk and basic substances;

– the uncertainty regarding the application of the Directive in particular in relation to data protection and data waiving possibilities; and

– the high and heterogeneous fees for approval of active substances and authorisation of products.

It appears, therefore, necessary to modify certain provisions of the Directive (policy issues 2 to 5) in order to make it more effective and efficient, reducing unnecessary burdens for Member States and industry whilst maintaining a high level of protection of human health and environment. In addition, the need to ensure coherence and to establish a level playing field between EU producers and third-country producers of treated materials necessitates a change of the scope of the Directive (policy issue 1).

The Impact Assessment addresses five policy issues that require action:

POLICY ISSUE 1: SCOPE

– Unchanged policy;

– Extend scope to cover processing aids and food contact materials;

– Extend scope to cover treated materials.

The policy options are cumulative. The assessment concluded that including treated materials in the scope of the Directive would significantly increase the costs to industry. However,

[1] Withdrawal refers here to the situation when some companies decided not to support existing active substances in the Review Programme or the information provided by them was not sufficient.

although the equal treatment of industry, and environmental and human health benefits are difficult to quantify, they are likely to be significant. Including, in particular food processing aids in the scope of the Directive is likely to result in a complicated process of authorisation under two legal frameworks[2] which may lead to some duplication of efforts. The related costs are likely to outweigh the limited benefits resulting from better control of environmental impacts and greater regulatory certainty.

POLICY ISSUE 2: PRODUCT AUTHORISATION

– Unchanged policy;

– Strengthening of mutual recognition;

– Single Member State authorisation;

– Community authorisation.

The policy options are alternatives but within them certain elements could be combined. The assessment concluded that a Community authorisation or a single Member State authorisation would be the most efficient systems and would provide incentives for innovation of products based on new active substances/low risk products. However, as the Member States have expressed significant concerns about a full centralisation of the product authorisation or a single Member State authorisation due to reduced role for the Member States, a combination of the Community authorisation for certain products with the strengthening of the mutual recognition process for other products appears to be the most realistic solution.

POLICY ISSUE 3: DATA SHARING

– Unchanged policy;

– Mandatory sharing of vertebrate animal test data at product authorisation stage;

– Mandatory sharing of vertebrate animal test data at product authorisation stage and active substance approval stage.

The policy options are mutually exclusive; they address the same problem and offer different solutions to it. The assessment concluded that the last option of mandatory data sharing at product authorisation and active substance approval stage implies the highest total cost savings to applicants, possibly the highest number of safer products remaining on the market and the highest number of animals saved.

POLICY ISSUE 4: DATA REQUIREMENTS

– Unchanged policy;

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[2] For processing aids used on food of animal origin, this would include the Regulation (EC) No 853/2004 and the Biocides Directive. For processing aids used on food of plant origin, this would include the national legislation, where available, and the Biocides Directive.

– Rewording provisions concerning data waiving and the use of existing information;

– Reformulating the system for low-risk substances/products.

The policy options are cumulative and address two types of problems: high data requirements and low attractiveness of the simplified procedures, in particular for low risk and basic substances. The assessment concluded that all the options have significant potential to reduce costs for industry and that the last two options would also significantly reduce the numbers of vertebrate animal tests. In order to meet the objectives of the revision, the best option seems to be a combination of data waiving with the use of existing information and a new approach to low risk biocidal products.

POLICY ISSUE 5: FEES CHARGED BY MEMBER STATES FOR CARRYING OUT THE PROCEDURES OF THE DIRECTIVE

– Unchanged policy;

– Partially harmonised fee structure;

– Centralised fee system;

– Specific provisions for SMEs.

The policy options are alternatives but within them certain elements could be combined. The assessment concluded that a partially harmonised fee structure may encourage the development of more new active substances and the retention of more existing active substances. It should also reduce the costs for the inclusion of substances for several product types. The last option will make the procedure less costly for SMEs, which should help them to stay on the market. A fully centralised fee system would raise questions concerning the subsidiarity principle as it would transfer the competences over setting the levels of fees from the Member States to the Community.

OVERALL COSTS AND BENEFITS

If left unchanged, the current legal framework for biocides would result in very high costs for the industry in order to comply with the provisions on the evaluation of active substances and authorisation of biocidal products. The total costs and benefits of the policy options presented in the impact assessment should be seen in light of this fact.

The impact assessment shows that the **combined overall costs of all preferred options** to the industry would amount to a range from **€193.6 to 706 million[3] over a period of 10 years**. These costs are attributable to the extension of the scope of the Directive to treated materials and cover the costs of including additional active substances in Annex I, the costs of the authorisation of additional products and the labelling costs of treated materials.

The **overall cost savings of all the preferred options for the industry** could range from **€2.7 to 5.7 billion[4] over a period of 10 years**. Due to reasons described in detail in Section 6

[3] Net present value € 162.2 million to 591.6 million

[4] Net present value € 2.3 billion to 4.8 billion

(Comparing the options), it is, however, unlikely that the cost savings would materialise in such scale. The actual savings are likely be closer to the lower end of the range but would certainly outweigh the total costs.

Concerning the environment and human health impacts, the impact assessment shows that the extension of the scope to treated materials will result in significant environmental and human benefits even though these are difficult to quantify. The other policy options will help maintain the current high level of environmental and human health protection.

Regarding the social impacts, no significant impacts on employment are expected. However, the individual policy options, in particular the changes in product authorisation, obligatory data sharing, improved waiving provisions and the revised concept for low risk biocidal products may have positive impacts on employment.

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Overview

The revision of Directive 98/8/EC (3) concerning the placing of biocidal products on the market (the Directive) is part of the 2008 Commission Legislative and Work Programme (1) and is included in the Commission strategy for simplifying the regulatory environment (2).

A number of stakeholders, experts and competent authorities of the Member States have been consulted. An Inter-Service Steering Group to support the work on the Impact Assessment was established. The need for a revision addressing the scope of the Directive, product authorisation, data sharing, data requirements and fees was highlighted during the consultation process.

This Impact Assessment follows the structure given in the Commission guidelines (4). It aims to consider the environmental, economic and social aspects of the revision of the Directive in an integrated and proportionate way.

1.2. Inter-Service Steering Group

Within the Commission, internal consultation has been pursued through an Inter-Service Steering Group (ISSG) set up in December 2007. The ISSG was led by the Directorate-General Environment with the participation of DG's Enterprise and Industry, Health and Consumer Protection, Agriculture, Joint Research Centre, External Relations, Trade, Competition, Internal Market, Legal Service and the Secretariat General. The ISSG met on 3 December 2007, 5 June 2008 and 18 July 2008.

1.3. Preparatory work

To support this impact assessment, several studies were carried out by external contractors:

- a study to assess the impact of the revision of Directive 98/8/EC concerning the placing of biocidal products on the market (5);
- a study on the impacts of the implementation of Directive 98/8/EC on biocidal products (6);
- a study on impacts of possible measures to manage articles or materials treated with biocides, in particular when imported (7); and
- a study on the assessment of different options to address risks from the use phase of biocides (8).

1.4. Stakeholder consultations

During these studies, stakeholders (consultants, individual companies, industry associations, NGOs, Member State competent authorities) were consulted through

several questionnaires and interviews. A Stakeholder Consultation Meeting was also held on 23 May 2008 in Brussels.

In addition, an expert workshop was organised on 23 April 2008 to discuss the use phase of biocides.

Concerning the consultation of the competent authorities, a first workshop dedicated to the revision of the Directive was organised by the Presidency of the EU in Slovenia in January 2008. Representatives of Member States competent authorities then dealt in detail with the key issues for the revision during a meeting held on 28 – 30 May 2008. In addition, several bilateral meetings were held between the Commission services and representatives of Member States competent authorities.

Stakeholders were very supportive to the extension of the scope with respect to treated materials. In particular, the industry demanded that a level playing field is created concerning materials treated with biocidal products that are placed on the EU market. The industry as well as the Member States were also in favour of a labelling system that would facilitate the enforcement and inform consumers about the use of biocidal products in treated materials.

Regarding product authorisation, the industry was clearly in favour of a fully centralised Community-wide authorisation system. However, the Member States opposed this and argued that the role of Member States in the authorisation process should be retained.

All stakeholders agreed on the changes concerning data sharing and data requirements. The Member States had some concerns about the implementation of the concept on low risk biocidal products, in particular the definition and the details of the screening process (see section 4.4.3).

Finally, with respect to fees, the industry fully supported the proposal to introduce a partially harmonised fee structure. The provisions aimed at SMEs were welcome in particular by SMEs. The Member States were in favour of keeping the decision on fees at national level.

1.5. The Impact Assessment Board

This Impact Assessment was submitted to the Board on 1 August 2008 and discussed at the Board meeting of 27 August 2008. The Board submitted its opinion on 3rd September 2008 proposing the following changes to the assessment:

- inserting more information on the market with biocidal products;
- clarifying the relevance of the subsidiarity principle;
- inserting a section on methodology, in particular clarifying the assumptions underlying the assessment;
- detailing the impacts on the different users of biocidal products;

– inserting more information on the situation concerning imports of treated materials;

– including more information on how the costs of the different policy options compare to the value of the market;

– setting out the advantages of the hybrid system (mutual recognition for most products and centralised Community authorisation at EU level for some products) compared to the current situation;

– calculating the total costs and benefits of the final policy package; and

– reflecting better the results of the stakeholder consultation.

All these recommendations have been introduced in the relevant sections. The modified impact assessment was re-submitted on 9th September 2008. The Board issued a new opinion on 2nd October 2008 in which it recommended:

– to strengthen the subsidiarity analysis in particular as regards the policy issue on fees. This has been done in section 5.5.2.;

– to clarify the structure of the options. The difference between options (a) and (b) for policy issues 1 (scope) and 2 (product authorisation) has been clarified in the relevant sections. Additionally, the problems described under sections 4.2 and 4.5.1 have been transferred to the problem definition section.;

– to further assess the impacts of the proposed options, notably

(1) to provide more information on impacts of various types of affected parties (big companies versus SMEs, substance producers versus product manufacturers) and show how benefits/costs evolve over time. See section 5.

(2) to be more specific about the level of data confidence and more transparent about uncertainty when aggregating data: Annex V sets out the standard assumptions on markets and numbers of products and substances used in the analysis of the various policy options, indicating the source of the estimate and noting any particular areas of uncertainty. Annex VI sets out the assumptions on costs of product authorisation and support of active substances. The assumptions have been validated with stakeholders; however a high degree of uncertainty remains.

(3) to provide a clear definition of market value and to delimit business compliance and administrative costs. In section 5.1.3. 'market value' has been replaced by 'annual market turnover'. Business compliance and administrative costs have been delimited in Annex VII.

(4) to quantify the effects on employment. See section 5.

– to use the EU Standard Cost Model and to include the EU Standard Cost Model reporting sheet. The reporting sheet has been included in Annex VIII. The estimates are consistent with the European Standard Cost Model in the sense that they examine the costs associated with different information obligations. The

"time-based" methodology could not be used because most of the costs in the report are charged on a fixed-price basis.

2. PROBLEM DEFINITION

2.1. Background

Background information on the requirements of the Directive is provided in Annex II of this document.

Biocidal products refer to a wide category of products divided into 23 product types including disinfectants, pest control products, wood preservatives, anti-fouling products and embalming products. Professional users are prevalent in all preservatives, in particular wood preservatives, some pest control products (avicides and piscicides), anti-fouling products and embalming and taxidermist products. Non-professional users (consumers) prevail in some pest control products (rodenticides, insecticides, repellents and attractants) and some disinfectants.

The value of the global biocidal products market was in 2000 estimated at around € 3 billion per year, with North America representing about 43% and Europe 27% (the latter approximately worth € 890 million per year and volumes estimated at 89,000 tonnes of products placed on the market per year)[5]. The European biocides market is dominated by three large companies that hold 25% of the market, while the presence of small and medium-sized companies is also quite important, especially with regard to the manufacture of "niche" or speciality biocides. Within the biocides market, one can distinguish producers of active substances, formulators of finished biocidal products, and companies that are active in both markets. As a result of the implementation of the Directive in Europe, there is currently a tendency for consolidation of the market and in particular, of active ingredients' producers to buy companies that formulate finished products.

The Directive sets out a two-tiered system of evaluating active substances at the Community level and authorising biocidal products containing these substances at the national level. The product authorisation stage of the Directive has not yet been implemented. It will be implemented gradually following the inclusion of active substances in Annex I[6]. In case the companies intend to place their product on the market in several Member States, they can apply for a mutual recognition of the original product authorisation.

This system has the objective to ensure a functioning internal market in biocidal products and a high level of protection of human health and the environment. The protection of human health and the environment is very important with respect to the use of biocidal products as biocidal products can pose risks to humans, animals and the environment in a variety of ways due to their intrinsic properties and associated use patterns. For example, the use of wood preservatives or anti-fouling products

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5 For more details see http://www.icis.com/Articles/2002/05/21/170110/biocide-deadline-comes-and-goes.html and http://www.personalcaremagazine.com/Story.aspx?Story=2644; the information was confirmed with representatives of the industry;

6 One biocidal product can contain several active substances. However, an authorisation for a biocidal product can only be issued once all active substance(s) contained therein have been included in Annex I or IA.

often implies a direct contact of the biocidal product with aquatic or marine environment. In addition, biocidal products may have negative effects on non-target organisms. With respect to human health, biocidal products may leave residues which may have negative impact on human or animal health (e.g. through drinking water, food or feed, indoor air or consequences in the place of work).

The above-mentioned studies and the report on the functioning of the Directive highlighted the following issues:

– Impacts on the market remain to be seen. However, the main lesson from the first years of implementation of the Directive is that several substances and products have been removed from the market not because of public health or environmental concerns but because the costs of producing data for meeting the requirements of the Directive were felt to be prohibitive (6).

– High costs of the active substance dossiers already had a significant impact on the number of substances participating in the Review Programme. Over 60% of active substances which were on the market in May 2000 were not supported under the Review Programme and therefore, their marketing was discontinued in September 2006. The impacts of the withdrawal[7] on products are difficult to assess but some Member States indicate that up to 18% of products had to be phased out[8]. High costs of the product authorisation application, in particular when multiplied by the number of countries where a particular product is marketed or including the costs of the mutual recognition, may lead to similar impacts with respect to the products.

– Price increases for biocidal products of between 10% to 30% are anticipated by the industry because of the extensive data requirements for dossier preparation necessitating significant investments. Small and medium-sized enterprises (SMEs), as defined in the Commission Recommendation of 6 May 2003 (9) are particularly affected, while larger companies are more likely to be able to bear the costs of dossier preparation. High costs of the dossier preparation are likely to have negative impact on the product availability which in return increases the risks of resistance development[9]. The lesser the choice of products, the more they will be used which increases the risk of resistance development.

– The industry indicates that the development of new active substances with potentially better risk or efficacy profiles is discouraged by the Directive because company resources are currently focused on defensive research in order to comply with the Review Programme requirements. In particular, the development of low risk active substances or basic substances is not supported because of the low attractiveness of simplified procedures[10].

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7 Examples include the use of lavender oil as repellent, copper sulphate as wood preservatives, phenothrin as insecticide, zinc as anti-fouling product, etc.

8 Study on Impact of the implementation of Directive 98/8/EC concerning the placing on the market of biocidal products

9 Resistance is the capacity of bacteria to withstand the effects of a harmful chemical agent.

10 Simplified procedures include for example the registration of a low risk biocidal product (as opposed to authorisation of 'normal' biocidal products) on the basis of a reduced data package with precise deadlines for the issuing of the registration and mutual recognition of the registration.

– The implementation of neighbouring legislation such as the REACH Regulation or the forthcoming Regulation on plant protection products is unlikely to have a significant impact on biocides. The REACH Regulation may have some impact on the evaluation of non-active substances[11] which may be required under the Directive but will have very limited implications for the evaluation of active substances and authorisation of biocidal products. The interaction with the legal framework on plant protection products is largely limited to solving borderline issues concerning scope. With respect to the rules on mutual recognition of products, it should be clarified that Regulation (EC) No 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC does not apply to the mutual recognition process under the Biocides Directive[12].

– The implementation of the Directive is too recent for evidence to be available on impacts on pest control and on the level of human/animal health and environmental protection. Some active substances with highly hazardous profiles (e.g. strychnine, arsenic compounds) have been taken off the market, representing a clear environmental and health benefit. However, some stakeholders fear that a reduced variety of active substances may lead to future treatment gaps and the development of tolerance and resistance of target organisms .

The main reasons for these impacts are:

– the delimitation of the scope, in particular the loophole related to treated materials places EU producers at a disadvantage and is also a consumer and environmental protection issue;

– the lack of expertise in dossier preparation and evaluation;

– the uncertainty regarding the application of the Directive in particular in relation to data-protection, data waiving possibilities, technical guidance for risk assessments and efficacy testing;

– the low attractiveness of simplified procedures such as Annex IA (low-risk substances) and Annex IB (basic substances);

– the extensive data requirements for dossier preparation leading to high costs; the costs for product authorisation must be, in addition, multiplied by the number of markets on which the product shall be placed or it must include the costs of the mutual recognition including possible repetition of tests;

– the high and heterogeneous fees for approval of active substances and authorisation of products.

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[11] Non-active substances are substances which do not have general or specific action on or against harmful organisms. They include pigments, dyes, perfumes, solvents, etc. Non-active substances fall within the scope of REACH and thus have to be registered and evaluated under the REACH Regulation. The results of this evaluation may be later used during the product authorisation stage under the Biocides Directive.

[12] The Regulation does not apply to technical rules which are subject of harmonisation at Community level.

While there are a large number of issues of varying importance that are likely to be addressed in the revision of the Directive, there are a few where it has been identified that there might be significant impacts. These are set out in section 2.3 and are the subject of this Impact Assessment.

In cooperation with the stakeholders, **various ways have been identified to significantly reduce costs** related to the substance evaluation and, in particular to product authorisation and mutual recognition. These include for example obligatory sharing of vertebrate animal data, revision of the concept for low risk biocidal products or improved rules on data waiving. These measures which are presented in the impact assessment have high potential to reduce the costs. This would lead to the situation where more products would remain on the market and innovation with respect to new products would be encouraged. Importantly, if no action is taken, many companies are, due to high costs of the product authorisation and mutual recognition, likely to stop marketing their products which will lead to problems with product availability. Product availability is decisive for example for the development of resistance in target organisms. This may be a problem mainly for Member States with smaller markets where companies with low turnover will not be able to cover the expenses linked with the product authorisation or mutual recognition and will no longer find it economically viable to supply such products.

In addition, the changes to the Directive could make it simpler to understand which would facilitate the regulatory compliance. This would mainly benefit SMEs which often lack the human resources to ensure regulatory compliance. Simplification would also reduce the need for human resources on the side of the Member States' authorities and would facilitate enforcement.

Given the potential cost savings to the industry that could be achieved with the actions described in this assessment, it seems appropriate to act now and not to postpone the changes.

2.2. Methodology

The following basic assumptions were used in the impact assessment:

Number of biocidal products to be placed on the market over the next 10 years

– Minimum number of products: 4 500

– Maximum number of products: 9 000[13]

Total costs of an active substance evaluation[14]

[13] These numbers are estimates provided in the RPA Report (5). On the basis of stakeholder consultation, the total number of biocidal products currently on the market may be higher as some Member States, in particular Germany and France, report a total number of 18.000 biocidal products. This number may, however, contain many duplicate entries. In addition, it is expected that the market will consolidate after the end of the Review Programme. Some companies may leave the market or reduce the number of markets on which they are active in response to the costs of the product authorisation under the provisions of the Directive and non-inclusion decisions about certain substances.

– Minimum total costs of an active substance dossier: € 3 million per substance

– Maximum total costs of an active substance dossier: € 5 million per substance

Total costs of a product authorisation

– Minimum average costs of product authorisation: € 90,000 per product

– Maximum average costs of product authorisation: € 200,000 per product

It should be noted that there are further assumptions including the number of cases where mutual recognition is sought, the rate of referral to the Commission in cases of disagreements over mutual recognition, the average number of markets on which biocidal products are placed, the average number of active substances on the market, etc. These assumptions were validated with the stakeholders (i.e. individual companies, industry federations and Member States) to make them as robust as possible. Because of the high degree of uncertainty involved, the costs and benefits of different options were calculated with help of scenarios. An optimistic and a pessimistic scenario were prepared:

– the **optimistic scenario** refers to situation where there are many applications for product authorisations combined with a high incidence of mutual recognition and a relatively low rate of referral to the Commission in case of disagreements over mutual recognition;

– the **pessimistic scenario** refers to situations where there will be fewer applications for product authorisations combined with a lower incidence of mutual recognition and a higher number of cases referred to the Commission in case of disagreements over the mutual recognition;

The costs and benefits of the outlined policy options are laid down in ranges which are direct consequences of using the scenario approach. The lower range of the cost savings refers normally to the pessimistic scenario and the upper range to the optimistic scenario.

Most of the major costs in the report such as data costs and competent authority fees are charged on a fixed-price basis, rather than incurred in the form of person-hours, so the number of person-hours is not relevant for assessing these costs. Nevertheless, these estimates are consistent with the European Standard Cost Model in that they examine the costs associated with different information obligation. This was done using the best available data and including data provided by stakeholders.

2.3. The issues/problems that require actions

It should be noted that the impact assessment was prepared at a time when the provisions of the Directive on product authorisation and mutual recognition were not yet implemented. There is no practical experience on product authorisation and mutual recognition available. This has implications for all policy options presented in

[14] It is assumed that the costs of an active substance dossier are one-off costs which are incurred once in a 10-year period. This is explained through the fact that the inclusion of an active substance is valid for a period not exceeding 10 years.

the impact assessment. Nevertheless, there are several indications that problems may be anticipated:

– slow progress of the Review Program for the evaluation of existing active substances[15];

– current provisions of the Directive, in particular on mutual recognition lack precision and can be interpreted in different ways by the Member States;

– problems with the functioning of mutual recognition provisions encountered in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market which, mutatis mutandis, could also occur in the present case.

– concerns raised by all stakeholders, in particular the industry, with regards to the smooth functioning of the product authorisation and mutual recognition.

It was concluded that in order to ensure harmonised conditions for placing biocidal products on the market, changes to the Directive are required.

2.3.1. Policy issue 1: The scope needs to be revised

2.3.1.1. Biocides used in food processing and food contact materials

Food processing aids are substances intentionally added to food to fulfil a certain technological purpose (17). Some of these substances, although they are clearly acting as biocidal active substances, are currently not covered by the Directive. This raises the question of coherence with respect to the scope of the Directive.

Some processing aids used on food of animal origin with a biocidal activity are covered by Regulation (EC) No 853/2004 (18). This Regulation indeed prohibits the use of any substance other than potable water to remove surface contamination from products of animal origin unless the use of such a substance has received an approval. However, compared with the Directive, the approval procedure under Regulation (EC) No 853/2004 does not extensively address environmental concerns despite the most recent efforts[16].

In addition, Regulation (EC) No 853/2004 does not apply to processing aids used on food of plant origin. There is no other Community legislation requiring an evaluation of 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.

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15 On 9 September 2008, i.e. 8 years after the implementation of the Directive, only 13 active substances out of 320 substances were included in Annex I ('normal' active substances) and one active substance in Annex IA (low risk active substances) of the Directive.

16 In the draft Commission Regulation implementing Regulation (EC) N° 853/2004 of the European Parliament and of the Council as regards the use of four antimicrobial substances (chlorine dioxide, acidified sodium chlorite, trisodium phosphate, peroxyacids) to remove surface decontamination of poultry carcases strict conditions for the management of waste water are provided for in order to ensure the protection of the environment.

The situation of food contact materials is similar to that of food processing aids. Despite the fact that Community legislation on food contact materials exist, the evaluation of environmental effects associated with the use of biocidal products in food contact materials is not foreseen but Regulation 1935/2004/EC sets a framework for the regulation of food contact materials (19). A series of implementing measures cover specific types of contact materials (e.g. ceramics, regenerated cellulose film, plastic materials).

The Guidelines of the Scientific Committee on Food for the submission of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation *"do not include any consideration of environmental aspects such as persistence in the environment, ecological impact of their constituents and their fate after the food contact material has been submitted to waste disposal treatment.*" (20).

Industry has submitted approximately 10 applications for the use of so-called "surface biocides" in food packaging, mainly for silver compounds and triclosan to be embedded in packaging walls. None as yet have received approval.

2.3.1.2. Treated materials

A major legislative loophole was identified with respect to materials treated with biocidal products in order to protect the material itself. The Directive presently does not cover the placing on the market of this type of treated materials. Therefore, nothing – apart from the case-by-case measures adopted within the scope of Directive 76/769/EEC (11), prevents the placing of materials treated with biocidal products containing not approved or even banned active substances on the market.

For example, wooden poles for electricity which are manufactured in the EU can only be placed on the market if they are treated with authorised biocidal products (containing approved active substances). However, imported electricity poles can be treated with any biocidal product. Concrete cases include the imports of wooden electricity poles treated with products containing arsenic or chromated copper arsenate (CCA).

There are no statistics available on the amounts of imported treated materials placed on the EU market containing unauthorised or banned active substances. Even though some treated articles may be found in the RAPEX notifications[17], it is very difficult to identify them as these cases are not put in connection with biocidal products. Non-EU producers represent a non-negligible share of the EU market with treated materials which is estimated at €22.2 billion per year; for example imports amount to 10-20% of the EU market for treated wood and 25 to 40% of the EU market for wool carpets (5).

Apart from the possible negative environmental and human health impacts, this situation places in particular the EU producers at a disadvantage with respect to the

[17] RAPEX is the EU rapid alert system for all dangerous consumer products, with the exception of food, pharmaceutical and medical devices. It allows for the rapid exchange of information between Member States via central contact points and the Commission of measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers.

EU market. This is due to the fact that EU producers of treated materials can only buy authorised biocidal products containing approved active substances as only these can be lawfully placed on the EU market. Non-EU producers of treated articles do not have to bear the costs of compliance with the Directive and to participate in the cost of the evaluation of active substances and authorisation of biocidal products used in the treated materials. This effectively renders the EU producers of treated materials less competitive compared with non-EU producers of these materials.

2.3.2. Policy issue 2: Product authorisation is too complex

The evaluation of active substances is done at *Community level* and the subsequent authorisation of products containing the approved substances (i.e.: those listed in Annex I of the Directive) is done at the *national level*, by Member States. As mentioned above, the product authorisation stage has not yet been implemented. Until it is implemented, some Member States operate national product authorisation schemes based on their national legislation. However, it should be noted that some Member States with high estimated numbers of products do not have authorisation procedures in place at the moment (e.g. France, Germany). There are no statistics on the lengths of the national proceedings or the appeal options available to the applicants.

An important element of the Directive is the principle of *mutual recognition* of authorisations. In accordance with that principle, a company, once it has obtained for a product a first authorisation in a Member State, may apply for the mutual recognition of that first authorisation by other Member States.

As mentioned above, because the product authorisation has not yet started, no practical experience of the authorisation and mutual recognition procedures is available. However, experience from other regulatory frameworks such as plant protection products (14), indicates that some changes might help in anticipating future problems.

Mutual recognition of product authorisations is considered as the major benefit of the Directive. However, stakeholders expressed concerns regarding the effective and homogenous application of mutual recognition. Concerns relate to the difficulty for Member States to trust each other's assessment of a dossier, due to divergent interpretation of data requirements, or to different national approaches regarding the level of protection on the national market, resulting in requests for additional tests. The representatives of the industry expressed their concerns that some Member States may systematically require additional information including testing and repetition of the efficacy studies for the purposes of the mutual recognition. This would render the process very time and cost intensive for the industry as well as for the competent authorities which would have to evaluate the additional information.

In addition, the negative past experience with mutual recognition of Plant Protection Products is the basis for these concerns. This concerns mainly the lack of mutual trust among the Member States. An example of a functioning system of mutual recognition exists under the Medicinal Products legislation, which has now been in operation for more than 10 years. The success there was built gradually on basis of informal cooperation between Member States, the use of guidance documents and the experience gained through disagreements concerning the mutual recognition.

2.3.3. *Policy issue 3: Rules for data sharing are insufficient*

The Directive provides for a system of data protection, which prevents Competent Authorities from using data submitted by a first applicant for the benefit of a subsequent applicant, unless the first applicant has agreed to it. This system is intended to ensure that data owners can recuperate the costs of their investments.

The Directive urges applicants to co-operate in compiling the necessary data for the evaluation of both active substances and biocidal products, but it does not explicitly provide for a system of mandatory data sharing. Instead, the data owner may decide – but is not obliged – to give a subsequent applicant the right to refer to its data by granting a 'letter of access'. Whenever an agreement cannot be reached between the data owner and the subsequent applicant, the latter may be either obliged to duplicate the studies (particularly undesirable where animal studies are concerned), or to abandon the market.

The fact that data sharing is not obligatory has given rise to problems for industry and competent authorities.

Data sharing aims at avoiding the submission of multiple dossiers for the same active substance. This was particularly relevant for the Review Programme, to limit duplication of work and complication of the evaluation process. Data sharing aims also to avoid the duplication of testing on vertebrate animals.

Data sharing is primarily relevant for the tests done with the *active substances*. The issue of data sharing will however also arise in relation to *biocidal products* as dossiers for product authorisation must contain data on the active substance. In the absence of a mechanism of forced data sharing, companies unable to obtain a letter of access would need to re-generate certain key data or abandon the market.

There is a concern amongst stakeholders that under the existing rules manufacturers of active substances who are also biocidal product manufacturers would refuse letters of access to competing product manufacturers, thus restricting new entrants access to the market.

2.3.4. *Policy issue 4: Data requirements are too extensive*

The requirements of the Directive in terms of toxicity and ecotoxicity studies aim at guaranteeing a high level of protection for human and animal health and for the environment and do so effectively.

These data requirements are however a major burden for companies that intend to support active substances. The costs of performing all the studies required are high, estimated at maximum 3-5 million EUR (6), and the active substances would need to be marketed over a long time to recover these costs. This has led industry to focus its resources on supporting existing active substances within the Review Programme rather than on the development of new ones; second to abandon its support of certain existing active substances, when there was no prospect of an economic return on the investments to be made. Furthermore, these data requirements are perceived as excessive for certain substances that are considered to be of low risk. Data waiving is, therefore, a crucial issue, especially for very low exposure products.

The possibility to waive data requirements is provided for under the Directive. There is however no clear guidance on data waiving and the application of this principle is left to the discretion of the Member States, which can lead to different approaches and entails the risk of unequal treatment.

2.3.5. Policy issue 5: Fees charged by Member States for carrying out the procedures of the Directive are high and varying and the conditions for payment are unclear

The main problem with the current provisions on fees is that they contribute to the heterogenous fee structure and significant differences in the levels of fees applied currently by Member States. Furthermore, it should be noted that the conditions of payment currently also vary among the Member States.

Varying and high fees

According to the existing provisions, it is currently the Member States who are responsible for deciding on the structure and level of fees. The Directive only requires that the fees correspond as far as possible to costs incurred by the Member States in carrying out all the different procedures associated with the provisions of this Directive. Some Member States understand this in a way that "all procedures associated with the implementation of the Directive" shall also include for example enforcement. As a consequence, the fees in some Member States may reflect a much wider scope of costs than those linked to the individual product authorisation application. In addition, the rules for setting fees differ significantly. In some Member States, the fee is determined according to a model calculation which takes into account the risk profile of the product. In others, the risk profile will not be considered at all.

There are differences in the structure and level of fees from one Member State to another: fees vary by a factor of more than 10 for product authorisation, by almost as much for active substance evaluation (Figure 1) and by a factor of more than 100 for mutual recognition (5).

The fee may account for a significant portion of the total costs of supporting an active substance (from 5% to 75%). Industry has indicated that fees are disproportionately high for SMEs and act as a disincentive to the development of new active substances. This may hinder the innovation, in particular with respect to low risk biocidal products.

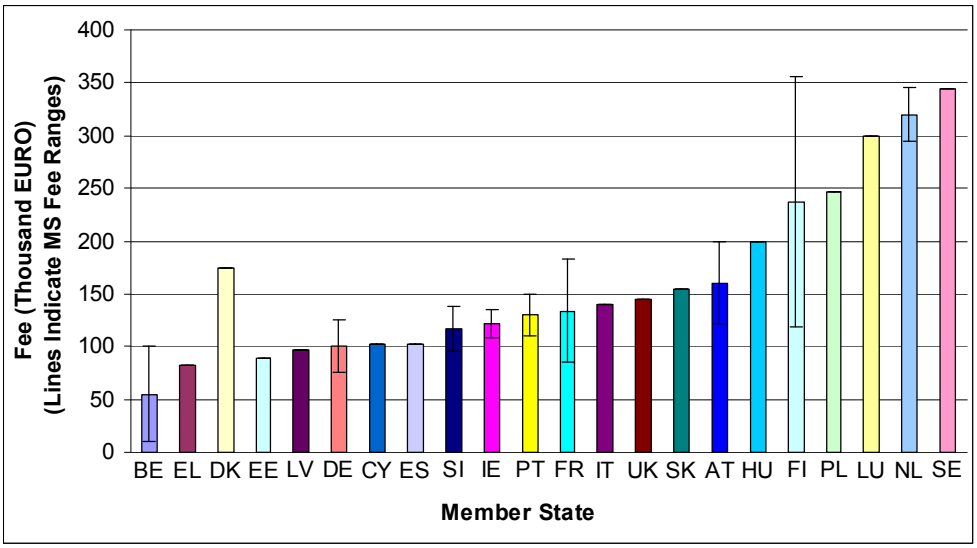

Figure 1: Member State Fees and Fee Ranges for Active Substance Evaluation

It is likely that the main reasons for the differences in the level of fee are the national attitude to cost recovery. In some Member States, the competent authorities directly finance their activities (and thus their costs) through the fees. In others, the competent authorities receive a contribution from the national budget independent of the fees received.

The fact that fees differ between Member States might encourage industry to submit product dossiers in Member States applying lower fees, leading potentially to an overload of work for these Member States and a loss of revenue for the more expensive ones. In practice, the level of fees is, however, only one factor in the industry choice of which Member State to submit a dossier, others include competence, responsiveness and approach towards data waiving.

Unclear conditions for the payment of fees

There are also variations in the conditions of payment. Some Member States enable payment in instalments and reimburse the fee or its part after a negative result of the completeness check. Other Member States require an upfront payment and do not reimburse the fee or its part if the application does not pass the completeness check. This is mainly a problem for SMEs for which paying the entire fee upfront may represent a significant financial burden.

2.4. It should be noted that the structure of the fees, the fee levels and the payment conditions may have an adverse impact on the decision as on how many countries the company will intend to place its products. This may lead to problems with product availability in countries with relatively small market and high fees. High fees may also have a negative impact on the innovation, in particular of SMEs.The principle of subsidiarity

According to the subsidiarity principle, in areas which do not fall within its exclusive competence, the Community shall take action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can

be better achieved by the Community. This principle is of high relevance to all policy areas discussed under this impact assessment.

Currently, the granting of product authorisations is in the competence of Member States whereas the evaluation of active substances is done at the Community level. With respect to data sharing, Member States have currently the possibility to introduce national measures obliging the applicant and holders of former authorisations located within their territory to share the data on vertebrate animals. The Member States are also currently responsible for setting the fees for the procedures under the Directive. Any changes to this division of tasks between the Commission and the Member States would have to comply with the subsidiarity principle. More on the individual policy options and their compatibility with the subsidiarity principle can be found in Section 5 (Analysis of impacts).

3. OBJECTIVES

The aim of the revision is in line with the Commission's strategic objectives and better regulation principles (24),(25),(26),(27), to improve and make the regulatory provisions more effective and efficient, reducing unnecessary burden for Member States and industry whilst maintaining a high level of protection of human and animal health and the environment.

The **general objective** is to review the Directive in order to:

- Facilitate the harmonisation of the EU market for biocidal products;
- Continue to provide a high level of protection for humans, animals and the environment;
- Increase the competitiveness of the EU industries affected by this Directive.

In order to achieve the general objectives and address the different problems identified, the following **specific objectives** have been established:

- Ensure coherence of the scope of the Directive, in particular with respect to treated materials;
- Simplify the product authorisation system;
- Avoid duplication of tests on vertebrate animals and reduce the number of animal lives used in the tests;
- Improve the provisions for low risk biocidal products in order to encourage development of such products;
- Provide clarifications and increase legal certainty on waiving of data requirements;
- Improve the proportionality of fees and clarify payment conditions.

4. POLICY OPTIONS

4.1. Policy issue 1: Scope

The policy options presented below are cumulative. In fact, they look at whether the scope should be extended and if so, to what extent, to ensure an overall coherence in the approach towards delimiting the scope. Different options are considered including the extension to food processing aids, food contact materials and treated materials.

4.1.1. Option (a): Unchanged policy

In this option only the list of Community legislation mentioned in Article 1 of the Directive would be updated to take account of developments in other Community legislation. This option does not imply regulatory changes.

4.1.2. Option (b): Extend scope to cover processing aids and food contact materials

This option would imply regulatory changes to include processing aids and food contact materials in the scope of the Directive.

Extension of the scope of the Directive to include *food processing aids* could be achieved by amending Article 1(2), which addresses the interaction with other EU legislation and also by amending Annex V, the list and definition of different product types. Further provisions may be needed to incorporate biocides used to remove surface contamination of animal carcasses, as these are addressed in Regulation (EC) No 853/2004 (28). This would have the objective to coordinate the procedure for approval of processing aids other than potable water under this Regulation with the procedures provided for under the Directive.

Placing on the market of food contact materials is not within the scope of the Directive under Article 1(2). If surface biocides for food contact materials were brought under the scope of the Directive, the question arises under which product types[18] they would be evaluated. The most suitable product types seem to be product type 7 or 9 (film and plastic preservatives). This is because surface biocides are intended to protect the material itself. Assigning food contact materials to product-type 7 or 9 might reduce the efforts required for dossier preparation and evaluation, as substances used as surface biocides will have already been assessed for very similar types of use[19].

4.1.3. Option (c): Extend scope to cover treated materials

The option would consist of the adoption of a general obligation that only materials treated with biocidal products authorised under the Directive in order to protect the material itself could be placed on the EU market. If a company wishes to place on the

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[18] Biocidal products are classified in 23 product types. These product types are also used at the stage of evaluating active substances – active substances are always evaluated for a certain product type (e.g. carbon dioxide for product type 14 (rodenticides)).

[19] This refers to a situation when an active substance used in food contact material has been already evaluated under the Biocides Directive, for example for its use as a film preservative in plastics.

EU market a material treated with a biocidal product that has not been previously authorised in the EU, a full assessment of that product under the Directive would be required. The US has a system similar to this (7).

This option would also require *labelling* for all or the most relevant treated materials, to facilitate enforcement and to enable informed choices by consumers. Quality labels are already in place for several product-types, e.g. ecolabels, national labels of industrial organisations and in Sweden and Germany, a system for labelling treated wood. Such labelling could follow the approach in Article 15 of Regulation (EC) 1935/2004 (19), including:

– the indication "treated with approved biocide" or a symbol illustrating this (one would have to be developed for this purpose).

– the name of the active substance and the number of product authorisation could also be included;

– if necessary, any special instructions to be observed for safe and appropriate use and disposal;

– name or trade name and address of manufacturer, processor, or seller responsible for placing the treated material on the market.

As an alternative, companies placing treated materials on the EU market could be required to undertake self-certification. The self-certification could be modelled on the system which exists under the ROHS Directive (21) . Producers and importers of electrical and electronic equipment voluntarily label their products as not containing any of the hazardous substances prohibited under the ROHS Directive by using material compliance declarations. Alternatively, a system of third-party certification could be envisaged where companies placing treated materials on the EU market would be required to obtain a certificate from a designated body.

The option would require Member States to ensure adequate *enforcement* of its provisions through market surveillance mechanisms so as to ensure that treated materials sold in the EU contain authorised biocides only.

4.2. Policy issue 2: Product authorisation

The policy options concerning the product authorisation as presented below are alternatives but within them certain elements could be combined (e.g. strengthening of mutual recognition with Single Member State authorisation *or* strengthening of mutual recognition with Community authorisation).

Mutual recognition as it exists today could provide significant benefits by enabling biocidal products to be sold in all Member States without the need for re-formulation and at lower costs than seeking separate authorisation in each Member State.

The options presented below provide solutions for the problems outlined in section 2.3.2. In addition, they aim to provide incentives for innovation directed at low risk biocidal products and products based on new active substances.

4.2.1. Option (a): Unchanged policy

In this option, the Commission would continue to facilitate mutual recognition by providing support to the informal group, composed of Member States representatives. This group has been set up to provide a forum to discuss general issues of mutual recognition, to develop guidance documents on mutual recognition and to discuss specific products that could be considered problematic during mutual recognition procedures. This option does not imply regulatory changes.

4.2.2. Option (b): Strengthening of mutual recognition

This option would include regulatory changes to clarify and improve the provisions on mutual recognition and on conflict resolution in particular.

Mutual recognition would be improved in two ways:(1) Applicants could submit in parallel the application for the first authorisation and the application for the mutual recognition of that first authorisation. This would allow the different Member States concerned to interact during the assessment of the dossier by the Reference Member State and would thus streamline and facilitate the process of mutual recognition. (2) Member States could take the initiative to launch a mutual recognition procedure, when they receive an application for the authorisation of a product already authorised in another Member State. In that case, the second Member State would not assess the application and would wait to receive the assessment report of the first Member State before granting the authorisation on the basis of the conclusions of that assessment report.

These modifications are based on similar provisions under other Community legislation (12),(13),(14). At present, neither is possible.

4.2.3. Option (c): Single Member State authorisation

A biocidal product authorised in one Member State could be placed on the entire EU market, without the need for any further administrative procedures, other than complying with labelling rules.

The system would include a clause stating that Member States may object to authorisation within a certain time period. The conditions for objections would be described in a detailed and clear way. Objections would be notified to the Commission and dealt with in the Standing Committee.

If there are no objections and the product is authorised, the applicant would then notify any other Member State that it wishes to market the product, and submit a proposed label, packaging and safety data sheet for approval (i.e. in particular, in the national language).

During stakeholders' consultation, Member States opposed this system on the grounds that it reduces the role of the individual Member States in the authorisation process. To take account of it, this option could work as part of a dual system: certain categories of biocidal products would receive single Member State authorisation, while others would go through Member State authorisation and mutual recognition (options (a) and (b)).

4.2.4. Option (d): Community authorisation

Community authorisation, directly valid in the 27 EU Member States, would be issued at the Community level.

A specific procedure for product authorisation would be created, 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 Directive, the role would have to be given to an existing agency set up under other Community legislation. The agency would be involved in the risk assessment of biocidal products either by preparing the assessment or giving an opinion on the Rapporteur Member State assessment.

Some stakeholders, in particular representatives of the industry, expressed a support for a fully centralised system of Community authorisations applicable to all biocidal products. This option was initially considered but due to the following reasons not further pursued:

– the operation of a fully centralised system of Community authorisations would require significant financial and human resources (e.g. operative costs of the Agency, costs of organising the meetings of experts, etc.)

– the total number of biocidal products is high – between 4.500 to 9000 products[20] – and all of them would have to pass through the centralised system in a limited time (around 10 years) after the entry into force of the proposal;

– the sensitivity of some Member States with regards to the authorisation of certain product types (e.g. disinfectancts) should be taken into consideration.

As a complete centralisation may not be possible due to the above-stated reasons, a partial centralisation could be proposed for just two types of products:

(1) Biocidal products based on new active substances;

(2) Low risk biocidal products, potentially without a prior active substance approval

– this will also need to include a screening phase to assess whether the products submitted do indeed match specified criteria for low risk (see section 4.4.3).

This option could also work as part of a *dual system*: certain categories of biocidal products (low risk products and products based on new active substances) would receive Community authorisation, while others would go through Member State authorisation and mutual recognition (options (a) and (b)). This option would include measures aimed at increasing the efficiency of the mutual recognition system. This would maintain the current role of Member States with respect to the product authorisation in accordance with the subsidiarity principle.

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[20] This number is an estimate provided in the RPA Report. On the basis of stakeholder consultation, the total number of biocidal products may be higher as some Member States, in particular Germany, report a total number of 18.000 biocidal products. This number may, however, contain many duplicate entries. In addition, it is expected that the market will consolidate after the end of the Review Programme.

It should be noted that the Community authorisation scheme would be optional – companies would have a choice to go through the Community authorisation system or apply for an individual Member State authorisation. The latter may be more interesting for companies which want to market their products only in a limited number of Member States.

4.3. Policy issue 3: Data sharing

The policy options presented below are mutually exclusive. They all address the same problem and offer different solutions to it.

4.3.1. Option (a): Unchanged policy

The current system of voluntary data sharing at the product authorisation stage, with the possibility for Member States to introduce rules requiring mandatory sharing at national level, would be maintained. It is foreseen to clarify the requirements and further encourage data sharing. These improvements would not result in changes to the current policy on data sharing.

4.3.2. Option (b): Mandatory sharing of vertebrate animal test data at product authorisation stage

This option would make the sharing of (and compensation for) vertebrate animal test data mandatory at the *product authorisation* level. A company requesting a product authorisation would be required to contact the Competent Authority to get a permission to carry out the tests or to find out who holds the data before undertaking any animal testing.

Applying the "REACH model"[21], the Competent Authorities would inform the applicant of the names and addresses of the company which previously carried out any relevant studies which are still protected by data protection provisions. To ensure that data sharing works properly, a centralised inventory of studies could be set up by the Commission, along the lines envisaged under REACH, to ensure that all the information needed is accessible. Where a study involving tests on vertebrate animals has been carried out while they were still protected by data protection provisions, the applicant would be required to request from the previous company the information he needs in order to make its application for authorisation. The data holder would then have to share its data with the applicant, with an effective compensation procedure for the costs to be shared on a fair and transparent basis.

A clause on dispute resolution by arbitration would also be added. The provision could indicate that the data holder and the 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". If there is a failure to reach an agreement, the potential applicant(s) would inform the Commission/Agency, which

[21] See Title III of the REACH Regulation (EC) No 1907/2006 – obligatory data sharing of vertebrate animal data in exchange of compensation and equal sharing as default compensation mechanism in case of disagreement

would have the ability to give the applicant the authorisation to use the data upon payment of a share of the costs (this would be subject to the possibility of appeal).

4.3.3. Option (c): Mandatory sharing of vertebrate animal test data at product authorisation stage and active substance approval stage

The obligation to share data would be expanded to *cover the evaluation of active substances as well as the product authorisation stage*. This would mean that if an applicant for example wished to apply for an inclusion of a substance in Annex I for a new product type, he/she would be able to obtain the data from the previous applicant in exchange for compensation. The procedure could be similar to that outlined for the sharing of data at the product authorisation stage (see Option b)).

In order to stimulate innovation and encourage companies to invest in the development of better and safer chemicals an exception might be proposed for new active substances where for the first 10 years (out of 15) of data protection, the sharing of vertebrate animal tests would be voluntary and not compulsory.

4.4. Policy issue 4: Data requirements

The three policy options presented below are cumulative. The options address two types of problems: high data requirements and low attractiveness of the existing simplified procedures, in particular Annex IA (low risk substances) and Annex IB (basic substances).

4.4.1. Option (a): Unchanged policy

This option retains the existing provisions and the current system. As part of the business as usual approach, 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. It is important to note that these clarifications would not entail changes to the current policy on data waiving.

It is also foreseen to prepare detailed appropriate guidance in the form of Notes for Guidance, published in the Official Journal.

4.4.2. Option (b): Rewording provisions concerning data waiving and the use of existing information

It should be noted that the measures proposed below have similar objectives; however, they look at the issues from different angles. There are strong links between the different measures (e.g. revising the core/additional data may lead to tiered data requirements).

Strengthen data waiving provisions: this option proposes to take into consideration the waiving grounds set out in Article 13 of REACH in the biocides methodology. The REACH text contains in Annex XI further guidance on the application of the waiving provisions, which could be used to provide higher certainty with regard to the interpretation of the waiving provisions in the Directive. This could be complemented by the use of official and more binding implementing rules.

An obligation for Member States could be included to inform applicants of their right to request a waiver including the grounds for such a waiver and provide assistance to applicants in this respect. These changes would significantly modify the current policy approach towards data waiving.

Revise the proportion of core data/additional data: for the evaluation of an active substance under existing provisions the applicant is required to submit a dossier satisfying the requirements of Annex IIA (core data which are identical for all active substances) and, where specified, the relevant parts of Annex IIIA (additional data). All data (core and additional data requirements) can be waived if appropriate justification is provided. However, some Member States have been reluctant to waive core data arguing that this data is core data and, therefore has to be submitted in all cases. This situation could be clarified by renaming Annex IIA and IIIA, specifying that waiving provisions are applicable to all data requirements or moving some core data to the additional data. In addition, the core data set could be thoroughly reviewed and data requirements could be tiered as below.

Use of existing information: more guidance on the possibility of using, where available, existing information (e.g. tests and studies developed under other legal frameworks) could be considered. This is similar to REACH, which also provides guidance on how to evaluate the information in terms of validity and reliability. The use of existing information could be extended by including a clause in the Directive stating that assessments carried out under other Community legislation shall be taken into account, where such legislation appropriately covers the objectives of the Directive. In addition, data requirements for product authorisation could also be reduced where the product has already been authorised under other Community legislation (with similar exposure scenarios and analysis of risks). The assessment carried out within the framework of the Directive could then be limited to aspects not assessed under these other pieces of legislation e.g. exposure and efficiency.

Tiered data requirements: using tiered data requirements would mean that only a limited set of data would be required upfront. If remaining concerns justify it, the competent authorities would be allowed to request additional data from the applicant. It might also be possible to link data requirements specifically to product-type; this would mean that product-types associated with use patterns which involve only reduced exposure would benefit from reduced data requirements. This would allow a more systematic data waiving or a tiered approach in determining the data set.

4.4.3. Option (c): Reformulating the system for low-risk substances

The key issue in revising the concept of 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 substance level alone. Around 50 biocidal active substances supported so far under the Directive are included in positive lists under other legislation[22], which are considered to indicate low risk.

[22] For example substances included in Annex IV and V of REACH Regulation (EC) No 1907/2006, US GRAS List, US minimum risk pesticides, etc.

Substances could be identified as being low-risk based on expert judgment (e.g. standing expert group) 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.

Alternatively, the definition of low-risk biocidal products would be introduced in combination with a direct authorisation of these products without their active substances being previously approved at EU level. This would avoid some of the major costs linked to the active substance approval and would make qualifying for low risk status much more attractive. A screening stage would be needed, whereby a rapid decision would be taken at the Community level on whether the product would be eligible as a low risk product. The screening process could be organised by the Agency which would decide on whether a concrete product qualifies as a low risk biocidal product. The final approval of the low risk products could either be made at the EU level (centralised procedure) or at the national level. In that latter case, mutual recognition could be applied to national authorisations.

4.5. Policy issue 5: Fees charged by Member States for carrying out the procedures of the Directive

The policy options set out below are alternatives but within them certain elements could be combined (e.g. harmonised fee structure with specific provisions for SMEs). In particular, the last option (Specific provisions for SMEs) is a rather horizontal option which can be combined with any system of setting fees.

4.5.1. Option (a): Unchanged policy

Under this option, the current system, with fees and conditions set at Member State level, would be retained with minor clarifications of the payment conditions, such as the timing of payment.

4.5.2. Option (b): Partially harmonised fee structure

This option would involve the partial harmonisation of fee structures in the Member States; Member States would remain free to set the level of fees, but the structure of fees would be mandatory. Three aspects of such a partial harmonisation have been considered in more details: (a) reduced fees for multiple submissions; (b) variation in fees by product-type; (c) payment by instalments.

Reduced fees for multiple submissions: 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. Those Member States that already apply reductions for subsequent product-types apply discounts of approximately 30% on average, of their initial fee (9). In addition, lower fees could also be set for simplified or "accelerated" reviews of similar authorisation cases, such as re-authorisation and minor changes in composition, as well as for low-risk products.

Variation in fees by product-type could be introduced if different data requirements for different product-types were adopted, to reflect the level of analysis needed. It 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.

Instalment system for payments to spread the costs for industry over the period of the evaluation procedure, with a separate fee levied for a completeness check. This might consist of charging a part of the fee at the beginning and the rest of the fee at the end of the process. It could also be specified that any unused fees, paid in advance, should be returned to the company if an evaluation could not be finalised. For example, if an application does not pass the completeness check and is not evaluated, the fees for dossier evaluation would be repaid.

4.5.3. Option (c): Centralised fee system

In this option, the standard fees would be set at the EU level by specifying the amount of 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. It should be noted that the Member States were opposed to such system on grounds of subsidiarity principle. The fees provided for under the REACH Regulation are set out by Commission Regulation (EC) No 340/2008 (15) and this Regulation applies to all Member States and may therefore provide a possible indicator of standard fees under the Directive.

4.5.4. Option (d): Specific provisions for SMEs

Reduced fees could be charged for SMEs, since high fees are more often an obstacle for SMEs to support substances or to keep their products on the market. Such fee reductions are offered by REACH: 30% for medium companies; 60% for small sized companies; and 90% for micro enterprises.

Another possibility is to introduce reductions on annual fees as is done in the legislation on medicinal products for products authorised by the Community. The annual fee would apply during the validity of the product authorisation. SMEs would then be eligible for a reduction of the annual fee.

4.6. Options discarded at an early stage

It should be noted that some policy options were discarded at an early stage of the impact assessment process.

Firstly, the option to repeal the Directive and place all biocidal products under the REACH Regulation or the Plant Protection Products Directive was not pursued further. This is mainly due to the fact that the Directive is a specialised legal act, adapted to the needs of this particular sector. For example the tiered tonnage approaches of the REACH Regulation are not well-suited to biocides, where some of the most dangerous products (e.g. rodenticides) may be produced using small quantities of the active substance. In addition, there was no support for these options from either the stakeholders or the Member States.

Secondly, the option to reduce (and combine) different product types was looked at in context of the product authorisation. However, the classification according to products types has an important impact on the evaluation of the active substance. As the Review Programme for the evaluation of existing active substances is ongoing, it was deemed too late to realistically pursue this option.

The issue of the use phase of biocides was briefly considered in the initial stages of the impact assessment. However, it was found that the issue of the use phase of biocides was not significant when taken in the overall context of the revision of the Directive. It was therefore decided not to pursue this further in the framework of this impact assessment.

5. ANALYSIS OF IMPACTS

It should be noted that the policy options in the five policy areas are largely compatible from the perspective of an overall policy package. For example, it would be possible to combine mandatory sharing of vertebrate animal test data at the product authorisation stage with unchanged policy on data requirements or a centralised fee system with unchanged policy on product authorisation. The only exception is the combination of a fully centralised authorisation scheme with an unchanged policy on fees (Member States being completely responsible for the fee structure, the levels of fees and the payment conditions) or partially harmonised fee structure. A fully centralised authorisation scheme would require a centralised fee system in which the fee structure, the levels of fees and the payment conditions are decided at Community level. An example for this is the REACH system operated with help of the European Chemicals Agency where the fees were set by means of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to the REACH Regulation.

Despite the fact that the policy options in all five areas are largely compatible, their simultaneous implementation may have impact on the costs and cost savings. For example, the above-cited combination of an unchanged policy on product authorisation and a centralised fee system may result into difficulties for some Member States. As the fees would be determined for all Member States centrally at the Community level, some Member States would be faced with a situation that their costs of evaluating a product authorisation application are not fully covered by revenues from the fees. On the other hand, in other Member States the revenue from fees may outweigh the costs of the application evaluation. For companies this would mean that they would have to pay more than necessary to review their product authorisation application.

Due to the lack of data it is not possible to include in the impact assessment information concerning impacts on various types of affected parties (big companies versus SMEs, substance producers versus product manufacturers) and to show how benefits/costs evolve over time.

It was not possible to quantify the impacts on employment due to the lack of basic market data on the biocides sector.

5.1. Policy issue 1: Scope

The three options introduced with respect to the scope of the Directive concern the question as to whether additional products should be included within its scope or not.

5.1.1. Costs and benefits of Option (a): Unchanged policy

This option implies no additional costs and no significant benefits.

5.1.2. Costs and benefits of Option (b): Extend scope to cover processing aids and food contact materials

Including biocides used as food processing aids within the scope of the Directive would give rise to administrative costs for industry in preparing applications for the authorisation of about 3-7 active substances and an unknown number of biocidal products used as food processing aids, as well as the costs of the mutual recognition of these products. The **costs for industry** could range from **€4.5 million to €35 million[23] for the inclusion of active substances** and **from €5 million to €51 million[24] for the authorisation of biocidal products**, depending on the assumptions adopted. These costs would be incurred over a longer period of time necessary for the implementation of such provisions (around 10 years). For the inclusion of active substances, the figures are based on two scenarios with respectively 3 and 7 active substances to be supported for inclusion. For the authorisation of biocidal products, two scenarios were developed for 42 and 196 additional biocidal products to be authorised.

Competent authorities will face administrative costs for the assessment of applications for active substance evaluation and product authorisation combined with mutual recognition, where appropriate. They will not face any net costs, however, assuming that the level of fees they charge are sufficient to meet their costs.

On the other hand, bringing food processing aids under the Directive may provide a **benefit of a greater regulatory certainty to industry**. It is also likely to bring about some **environmental benefits**, due to increased control of processing aids and possibly a reduction in their use or a shift towards lower risk products and uses. However, a quantification is not possible due to uncertainty about the risk profile of the aids and actual responses to the proposed policy change.

Including biocides used in food contact materials within the Directive would require inclusion in Annex I of the Directive of the active substances they contain; this could **cost industry a range from €5 million to €50 million[25] for the inclusion of active substances**, depending on the assumptions adopted, and from **€8.3 million to €73 million[26] in biocidal product authorisation spread over a period of 10 years**. The costs of active substance inclusions are based on two scenarios with 5 and 10 substances to be included. For product authorisations, the costs are based on 70 and 280 additional biocidal products to be authorised.

5.1.3. Costs and benefits of Option (c): Extend scope to cover treated materials

The cost and benefit evaluation focused on two types of treated materials: water-based paints containing in-can preservatives and treated wood. These sectors were chosen because they have quite different characteristics and thus the analysis provided a broad range of potential impacts.

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23 Net present value €3.8 million to € 29.3 million discounted to the start of the period using 4% discount rate.

24 Net present value €4.1 million to €42.7 million

25 Net present value € 4.2 million to € 41.9 million

26 Net present value € 6.9 million to € 61.2 million

The **total costs of the inclusion of additional active substances for importers**[27] **of all treated materials would be in a range between €36 million and €140 million**[28] **spread over a period of 10 years**. These costs depend on the number of additional active substances to be included in Annex I and the average cost of Annex I inclusion per substance (between €3 and 5 million).

The **total costs of authorisation of biocidal products for imported treated materials** would be in a range from **€3.6 million to €52 million**[29] **spread over a period of 10 years**. The costs depend on the number of biocidal products applying for product authorisation and the average costs of the authorisation (between €90,000 and €200,000). In practice, switching to biocidal products that are already authorised under the Directive may be a less costly option for concerned third-country producers. This would also mean that the trade implications would be minimal.

However, it should be stressed that the cost is rather low when compared to the value of the sales. For example, the costs of Annex I inclusion of additional active substances with regard to imported water-based paints are **0,5 to 1,7% of the value of imported paints spread over 10 years**. For imported treated wood, these costs would reach **0,8 to 2,1% of the value of imported timber spread over 10 years**. Similarly, the costs of the authorisation of additional biocidal products would be **0,04 to 0,15% of the value of imported water-based paints spread over 10 years** and **0,1 to 2,4% of the value of imported timber spread over 10 years**.

This option would also pose costs to both importers and EU manufacturers for labelling of treated materials. The **total costs of labelling could range from €154 million to €514 million**[30] for all treated materials (5). The costs would be incurred over a period of 10 years to allow for the implementation of these provisions. These costs represent **0.07 to 0,23% of the estimated total market turnover of all treated materials placed on the market in the EU spread over 10 years** (5). An alternative to labelling would be self-certification, which would impose lesser costs for industry but would generate lesser consumer benefits and could make market surveillance more costly and difficult.

It will also imply additional costs with regard to ensuring that only authorised biocidal products are used; and some additional **costs to the Commission and Competent Authorities**, in relation to additional product authorisations as well as the need to train customs officials to ensure understanding of the enforcement issues such as the new labelling requirements as well as the product identification and testing.

Extending the scope of the Directive to include treated materials will imply **benefits to EU industry** in the creation of a level playing field with third-country manufacturers of treated materials. This may in particular improve the position of EU industry on the EU market with treated wood (imports amount to 10-20% of the market) and wool carpet (imports amount to 25-45% of the market). This may also

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27 As mentioned in Section 3.2.1.3, EU manufacturers of treated materials already use only authorised biocidal products.

28 Net present value € 30.2 million to € 117.3 million

29 Net present value € 3.0 million to € 43.6 million

30 Net present value € 129.0 million to € 430.1 million

improve the situation of SMEs, which produce and place treated materials on the EU market.

By ensuring that all active substances and biocidal products in treated materials are subject to strict testing and authorisation procedures, this option is expected to have potentially **significant benefits in terms of the health and environmental impact** of materials placed on the EU market. The environmental and human health impacts are likely to be significant given the size of the market with treated materials in the EU. The environmental and health benefits are, however, difficult to quantify due to missing evidence linking the use of biocidal products to quantified impacts on health and the environment. However, some anecdotal evidence on the benefits is available. This evidence mainly concerns imported products such as treated wood or treated textiles which contained unauthorised substances. The exposure to these substances can lead to severe allergic reactions, in particular in cases of old people, children, people with reduced immunity system, etc. The consequences include hospitalisation, the costs of medical treatment, the costs of missed days at work, etc. Environmental impacts include leaching of such hazardous substances to soil and groundwater, impacts on aquatic organisms and the local ecosystems.

In addition, it would also provide for an improved protection of workers' health with respect to intermediate goods (e.g. leather used for the production of textiles or wood used for furniture) and allow consumers to make informed choices.

5.2. Policy issue 2: Product Authorisation

5.2.1. Costs and benefits of Option (a): Unchanged policy

Compared to the current situation, this option imposes negligible **administrative costs on the Commission, Competent Authorities and possibly selected industry** representatives in terms of organising additional meetings to prepare guidance documents and discussing specific product issues.

Under current legal framework, the **overall administrative costs of product authorisation to the industry would be € 2.9 billion[31] spread over a period of 10 years.** These costs are based mainly on the number of products, the frequency of mutual recognition and the rate of referral to the Commission in case of disagreement about the mutual recognition. These costs are based on the assumption that Member States may require additional information during mutual recognition. In addition, it assumes that companies intend to place their products on a high number of markets. In reality, companies may choose to limit the number of markets in which they are active.

The most important costs would be those of the current situation and would be associated with **possible delays and even a failure of the mutual recognition process**. The failure of mutual recognition is likely to be particularly problematic for SMEs which cannot afford the costs of additional full product authorisation fees if they intend to market their products in more than one Member State. However, as the overall market for biocidal products is unlikely to change significantly, market losses for some companies will be balanced by gains for others.

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[31] Net present value € 2.4 billion

The costs of mutual recognition to Member States are assumed to be covered by the fees charged. However, there is a risk that some Member States could face an overload of dossiers for review, resulting in delays in authorisation decisions. The **failure of mutual recognition could result in reduced product availability** in some Member States with smaller markets.

The costs of this baseline scenario depend on the number of products, which will be authorised via mutual recognition, and the number of cases where Member States will not be able to agree and where the matter will have to be referred to the Community level for settlement. For this baseline scenario, it has been assumed that between 10 and 50% of all products would be authorised via mutual recognition and that the rate of referral would be 30%.

5.2.2. Costs and benefits of Option (b): Strengthening of mutual recognition

Under this option both the **Commission and Competent Authorities** will face **direct costs** associated to facilitating the process of mutual recognition similarly to Option (a).

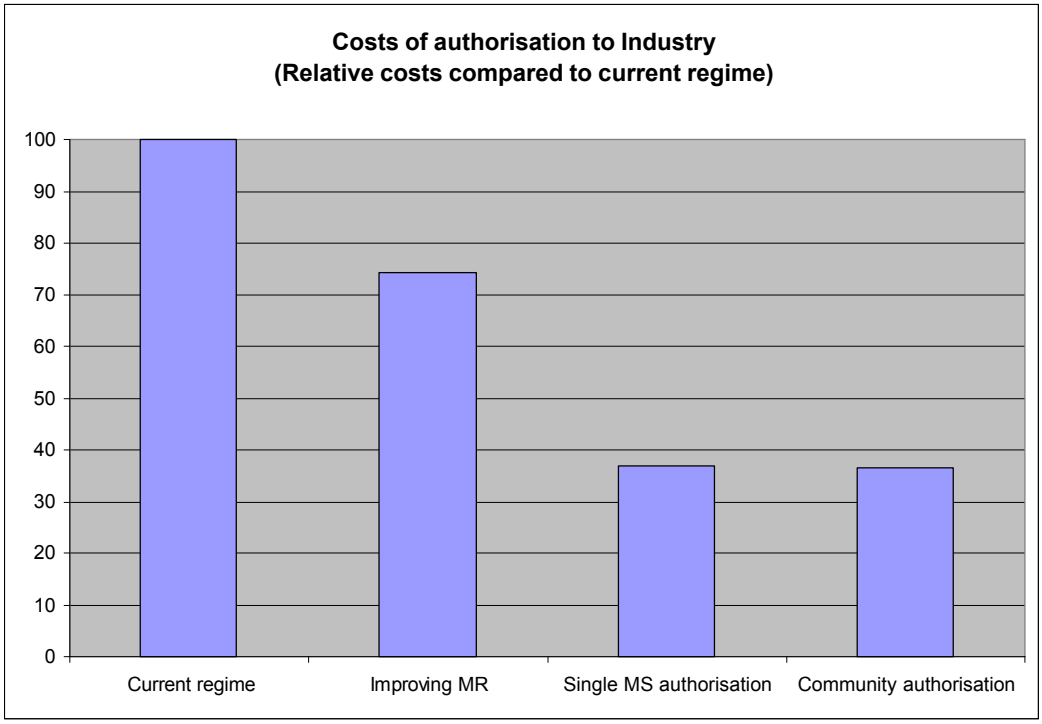
For **Competent Authorities** in charge of product dossiers, this option may pose additional **administrative costs for co-ordination** with other Member States. This cost may fall disproportionately on a small number of "respected" Competent Authorities. This cost could be compensated for by an increase in the fee payable to the authority in charge of the dossier assessment. By reducing the administrative costs of product authorisation, this option may encourage industry to increase the number of products that it places on the market, and/or to place each product on a larger number of markets. It could also result in a larger number of products remaining on the market.

Improving and strengthening the mutual recognition procedure should create greater legal certainty. The **total administrative costs to industry** under Option (b) are estimated at **€ 2.2 billion**[32] **spread over a period of 10 years**. They are at around **75% of those of Option (a)** (see Table 1). The costs depend, as for Option (a) on the number of products, which will be authorised via mutual recognition, and the number of cases where Member States will not be able to agree and where the matter will have to be referred to the Community level for settlement. For this scenario, it has been assumed that between 30 and 70% of all products would be authorised via mutual recognition and that the rate of referral would be 10%.

Table 1 compares the costs expressed in percentages to industry of the different product authorisation options.

[32] Net present value € 1.8 billion

Table 1



5.2.3. Costs and benefits of Option (c): Single Member State authorisation

A single Member State authorisation, where a biocidal product authorised in one Member State could be placed freely on the EU market, would reduce costs for industry because only a single application for authorisation would be needed. The **total administrative costs** of this option **to the industry are estimated at € 1 billion[33] spread over a period of 10 years**. The administrative costs would be **below 40% of those of Option (a)** (see table 1); the reduction in costs would be particularly significant for SMEs placing products on several Member State markets. The costs again depend mainly on the rate of referral of applications to the Community level, which has been estimated at 10% of all applications.

The option should also significantly **reduce costs to Competent Authorities** as only one Member State would review the dossier. However, there is a risk that due to easy access some Member States will experience a high number of applications leading to potential problems with resources and possibly delays. Other Member States may receive few applications, generating insufficient revenue from fees to retain the necessary expertise in dossier assessment. This option could imply a high number of objections from the other Member States which have not assessed the dossier, which would increase the administrative costs for dispute resolution. These costs would not be covered by product authorisation fees.

A single Member State authorisation **should not result in any impacts on public health**, as the data requirements would not change. However, a number of Member States have expressed concerns that assessment by one Competent Authority only

[33] Net present value € 0.84 billion

might not take full account of potential health and environmental impacts across the EU.

5.2.4. Costs and benefits of Option (d): Community authorisation

A system of Community authorisation for product authorisation would require the role to be given to an existing agency set up under other Community legislation. The agency would require 100-150 staff, with **operating costs of €18 million to €20 million**[34] **per year**, which would be in part recovered in fees. For comparison, the European Chemicals Agency (ECHA) is expected to have around 450 staff and the budget of €90million per year. The European Agency for the Evaluation of Medicinal Products (EMEA) operates with 500 members of staff and an annual budget of more than € 160 million (23).

There would be a net saving in costs to public authorities, because of reduced duplication of work. The **costs to industry** would be similar to the costs of a single Member State authorisation, at **€ 1 billion spread over a period of 10 years**[35]**,** and at **less than 40% of the costs of Option (a)** (see table 1).

A system of Community authorisation would likely improve the product availability as the costs of the Community authorisation would be lower than the costs of Member State authorisations combined with the costs for the mutual recognition.

There could be additional **benefits to health and the environment** as the assessment by a central authority would improve the overall consistency.

However, as explained above (see sections 4.2.3 and 4.2.4) both a Community authorisation and a single Member State authorisation scheme on its own are unlikely to be supported by the Member States.

A dual system could however be applied in which only certain products would be eligible for a Community authorisation. The rest of the products would obtain a Member State authorisation and could go through a mutual recognition process if there is an interest to market them in more than one Member State. Such **a dual system would better reflect the principle of subsidiarity** by maintaining the role of Member States with respect to the product authorisation of a majority of products.

Compared to Option d) and a full centralisation, such a dual system would not offer the same magnitude of efficiency gains to the costs of industry as only certain categories of products would pass through the centralised system. However, it would provide **some efficiency gains compared to Option a)**. The efficiency gains would stem from the different measures described under Option b) aimed to improve mutual recognition and the centralised Community authorisation for certain categories of products under Option d). The functioning of the dual system could however be revised after a certain period and additional products potentially included in the Community authorisation system.

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34 Net present value € 15.1 million to €16.8 million

35 Net present value € 0.8 billion

5.3. Policy issue 3: Data sharing

The main scope for data sharing is likely to be between applicants for product authorisation and holders of data on the active substance(s) contained within the product. Most stakeholders who were consulted believed that data sharing would work reasonably well, although some concerns were expressed.

The three options presented below address the problem related to high costs of compiling a dossier, in particular the dossier on the active substance, and the objective of reducing vertebrate animal testing.

5.3.1. Costs and benefits of Option (a): Unchanged policy

There will be some **cost savings to applicants** for product authorisation through a basic functioning of mutual recognition.

Developing improved guidance on data sharing would incur some **limited costs for the Commission services and Member States**. However, the data sharing guidance under the Directive could draw upon the guidance prepared for REACH and for the proposed Regulation on Plant Protection Products (22).

There would also be additional **costs to Competent Authorities** in setting up and maintaining registers of test and study reports for active substances. These costs would be offset by reduced duplication of assessment. There are no data available at present to estimate the scale of these **benefits to public authorities**. However, the impact assessment on the proposed Plant Protection Products Regulation (16) identified significant potential reductions in staff days needed per application through data sharing.

Increased data sharing could also help to ensure that a larger number of products remains on the market and reduce the numbers of vertebrate animal tests carried out.

There would also be **benefits to data holders**, who would gain some return on their costs for data generation.

5.3.2. Costs and benefits of Option (b): Mandatory sharing of vertebrate animal test data at product authorisation stage

Mandatory sharing of vertebrate animal test data at the product authorisation stage could **save applicants costs in the range from €675 million to €2.6 billion[36] spread over a period of 10 years compared to Option a)[37]**. The savings depend on the number of submitted product authorisation dossiers, the average number of active substances per dossier, the number of data sets needed, the percentage of vertebrate animal tests required to be repeated, and total costs of data sharing. These savings could be reduced, however, if the REACH approach of sharing costs equally as a default option in cases of disagreements was adopted.

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36 Net present value € 565.6 million to € 2.2 billion

37 It should be noted that cost savings in such scale are unlikely to materialise because they are based on the assumption that under the existing framework the companies would regenerate parts of the data package. In reality, many companies, particular SMEs, would be unable to face such costs and would stop marketing their products in the EU.

There could also be **benefits to public authorities** from data sharing, because they would not have to review new data sets. There are no data available at present to estimate the scale of these benefits, but they should be greater than for Option a) because of the obligatory nature of data sharing in Option b).

Furthermore, it would become easier to extend the inclusions of an active substance in Annex I to additional product types because the data sharing would facilitate the access to existing vertebrate animal data on the active substance. Mandatory data sharing could also help to ensure that a higher number of safer products remain on the market, with potential benefits for health and the environment. It will also prevent duplication of vertebrate animal tests at the product authorisation stage, which would result in a **reduction of the numbers of vertebrate animals required for repeated tests between 450,000 and 844,000 animals over a period of 10 years**. Thus, a great number of animal lives could be saved by this Option.

This option could have a potential **cost for some applicants** under the default for cost sharing, if it resulted in a requirement to pay for access to data up-front, rather than over a period of time through long-term supply contracts. If this happened, it could be particularly problematic for SMEs, which generally have fewer resources available for up-front payments. However, as the option encourages data owners and applicants to reach agreement on cost sharing, it should be possible for "staged" payment of this type to continue.

There could also be some **costs to those involved in placing biocidal products on the market** if data sharing led to an increased number of products on the market and, in particular, an increased market share for generic products. The impact assessment for the proposed Plant Protection Products Regulation (16) considered that this impact could be significant, but stakeholders consulted have indicated that other factors are more significant in determining the profitability of biocidal products.

In case of disagreements over data sharing (e.g. disputes on the costs of studies, identity of the substance), there would be additional costs to the applicants linked to the court proceedings or arbitration. However, there is an uncertainty as to the frequency of such disagreements and therefore, the quantification of potential costs is difficult. It is likely that companies will prefer out-of-court settlement of cases involving disagreements.

This Option could give rise to additional **costs for the Commission, in preparing guidance on data sharing**, similar to those of Option (a). There would also be additional **costs to Competent Authorities in setting up and maintaining registers of test and study reports** for active substances, similar to Option (a). If a centralised data system was set up, by the Commission, for example, the costs could be similar to those for the ECHA classification and labelling inventory, at around €130,000 to €260,000 per year.

5.3.3. Costs and benefits of Option (c): Mandatory sharing of vertebrate animal test data at product authorisation stage and active substance approval stage

Option c) could generate **additional benefits to industry, compared to Option a), in the range between €1.4 billion and €2.7 billion[38] spread over a period of 10 years**. The savings depend on the number of active substances reintroduced as a result of the mandatory data sharing, the average costs of active substance vertebrate animal test data and the number of manufacturers per substance.

Compared to Option (b), this means a net saving in the range between **€ 150 million and € 760 million[39] spread over a period of 10 years**.

Nevertheless, it should be noted that such high savings are unlikely because they assume that under existing legal framework companies would regenerate large parts of the studies for the purposes of the product authorisation. Companies, in particular SMEs, would unlikely be able to incur the costs for such regeneration and would probably stop marketing their products in the EU. The cost savings of Option c) would rather have the form of maintaining a wider choice of products on the market compared to Option a).

Compared to Option (b), it is unlikely that extending the requirement for data sharing to active substances would result in significant additional costs to public authorities, although some additional costs might be incurred in extending guidance on data sharing to include active substances.

There could also be **benefits to public authorities** from data sharing, because they would not have to review new data sets. There are no data available at present to estimate the scale of these benefits, but they should be greater than for options a) and b) because of the higher level of data sharing.

There would also be additional **benefits for active substances manufacturers**. Since most existing substances will have been evaluated at Community level by the time an amendment to the Directive is adopted, these benefits will only affect active substances evaluated after the change.

However, it is unlikely that completely new active substances will be introduced by more than one company, so there would be no possibility of data sharing. In addition, the proposal to exempt new substances from obligatory data sharing requirements for 10 years (out of 15 years of data protection) in order to stimulate innovation would limit the benefits.

There could also be some revenue losses for those involved in placing biocidal products on the market if data sharing led to an increased number of products on the market and, in particular, an increased market share for generic products. The impact assessment for the proposed Plant Protection Products Regulation (16) considered that this impact could be significant; there would also be issues of fairness, because of the lower costs faced by these new entrants to the market.

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38 Net present value € 1.2 billion to € 2.3 billion

39 Net present value € 125.7 million to € 636.8 million

In case of disagreements over data sharing (e.g. costs of studies, identity of the substance), there would be additional costs to the applicants linked to the court proceedings or arbitration. As mentioned in Option b), there is an uncertainty as to the frequency of such disagreements and therefore, the quantification of potential costs is difficult. It is likely that companies will prefer out-of-court settlement of cases involving disagreements.

The risk of duplication of vertebrate animal tests at both the product authorisation and active substance stages will be removed. The reduction in the numbers of animals through reduced duplication at the products authorisation stage will be the same as in Option b). In addition, the number of animals used at the active substance stage will be reduced by a number between 170,000 to 480,000 animals[40]. Therefore, this option will **reduce the numbers of animals used in duplicated tests by around 1 million in total over 10 years**.

5.4. Policy issue 4: Data requirements

5.4.1. Costs and benefits of Option (a): Unchanged policy – clarification

With further guidance and increased clarity regarding the data requirements of the Directive, there is the potential for the waiving of many tests and the routine use of data generated under other legislation. This could **reduce the costs to industry of testing for the purposes of product authorisation by a range from €698 million to €1.4 billion[41] spread over a period of 10 years**. This saving is based on two scenarios with 4,500 and 9,000 estimated applications across the EU 27 over the next 10 years.

The harmonisation of data requirements, including efficacy testing, also has the potential to reduce the likelihood of mutual recognition applications being refused by Competent Authorities.

The development of guidance would require some additional resources and discussions among **Competent Authorities**, but this would be offset by reductions in the time and effort that would have been used to evaluate additional tests. It is likely that SMEs in particular would benefit from improved guidance because they do not have the relevant information. There would also be potentially positive impacts on **product availability**.

If the assessment of waiving arguments based on existing guidance is carried out carefully, the level of protection should not be affected and there should be **no adverse environmental impacts**.

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40 It should be noted that the numbers are only estimates based on assumptions including the number of products, percentages of vertebrate data required to be repeated and the number of vertebrate animals per test. These assumptions do not take into account potential data waiving and specific data requirements for certain product types.

41 Net present value € 584.9 million to € 1.2 billion

5.4.2. Costs and benefits Option (b): Rewording provisions concerning data waiving and the use of existing information

There are a number of ways in which the data requirements of the Directive could be reworded, 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 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 (e.g. repeating efficacy testing in every Member State).

Based on theoretical modelling, data waiving has the potential to reduce active substance testing costs by 75% and product testing costs by 66%, giving **savings to industry of €85 million[42] for additional active substances and in the range from €341 million to €682 million[43] for product authorisations spread over a period of 10 years**. The savings are based on two scenarios with 4,500 and 9,000 estimated applications for product authorisation. This should provide an economic incentive for industry to increase the number of applications for product authorisation, in particular for new substances, with potential benefits for health and the environment. An increased number of products on the market would imply positive impact on the employment. In addition, **Competent Authorities** would save the time and effort that would have been used to evaluate the results of additional tests.

However, it should be noted that in practice, it may be difficult to realise savings of this scale. This is mainly due to the elements of uncertainty which require further data to support certain conclusions in the process of assessing the risks of biocidal products. Some degree of uncertainty linked to the risks of the biocidal products may be acceptable to the competent authorities, but the exact extent will vary.

There would also be a **reduction between 350,000 and 1.5 million vertebrate animals used for testing spread over the next 10 years.**

5.4.3. Costs and benefits Option (c): Reformulating the system for low-risk substances

The most significant benefit to industry may result from **the retention of additional low-risk biocidal products, which would otherwise not be supported**. It should be noted that low-risk products are a preferred alternative to other biocidal products because of the lower risk posed to human health and the environment. The benefits to human health and the environment can not be quantified because of the missing information on the risk profiles of low risk biocidal products and the number of products which may qualify as low risk biocidal products.

Positive listing of low risk substances could result in **cost savings to industry ranging between €159 million and €340 million[44] spread over a period of 10 years**, compared to the costs of active substance approval and product authorisation under the current system. The costs savings are greatest where low risk active

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42 Net present value € 71.2 million

43 Net present value € 285.7 million to € 571.4 million

44 Net present value € 285.7 million to € 571.4 million

substances are included in Annex IA, as this removes the need for testing at the product authorisation stage.

Reducing the requirements for low risk substances could also **reduce the numbers of vertebrate animals used for testing: a number between 30,000 and 343,750 vertebrate animals used over a period of 10 years**.

The impact for public authorities would be that dossiers and/or literature data on potential low-risk substances would have to be evaluated, but **Competent Authorities would save time and effort** that would have been used to evaluate additional tests. Reduced requirements for low risk products could have **a significant positive impact on product availability** and could increase the numbers of safe products placed on the EU market, giving public health and environmental benefits.

The **impacts on public authorities** will depend largely upon the definition of low risk products adopted and upon the data requirements for their authorisation. The Commission Services and Competent Authorities would have to develop guidance and the effort required to achieve a harmonised approach could be considerable. Some active substance perceived as being low risk, which have not been supported for Annex IA inclusion, might be re-introduced through direct authorisation of products containing them.

5.5. Policy issue 5: Fees charged by Member States for carrying out the procedures of the Directive

5.5.1. Costs and benefits of Option (a): Unchanged policy

As fee levels are already published, the main change from increasing the transparency of the current system, with fees and conditions still set at Member State level, would be to clarify the conditions for payment of fees. The **direct impact on Member States** across the EU27 of increased transparency on fees is likely to be negligible. Greater clarity may make it easier for **companies** to plan ahead. However, it is not clear whether such planning will result in authorisation being sought for more or fewer products. There are **unlikely to be significant social or environmental impacts**.

In addition, companies may tend to prefer mutual recognition to parallel applications in different Member States where they intend to place their products on the market. This may increase the number of cases going through the mutual recognition which may in return cause some Member States to increase their fees for mutual recognition (rather than the authorisation fees).

5.5.2. Costs and benefits of Option (b): Partially harmonised fee structure

The partial harmonisation of the fee structure would contain the following impacts:

– Reduced active substance evaluation fees for multiple submissions would have a **limited impact on manufacturers of existing active substances**, as the review programme will be largely complete by the time that any changes are introduced. However, it could encourage industry to add more product-types to new active substance dossiers and the **potential benefits to formulators of biocidal products** could be significant.

– Variation in fees by product-types: the scale of impact will be determined by the number of applications for product authorisations that would fall into the different categories. At present, there is no information available on this. However, assuming that Member States adjust their fees so that the overall revenue they receive is maintained, the **overall effect on industry will be cost-neutral**. Instead, there would be a transfer of costs within industry, with certain companies paying higher fees and others paying lower fees.

– **Refund of unused fees could result in significant savings to companies** whose dossier does not pass the completeness check, and might encourage industry to seek the evaluation of active substances not previously supported.

It is likely that Member States would adjust the level of their fees so that there would be no overall reduction in revenue as a result of harmonisation of structures. However, there could be **limited administrative costs for Member States** in modifying their fees in line with a harmonised fee structure. There are **unlikely to be significant social or environmental impacts**.

The current role of the Member States with respect to the setting of the levels of fees would remain. This is in accordance with the subsidiarity principle: Member States are best placed to set the levels of fees because the costs to cover the work to be done are not the same in the different Member States. However, Member States would be free to set the fee levels but only within the framework of the partially harmonised fee structure. The structure would harmonise the criteria on basis of which the fee would be set. A full authorisation would cost more than a renewal of the authorisation in all Member States; an authorisation of a low risk biocidal product would cost less than an authorisation of other products in all Member States. Concerning the level of fees, there will likely be differences in the level of the fees among Member States in the future. However, these will be related to the costs of the services to that Member State rather than the structure of setting the fee.

5.5.3. Costs and benefits of Option (c): Centralised fee system

The impact of this option would clearly depend upon the level at which the range of fees is set. **Industry would benefit from increased market harmonisation** across the EU and from the reduction of the high level of fees charged by some Member States. Conversely, industry would not be able to reduce costs by choosing to apply for authorisation only in Member States with very low fees.

For example, limiting fees to 25% above or below the current average would mean that 6 to 9 **Member States** would have to reduce their fees; this could mean that staffing and other costs would not be recovered. By contrast, 11 to 17 Member States would have to increase their fees to fit within this range. This may cause a problem in Member States where fees are limited by law to the level needed to recover costs.

Any distortion of the market caused by varying fee rates across the EU would, however, be removed; this could potentially result in greater **product availability** in Member States with high current fee levels, especially if the market in these Member States is small. There are unlikely to be significant **social or environmental impacts**.

A fully centralised fee system would raise questions concerning the subsidiarity principle as it would transfer the competences over setting fees from the Member States to the Community. A full harmonisation would mean that the fees applicable to all Member States would be decided at Community level. This may lead to a situation that in some Member States the fees levied will not cover the costs linked to processing the individual applications. In other Member States the fees would go beyond what may be necessary to cover the costs. Material and human resources costs of the services can not be harmonised in all Member States unless a fully centralised authorisation scheme is put in place. As this has been refused in sections 4.2.3, 4.2.4 and 5.2.4, a centralised system of fees including the setting of the fees level is only proposed with respect to the Community authorisations of certain biocidal products. For those products the Agency will be responsible for assessing the application and, therefore, a fully centralised fee system is justified.

5.5.4. Costs and benefits of Option (d): Specific provisions for SMEs

Reduced fees for SMEs could benefit them significantly, as high fees are more often an obstacle for SMEs to support substances or to keep their products on the market. **Cost can be reduced by a range of €75,600 to €639,000[45] spread over a period of 10 years** if fee reductions would be offered to SME's following the REACH model. Such reductions would likely have positive impact on the employment by SMEs.

If Member States took steps to ensure that their revenue from fees remains the same (by charging higher fees to large companies), there would be a **significant transfer of costs from SMEs to large companies**.

The **availability of products** formulated by SMEs, including safer products, **is likely to increase**. However, increased costs to larger companies could reduce the numbers of products, including safer products, placed on the market by these companies.

6. COMPARING THE OPTIONS

See Tables 2.21, 3.18, 4.10, 5.13, and 6.11. The preferred options are marked in grey.

It should be noted that only in one policy area, namely the data sharing, it is possible to choose one policy option (*mandatory sharing of vertebrate animal data at the active substance evaluation stage and the product authorisation stage*). All other policy areas require **a combination of various options in order to adequately address the problem** and adapt the solution to the current situation on the market with biocidal products. In particular, with regard to product authorisation, the Member States have expressed serious concerns about a full centralisation of the product authorisation under the Directive. Thus, the combination of a partial centralisation for certain biocidal products with a strengthening of the mutual recognition process seems the best variant under these circumstances and taking into account the subsidiarity principle. The same applies to fees where the harmonised fee structure should be accompanied with specific provisions to SMEs. With respect to the scope issues and data requirements, the assessed options did not always address the same problem. This means that more than one option may be suitable for these policy areas.

[45] Net present value €63.300 to € 535.400

The impact assessment shows that the **total costs of all preferred options to the industry would amount to a range from €193.6 to 706 million spread over a period of 10 years**. They represent between **0.09% and 0.32% of the overall value of the EU market with treated materials spread over 10 years**[46]. These costs are attributable to the extension of the scope of the Directive to treated materials. The costs cover the costs of including additional active substances in Annex I, the costs of the authorisation of additional products and the labelling costs of treated materials.

In theory the **total cost savings of all the preferred options for the industry could range from €2.7 billion to 5.7 billion spread over a period of 10 years**[47]. The cost savings (compared to Unchanged Policy option) would be achieved through the options concerning product authorisation, data sharing, data requirements and fees. In practice, these cost savings are very unlikely to materialise in such scale and are expected to be closer to the lower end of the range because of the following reasons:

– the majority of the savings would be achieved under obligatory data sharing of tests involving vertebrate animals at the substance evaluation and product authorisation stage. The savings are calculated in comparison to the Unchanged Policy (Option a)) which assumes that companies would regenerate significant parts of the data package for the purposes of the product authorisation under the existing legal framework. As already explained in Section 5.3.3, many companies, in particular SMEs, are unlikely to bear such costs and would rather stop marketing their products;

– with respect to the product authorisation and mutual recognition, the Unchanged Policy (Option a)) is based on the assumption that the Member States could potentially request significant amount of additional information including testing. This remote eventuality would be a failure of the mutual recognition as foreseen by the current Directive.

These calculations also do not take into account the various links between the different policy areas (e.g. between data waiving and data sharing, between product authorisation and fees). Such links cover for example the situation when a well functioning data waiving system reduces the efficiency and thus also the benefits that could be achieved by an obligatory data sharing scheme. It is, however, difficult to quantify the impacts of such linkages. The calculations also do not consider the numerous uncertainties mentioned throughout this assessment. Nevertheless, the calculation of the overall costs and benefits clearly shows that the **cost savings, mainly to the benefit of the industry, largely outweigh the costs of the proposed options**.

The total costs and cost savings of all preferred options for the industry are presented in Table 7.1 below. It should be, however, noted that only quantifiable costs and cost

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46 Based on the overall EU market with treated materials of €22.2 billion per year (€222 billion over 10 years).

47 The cost savings include the cost savings achieved through improvement of mutual recognition and partial centralisation of product authorisation, introduction of obligatory data sharing at substance and product authorisation stage, strengthening of the waiving provisions, revision of the concept relating to low risk biocidal products and reductions of the fees for SMEs.

savings were included. A detailed overview of the costs and cost savings is available in Annex IV of this document.

Preferred option	**Total costs / cost savings**
Scope: extend scope to treated materials	Costs between €193.6 and 706 million spread over 10 years
Product authorisation: Facilitation, improvement and strengthening of mutual recognition	Cost savings up to €700 million spread over 10 years[48]
Product authorisation: Community authorisation for certain categories of products	Cost savings up to €1.9 billion spread over 10 years[49]
Data sharing: Mandatory sharing of vertebrate animal test data at product authorisation and active substance approval stage	Cost savings between €1.4 and 2.7 billion spread over 10 years
Data requirements: Rewording provisions concerning data waiving and the use of existing information	Cost savings between €426 and 767 million spread over 10 years[50]
Data requirements: Reformulating the system for low risk biocidal products	Cost savings between €159 million and 340 million spread over 10 years
Fees: Partially harmonised fee structure	N/A
Fees: Specific provisions for	Cost savings between €75,600 and 639,000 spread

48 The total cost savings from the combined options in product authorisation (Option b) and Option d)) will be in the range between €700 million and €1.9 billion. These savings cannot be added up in the total costs because the two options would be combined. The measures in the options will interact and therefore, the savings will go beyond what would only be achieved with just one of the options but will remain less than the sum of the individual savings..

49 The total cost savings from the combined options in product authorisation (Option b) and Option d)) will be in the range between €700 million and €1.9 billion. These savings cannot be added up in the total costs because the two options would be combined. The measures in the options will interact and therefore, the savings will go beyond what would only be achieved with just one of the options but will remain less than the sum of the individual savings.

50 The figure has been calculated by adding up €85million for additional active substance inclusions spread over 10 years and a range between €341 million and 682 million for additional product authorisations spread over 10 years.

SMEs	over 10 years
Total costs	**Between €193.6 and 706 million spread over 10 years**
Total cost savings	**Between €2.7 billion and 5.7 billion spread over 10 years**

When comparing the costs and benefits of the different options, **the only option which could give rise to a significant cost increase for industry is the extension of the scope to treated materials**. **In all other policy areas, the options will reduce costs for industry** compared to the continuing the current policies. In practice, the final costs of extending the scope to treated materials could be much lower than this, as manufacturers are likely to switch to substances on Annex I and authorised products where possible, avoiding these costs. The environmental and human health benefits resulting from extending the scope to treated materials cannot be easily quantified partially due to the missing evidence linking the use of biocidal products with quantified health and environmental benefit but they are likely to be significant. The same applies to the competitiveness benefits for the EU industry with respect to their position on the EU market. In addition, the labelling would have benefits with respect to consumer protection.

The costs and benefits will be incurred gradually over a period of ten years. Both the inclusion of active substances and the product authorisations are granted for a period of ten years. The timing will be postponed for provisions which will require a transitional period (e.g. treated materials).

The options on scope, product authorisation and data sharing will require **additional work by public authorities** linked with the development of guidance documents. The related costs are, however, likely to be minor. Furthermore, the preferred options in product authorisation and data requirements require an existing Agency to play a role in the product authorisation process and the screening process with regard to low risk biocidal products.

Policy options in product authorisation, data sharing and data waiving have the potential to simplify the Directive. This would be in line with the Commission's strategy for simplifying the regulatory environment. This may benefit particularly SMEs which often lack human and financial resources to ensure compliance with the requirements of the Directive. For example, the obligatory sharing of vertebrate animal data will mean that the formulators of biocidal products will no longer be allowed to repeat studies for the purpose of product authorisation. This will reduce the costs of the product authorisation. In addition, the review of product authorisation applications will become simpler and less resource intensive for the competent authorities.

Apart from the options on the scope of the Directive, **most of the other options are likely to increase the product availability** compared to the current policy. This is mainly because the options will lead to a reduction in the costs of authorisation to the industry, encouraging authorisation of more products or authorisation in more

markets. This will benefit mainly consumers as they will have a wider choice of products to choose from.

No significant overall **impacts on employment** are anticipated as the overall market remains the same. Potentially, the preferred options in all policy areas could have positive impacts on employment. In particular, changes in product authorisation, obligatory data sharing, improved waiving provisions and a revised concept for low risk biocidal products could lead to incentives for development of new products and thus to an increased employment relative to the baseline. However, there may be job losses as some companies may be forced out of the market due to increased competition.

The different users of biocidal products will be affected in the same manner by the preferred policy options in all policy areas but scope. With respect to scope, the producers of treated materials will be affected most significantly. Examples include the chemicals sector (water resistant and fungi-based paint manufacture), timber processing and leather industries. The changes may also lead to increased prices of imported treated materials, which might however be reduced if producers switch to already authorised products.

The policy options concerning data requirements, data sharing and fees will benefit both active substance producers and formulators of biocidal products. However, given the ongoing implementation of the Review Programme for the evaluation of existing active substances, the changes will have more impact on the formulators than the active substance producers. The options concerning product authorisations will have impact only on biocidal product formulators. The changes concerning the scope may have implications for both active substance producers and biocidal product formulators.

Improved data waiving and obligatory data sharing may particularly benefit SMEs as they often lack financial and human resources necessary for ensuring regulatory compliance. SMEs may also profit the most from the special provisions for SMEs outlined under fees.

Big companies which place their products on the market in all or a majority of Member States may benefit, in particular, from the possibility to apply for a Community authorisation for certain types of biocidal products. This will enable them to place their products on the market throughout the Community without the need to request an authorisation in all Member States or go through the mutual recognition process. They will also benefit from the improved data waiving and obligatory data sharing. Concerning the fees, the reductions for SMEs will likely have to be compensated by higher fees for big companies.

Professional and non-professional users will be affected similarly. The preferred options would lead to a wider choice of biocidal products on the market, more low risk biocidal products and improved safety with respect to the treated materials.

The options on scope of the directive are likely to have positive impacts on both **health and the environment** because they extend controls to products not fully regulated at present, and thus remove the risks that these products may pose to health or the environment. The options in other policy areas may have indirect

environmental and health benefits, because they encourage industry to retain or introduce more low risk products on the market, by reducing the costs of the authorisation. Low risk products are considered a preferred alternative to other biocidal products. The environmental and human health benefits of using low risk products are, however, not easily quantifiable due to the missing information on the risk profiles of low risk biocidal products and the number of products which may qualify as low risk biocidal products. The options on data sharing and data requirements also **significantly reduce the numbers of vertebrate animal tests**.

With respect to the **subsidiarity principle**, Member States will retain their roles with respect to the mutual recognition which would be applicable to the majority of products on the market while the Community authorisation would apply only to low risk products and products based on new active substances. Similarly, with regards to the fees, Member States will continue to set the amount of the fees. Thus, none of the options goes beyond what is necessary to achieve the objectives of the Directive including the functioning of the internal market with biocidal products and the high level of environmental and human health protection.

Table 7.2 presents a **summary of benefits and costs to stakeholders of all the considered options.** The preferred options are marked in grey.

SCOPE			
(a) Unchanged policy	**(b) Include borderline issues**		**(c) Include treated materials**
	Food processing aids	**Food contact materials**	
Minor costs associated with updating the Directive	Administrative costs between €4.5 million and €35 million spread over 10 years for active substance evaluation; €5 million to €51 million spread over 10 years for biocidal product authorisation.	Administrative costs of a range between €5 million and €50 million spread over 10 years in active substance evaluation; €8.3 million to €73 million spread over 10 years for biocidal product authorisation.	Administrative costs of a range between €36 million and €140 million spread over 10 years for Annex 1 inclusion of active substances; €3.6 million to €52 million spread over 10 years for product authorisation; €154 million to €514 million spread over 10 years for labelling. Improved protection of environment, consumer and workers health
PRODUCT AUTHORISATION			
(a) Unchanged	**(b) Strengthening of mutual recognition**	**(c) Single Member State authorisation**	**(d) Community authorisation**
Total administrative costs to industry: € 2.9 billion spread over 10 years	Total administrative costs to industry: € 2.2 billion spread over 10 years Cost savings to industry: 0.7 billion spread over 10 years	Total administrative costs to industry:€ 1 billion spread over 10 years Cost savings to industry: 1.9 billion spread over 10 years	Total administrative costs to industry: € 1 billion spread over 10 years; Incentives for innovation of products based on new active substances / low risk products

			Cost savings to industry: 1.9 billion spread over 10 years
DATA SHARING			
(a) Unchanged policy – clarification and encouragement	**(b) Mandatory sharing of vertebrate animal test data at product authorisation stage**	**(c) Mandatory sharing of vertebrate animal test data at product authorisation and active substance stage**	
Some cost savings to applicants for product authorisation through a basic functioning of mutual recognition Risk of duplication of testing with vertebrate animals not fully addressed	Additional theoretical cost savings on top of basic functioning of mutual recognition to applicants for product authorisation compared to option (a) by a range between € 675 million and €2.6 billion spread over 10 years Number of animals saved: between 450,000 and 844,000 spread over 10 years	Additional theoretical cost savings on top of basic functioning of mutual recognition to applicants for product authorisation compared to option (a) by a range between €1.4 billion and €2.7 billion spread over 10 years Possibly a higher number of safer products will remain on the market than under options (a) or (b) Number of animals saved: around 1 million spread over 10 years.	
DATA REQUIREMENTS			
(a) Unchanged policy - clarification	**(b) Data waiving and use of existing information**	**Option (c) Low-risk substances**	

Theoretical benefits of 100% waiving: between €698 million and €1.4 billion spread over 10 years, but unlikely to be realised in practice	Potential reduction in testing costs of €85 million over 10 years (active substances); a range between €341 million and €682 million spread over 10 years (products) from increased waiving, + benefits from use of existing data. Number of animals saved: between 350,000 and 1,5 million spread over 10 years.	Potential cost savings from positive listing of low risk substances: a range between €159 million and €340 million spread over 10 years. Number of animals saved : between 30,000 and 343,750 spread over 10 years

FEES			
(a) Unchanged policy - more transparency	**(b) Partially harmonised fee structure**	**(c) Centralised fees system**	**(d) Specific Provisions for SMEs**
Minor increase in clarity	Reduction in costs for inclusion/authorisation of several PTs; More effective budget planning by Competent Authorities. May encourage more new active substances and retention of more existing active substances. Increased availability of some products especially from SMEs	11-17 MS may have to increase current fees. 6-9 MS may have to reduce current fees.	Cost reductions: a range between €75,600 and €639,000 spread over 10 years More products on the market from SMEs Procedure less costly for SMEs, helping them to stay on the market

7. MONITORING AND EVALUATION

Monitoring and evaluation will be on the basis of measurements against the general objectives set out in Section 4. The core indicators for the general policy objectives are shown in the table below.

There are a number of sources of information in place or under development that can be used to obtain information on the core indicators.

According to ***Article 24*** of the Directive Member States have to take the necessary arrangements to monitor whether biocidal products placed on the market comply with the requirements of the Directive. Every three years Member States have to submit to the Commission by 30 November of the third year a report on their action in these matters together with information on any poisonings involving biocidal products. The Commission within one year of receipt of this information prepares and publishes a composite report.

The Commission is in the process of preparing a ***Community Register for Biocidal Products (R4BP)*** to facilitate the information exchange as foreseen in Article 18.1 of the Directive, which stipulates that Member States shall on a quarterly basis inform each other and the Commission of biocidal products for which an authorisation was granted, refused, modified, renewed or cancelled. The register will be operable by the end of 2009. The overall goal of the R4BP system is to provide a notification system to signal that a company intends to initiate an authorisation procedure for a product in a Member State, or a mutual recognition procedure for a product and to signal that a Member State has taken certain decisions on procedures or authorisations. It also aims to allow Member States and companies to keep track of the main milestones of procedures (i.e. dates of dossier submission, of dossier acceptance, start of evaluation, end of evaluation and authorisation) and to communicate information about all initiated procedures to all concerned Member States. The R4BP will help Member States identify which products are authorised on other Member States respective markets, which substances these products contain and for which product-types they are authorised and it will collect standardised data on the products concerned. Finally it aims to offer assistance to the Member States to fulfil their quarterly and annual information reporting obligations and to allow the Commission to analyse and query the available information in the system and to provide a status report of pending and finalised procedures upon demand.

A ***new reporting article*** related to the use phase could be included in the revised Directive and could provide important information on quantities of biocidal products placed on the market.

As for the evaluation, the Commission will review the Composite Reports due in 2010 and 2013 to assess the impact of the revision of the Directive.

Objective	**Indicator**	**Data source**
Facilitate the harmonisation of the EU market for	Number of active substances evaluated	Progress report extracted from DG ENV's database

biocidal products	Speed of product authorisation	Community Register For Biocidal Products
	Number of conflicts in Mutual Recognition that require resolution at Community level	The Commission/Agency will keep track of the number of conflict resolutions
Continue to provide high level of protection for humans, animals and the environment	Number of biocidal products on the market	Reporting obligation from MS to the Commission. Community Register for Biocidal Products
	Number of poisoning incidents	Reporting obligation from MS to the Commission under Article 24 of the Directive.
	Number of low risk biocidal products	The Agency will keep track of the decisions about low risk biocidal products
	Number of data sharing failures (linked to animal testing)	The Commission/Agency are informed when there is no agreement.
Increase the competitiveness of the EU industries affected by this Directive	Number of new active substances	Agency
	Number of unfavourable controls/inspections in the market surveillance activities in particular for the treated materials	Member States

ANNEX I
REFERENCES

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(2) Second progress report on the strategy for simplifying the regulatory environment (Brussels, 30.01.2008 - COM(2008) 33 final

(3) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (*Official Journal L 123, 24 April 1998, p.1*). All relevant information regarding the Biocidal Products Directive 98/8/EC and its implementing Regulations can be found at: http://europa.eu.int/comm/environment/biocides/index.htm

(4) Commission Impact Assessment guidelines of 15 June 2005 (SEC 2005 - 791).

(5) Study to assess the impact of the revision of Directive 98/8/EC concerning the placing of biocidal products on the market (final report submitted on 14th August 2008 – when approved available at: http://ec.europa.eu/environment/biocides/study.htm).

(6) Study on the impacts of the implementation of Directive 98/8/EC on biocidal products (2007 - available at: http://ec.europa.eu/environment/biocides/study.htm)

(7) Study on impacts of possible measures to manage articles or materials treated with biocides, in particular when imported (2006 - available at: http://ec.europa.eu/environment/biocides/study.htm)

(8) Study on the assessment of different options to address risks from the use phase of biocides (ongoing)

(9) Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124 of 20.5.2003, p. 36)

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(11) Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (*Official Journal L 262, 27.9.1976, p. 201–203*)

(12) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use *(Official Journal L 311, 28/11/2001 p. 67 - 128)*.

(13) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (*Official Journal L 311, 28/11/2001 p. 1 - 66*).

(14) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (*Official Journal L 230, 19.8.1991, p. 1*).

(15) Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

(16) Commission Staff Working Document Report on the Impact Assessment for a Regulation Replacing Directive 91/414/EEC on Plant Protection Products Annex 2, part 5 {COM(2006) 388 final} {SEC(2006) 930}

(17) Council Directive of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (OJ L 40, 11.2.1989, p. 27)

(18) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin *(Official Journal of the European Union L 139 of 30 April 2004)*

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(20) Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation (http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf)

(21) Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (*OJ L 37, 13.2.2003, p. 19–23)*

(22) Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market (COM(2006) 388 final)

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(28) Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin

ANNEX II

Background information on Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

Aims of the Biocidal Products Directive

The European Parliament and Council Directive 98/8/EC[51] on the placing on the market of biocidal products (hereafter "the Directive") was adopted on 16th February 1998. It aims to harmonise the European market for biocidal products and their active substances; at the same time it aims to provide a high level of protection for humans, animals and the environment.

What is a biocidal product?

Biocidal products are active substances or preparations containing one or more active substances, intended to destroy, deter, render harmless, prevent the action of, or exert a controlling effect on harmful organisms, such as microbes, insects, mice, rats, etc. For example, a repellent used to 'deter' a mosquito is a biocidal product.

The scope of the Directive is very wide, covering 23 different product-types. These include disinfectants used in different areas, chemicals used for preservation of products and materials, non-agricultural pesticides and anti-fouling products used on hulls of vessels. The Directive does not apply to certain products already covered by other Community legislation, such as plant protection products, medicines, and cosmetics. Moreover, the Directive does not apply to articles (e.g. textiles and clothes, wood, plastic objects) treated for internal effect with biocides imported from the third countries.

How does the Directive work?

The Directive sets out a Community harmonised system for the *authorisation and placing on the market* of biocidal products; for the *mutual recognition* of these authorisations within the Community; and for the establishment at Community level of a *positive list of active substances* which may be used in biocidal products.

The Directive was modelled on Directive 91/414/EEC concerning the placing of plant protection products on the market, and takes a similar approach to the authorisation procedure, in the sense that it provides for a two-tier system, based on the evaluation and approval of the active ingredients at Community level, and the subsequent authorisation of biocidal products containing these ingredients at Member State level.

The basic principles of the Directive are the following:

- *Active substances* have to be assessed and the decision on their inclusion into Annex I, IA or IB of the Directive shall be taken at Community level.

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51 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24 April 1998, p.1). All relevant information regarding the Biocidal Products Directive 98/8/EC and its implementing Regulations can be found at: http://europa.eu.int/comm/environment/biocides/index.htm

- Member States shall authorise the *biocidal products* in accordance with the rules and procedures set in Annex VI of the Directive. They can only authorise products which contain active substances included in Annex I.

- A biocidal product authorised in one Member State shall be authorised upon application also in other Member States in the process of *mutual recognition* unless there are specific derogation grounds.

10-Year Review Programme

The Directive established a 10-year review programme[52] for the systematic examination of active substances used in biocidal products that were present on the market before its entry into force (14 May 2000), in order to allow for their risk and efficacy assessment, and ultimately their inclusion in the above-mentioned positive list (Annexes I, IA or IB to the Directive). During this 10-year period, Member States may continue to apply their systems or practices for the placing of biocidal products on the market ('the transitional period').

In a first step, industry was invited in 2000 to identify all existing active substances and to notify to the Commission those substances that they would intend to defend within the review programme[53].

In a second step, four priority lists were established for the evaluation of the defended substances and the evaluation work distributed among Member States.

Mutual Recognition of Authorisations

The authorisation system is based on the principle of mutual recognition of authorisations. Under this principle, a biocidal product that has already been authorised or registered in one Member State must be authorised in another Member State within 120 days or registered within 60 days of an application being received by the other Member State.

Product Authorisation stage

The product authorisation stage has not yet started.

A Product Authorisation and Mutual Recognition Facilitation Group has been set up with Member States and Stakeholders in order to smooth the working of the product authorisation stage and anticipate issues with the mutual recognition of authorisations and registrations in particular.

What should a "Active Substance Dossier" include ?

Dossiers on active substances are required to address at least the following points:

– I. Applicant: name, address, etc.

– II. Identity of the active substance

52 From 14 May 2000 to 14 May 2010.

53 See Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products. (OJ L 228, 8.9.2000, p.6 - Regulation as amended by Regulation (EC) No 2032/2003)

– III. Physical and chemical properties of the active substance

– IV. Methods of detection and identification

– V. Effectiveness against target organisms and intended uses

– VI. Toxicological profile for man and animals including metabolism

– VII. Ecotoxicological profile including environmental fate and behaviour

– VIII. Measures necessary to protect man, animals and the environment

– IX. Classification and labelling

– X. Summary and evaluation of Sections II to IX

ANNEX III: GLOSSARY

PT: Product-type

PT 1: Product-type 1: Human hygiene biocidal products

PT 2: Product-type 2: Private area and public health area disinfectants and other biocidal products

PT 3: Product-type 3: Veterinary hygiene biocidal products

PT 4: Product-type 4: Food and feed area disinfectants

PT 5: Product-type 5: Drinking water disinfectants

PT 6: Product-type 6: In-can preservatives

PT 7: Product-type 7: Film preservatives

PT 8: Product-type 8: Wood preservatives

PT 9: Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

PT 10: Product-type 10: Masonry preservatives

PT 11: Product-type 11: Preservatives for liquid-cooling and processing systems

PT 12: Product-type 12: Slimicides, Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

PT 13: Product-type 13: Metalworking-fluid preservatives

PT 14: Product-type 14: Rodenticides, Products used for the control of mice, rats or other rodents.

PT 15: Product-type 15: Avicides, Products used for the control of birds.

PT 16: Product-type 16: Molluscicides, Products used for the control of molluscs.

PT 17: Product-type 17: Piscicides, Products used for the control of fish; these products exclude products for the treatment of fish diseases.

PT 18: Product-type 18: Insecticides, acaricides and products to control other arthropods (e.g. insects, arachnids and crustaceans).

PT 19: Product-type 19: Repellents and attractants, Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

PT 20: Product-type 20: Preservatives for food or feedstocks

PT 21: Product-type 21: Antifouling products, Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

PT 22: Product-type 22: Embalming and taxidermist fluids, Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

PT 23: Product-type 23: Control of other vertebrates, Products used for the control of vermin.

ANNEX IV: TABLES TO COMPARE THE OPTIONS

SCOPE

Table 2.21: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Scope				
Stakeholders	**Option**			
	(a) Unchanged policy	**(b) Include borderline issues**		**(c) Include treated materials**
		Food processing aids	**Food contact materials**	
EU industry	Benefits Minor increase in clarity over borderline issues	Benefits Clearer and more harmonised regulatory regime	Benefits Possibly increased regulatory certainty	Benefits Harmonisation of rules and level playing field with third country producers
	Costs Minor costs associated with updating the Directive	Costs Administrative costs[54] ranging between **€4.5 million and €35 million spread over 10 years** for active substance evaluation. Administrative costs of a range between **€5 million and €51 million spread over 10 years** for biocidal product authorisation.	Costs Administrative costs of a range between **€5 million and €50 million spread over 10 years** in active substance evaluation. Administrative costs of a range between **€8.3 million and €73 million spread over 10 years** in biocidal product authorisation.	Costs Administrative costs **of a range between €36 million and €140 million spread over 10 years** for inclusion of active substances in Annex 1 Administrative costs of a range between **€3.6 million and €52 million spread over 10 years** in biocidal product authorisation. Labelling cost of a range between **€154 million and €514 million spread over 10 years.**

[54] See section 2.2 why the EU Standard Cost Model was not used.

Table 2.21: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Scope				
Stakeholders	**Option**			
		(b) Include borderline issues		
Administration (implementation and enforcement)	Benefits Minor increase in clarity over borderline issues	Benefits Clearer and more harmonised regulatory regime	Benefits Clearer and more harmonised regulatory regime	Benefits Greater regulatory certainty. Framework for addressing risks from imported treated materials
	Costs No significant impacts	Costs Possible duplication of effort, as both food safety and biocidal product regulators would review requests	Costs Possible duplication of effort, as both food safety and biocidal product regulators would review requests	Costs Administrative cost in additional active substance and product authorisations. Should be off-set by fees. Some costs related to training and improvement in customs controls, and labelling requirement
Product availability	*Benefits* Not applicable	*Benefits* Not applicable	*Benefits* Not applicable	*Benefits* Possibly more substances supported and thus more products available on the market
	Costs Not applicable	Costs May reduce the number of products, due to costs of authorisation	Costs May reduce the number of products, due to costs of authorisation	Costs Possibly increased prices of treated materials
Social impacts	Benefits Not applicable	Benefits Potential health benefits to workers using the products which will be included	Benefits Not applicable	Benefits Improved protection of consumer health, as risks related to substances in imported treated materials are assessed

Table 2.21: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Scope				
Stakeholders	**Option**			
		(b) Include borderline issues		
				Improved protection of worker health for intermediate goods (e.g. wet-blue tanned leather) With labelling, consumers better able to make informed choices
	Costs Not applicable	*Costs* New products covered may increase costs on SMEs and lead to loss of jobs	*Costs* New products covered may increase costs on SMEs and lead to loss of jobs	*Costs* Not applicable
Environmental impacts	*Benefits* Limited – possibly better information due to clearer regulatory framework	*Benefits* Environmental benefits, due to increased control and possible reduction in use or switch to lower risk products and uses.	*Benefits* Greater control over environmental impacts of use and disposal of food contact materials	*Benefits* Improved environmental protection, as risks related to biocides in imported treated materials are assessed
	Costs Not applicable	*Costs* Not applicable	*Costs* Not applicable	*Costs* Not applicable

PRODUCT AUTHORISATION

Table 3.18: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Product Authorisation				
Stakeholders	**Option**			
	(a) Unchanged policy	**(b) Strengthening of mutual recognition**	**(c) Single Member State authorisation**	**(d) Community authorisation**
EU industry	*Benefits:* Increase in effectiveness of mutual recognition would reduce costs of authorisation	*Benefits:* Potential benefits due to greater certainty about mutual recognition. Reduction of administrative costs compared to option (a)	*Benefits:* Potential benefits due to automatic ability to sell products across EU Significant reduction of administrative costs compared to Option 1 + 2 *Benefits significantly reduced under dual system*	*Benefits:* Potential benefits due to automatic ability to sell products across EU. Significant reduction of administrative costs compared to Option 1 + 2 *Benefits significantly reduced under dual system*
	Costs Total administrative cost of product authorisation **€2.9 billion spread over 10 years**.	Costs Total administrative costs of **€2.2 billion spread over 10 years (= 75% of option (a))**	Costs Total administrative costs **€1 billion spread over 10 years** **(= below 40% of option (a))**.	Costs Total administrative costs **€1 billion spread over 10 years**. **(= below 40% of option (a))**.
Administration (implementation and enforcement)	Benefits No changes in the legislation to implement Greater clarity on operation of authorisation and mutual recognition	Benefits Potential to share the burden of evaluation. Better information exchange. Possibility to initiate mutual recognition and to authorise a product without application.	Benefits Efficiency savings due to reduced duplication. Benefits reduced under dual system	Benefits Overall efficiency savings due to the ending of duplication Benefits significantly reduced under dual system

Table 3.18: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Product Authorisation				
Stakeholders	**Option**			
	(a) Unchanged policy	**(b) Strengthening of mutual recognition**	**(c) Single Member State authorisation**	**(d) Community authorisation**
	Costs Limited costs of in preparing guidance (<€350,000) and possibly holding workshops	Costs Limited costs of preparing guidance (<€350,000) and possibly of holding workshops. Potential increase in administrative costs for a small number of MS. Potential loss of fees.	Costs Potential costs associated with dispute resolution which may not be covered by fees Costs increased under dual system	Costs A central agency would require significant financial resources and experienced staff Potential costs associated with dispute resolution which may not be covered by fees
Product availability	Benefits More efficient operation of mutual recognition could reduce the numbers of products lost to the market	Benefits Could reduce the numbers of products lost to the market and facilitate placing on the market of safer products	Benefits Reducing costs of authorisation, could significantly reduce the numbers of products lost to the market for economic reasons and facilitate placing on the market of safer products Benefits reduced under dual system	Benefits Reducing costs of authorisation, could significantly reduce the numbers of products lost to the market and facilitate placing on the market of safer products Benefits reduced under dual system
	Costs No changes	Costs No changes	Costs Not applicable	Costs Not applicable

Table 3.18: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Product Authorisation				
Stakeholders	**Option**			
	(a) Unchanged policy	**(b) Strengthening of mutual recognition**	**(c) Single Member State authorisation**	**(d) Community authorisation**
Social impacts	Benefits None	Benefits Potentially reduced loss of safer products for economic reasons.	Benefits Potentially reduced loss of safer products for economic reasons. Impacts on employment unclear, as overall market is unlikely to grow. Impacts would be reduced under dual system	Benefits Potentially reduced loss of safer products for economic reasons. Guarantee of harmonised requirements, leading to more reliable assessment. Impacts would be reduced under dual system
	Costs Potential loss of some safer products if mutual recognition fails. Impacts on employment unclear	Costs Employment impacts unclear.	Costs MS concerns about possible effects from failure to consider localised health impacts Fewer staff needed by Competent Authorities for authorisation procedures Impacts would be reduced under dual system	Costs Fewer staff needed by Competent Authorities. Impacts would be reduced under dual system

Table 3.18: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Product Authorisation				
Stakeholders	**Option**			
	(a) Unchanged policy	**(b) Strengthening of mutual recognition**	**(c) Single Member State authorisation**	**(d) Community authorisation**
Environmental impacts	Benefits None	Benefits Reduced loss of safer products for economic reasons.	Benefits Reduced loss of safer products for economic reasons Impacts would be reduced under dual system	Benefits Reduced loss of safer products for economic reasons. More incentives for innovation with respect to biocidal products based on new active substances and low risk biocidal products Impacts would be reduced under dual system
	Costs Potential loss of some safer products if mutual recognition fails	Costs None	Costs MS concerns about possible effects from failure to consider localised environmental impacts Impacts would be reduced under dual system	Costs None

DATA SHARING

Table 4.10: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Data Sharing			
Stakeholders	**Options**		
	(a) Unchanged policy – clarification and encouragement	**(b) Mandatory sharing of vertebrate animal test data at product authorisation stage**	**(c) Mandatory sharing of vertebrate animal test data at product authorisation stage and active substance approval stage**
EU industry	*Benefits:* Some cost savings to applicants for product authorisation through a basic functioning of mutual recognition. Data holders would recover 58% to 85% of their animal testing costs	Benefits: **Additional theoretical cost savings** to applicants for product authorisation, **compared to Option (a) of a range between €675 million and €2.6 billion spread over 10 years**; Benefits would be significantly reduced under the REACH default of equal cost sharing. Data holders would recover 64% to 107% of their costs (or 100% under the REACH cost sharing default)	Benefits: **Compared to option (b):** potential savings to manufacturers of reintroduced active substances of a range between **€150 million and €760 million spread over 10 years** **Compared to Option (a): total additional benefits of a range between €1.4 billion and € 2.7 billion spread over 10 years**.
	Costs No direct costs, but no guarantee that data will be shared more effectively. Risk of use of data protection to provide an obstacle to new market entrants remains	Costs Potential costs to formulators of biocidal products from increased competition, if more products are placed on the market Costs of litigation in case of disagreement over data sharing	Costs Potential costs to manufacturers of active substances and formulators of biocidal products from increased competition, if more products are placed on the market Costs of litigation in case of disagreement over data sharing
Administration (implementation and enforcement)	*Benefits* Potential cost savings from reduced numbers of data sets to review and easier interpretation of EU legislation due to clarification and guidance	Benefits Potential cost savings from reduced numbers of data sets to review; savings likely to be greater than for Option (a)	Benefits Potential cost savings from reduced numbers of data sets to review; savings likely to be greater than for Option (a) or (b)

Table 4.10: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Data Sharing			
Stakeholders	**Options**		
	(a) Unchanged policy – clarification and encouragement	**(b) Mandatory sharing of vertebrate animal test data at product authorisation stage**	**(c) Mandatory sharing of vertebrate animal test data at product authorisation stage and active substance approval stage**
	Costs Commission: preparation of guidance on data sharing (<€350,000) CAs: development and maintenance of registers of test and study reports: between €160,000 and €310,000 per year	Costs Commission: preparation of guidance on data sharing (<€350,000) CAs: development and maintenance of registers of test and study reports: between €160,000 and €310,000 per year Costs for national courts or arbitration bodies – however, will be offset by the fees	Costs Commission: preparation of guidance on data sharing (<€350,000) CAs: development and maintenance of registers of test and study reports: between €160,000 and €310,000 per year Costs for national courts or arbitration bodies – however, will be offset by the fees
Product availability	*Benefits:* Improved guidance could help to ensure that the number of products remaining on the market is at the higher rather than lower end of the range	Benefits: Potentially more products will remain on the market than under Option 1, as increased data sharing will reduce the costs	Benefits: Potentially more products will remain on the market than under Option 1 and 2, as increased data sharing will reduce the costs and more active substances may be re-introduced
	Costs No change	Costs Not applicable	Costs Not applicable.
Social impacts	*Benefits:* May help to ensure that a higher number of safer products remains on the market	Benefits: May help to ensure that a higher number of safer products remains on the market than Option (a). Reduced costs for industry could help maintain employment.	Benefits: May help to ensure that a higher number of safer products remains on the market than Options (a) or (b). Reduced costs for industry could help maintain employment
	Costs	Costs	Costs

Table 4.10: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Data Sharing			
Stakeholders	**Options**		
	(a) Unchanged policy – clarification and encouragement	**(b) Mandatory sharing of vertebrate animal test data at product authorisation stage**	**(c) Mandatory sharing of vertebrate animal test data at product authorisation stage and active substance approval stage**
	No change	Not applicable	Not applicable
Environmental Impacts	*Benefits* No change	Benefits Potentially more environmentally-safe products on the market due to improved data sharing rules and thus less barriers for new entrants **Reduced number of vertebrate animals used for repeated test: between 450,000 and 844,000 spread over 10 years**	Benefits Potentially more products on the market due to improved data sharing rules and thus fewer barriers for new entrants. Benefits should be greater than for Option (b) **Reduced number of vertebrate animals used in duplicated tests: around 1 million spread over 10 years**
	Costs Risk of duplication of testing with vertebrate animals not fully addressed	Costs Not applicable.	Costs Not applicable.

DATA REQUIREMENTS

Table 5.13: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Data Requirements			
Stakeholders	**Options**		
	(a) Unchanged policy - clarification	**(b)Rewording provisions concerning data waiving and use of existing information**	**Option (c) Reformulating the system for low-risk substances**
EU Industry	Benefits: Less uncertainty related to data requirements; Improved flexibility: waiving option would be made operational; Harmonisation of data requirements amongst national authorities. Theoretical benefits of 100% waiving: a range between €698 million and €1.4 billion spread over 10 years, but unlikely to be realized in practice	Benefits: Improved flexibility, differences in substance risks better addressed; Maximum potential reduction in testing costs of €85 million spread over 10 years for active substances ; A range between €341 million and €682 million spread over 10 years for products from increased waiving, plus additional benefits from greater use of existing data.	Benefits: Reduced costs for manufacturers of low-risk substances and products containing them; Potential increase in business from more active substances and the products that contain them; Potential cost savings from positive listing of low risk substances of a range between €159 million and €340 million spread over 10 years. More flexibility in product development encourages innovation; Lower data requirements/costs compared to full assessment of the active substance; Product authorisation not delayed during the approval of the active substance;
	Costs: Continued discretion of MS as to waiving of data	Costs: More complex system of data requirements to understand.	Costs: Difficulties may remain over definition of low-risk substances; Applying for product authorisation may be more complicated, time consuming.

Table 5.13: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Data Requirements			
Stakeholders	**Options**		
	(a) Unchanged policy - clarification	**(b)Rewording provisions concerning data waiving and use of existing information**	**Option (c) Reformulating the system for low-risk substances**
Administration (Implementation and Enforcement)	Benefits: Less uncertainty related to data requirements; Moderate cost savings from reduction in workload	Benefits: More targeted evaluation; Less data to be assessed; Moderate cost savings from reduction in workload.	Benefits: More targeted evaluation at product authorisation stage where use conditions are known. Some potential low risk active substances available on the market without their Annex IA inclusion. Workload depends on number of low risk products to be assesses compared to the number of active substances re-introduced
	Costs: Time and resources required to develop and agree upon guidance. Justification of waiving decisions might increase workload	Costs: Could require greater coordination among Competent Authorities within a MS to share information; More resources and coordination required to inform the applicant about waiving grounds and provide any necessary assistance to the applicant.	Costs: Effort for dossier and/or literature data evaluation of potential low risk products Lower data requirement could lead to uncertainty during the evaluation stage Compensation may be requested by manufacturers who have already incurred costs for the authorisation for ASs that are defined as low risk
Product Availability	Benefits: Potential incentive for more product authorisation applications, through greater certainty.	*Benefits:* Reduced costs could lead to support of more substances by industry – more products available.	Benefit: Facilitate support of more substances by industry - more products available. More low risk products with distinct active substances on the market. t

Table 5.13: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Data Requirements			
Stakeholders	**Options**		
	(a) Unchanged policy - clarification	**(b)Rewording provisions concerning data waiving and use of existing information**	**Option (c) Reformulating the system for low-risk substances**
	Costs: No change	*Costs* Potential low quality products remain on the market.	Costs: Potential low quality products remain on the market.
Social Impacts	*Benefits:* Possible positive impact on employment if increased guidance leads to support of more products, especially by SME's.	*Benefits:* 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	*Benefits:* 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
	Costs: No change	*Costs:* Unknown risks of substances where requirements are waived might not become apparent and are not assessed.	*Costs:* Unknown risks of "low risk active substances" might not become apparent during product authorisation
Environmental Impacts	*Benefits:* No change	*Benefits:* Could reduce numbers of vertebrate animal used in testing by a range between 350,000 to 1,5 million spread over 10 years.	*Benefits:* Could reduce numbers of vertebrate animal used in testing by a range between 30,000 and 343,750 spread over 10 years Use of low risk products might replace known high risk products. More low risk products to be encouraged onto the market. More flexibility in pest control

Table 5.13: Comparison of the Benefits and Costs to Stakeholders of Options Relating to Data Requirements			
Stakeholders	**Options**		
	(a) Unchanged policy - clarification	**(b)Rewording provisions concerning data waiving and use of existing information**	**Option (c) Reformulating the system for low-risk substances**
	Costs: Loss of potential low risk active substances and products not addressed	Costs: Reduced data requirements might cause uncertainties in evaluation of environmental impacts.	Costs: Unknown risks of "low risk active substances" might not become apparent during product authorisation

FEES

Table 6.11: Comparison of the Benefits and Costs to Stakeholders of Options Related to Fees				
Stakeholders	**Options**			
	(a) Unchanged policy -increased transparency	**(b) Partially harmonised fee structure**	**(c) Centralised fees system**	**(d) Specific Provisions for SMEs**
EU industry	Benefits: Publication would facilitate budget planning for companies and may reduce differences between MS due to open comparison. Cost-neutral	Benefits: More PTs added to new active substance dossiers. Greater predictability of fees. Reduction in costs for authorisation across many PTs. Installments could bring significant benefits to SMEs. Cost-neutral overall	Benefits: Less disparity between MS: less risk of distortion of competition; Increased predictability will allow future planning.	Benefits: Cost reductions: a range between **€75,600 and €639,000 spread over 10 years**
	Costs Fees cost between €180 million to €520 million. High fees still a problem, especially for SMEs Cost-neutral	Costs Fees might still be considered as too high for supporting active substance or products. Potentially, significant increase in costs for authorisation with one PT. Cost-neutral overall	Costs	Costs Significant transfer of costs from SME's to larger industries
Administration	*Benefits*	*Benefits*	*Benefits*	*Benefits*

Table 6.11: Comparison of the Benefits and Costs to Stakeholders of Options Related to Fees				
Stakeholders	**Options**			
	(a) Unchanged policy -increased transparency	**(b) Partially harmonised fee structure**	**(c) Centralised fees system**	**(d) Specific Provisions for SMEs**
(implementation and enforcement)	Reduction in complaints and in the cost of dealing with complaints. Potential increase in revenue for cheaper MS as well as companies. Potential for cheaper MS to be overwhelmed by authorisation applications Cost-neutral	Clearer information may enable more effective budget planning by CAs; Clarity over fees to be charged so fewer objections from companies. May encourage more new a/s and retention of more existing a/s. Costs recovered by increased fees therefore cost-neutral	11 to 17 MS would have to increase current fees. Reduced work load.	Needs of SMEs can better be addressed by CAs. Cost-neutral
	Costs Potential loss of revenue for expensive MS as companies switch to cheaper MS Cost-neutral	*Costs* Less flexibility. Different costs of national staff might not be addressed adequately. Costs recovered by increased fees therefore cost-neutral.	*Costs* 6-9 MS would have to reduce current fees. Possibly lower revenues for Member States.	*Costs* Cost-neutral
Product availability	*Benefits* No major change	*Benefits* Potentially improved competition, more safe products on the market. Increase in availability of some products especially from SMEs and where AS has many PTs.	*Benefits* Potentially improved competition, more safe products on the market. Increase in availability of some products especially from SMEs and where AS has many PTs	*Benefits* More products on the market from SMEs.

Table 6.11: Comparison of the Benefits and Costs to Stakeholders of Options Related to Fees				
Stakeholders	**Options**			
	(a) Unchanged policy -increased transparency	**(b) Partially harmonised fee structure**	**(c) Centralised fees system**	**(d) Specific Provisions for SMEs**
	Costs No major change	*Costs* No change	*Costs* No change	*Costs* Potential loss of products from larger companies.
Social impacts	*Benefits:* No major change	*Benefits:* Slight increase in safer products. Slight increase in employment overall.	*Benefits:* Slight increase in safer products. Slight increase in employment overall.	*Benefits:* Procedure less costly for SMEs helping them to stay on the market Job increases in SME's.
	Costs No major change	*Costs* No major impacts.	*Costs* No major impacts.	*Costs* ob losses in larger companies.
Environmental impacts	*Benefits* No change	*Benefits* More (safe) products on the market from SMEs.	*Benefits* More (safe) products on the market from SMEs	*Benefits* Increase in (safe) products on the market from SMEs
	Costs No change	*Costs* No change	*Costs* No change	*Costs* Decrease in (safe) products on the market from larger companies.

ANNEX V: STANDARD ASSUMPTIONS ON MARKETS FOR BIOCIDAL PRODUCTS AND ACTIVE SUBSTANCES

Parameter	Value		Source	Notes
	Low	High		
Current Markets				
Total annual market for biocide active substance at the manufacturer level	€0.5 billion	€1.0 billion	UK HSE and data on global market, assuming European contribution of 30% (used in Study on the Impacts of the BPD)	Eurostat data does not distinguish between BPD and PPP substances
Total annual market for biocidal products at the manufacturer level	€1.5 billion	€3 billion	UK HSE (see above)	Eurostat data does not distinguish between BPD and PPP substances.
No. biocidal products currently on the market	15,000	18,000	Consultation (industry) and Composite Report[1]	Not necessarily consistent with MS registers, due to duplication
Average no. markets on which biocidal products are currently placed	10	15	Consultation (industry)	Very variable, with a range of 1 to 27
Markets Following Product Authorisation				
Likely no. product authorisation applications	4,500	9,000	Consultation (industry) indicates that between 50% and 75% of products will not be authorised	This number is likely to change if authorisation becomes less onerous/ costly
Average no. markets on which each biocidal product will be placed	10	20	Consultation (industry); 'typical' range	Actual range is 1 to 27; will depend on how onerous mutual recognition is.

Parameter	Value		Source	Notes
	Low	High		
No. active substances per product	1.5	2	Consultation (industry)	Some have more than this; may depend on definition of active substances and co-formulants
Average number of product types for each active substance	3.4		ECB and Member State assessment reports	
No. active substances that could be reintroduced as new substances	25	50	Consultation (industry)	Will depend upon market factors and data requirement options. Some consultees considered these numbers to be over-estimates
No. 'me too' active substances	25	50	Consultation (industry)	Will depend upon market factors and data requirement options. Some consultees considered these numbers to be over-estimates
Average no. products per active substance	13.8	27.5	Calculated	Likely no. of authorised products divided by expected no. active substances on Annex 1
No. manufacturers per additional active substance	3	5	Study on impacts of the BPD	REACH Impact Assessment used 5 – 16 manufacturers for up to 100t/y; from EUSES
1. This was the consensus of the majority of industry consultees, but one company believed that the totals could be much higher whilst another believed that the number of likely products authorisations appears to be high – unless this figure includes both the "core" biocides as well as variations with different trade names (i.e. for sale in specific				

Parameter	Value		Source	Notes
	Low	High		
countries) or with minor variations in the formulation				

ANNEX VI: STANDARD ASSUMPTIONS ON COSTS

Parameter	Value		Source	Notes
	Low	High		
Product authorisation				
Testing (average)	€48,000	€60,000	Consultation (industry)	Central estimate - actual cost estimates by industry ranged from €15,000 to over €150,000
Dossier preparation	€10,000	€70,000	Consultation (industry)	
Letter of access for use of data from the active substance dossier	€32,000	€90,000	Consultation (industry)	Most likely to be charged as % increase in active substance price (of below 5% to 50%) than a lump sum
Total cost of product authorisation application	€90,000	€200,000	Consultation (industry)	Based on average of responses
Fee – 1st authorisation (average)	€19,000		Consultation (CAs) and Composite report[2]	Average of responses
Mutual recognition fee (average per market)	€2,000		Consultation (CAs) and composite report[2]	Average of responses
Active substance[3]				
Total testing costs (including vertebrate	€2	€2.4	Study on impacts of the BPD,	Derived from testing cost for full data package Confirmed by

animal testing)	million	million	confirmed by consultation	stakeholder information
Vertebrate animal testing costs	€1.5 million	€1.8 million	Study on impacts of the BPD - testing cost for full data package, confirmed by consultation	75% of total testing cost.
Total cost of active substance dossier	€3.0 million	€5.0 million	Study on impacts of the BPD	
Fees	€160,000		Consultation (CAs) and composite report	Average

Notes

2. European Commission (2008): Composite Report in accordance with Article 24 of Directive 98/8/EC concerning the placing of biocidal products on the market Covering the period from December 2003 to November 2006

3. Details of the derivation of cost estimates for active substances are given Hydrotox, Oekopol, RPA (2007). Study on Impact of the Implementation of Directive 98/8/EC concerning the Placing on the Market of Biocidal Products (http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/study_implementation/report_101007pdf/_EN_1.0_&a=d)

ANNEX VII: DELIMITATION OF COSTS

		Administrative costs (€)	Testing costs (€)
Treated materials - inclusion of active substances in Annex I:	8.800.000	1.760.000	7.040.000
Treated materials - biocidal product autorisation	2.780.000	556.000	2.224.000
Treated materials - labelling	33.400.000	33.400.000	-
Product autorisation	-130.000.000	-130.000.000	-
Data sharing - industry	-205.000.000	-41.000.000	-164.000.000
Data requirements - active substances	-8.500.000	- 425.000	- 8.075.000
Data requirements - product authorisation	-51.150.000	-2.557.500	- 48.592.500
Data requirements - positive listing of low risk substances	-24.950.000	-1.247.500	- 23.702.500
TOTAL COSTS (€) per year	**-374.620.000**	**-139.514.000**	**- 235.106.000**

ANNEX VIII: EU STANDARD COST MODEL REPORTING SHEET

Directive 98/8/EC concerning the placing of biocidal products on the market						Tariff (€ per hour)		TIme (hour)		Price (per action or equip)	Freq (per year)	Nbr of entities	Total nbr of actions	Total cost	Regulatory origin (%)			
No.	Ass. Art.	Orig. Art.	Type of obligation	Description of required action(s)	Target group	i	e	i	e						Int	EU	Nat	Reg
1			Application for individual authorisation or exemption	Producing new data	Treated materials - inclusion of Active Substances in Annex 1					0,0	1	N/A		1.760.000		100%		
2			Application for individual authorisation or exemption	Producing new data	Treated materials - biocidal product autorisation					0,0	1	N/A		556.000		100%		
3			Information labelling for third parties	Designing information material (leaflet conception…)	Treated materials - labelling costs					0,0	1	N/A		33.400.000		100%		
4			Application for individual authorisation or exemption	Producing new data	Product autorisation					0,0	1	N/A		-130.000.000		100%		
5			Application for individual authorisation or exemption	Producing new data	Data sharing - industry					0,0	1	N/A		-41.000.000		100%		
6			Application for individual authorisation or exemption	Producing new data	Data requirements - active substances					0,0	1	N/A		-425.000		100%		
7			Application for individual authorisation or exemption	Producing new data	Data requirements - product auth,					0,0	1	N/A		-2.557.000		100%		
8			Application for individual authorisation or exemption	Producing new data	Data requirements - positive listing of low risk substances					0,0	1	N/A		-1.247.500		100%		

Total Administrative costs (€) -139.514.000