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

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Final Report

for

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List of Abbreviations

A.I.S.E	International Association for Soaps, Detergents and Maintenance Products
BPD	Biocidal Products Directive
CA	Competent Authority
CAS	Chemical Abstracts Service
CEC	Commission of the European Communities
CEFIC	European Chemical Industry Council
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytical Council
CIRCA	Communication & Information Resource Centre
DAR	Draft Assessment Report
DG	Directorate General
EC	European Communities or European Commission
ECCO	European Commission Co-ordination
EEC	European Economic Community
EFSA	European Food Safety Authority
EPA	(DK, USA) Environmental Protection Agency
EUROSTAT	Statistical Office of the European Communities
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (US)
EU	European Union
HSE	Health and Safety Executive (UK)
MS	Member State
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PPP	Plant Protection Products
PPPD	Plant Protection Products Directive
PT	product type
REACH	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMS	Rapporteur Member State
SCB	Standing Committee on Biocides
SMEs	Small and Medium sized Enterprises
TNsG	Technical Notes for Guidance
TNO	Netherlands Organisation for Applied Scientific Research
WHO	World Health Organisation

0 Executive Summary

Seven years after the entry into force of the Biocidal Products Directive (98/8/EC) (BPD) in 2000, the Commission is required to draw up a report addressing the implementation of the Directive, the functioning of simplified procedures and possible amendments and improvements. A study on the impacts of the Directive has been contracted to three consultants, with the aim of providing further information to the Commission. The findings of the study are presented in this report.

The objective of the study was to assess impacts of the BPD as perceived by the main stakeholders. Impacts include market effects, including benefits, following the removal of active substances from the review programme and the potential consequences of this for pest control and the level of protection. Additionally, the functioning of simplified procedures and potential amendments proposed by stakeholders have been considered.

The main information source was a stakeholder consultation, based on tailored questionnaires launched on the website of DG Environment in November 2006. Around 280 stakeholders from Competent Authorities (CAs), industry, users, and NGOs responded to the questionnaires and/or participated in the case studies. Additional information was obtained from EU statistics, national product registers, literature, internet sources, and CIRCA document analysis.

An in-depth analysis of selected topics was carried out through case studies covering the reasons for and impacts of the withdrawal of active substances, the difficulties in harmonising the work of CAs and opinions on simplified procedures. Potential amendments or recommendations for implementation were identified, covering reduced data requirements, frame formulations, variations in product authorisation and mutual recognition.

The main conclusions from the study are:

Impacts on the market are difficult to estimate, as statistics are inconsistent and do not distinguish between biocides and pesticides. Preliminary estimates on the production of biocidal active substances in the EU-15 suggest a total market volume of about 100,000 – 250,000 t/y, which corresponds to a market value of between 0.5 and 1.5 Billion Euro (based on the assumption that the biocide market corresponds to about 25% of the total pesticide market). The corresponding market for biocidal products is about three times larger.

From a total of 964 active substances initially identified, only 416 have been notified for at least one product type (PT). Of these, 367 active substances are still covered by the review programme for at least one PT and 49 have been definitely withdrawn. From available product registers, it is evident that only 13-33% of all active substances that have not been notified, and had to be removed from the market by September 2006, were contained in biocidal products. Substances withdrawn from the review programme are mainly potential basic substances, natural oils, insecticides and chromium compounds. The industry indicates that the development of new active substances is discouraged by the BPD, as its resources are focused on the review programme and the costs and risks of non-inclusion of an active are considered to be too high.

The numbers of biocidal products on the national markets differ, depending on whether or not approval schemes were in place before the BPD. Around 8-10% of all biocidal

products have been affected by the removal of non-notified active substances. In addition, another 5% of biocidal products will be removed because their active substances have been withdrawn from the review programme. Some of the substances withdrawn are classified as very dangerous to human health or the environment, and some can be considered as potentially low-risk substances. Price increases for biocide products of between 10 and 30% are anticipated by the industry; however, there is no indication as to the actual price increases at present.

Small and medium enterprises (SMEs) are particularly affected by the BPD, while larger companies are more likely to be able to bear the costs of dossier preparation. Users of biocides have already experienced impacts, because they have had to modify their product ranges.

The implementation of the BPD is too recent for evidence to be available **on impacts on pest control and the level of protection**. However, future treatment gaps and the development of tolerance and resistance of target organisms are feared by all stakeholders, due to a reduced variety of active substances and respective modes of action.

The main **benefits of the BPD** are widely seen as the harmonization of the currently quite diverse market and the mutual recognition scheme. However, there are considerable doubts about whether harmonisation can be achieved and whether mutual recognition will work in practice. CAs, NGOs and some industry stakeholders also welcome the removal of substances of very high concern from the market. Users appreciate a better overview and access to data on actives.

The main **reasons for unwanted impacts** are the extensive data requirements for dossier preparation, the high and varying fees for approval of active substances and authorisation of products, the lack of expertise in dossier preparation and evaluation, the lack of legal certainty due to comparative risk assessment of active substances and uncertainty regarding the application of the BPD (e.g. in relation to data-protection, free-riders, borderlines, waiving possibilities, technical guidance for risk assessments, efficacy testing and exposure). The industry is concerned about free-riders; in relation to this, data protection, clearer rules on data sharing and consortia are relevant and solutions are the subject of ongoing discussions.

Whilst the **functioning of simplified procedures** for basic substances and low-risk products is generally not considered to be advantageous, frame formulations are seen as an important instrument for cost-effective implementation of the directive. However, guidance on how the concept should be understood and implemented is urgently needed. The possibility to request derogations based on essential use is not well accepted by the industry or authorities. The mutual recognition scheme is widely accepted and is expected to simplify product authorisation, if harmonised implementation is ensured and relevant guidance developed.

Requests for **amendments** to the BPD have been submitted by all stakeholder groups. Amongst others, exclusion from the scope of the BPD is requested for essential oils and other natural substances, for food and feed material, as well as for embalming fluids and preservatives for food or feeds. Derogations have been suggested for niche market products (minor use products). A more centralised administration of the BPD has been proposed, following the example of the new chemicals regulation (REACH) and the revised Directive on Plant Protection Products (PPPD). A comparison with the data requirements of REACH indicates that there are several options to reduce data requirements for Annex 1 inclusion. However, implementing similar approaches would also mean a policy shift (risk-based data generation, less control by authorities). Several

proposals for modifying the definition of frame formulations have been submitted, each of which has benefits and drawbacks. Further, variations in the authorisation decision processs could be adopted, based on various models found in other legal frameworks. Mutual recognition has also been implemented in several other legal instruments. Models suggested as having potential to improve the application of the BPD include centralising (parts of) the decision making process from Member States to the Commission or an Agency, extracting relevant information from dossiers prepared under other Directives and more detailed procedural roles and transparency of evaluation of dossiers.

In **conclusion**, the study identified the need, and potential options, for amendments to address the unwanted effects of the BPD. Measures to reduce the number of substances being withdrawn, by reducing data requirements and facilitating product authorisation, would appear to be key. Furthermore, increased harmonisation of procedures and of interpretation of the requirements would appear to be urgently needed, to prevent unfair competition and failure to achieve the objective of a harmonised market.

The study reflects the opinion of the stakeholders and not necessarily those of the consultants or the Commission. Within the framework of the study, no verification of the reliability of stakeholders' concerns, suggestions and proposals for amendments could be performed.

1 Scope of the study

1.1 Background

The Biocidal Product Directive 98/8/EC (BPD) governs the authorisation and the placing on the market of biocidal products in the European Union. This Directive establishes a two-tier system where the Community evaluates and approves active substances; thereafter, individual Member States (MS) authorise products containing these substances. A basic provision of the BPD is the establishment of a positive list of active substances that may be used in biocidal products without unacceptable effects on the environment, human or animal health (Annex I or IA of the BPD). In addition, when requested by applicants, MS are obliged to mutually recognise authorisations and registrations granted by other MS.

An evaluation of all existing active substances is to be carried out during a transition period, ending in May 2010. During this review programme, a decision will be made as to whether these active substances should be included in Annex I, IA or IB of the BPD. In 2000, industry was invited to identify to the Commission all existing active substances. It was agreed that products containing existing undefended substances which had not been notified for evaluation in one of the four priority lists should be removed from the market by 1st September 2006. The same restrictions apply to biocidal products containing active substances which have been notified, but not for that product type. Other products, containing defended substances, can remain on the market while the substances are being evaluated. Biocidal products containing notified substances for which no dossier has been submitted within the time-frames set out in the Review Regulation, and for which no new participant took over the role of defending these substances, have to be removed from the market 12 months after the entry into force of the relevant non-inclusion decision (Regulation 2032/2003, as amended for the 2nd time by Regulation 1849/2006). Once the evaluation of an active substance is finalised, marketing authorisations must be granted, modified or cancelled, as appropriate, for products containing that substance.

1.2 Objectives of the Study

The aim of the study is to provide the Commission with key findings and lessons learned from the implementation of the Directive, six years after its entry into force and, more critically, after 1 September 2006, which was the deadline for removing all products containing undefended active substances from the market. The findings and lessons shall be accompanied by a set of detailed recommendations to mitigate any unwanted effects of the implementation of the Directive.

The key objective is to describe the impact of the Directive as perceived by the main stakeholders (competent authorities (CA), industry and users), on businesses, the availability of products, on prices, effects on competition, etc. This includes a quantitative (number of products available) and qualitative (adequacy of supply of products to respond to market demands and specific needs) analysis of the consequences of the removal of products containing undefended substances from the market by 1 September 2006.

A further objective of the study is to analyse whether, and if so how, the current regulatory framework should be amended to address the problems identified, taking into consideration the likely environmental, economic and social impacts of any amendment.

According to Article 18 (5) of the BPD on "Information exchange", the Commission shall draw up a report on the implementation of the BPD seven years after its entry into force (2000-2007). In particular, the report should address the functioning of the simplified procedures (frame-formulations, low-risk biocidal products and commodity substances). If necessary the report should be accompanied by proposals for changes to the BPD. The findings and recommendations of this study should provide a basis for the report to the Council.

The study reflects the opinion of the stakeholders and not necessarily those of the consultants or the Commission. Within the framework of the study no verification of the reliability of stakeholders' concerns, suggestions and proposals for amendments could be performed.

2 Approach and methodology

2.1 Workflow

The workflow for the study has been divided into three tasks:

Task 1 consisted of an analytical_overview and stakeholder consultation. A market analysis of biocidal products was carried out by gathering statistical information from various literature and internet sources and by evaluating several national biocidal product registers. Stakeholders from CAs, manufacturing and formulating companies, industry associations, users of biocides and other experts were consulted to obtain their general views on the positive and negative impacts of the BPD and the reasons why certain active substances have not been defended. The stakeholder consultation was supported by tailored questionnaires for CAs, producers, formulators, users and other stakeholders. Together with a project description, the questionnaires were actively distributed to all CAs and around 500 stakeholders. In addition, stakeholders were asked to forward the questionnaires to any other person who was directly or indirectly affected by the implementation of the Directive. The project was presented at the 23rd Competent Authorities Meeting on December 28th 2006 in Brussels, at the Fresenius Conference on the BPD on November 30th to December 1st 2006 in Bonn and at the biocide forum of the German chemical association (VCI) in Frankfurt on March 19th 2007. The first consultation round ended on 15th January 2007 and the answers and results of task 1 were presented in the progress report, together with an outline of potential case studies.

Task 2 consisted of four case studies, to examine in greater depth a number of the main issues identified under task 1:

1. Reasons for the withdrawal of active substances and potential measures to reduce the costs
2. Impacts of the withdrawal of active substances

3. Harmonisation of the work of CAs
4. Simplified procedures

As the process of evaluation of active substances is ongoing, the product types addressed have been drawn from to the first and second priority lists. The approach and results of the case studies are summarised in four case study reports (Annexes 1-4).

In **Task 3**, amendments to the Directive proposed by MS or stakeholders to address the negative impacts identified in tasks 1 and 2 were analysed, in order to identify their potential effects. Key advantages and disadvantages of the amendments, compared to the current situation, were identified.
The following potential amendments have been evaluated more in detail:

1. How could data requirements be reduced?
2. Frame formulations (Is a new definition needed?)
3. Variations to product authorisations (analysis of the minor/major variation concept)
4. Provisions for the operation of mutual recognition

The analysis consisted of a deeper evaluation of the information gathered and a comparison with the provisions of other regulatory instruments, such as REACH, PPPD, and the Medicinal Products Directive. The results were summarised in four reports on potential amendments.

The final report summarizes the results of tasks 1-3.

2.2 Data sources

The following main data sources have been evaluated:

- Literature and unpublished information from stakeholders and from the Internet
- Consultation with relevant stakeholders by means of personal interviews and targeted questionnaires
- Documentation and proceedings of conferences related to the BPD
- Examination of national product registers
- Working documents and minutes from CA meetings, Technical Meetings and from the Standing Committee on Biocidal Products.

The response rate to the questionnaires was very good and contributions were received from all stakeholder groups. The distribution of responses is summarised below:

	CAs	Producers	Formulators	Users of BP	Others
No of stakeholders	11	40	106	78	32
Member states involved	AT, BE, ES, DE, FI, FR, HU, IT, SV, SI, UK	AT, BE, CH, DE, ES, FI, FR, HU, IT, LU, NL, SV, UK	AT, BE, DA, DE, ES, FR, EL, IT, NL, PL, PT, UK	BE, CH, DE, ES, FR, IE, NL, SV, UK	AT, BE, CH, DA, DE, ES, FR, HU, IE, IT, LU, NL, PL, PT, SV, UK
PT		Most PT	Most PT	5, 6, 8, 9-14, 18, 19, 22	

About 65% of the formulators and 40% of the producers that contributed to the survey are SMEs. According to data provided by producers (as defined by Article 2 'Definitions' of Regulation 1896/2000), the volume of production of active substances was within a range of 0.2 to 3,300 t/y (median 140, n=38). Only a few high volume disinfectants (peracetic acid, chlorine and sodium hypochlorite) exceeded 3,500 t/a. Typical production volumes of biocidal products from formulators were within the range of 40 kg/y to 10,000 t/y per PT.

Detailed statements, containing information additional to the questionnaire, were received from a number of industry associations: the German Chemical Industry Association (VCI), the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E), the European Council of Paint, Printing Inks and Artists' Colours Industry (CEPE). From the NGOs, PAN Europe sent detailed comments with its response and several members of PAN Europe supported these comments by submitting their own replies to the questionnaires.

Competent Authorities from 11 MS responded to the questionnaires. Some of their comments were very detailed, recommending amendments to specific articles of the Directive.

DG Environment provided information extracted from Belgium, Denmark, Estonia, Finland, Latvia, Lithuania, Portugal, Slovakia, Slovenia, Spain, Sweden and The Netherlands databases to the contractors. This information was treated in a confidential manner. Several further national registers, which are publicly available on the Internet or were provided by competent authorities on request, have also been evaluated.

Further stakeholders, not included above, participated in the four case studies and also provided detailed information on other regulatory areas (see annexes 1-4).

Finally, the contractors have had direct access to discussion documents and meeting protocols from the competent authorities provided by the CIRCA Interest Group on Biocides. These documents are available to competent authorities and observers, indicating a substantial interest in keeping informed.

3 Analysis of impacts

3.1 Anticipated impacts of the BPD

In a UK impact assessment, the anticipated benefits for human health and the environment were described but not quantified.[1] The BPD was anticipated to stimulate competition and thus increase diversity of supply, without increasing prices. It was estimated that the implementation costs would drain resources from research and development of new active substances; however, this effect would be alleviated by the simplified procedures. In general, it was predicted that larger companies could benefit more from the impacts on the market than SMEs. A more recent UK impact assessment noted that some small companies

[1] UK HSE Biocidal Products Regulations 2001 - final version http://hse.gov.uk/ria/chemical/biocides.htm

with low turnovers of biocidal products could no longer find it economically viable to supply these products.[2]

The UK Chemical Industries Association estimated the cost for producing the necessary data at between 2.9 and 4.4 million EUR per active substance. 400 existing active substances were expected to be supported during the review process. The cost for authorisation/registration of biocidal products was estimated to vary between 14,000 and 183,000 EUR per product.

Impact assessments by the industry identified potential benefits through increased efforts to provide active substances and biocidal products that pose less risk to human health and the environment, as well as 'consolidation of the market'. Market impacts would result from the implementation costs, giving advantages to large companies rather than SMEs. The main concerns focussed on the costs of substance and product assessment, data protection rules and free-riding, the functioning of simplified procedures and the business risks from comparative assessments.

3.2 Impacts on the market

3.2.1 Scale of the biocides market

As biocides have not previously been regulated at EU-level, only limited and inconsistent statistical information on the volume and value of the European biocide market is available. In addition, there is an overlap with the pesticide market for plant protection products. Data on production volumes or value of active substances used in pesticides – including biocidal products - are collected by EUROSTAT. Rough estimates on the production of active substances (of both biocides and plant protection products) in the EU-15 (1998 – 2005) suggest a market volume of approximately 330,000 – 1 million t/y,, corresponding to a value of between 1.7 and 6 Billion Euro. However, the data are not directly comparable, because the reporting for different years is inconsistent.

The statistics generally do not distinguish between biocide and pesticide active substances and the biocides market is estimated by several sources at 25% of the total market in terms of values. In addition, as biocidal products achieve higher prices per volume, the tonnage of biocidal active substances is even lower than 25% of the total pesticide market.[3]

According to the UK Health and Safety Executive (HSE), in 2000 the total EU market for active substances of biocides (excluding pesticides) was estimated to be worth up to £330m (500 million EUR) and the corresponding market for biocidal products is about three times larger. It was further estimated that 800 products per year across the EU would

[2] UK HSE BIOCIDAL PRODUCTS REGULATIONS: GENERAL INDUSTRY CHARGE REGULATORY IMPACT ASSESSMENT 2003 http://hse.gov.uk/ria/chemical/biocides2003.pdf

[3] European Commission: The impact assessment of the thematic strategy on the sustainable use of pesticides. Commission staff working paper accompanying the proposal for a Directive of the European Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticides. COM(2006) 373 final, Brussels, 12.7.2006 http://ec.europa.eu/environment/ppps/pdf/sec_2006_0894.pdf

require authorisation/registration once their active substance(s) have been reviewed and added to Annex I. (HSE).[4]

For several sectors, detailed market information is available from internet sources. For example, the total consumption of formulated biocides in plastics is estimated for Europe to amount to around 5.000 tons in 2005, with about two-thirds of this used for the preservation of organic plasticizers in flexible PVC.[5]

Comparative data on biocides consumption in 1998, before the implementation of the BPD, are available from a market analysis by Kline & Company.[6] In 1997, the West European 'specialty biocides' market was valued at 890 million DM (equivalent 500 million US$), representing a 24% share of the total world biocides market.[6]

3.2.2 Withdrawal of active substances

The Review program for the evaluation of existing active substances was established by the first and the second review Regulation and their amendments. In November 2006, DG Environment provided an Access database to the contractors containing three lists of active substances which were identified, which were included in and which were withdrawn from the review programme, respectively. As active substances withdrawn from the review programme for one PT might be defended for another PT, a fourth list was established containing all active substances which had only been identified but never notified. These four lists were used in this study for the evaluation of national product registers. However, only dossiers for the first two priority lists had already been submitted at the time of the study and so withdrawal from the review programme could be monitored only for PT 8, 14, 16, 18, 19 and 21. The data do not take into account changes introduced with Regulation 1849/2006 (amending Regulation 2032/2003) from 14th December 2006 and later adjustments.

Figure 1 provides an overview of the status of the review programme in November 2006. From a total of 964 identified active substances, only 416 have been notified for evaluation in one or more PTs, while 548 active substances remained only identified. Currently, 367 different active substances are still in the review programme for at least one PT. About 139 previously notified active substances have been withdrawn from the review programme for one or more PTs. However, 90 of these are still supported for other PTs. Therefore, only 49 actives that were formerly notified were completely withdrawn, and are already definitely excluded from the review programme during the evaluation of the first two priority lists.

[4] http://hse.gov.uk/ria/chemical/biocides.htm

[5] Anonymous 2006. Steady growth predicted for biocides Plastics Additives & Compounding. January / February 2006
http://www.addcomp.com/features/archive/janfeb06/janfeb06.htm

[6] Kline & Company Inc. Speciality biocides Western Europe 1998. Kline Europe, S.A., Brussels, Belgium, http://www.klinegroup.com/reports/brochures/y347/brochure.pdf

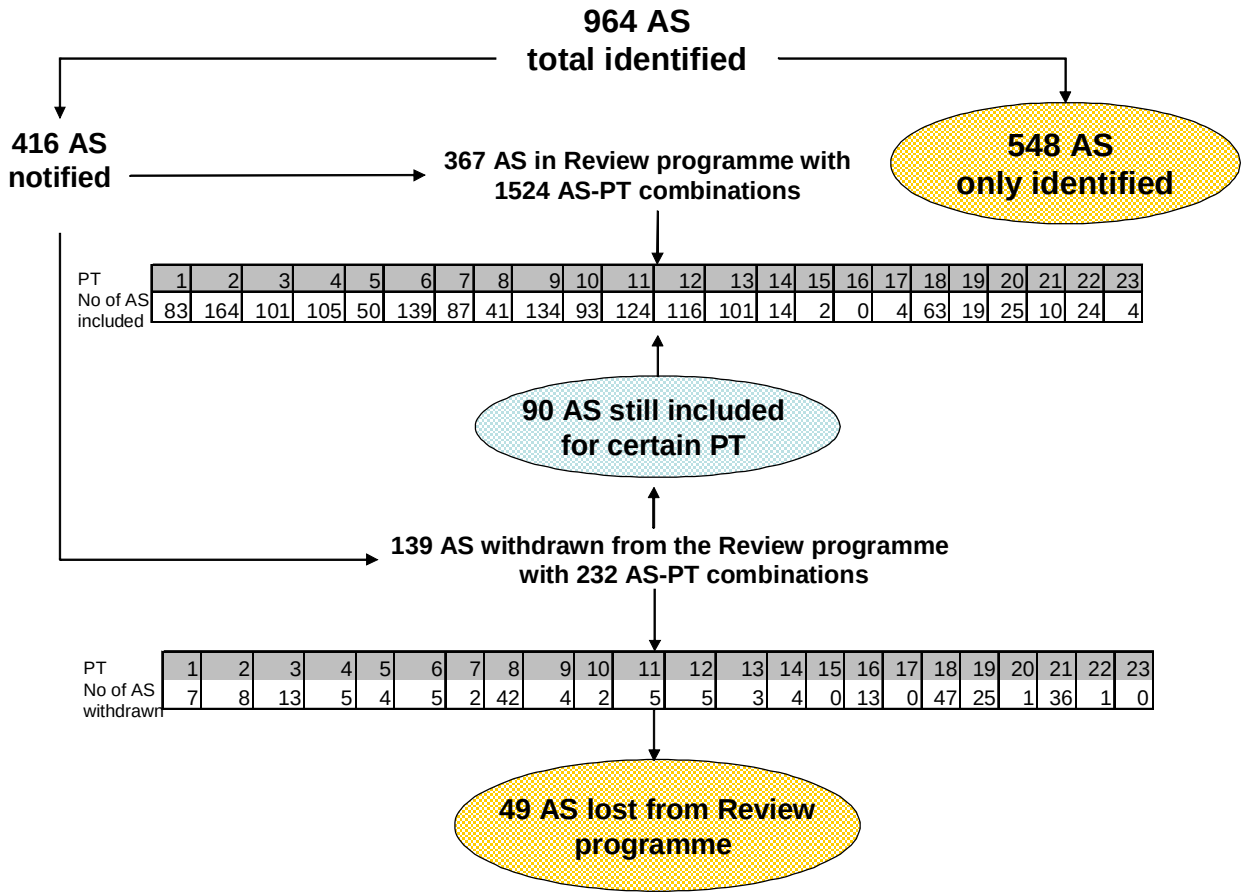

Figure 1: Status of the review programme concerning existing active substance (November 2006)

3.2.3 Withdrawal of biocidal products (evaluation of national product registers)

The evaluation of the impact of the BPD on the market for biocidal products consisted of two steps. First the total number of products containing identified but not notified active substances has been evaluated (immediately affected by September 1st 2006) without any further link to PTs. Second the number of biocidal products containing active substances withdrawn from the review programme has been assessed (notification, but no dossier submission). Here the relevant PT has been considered.

The number of biocidal products containing specific active substances does not necessarily reflect the importance of those active substances in terms of market share or special requirements from specific application areas. Because no consumption data are available, these aspects could only be considered on a case-by-case basis.

The 1st Composite Report submitted in accordance with Article 24 of the Directive, covering the period of May 2000 to November 2003, gave a first overview of the number of biocidal products registered in several MS during this period. Not surprisingly, in MS

with authorisation regimes in place before the entry into force of the BPD, fewer biocidal products were on the market than in countries that only had a registration procedure or no obligation at all for registering biocidal products. The number of biocidal products differed between 250 in Denmark, and 6000 in Spain[7]. However, existing national registers did not always cover all product types and are therefore not fully comparable.

DG Environment provided Access data bases from Belgium, Denmark, Estonia, Finland, Latvia, Lithuania, Portugal, Slovakia, Slovenia, Spain, Sweden and The Netherlands to the contractors. The data has been provided by CAs and reflects the situation in 2005/06. The databases have been compared with the lists of active substances identified, but not notified, and of active substances that were withdrawn from the review programme. Table 1 presents the results on the occurrence of biocidal products in these countries, indicating that around 1460 biocidal products (14% of the total number) were affected. [8]

Table 1: Data analysis of the product register provided by DG Environment (Reference year: 2005/06

	BE	DK	EE	FI	LT	LV	NL	PT	SE	SI	SK	sum
total number of BP (all PTs)	915	385	153	508	66	1537	1587	554	672	1505	2360	10242
number BP with AS only identified but not notified	54	8	8	68	4	203	118	31	47	137	233	911
% of total BP	**6**	**2**	**5**	**13**	**6**	**13**	**7**	**6**	**7**	**9**	**10**	**9**
number of BP with AS notified but withdrawn from Review programme	57		2	33		87	54	125	47	71	75	551
% of total BP	**6**	**0**	**1**	**6**	**0**	**6**	**3**	**23**	**7**	**5**	**3**	**5**
total % of BP to be removed	**12**	**2**	**7**	**20**	**6**	**19**	**11**	**28**	**14**	**14**	**13**	**14**

BP: Biocidal Products
AS: Active Substances

Table 2 lists national biocidal product registers which have been evaluated more in detail.

Table 2: National Biocidal Product Registers

Member State	Website	Number of Products	PT
Danish Environmental Protection Agency	http://glwww.mst.dk/homepage/	558	8, 12, 14, 15, 18
Dutch Board of Authorisation of Pesticides (CTB)	http://www.ctb-wageningen.nl/	774	2-14, 18, 19, 21, 23
German BAuA	https://195.138.41.34/baua_biozid/offen/suchmaske.php	15200	1-14, 16, 18-22
United Kingdom Health and Safety Executive	http://www.hse.gov.uk/pesticides/bluebook/partb.htm http://www.hse.gov.uk/biocides/listbpappcopr.pdf	2308	2, 7, 8, 14, 15, 18, 19, 21
Swedish Chemical Agency KEMI	http://apps.kemi.se/bkmregoff/default.cfm	444	8, 9, 12, 14, 15, 18, 21

[7] European Commission. 2004. First Composite Report in accordance with Article 24 of Directive 98/8/EC concerning the placing of Biocidal Products on the market covering the Period May 2000 to November 2003. Directorate General Environment, Brussels, 22.10.2004 (http://ec.europa.eu/environment/biocides/pdf/composite_report.pdf

[8] The sum of biocidal products in Table 1 not necessarily refers to different biocidal products because identical products might be on the market of several Member States.

In Germany around 8% of all biocidal products had to be removed by 1st September 2006, while a further 4% are affected by the withdrawal of active substances from the review programme. In the UK, 18% in total had to be withdrawn. The analysis of product registers indicates that only a small proportion of the approximately 550 existing active substances identified but not defended were previously used in biocidal products on the market.

The number of non-notified active substances for which the product registers provides evidence that they were used in biocidal products before the 1st September 2006 deadline varies across the EU. In Sweden, about 70 previously-used active substances were withdrawn, in Germany and Portugal up to 180 such substances were withdrawn. This corresponds to about 13% to 33% of all identified but not notified existing actives (n=548).

However, the true number of active substances affected by the Directive at this stage, and their market volumes and shares, cannot be specified because existing national registers do not cover all product types and very little comparative data from the period before the implementation of the Directive is available. Nevertheless, the lower number of non-notified active substances on the market might indicate that industry tended to identify all possible active substances, in order to maintain their potential for future applications. This is confirmed by the fact that the claim of a specific biocidal efficacy has recently been questioned for several substances (i. e. chromium trioxide, pine tar and acetic acid).

Due to the data requirements of a notification, and the obligation to confirm ownership of the data, performing this step indicates *a priori* a substantial interest by the producer in the active substance. Therefore, the withdrawal of around 50 additional active substances from the 1st and 2nd priority lists of the review programme is of particular concern.

According to stakeholders, uncertainty over the use pattern of active substances has also caused the withdrawal of subsequent notifications. This may be the reason why no dossier for a molluscicide has been submitted to the Review Program. The market survey indicated that no molluscicidal products covered by the BPD were on the market, because they are already covered by cooling water biocides (PT11) and other biocidal products of PT 2 (application areas include, *inter alia*, swimming pools, aquariums, bathing and other waters). Additionally, some disinfectants and repellents wrongly included in PT18 have been removed. Given the ongoing progress of the review programme (2nd amendment of the 2nd Review Regulation 2032/2003) and the uncertainty regarding the current status of different product registers, the evaluation has to be carried out carefully and on the basis of a non-ambiguous identity of the active substances involved. Table 3 summarises the most important active substances from all product registers (in terms of number of products containing them) which have not been supported.

Table 3: Summary of most important active substances not supported

	Potential basic substances	Wood preservatives	Rodenticides	Insecticides	Repellents	Antifoulings
Only identified, non-notified	Sodium hydroxide Acetic acid Potassium hydroxide Sodium carbonate Urea	Copper sulphate pentahydrate Copper(I) oxide Deltamethrin	Cholecalciferol	Phenothrin Trichlofon Resmethrin Methoprene	Citronella oil Lavender oil Neem Cedarwood oil Eucalyptus oil Methyl-4-hydroxibenzoate	Acypetacs Zink Tributyltin Naphthenate Tributyltin oxide
Withdrawn from review programme	Sodium hydrogencarbonate Ethanol	2-octyl-2H-isothiazol-3-one Chromium trioxide Diarsenic pentaoxide Dicopper oxide Copper sulphate Deltamethrin Cyfluthrin Fenitrothione	Diphacinone Trimagnesiumdiphosphide Bromethalin	Allethrin Chlorpyrifos 14-dichlorbencene S-Bioallethrin Phoxim Bioresmethrin Methomyl Pirimiphos-methyl Boric acid Fenithrothion Amitraz	Permethrin Piperonyl butoxide Naphthalene Bone oil Australian Tea Tree oil Silicon dioxide	Diuron, Chlorothalonil, Ziram,

Several compounds are comparable and belong to the same parent compound (such as copper sulphate and copper sulphate pentahydrate). It can be expected that during the evaluation of a parent compound, its salts and hydrates will be covered as well. Disodium octaborate and sodium perborate monohydrate will be assumed to be comparable to parent compounds during their dossier evaluation. While dicopper oxide (CAS 1317-39-1) has been withdrawn from the review programme, copper oxide (CAS 1317-38-0) is still being supported. A particularly high percentage of active substances for wood preservatives (PT8), insecticides (PT18) and repellents/attractants (PT 19) have been withdrawn from the review programme.

The evaluation of product registers indicated that the removal of a large proportion of bio-cidal products can be attributed to a relatively limited number of active substances which can be grouped as indicated below.

Several substances foreseen as potential basic substances have not been notified or have been withdrawn, including sodium hydroxide, sodium hydrogensulphate, acetic acid, sodium carbonate, sodium hydrogencarbonate sulphuric acid, sodium perborate tetrahydrate, potassium hydroxide, iron sulphate and urea.

Additionally, essential oils are particularly affected. Almost 50 essential oils from plants have not been defended as active substances. Among them are Basil oil, Cajuput oil, Cedarwood oil, Celery oil, Chamomile oil, Citronella oil, Clove leaf oil, Coriander oil, Cornmint oil, Cumin oil, Cypress oil, Eucalyptus oil, Juniperberry oil, Neem oil, Lavender oil, Lemongrass oil, Geranium oil, Litsea cubeba oil, Melaleuca oil, Pine oil, Black pepper oil, Palmarosa oil, Patchouli oil, Pennyroyal oil, Peppermint oil, Rosewood oil, Rue oil, Spearmint oil, Thyme oil, Valeriana officinalis oil and also many other essential oils or natural extracts.

Another group particularly affected are insecticides, several of which were formerly among the most important ones used in PT 18 (Allethrin, Chlorpyrifos and Phenothrine). In total, 47 active substances have been removed from the review programme for PT18 while 63 active substances are still being defended. Allethrin and Phenothrine are not included in

Annex I of Directive 91/414/EEC on Plant Protection Products while Chlorpyrifos was included in 2005.

No dossier for chromium compounds have been submitted for PT 8 as wood preservatives, because the substances have been considered as fixative agents, but copper and arsenic compounds have also been affected.

Although dossiers for active substances for PT 22 “Embalming and taxidermist fluids” will only be submitted with the 4th priority list by 31 October 2008, around 60 users of formaldehyde for funeral services indicated in their questionnaires that their suppliers have announced that they will no longer support formaldehyde for PT 22.

The reasons for the removal of active substance from the review programme are addressed more in detail in case study 1 (see Annex 1).

3.3 Unwanted impacts identified by stakeholders

The analysis of stakeholder responses to the questionnaires shows that the BPD has led to the withdrawal of a substantial number of active substances, among them several essential oils which industry considers as of low hazard potential and commodity substances. This indicates that the aim of removing high-risk products from the market, as well as offering simplified procedures for niche markets of commodities, has not been fully achieved.

3.3.1 Increased prices

A common response on anticipated effects of the BPD from producers was that prices of active substances will rise because of the costs of the BPD, which may be passed on to downstream users. It was also argued that the market will determine the prices and that “generic” active substances and stockpiling will delay the implementation of price increases. According to stakeholders, the predicted increase in prices for both active substances and biocidal products has not yet occurred during the transition period. Formulators anticipated price increases of between 2% and greater than 100%, with a majority estimating a range between 10% and 30%. Users of biocides assumed that the price of products that contain biocides will increase, but there has been no evidence of this yet further down the supply chain.

3.3.2 Development of new active substances

One aim of the BPD was to enhance the development of new, “better”, active substances and new, “better”, biocidal products. Since the implementation of the BPD, dossiers on only seven new active substances have been submitted and they are currently under evaluation.[9] In fact, most of these new active substances cannot really be considered as "new” chemicals, because they are approved active substances under the PPPD. Meanwhile, two of these dossiers have been withdrawn by the industry.

Some of the producers who responded to the consultation plan to invest in the development of new actives and they see this as a market opportunity. However, most of the producers

[9] Status of Evaluation of Application received in accordance with Article 11 of Directive 98/8/EC CA-June07-Doc.7.1

consulted are not considering developing new actives or alternatives, because the expected costs associated with BPD compliance, the time frame of registration and the risk of failing registration are significant and disproportionate to the size of the market. In addition, R&D opportunities are limited by the high BPD costs and by the lack of legal certainty, e. g. due to comparative risk assessment. In total, the risk is perceived as unacceptably high for new investment and incentives to invest in innovation are not considered to be provided by the BPD. This issue is discussed further in case study 1 (see Annex 1 of this report).The development of other alternatives has not been indicated by industry or users.

The limited number of requests for approvals for new active substances indicates that industry is focusing on (new applications of) existing substances and has dedicated its resources to the review programme, in order to retain market share. The strategic decision to develop new active substances has been postponed. However, it is notable that even before the implementation of the BPD only a small number of new active substances had been introduced to the biocide market each year.

3.3.3 Impacts on pest control and level of protection

From the questionnaires, there was no clear evidence of the impacts of the BPD on the ability to control pests, as the time since implementation is too short. Several stakeholders were concerned that tolerance and resistance of target organisms may become a problem, due to a reduced diversity of active substances and thus modes of action. This is mainly a concern for PTs against pests (rodenticides, insecticides) and for disinfectants, but seems less significant in the PTs for protecting materials. The impacts on pest control and level of protection have been analysed more in detail within case study 2 (see Annex 2 of this report).

3.3.4 Free-riders and competition

Industry respondents supporting active substances require a return on their investment in testing of active substances and dossier preparation and are concerned about free-riders and the evolution of a 'grey' market. However, no clear definition of free-riders exists and this term is used differently in different contexts:

- Notifiers of active substances had to submit basic data which allowed the placing on the market of notified substances until their evaluation was finalised and beyond the deadline of September 1st 2006. Other suppliers of these active substances reap the benefit of this notification, without sharing the costs.
- Dossier generation for active substances also benefits other suppliers beyond the inclusion of these actives in Annex I, until the requirement to submit dossiers for authorisation/registration of biocidal products becomes effective.
- After the deadline for dossier submission, free-riders will have to exit the market. However, the free-rider issue then becomes then a question of enforcement and control of the market (need for letter of access to all data required).
- Basic substances (inclusion in Annex IB) are generally available to the public without authorisation and the data owner cannot control other suppliers, thus free-riders could make use of that listing without facing costs.

However, as large companies in particular are able to defend their active substances, limiting data access might also be used to restrict new entrants to the market. Therefore data sharing and competition should be encouraged by the regulators in order to avoid the formation of monopolistic structures. Sometimes the term “free-rider” is wrongly used by data owners to refer to competitors that wish to have access to their data and are willing to share costs, but to whom the data-owner does not want to provide access.

Several instruments for balancing free-rider issues and data protection are currently being discussed, particularly the time period between the inclusion of active substances in Annex I and product authorisation. The concern of the data owner is to keep this period as short as possible, in order to reduce the period during which free-riders can still have access to the market. On the other hand, the period must be sufficiently long to permit the generation of data and the preparation of the biocidal products dossiers. Therefore, the free-rider issue is directly linked to data protection. A lack of confidence in the implementation of the rules of the BPD to prevent free-riding, and thus concern that the cost of dossier preparation would not be recouped from product sales, may have been the reason that some companies did not prepare a complete dossier.

3.4 Benefits identified by stakeholders

Implementation of the BPD is expected to result in benefits to health and safety, trade and the environment and some cost savings might also be realised. However, these benefits are difficult to quantify.

3.4.1 Harmonisation of the marketing requirements

The harmonisation of marketing requirements and mutual recognition of authorisations/registrations are considered as being the most important benefits by the industry. In addition, harmonisation is expected to stimulate competition, because it should make it easier to place a product on the market of many different MS. This will enhance competitions both between companies established within the EU and with those outside, which will in turn widen consumer choice and reduce prices.[7] Some industry representatives responding to the consultation concluded that “the new regulation is a lot of work, but it is good for the industry”. "It will give some regulation and sense into what is quite a diverse industry, and will get rid of some operators who are offering substandard products and inadequate product stewardship”.[10] According to producers, the main benefits of the BPD are the development of a single market, the harmonisation of requirements and mutual recognition. Additionally, they see benefits from developing comprehensive active substance dossiers and opening up new market opportunities with a “legal” biocide. According to one producer, the European model has gained a world wide reputation and products are expected to gain easier admission to other markets on the basis of an existing EU dossier. Many countries prefer to orient themselves towards EU rather than to US standards.

Formulators also see harmonisation of the marketing requirements (provided mutual recognition works) as the main benefits of the BPD. In addition, the fact that products,

[10] Alperowicz, N. 2002. Industry opinion split on market effect of European Directive (Biocide) Chemical Week, August 21, 2002 http://www.chemweek.com

once authorised, are considered as safe for human health and the environment is seen as beneficial. The possibility to use of letters of access is valued by formulators, as well as the fact that small volume low quality products may disappear from the market.

The questionnaire responses from both producers and formulators indicate, however, that industry doubts that harmonised standards for the safety of biocidal products will be implemented, with national authorities continuing to impose different (additional) requirements. According to CAs, the main benefits of the Directive are a harmonised procedure for the evaluation of active substances as a prerequisite for product authorisation and mutual recognition as the key to the internal market. However, the benefits of the Directive for market harmonisation are not visible yet, because the market is still in transition.

3.4.2 Withdrawal of active substances of concern

The withdrawal of substances of concern is also recognised as beneficial by the public. In general, the BPD will limit the availability of hazardous biocides. It is anticipated that leading producers of biocide active substances will increasingly focus on newer, safer products and formulations to enhance their market share and profits.[11]

One benefit of the BPD is that the phase-out of several active substances of concern already considered under the Dangerous Substances Directive (76/769/EEC) has been accelerated. An example is the use of arsenic compounds as wood preservatives in a limited range of applications. Directive 76/769/EEC permits the use of certain arsenic compounds as biocides for the treatment of wood. However, according to the BPD, products containing arsenic and arsenic compounds cannot be placed on the market for that purpose because the active substances are undefended and products cannot be authorised. Therefore Directive 76/769/EEC has been amended by 2006/139/EC. It is also notable that the marketing and use of diarsenic pentaoxide that has been withdrawn from PT 8 is already restricted by Directive 76/769/EEC (was assessed as category 1 carcinogens) and that others (e.g. Chlorpyrifos, Naphthalene, Diuron) are included in the list of priority substances to be phased out, in Annex X of the Water Framework Directive 2000/60/EC. Tributyltin compounds have also been banned in the framework of Directive 76/769/EEC.

In the questionnaire responses, producers recognised that the BPD enhances health, material and environmental safety, particularly in those countries where registration schemes were not previously in place. Most respondents believe, though, that the level of protection of health and the environment has decreased rather than increased, due to the removal of active substances which are no longer available for pest control.

Formulator respondents say that the control of hazardous substances and withdrawal of mutagenic and carcinogenic actives is beneficial. They also pointed to the fact that formulators will now have a better overview of, and better access to, data on active substances in order to make safer formulations. However, it is also suspected that many biocides that are not defended today will continue to be sold elsewhere in the world, thus putting EU producers at a global disadvantage. Some formulators do not anticipate real advantages

[11] Hirani, B.R., Koul, V.K. 2005. Commercial exploitation of biocides. chimica oggi - Chemistry Today Vol 23 (6), November/December 2005
http://www.teknoscienze.com/images/documenti/supplements/inserto%20HIRANICO6.pdf

from the BPD for the health of consumers and society,, as old and very toxic biocidal products (such as lindane, PCP) have already been removed from the market.

Several users of biocides indicated that existing safety standards have been applied to their sector prior the BPD, and they do not see any additional advantages from the risk assessment of biocides. Other users agree that, in principal, the optimisation of actives applied and their dosage should be improved by additional information made available.

According to CAs, the differentiation of active substances between those which are promising and hence supported by industry, and those that are non-sustainable and hence withdrawn, is seen as one of the benefits of the BPD. The phase-out of non-supported biocidal products in the review programme has already created considerable benefits for the protection of the environment and human and animal health by removing well known high-risk active substances. For the NGOs, the advantages may be summarized in a number of principles and provisions including a high level of protection for human health and the environment, the non-authorisation of biocides if there is another substance of the same PT with significantly lower risks (in other words, comparative assessment and substitution principle) and the differentiation between low risk substances and substances of concern.

3.4.3 Consumer protection

According to formulators, the requirements of the review and evaluation of the risks of actives will increase the protection of human health and the environment. But gaps still exist (such as on treated articles). However, as no products have yet been authorised under the BPD, it is too early to assess any positive impact. As, in their view, many potentially low-risk actives have been removed from the market without being evaluated, reduced protection of human health may result.

Several users of biocides indicated that they have had sufficient information on active substances from safety data sheets or technical bulletins in the past, and they do not expect an improvement in the quality of information from the BPD. Other respondents agreed that better communication and labelling is useful, to determine the correct use level for their products and to help to evaluate finished articles.

According to NGOs, non-chemical alternatives (e.g. pest control management) should also be considered further. In their view, a Directive on the Sustainable Use of Biocides (with the objective of reducing the use and the risks of biocides) should be considered in a future revision of the BPD.

4 Key findings

4.1 Reasons for unwanted impacts of the BPD

Stakeholders responding to the study identified a number of reasons for the unwanted impacts of the BPD. These included:

- The extensive data requirements for dossier preparation
- Issues related to data protection and sharing
- The level of fees for evaluation of active substance and product authorisation
- Uncertainty and inconsistency in the evaluation of dossiers and comparative risk assessment
- Lack of harmonisation of implementation and enforcement
- Interfaces with other regulatory instruments

These key findings are summarised below; further details are provided in the case study annexes to this report.

4.1.1 Data requirements

The data requirements for dossier preparation are one of the main issues raised by companies that intend to support active substances. The industry indicates that the cost of performing all studies completely from scratch could give rise to costs of between 3-5 million EUR. Further detailed breakdown of the costs of data generation is provided in case study 1 (see annex 1 to this report). The high cost means that the active substances would need to be marketed over a long time period to recover the costs. Hence, industry has focused its resources primarily on supporting existing actives, diverting resources from the development of new substances.

Responding CAs face uncertainty about data requirements and indicate that the necessary technical guidance is missing (e.g. on analytical methods, identity, technical equivalence, type of exposure scenario to be applied). As a consequence, data requirements have been applied differently in different Rapporteur Member States (RMS), which is considered unacceptable by respondents. It was also indicated that data requirements for low and very-low exposure products, in particular, are considered as too high for smaller companies. As product authorisation applies to formulations, which are mainly produced by SMEs, the cost of dossier preparation (including data requirements) is an important reason for many companies to consider the phase-out of their products. Possible amendments to the Directive in order to reduce the cost of dossier preparation are discussed in chapter 5.

4.1.2 Data sharing and data protection

According to producers, the formation of consortia is the only way for SMEs in particular (through sharing costs) to participate in the registration and authorisation process. With some exceptions, though, individual respondents considered consortia to be disadvantageous, as they consume time, might slow down the process of dossier preparation, can pose additional legal burden and costs to organise data sharing and protection (among competitors), or to verify the identity of the substance and to comply with European competition law. Multinational companies are seen as having little interest in forming consortia (they are often the owners of the required data). Refusing to form consortia may be also a legal way to obtain a monopoly position within the EU. More detail on the benefits and disadvantages of consortia is provided in case study 1 (see Annex 1 to this report). In this respect, respondents suggested that mandatory data sharing rules could ensure that all biocide markets will remain competitive, without undermining the fundamentals of the BPD.

According to CAs, they receive multiple dossiers if participants defending the same active substance do not reach agreement on data sharing. Evaluating these in several different assessment reports is laborious and might lead to conflicting conclusions. This also runs contrary to the aim of the BPD, to reduce duplicate testing with vertebrate animals.

The provisions on data protection are laid down in Article 12 of Directive 98/8/EC. In principle, the second or subsequent applicant (usually a formulator) needs a written agreement (letter of access) of the first applicant (data owner, usually a producer) in cases where they have no data of their own and data protection periods have not yet expired. As the beginning of the data protection period is linked to the entry of an active substance into Annex I or IA, it is the data owners' interest to keep the time between Annex I inclusion and the obligation to have all products authorised as short as possible, in order to reduce the possibility of "free-riders" staying on the market without a letter of access. On the other hand, formulators and users of biocidal products are worried about an increasing dependence on individual producers. A balance of interests between data owners and subsequent applicants is required in order to ensure fair competition. MS may introduce national measures obliging the applicant and data holders based in their territories to share the data, with the aim to limit the duplication of animal tests. However, no guidelines on this exist.

4.1.3 Fees for approval of active substances and authorisation of products

Article 25 of BPD requires "Member States [to] establish systems obliging those having placed or seeking to place biocidal products on the market and those supporting entries for active substances onto Annex I to pay charges, corresponding as far as possible to their [CAs] costs in carrying out all the different procedures associated with the provisions of this Directive". At the 21st CA-meeting, a document on fees applied in MS was distributed. The range of fees for dossier evaluation of active substances was from 50,000 to 300,000 EUR and fees for the authorisation of biocidal products were from 1,000 to 70,000 EUR per biocidal product. Similar differences in fees were observed for registration and for the mutual recognition of biocidal products, but these are in general considerably lower. However, CAs as well as industry indicated that the fee conditions remain unclear and that fee increases have been announced.

From stakeholder responses, it can be concluded that the cost of dossier preparation for active substances is far higher than the fees for evaluation. Hence, fees contribute to the overall dossier preparation cost but there is little information proving them to be the decisive factor in the decision of whether or not to support active substances. Further information on the scale of fees paid by producers, and the contribution of these to the total costs of registration, are provided in case study 1 (see Annex 1 to this report). A possible harmonisation of fee conditions within MS has been analysed more in detail in case study 3 on harmonisation of the CA work (see Annex 3 to this report).

4.1.4 Evaluation of dossiers and comparative risk assessment

Both producers and formulators are concerned about differences in the quality of dossier evaluation by RMSs; this is addressed further in case study 3 (see Annex 3 to this report). Formulators expect that there may be delays in Annex I inclusion, and even in the decision

on non-inclusion, due to the lack of appropriate evaluation guidelines for risk assessments. However, CAs also complain about the poor quality of parts of (but not of all) the submitted dossiers and give this as one of the reasons for delays in the evaluation process. In particular, justifications for waiving have often been criticised as not robust enough. Additionally, CAs have received multiple dossiers for the same active substances, the evaluation of which is laborious and might lead to conflicting conclusions. Regulatory consultants seek rapid feedback mechanisms so that decisions can be re-appraised in the light of futher evidence (e.g. indication of obvious errors in emission scenarios). For many applicants, the comparative assessment of one active substance against others gives rise to concern because, depending on the outcome of the risk assessment, inclusion might not be granted even though all the data requirements have been met. This creates uncertainty for the industries concerned, both producers and formulators, and contributes to the withdrawal of substances. If this withdrawal is based on an internal risk assessment by industry, it could also be considered as a benefit. However, the industry complains that no guidelines for comparative assessments exist.

4.1.5 Implementation and Enforcement

Based on the questionnaire responses, it appears that compliance with the BPD is not enforced to the extent necessary. This was claimed in relation to the control of non-identified as well as non-notified substances within biocidal products. Furthermore, the level of market surveillance and control is stated to differ across the EU.

Another observation by the industry is that CAs have not assigned sufficient resources and competent staff to carry out the work under the review programme of active substances. This endangers timely dossier evaluation. Furthermore, data requirements are interpreted differently, as evidenced by the dossier evaluations. This may distort the market and even lead to conflicting conclusions on a substance's risks. Although numerous Regulations, Technical Notes for Guidance (TNGs) and other documents have been developed to provide guidance for the industry and the CAs, many uncertainties about the rules are perceived both by the industry and CAs. These issues have been analysed more in detail in case study 3 on harmonisation of the CA work (see Annex 3 to this report).

4.1.6 Impact of other regulations

The removal of identified active substances from the review programme is also influenced by other regulations. For example, methyl bromide has been banned by the Montreal Protocol on ozone depleting substances and the use of Chlorpyrifos and Chlorpyrifos-methyl has been restricted in the USA, where formerly it was one of the most important insecticides against household pests. The use of all tributyl tin compounds, such as tributyltin oxide and tributyltin acetate in Europe has also been restricted by Directive 76/769/EEC. Other examples are Pentachlorophenol, DDT, diarsenic pentaoxide and so on. Finally, biocidal active substances such as Diuron, Chlorpyrifos, pentachlorophenol, tributyltin compounds and nonylphenols have been identified as priority substances in the EU Water Framework Directive (2000/60/EC), with the aim of phasing out their release to water bodies. In addition, the inclusion of several biocides in the list of dangerous substances (Annex I of 67/548/EEC) results in classification and labelling requirements for products and, hence, has further consequences for the use pattern of biocides (e.g. of

chloromethyl/methyl isothiazolinone or carbendazim). For this reason, the removal of these substances from the market cannot be attributed exclusively to the impact of the BPD.

4.2 Instruments in the BPD aimed at avoiding unwanted effects

4.2.1 Simplified procedures

The BPD includes several instruments, notably the simplified procedures for basic substances, low risk products, and frame formulations, which are intended to deliver time and consequently cost savings in order to reduce unwanted effects.

According to the BPD, basic or commodity substances are active substances whose major use is non-pesticidal, but which have some minor use as a biocide either directly or in a product. The BPD gives examples of potential basic substances, such as carbon dioxide, nitrogen, ethanol, 2-propanol, acetic acid and kieselguhr (Article 2 (1c)). In the TNsG on Annex I inclusion the term "minor use" is interpreted as being a proportion of the total use of a substance of not more than 5%. However, the industry has not yet used the option to apply for inclusion of these substances in Annex IB. Therefore, many potential basic substances are no longer allowed for biocidal use, although they might pose lower risks. The concept of basic substances has not been successful, as it provides few cost and resource savings. Furthermore, notifiers cannot advertise the products as 'biocides' and cannot expect to recover evaluation costs, as the substances are freely available on the market.

The BPD defines low-risk biocidal products as those which contain only active substance(s) listed in Annex IA and which do not contain any substances of concern. Low-risk biocidal products are registered and not authorised, and data requirements for product registration are reduced (applicant, identity, intended uses, efficacy data, analytical methods, classification, packaging and labelling and safety data sheet). However, the advertising of a biocidal product may not mention terms such as 'low-risk biocidal product,' Article 22 (2)). The concept of low-risk biocidal products is not favoured by the industry, mainly because few applications for actives to be included in Annex IA have been made. This is because proving that an active substance is 'low risk' suitable for inclusion on Annex IA requires a full dossier (thus, there is no reduction in data requirements or costs for the active substance). Furthermore, the inability to advertise a product as 'low-risk' is criticised and waiving of data requirements is seen as a potential alternative to the simplified procedure. CAs, though, favour the concept and do not anticipate particular difficulties.

In the definitions of the BPD, the term 'frame-formulation' is used for a group of biocidal products that have the same use and user type and that contain the same active substances with the same specifications. Their composition must present only certain variations from a previously authorised biocidal product, which must not affect their level of risk or their efficacy. Several guidance documents on the principles of frame formulations have been developed by CAs but none has been approved up to now. Formulators of biocidal products indicated that they consider the concept of frame formulations as mostly beneficial or even as the only solution to reduce the costs of product authorisation. However, there was widespread uncertainty about the future rules and several formulators were not aware of the concept at all. Several formulators expressed concern that frame

formulations may leave producers of active substances (potential owners of frame formulations) in a strong position while small and medium-sized formulator companies will be in a weak position because the data owner might restrict access to the data of the active substance by combining the letter of access with another for the frame formulation. Additionally, greater flexibility in relation to changes in non-active substances is requested.

Frame formulations and potential amendments to the concept have been considered in case study 4 on simplified procedures (see Annex 4 of this study) and potential amendments are discussed in chapter 5.

4.2.2 Essential use biocides

The concept of essential use biocides was introduced by Regulation EC No 1048/2005. It enables MS to apply for an extension of use of undefended substances during the transition period up to 2010. However, essential use exemptions are only granted for the specific MS that applies for an essential use biocide. The concept of essential use biocides is not accepted by many stakeholders, due to the different dossier preparation requirements for CAs than for industry as well as its market distorting effect. Case study 2 gives further information about this concept (see Annex 2 to this report).

4.2.3 Mutual recognition

The principle of mutual recognition of authorisations of biocidal products is laid down in Article 4 of the BPD. Biocidal products already authorised or registered in one MS shall be authorised or registered in another MS within 120 days or 60 days respectively. Mutual recognition is widely accepted and seen as one of the main benefits of the Directive. However, concerns exist amongst both industry and competent authorities as to whether this concept will be applied in a harmonised way. Mutual recognition has been considered in case study 3 on harmonisation of CA work (see Annex 3 to this report) and an analysis of potential implementation options is presented in chapter 5.

4.3 Proposals for possible amendments

At the 13th CA meeting, a specific Working Group on essential and other specific categories of biocides was established. This group drafted a working document which contains a description of the problems and an analysis of how comparable problems have been tackled under other relevant European legislation. It also concluded that the BPD might have to be amended if none of the solutions within the current legal framework is found to be satisfactory. Several CAs submitted comments to this working document, with the result that most proposals are not supported unanimously by all MS. Some CAs consider that this work should be resumed.

During the stakeholder consultation (task 1) and the case studies (task 2) industry, associations and CAs provided detailed proposals for amendments, some of which addressed specific articles of the Directive. Many of the proposals have already been discussed at CA-meetings or Technical meetings, and several statements from industry and

CAs have been submitted, which can be reviewed in the CIRCA documents. Table 4 summarises these proposals.

Table 4: Summary of proposal for amendments made by participants

Proposal for amendment	Comments
Scope related issues (Borderlines, PTs, chemically classes, imports, etc.)	
Exemption of certain types of substances	Request for exclusion of food and feed, essential oils, as well as PTs 19, 20, 22
Analysis of borderlines of the Directive (PPPD/BPD, medicinal products, food additives/feed)	Clear guidance on borderlines; adaptation of list of legislation mentioned as exemptions from the scope
Inclusion into the scope of the Directive	In-situ produced biocides (e.g. ozon), treated articles, authorisation extension to other PTs.
Low risk product/substance concept (reduced data requirements for Annex IA substances)	Generally not accepted by MS because evaluation of substances is the only stage where risks are evaluated and improved waiving possibilities should therefore not be linked specifically to potential Annex IA substances.
Minor use concept (consider niche markets and specialised markets)	Re-establishment of the working group on niche markets and essential uses (see amendment analysis 1)
Dossier Annex I related issues (data requirements; waiving; dossier preparation and evaluation)	
Reduced data requirements or tiered approach (linked to market volumes, i.e. tonnage triggers for higher requirements, waiving possibilities, low risk products, low exposure products, specific product types (such as PT 19)	Risk-relevant pre-selection of data requirements, improvement of binding waiving decisions; apply REACH exemptions for naturally occurring substances or reduced requirements for low-risk substances (see amendment analysis 1)
Guidance on acceptability of US EPA data and non-GLP data	Adaptation of the BPD in line with other Community legislation, especially REACH
Adapted dossier formats (OECD model for PPPD, GHS)	Guidance on the acceptance of PPPD dossiers without re-writing; see “Mid-term meeting”
Harmonised / centralised dossier evaluation and risk assessment (harmonisation of evaluation, Central Agency)	Options for harmonisation of dossier evaluation (Working groups of experts on specific issues, improvement of ECB resources for peer review)
Issues related to product authorisation	
Improved mutual recognition (central registration number, acceptance of English for most parts of the dossiers)	Automatic authorisation of BPs in all MS if they do not object within a certain time period (see amendment analysis 4)
Other simplified procedures for product authorisation/registration/notification (subsequent authorisations, minor/major changes of a formulation)	(see case study 4 and amendment analysis 3)
Consideration of environmental objectives during mutual recognition	Amendment of Article 4 (1) of the BPD concerning special requirements MS may impose during the mutual recognition; consideration of the environment as a goal to be protected
Other aspects of the BPD	
Data sharing and protection	Specific paragraph/guidance on cost sharing/compensation, extension of data protection period, guidance on data sharing, mandatory data sharing, mandatory use of existing vertebrate studies; apply REACH rules
Harmonised fees	Provide a legally binding fee structure to help harmonisation (see case study 3)
Enforcement of compliance with Directive	European product register would facilitate market surveillance (see BP Register Vision Document), impose fines to CAs not complying with deadlines

Improve resources of CA, COM and ECB	See conclusions of the Seminar on the 'Mid-term review of the Review Programme'.
Prolongation of time frame for Review program beyond 2010	See conclusions of the Seminar on the 'Mid-term review of the Review Programme'.
Provisions of the REACH Regulation	Apply REACH approaches concerning data sharing, use of non-GLP data, obligation to use existing vertebrate studies, exclusion of naturally occurring substance or reduced requirements for low-risk substances, central agency, fees, Board of Appeal)

5 Conclusions and proposals for amendments

The proposals for amendments to the Directive, set out in table 4, have been prioritised and four regulatory areas have been analysed more in detail. These were described in working documents (amendment analysis reports) and are summarised below.

5.1 Amendment 1 on reduction of data requirements for Annex 1 inclusion

To analyse options for reducing data requirements under the BPD, a comparison was made with the REACH Regulation. The data requirements and decision making procedures on data needs are more flexible under REACH than in the BPD. The REACH system has not yet become operational, as the Regulation only entered into force on June 1st, 2007 and the first registration dossiers are expected 4 years later. Therefore, no statement on the success of this – clearly more risk-based - approach for data requirements can be given as yet. However, the tiered approach for data provision based on substance volumes, as well as the closer connection between expected exposures and necessary hazard information for risk assessment, appear to be helpful in reducing information requirements, in particular with regard to the human health information under the BPD. In 4 years time, due to the progress of the review programme, any amendments concerning data requirements would only become effective for the submission of dossiers of new active substances, including not notified and withdrawn substances.

Some of the guidance documents currently being prepared for REACH are relevant to applicants for Annex I inclusion, as well as for product authorisation, and could be approved for use under the BPD.

5.2 Amendment 2 on frame formulations

Stakeholders have proposed a range of amendments to the BPD, or potential models, to address the problems with frame formulations. Table 5 summarises the different proposals, and the advantages and drawbacks associated with each of these.

Table 5: Summary of advantages and drawbacks of suggested amendments

Extend the substitution principle to all non-active substances, not just pigments, dyes and perfumes	Could significantly reduce numbers of separate product authorisations required, because it would allow products with variations in non-active substances other than pigments, dyes and perfumes to be included in the frame formulation. This would reduce the amount of testing and associated costs for industry and the workload for CAs. Broad support from industry and CAs	Changes in non-active ingredients can significantly affect risks. This may require constraints on substitution for specific substances/PT, or additional testing.

Basing the frame on a 'worst case' product	Could significantly reduce numbers of separate product authorisations required, reducing the amount of testing and associated costs for industry and the workload for CAs. Using a theoretical 'worst case' product could allow the highest risks for all endpoints to be included. Broad support from industry and partial support by CAs	May make assessment of authorisation dossiers more complex for CAs. Establishing that a product is 'worst case', especially if theoretical, may limit the reduction in testing (and thus costs). Establishing that a worst case represents the highest risk for all endpoints may be complex
Frame to include all products with the same or lower hazard classification or risk phrases	Could significantly reduce numbers of separate product authorisations required, reducing the amount of testing and associated costs for industry and the workload for CAs. Information on hazard and risk phrases is readily available for products. Some industry support	Hazard classifications and risk phrases are based on hazard rather than risk. Changes to some ingredients can affect the risk without changing the classification. Some CAs opposed
Permit variations which reduce risks to health and the environment	Reduces the costs associated with products posing lower risks by reducing numbers of separate product authorisations required, reducing the amount of testing and associated costs for industry and the workload for CAs. Could encourage products with environmental/health benefits. General support from industry and CAs	Key issue is how to demonstrate 'reduced risks'.
Relate product efficacy to the claims made for the product, including allowing lower AS content to be offset by different usage conditions	Could reduce numbers of separate product authorisations required, because it would allow products with a lower AS content to be included within the frame, if their prescribed method for use offset the lower AS content (e.g. more of the product was used each time). This would reduce the amount of testing and associated costs for industry and the workload for CAs.	Different usage conditions could result in changes to risk (e.g. longer contact times could increase the risks associated with non-active ingredients). Level of support is unclear.
Permit products with variations in restrictions on the method of use and exposure levels to be included within the frame	Could reduce numbers of separate product authorisations required, because products with different use restrictions and different exposure levels could be included within the frame (for example, higher potential exposure levels could be offset by tighter use restrictions). This would reduce the amount of testing and associated costs for industry and the workload for CAs.	Relationship between risk and user restrictions/exposure levels is not straight forward, especially from consumer to professional user. Concern expressed by one CA.
Unique registration number for each product within a frame	Allows for product differentiation, which could enhance competition. Significant benefits for market surveillance. General support from CAs and industry.	No agreement yet on the format for a unique registration number or the system needed to support it. Resources needed to set up the system. An over-complex system could reduce the potential benefits and increase costs.
EU-wide guidance on frame formulations (does not require amendment of the Directive)	Increases certainty for industry (and reduces costs of uncertainty). Reduces workload for CAs in dealing with incorrect use of frame formulations in authorisation applications	Can only be developed once agreement has been reached on the definition and scope of frames. Could require extensive resources to develop and achieve agreement on guidance.

5.3 Amendment 3 on variations to product authorisations

Frame formulations provide one mechanism for the modification of biocidal products without the need to re-apply for authorisation. However, not all products are likely to be included within a frame formulation. For these products, the BPD contains provisions for the notification to the respective CA of changes which may affect that authorisation, the review of an authorisation and the modification of an authorisation (Articles 14, 6 and 7 respectively). Industry stakeholders claim that the lack of flexibility in these provisions impedes adaptation to, for example, labelling requirements, technical innovation and changes to substance costs and the action of "a competitive marketplace." The greater the flexibility allowed, the greater the number of products that can be adapted within their original authorisation and the greater the potential benefits in terms of reduced data and assessment.

Both the European Chemical Industry Council (CEFIC) and the Verband der Chemischen Industrie e.V. (VCI) have proposed that the Directive should include provisions for 'minor' changes to product formulations to be allowed within the terms of the original authorisation of such products.[12] However, neither of these bodies has suggested the wording for the amendment/s necessary to enact these changes. In the absence of such suggestions, Commission Regulation (EC) No 1084/2003, Council Directive 91/414/EEC and the US EPA Pesticide registration notice on minor formulation amendments (Registration Notice 98-10) offer potential models for addressing this problem. Rules setting out the data requirements necessary for applications to CAs for major changes need to be specified. The precise wording of one or more amendments providing for major changes to products within an existing authorisation needs to be drafted. The impacts of any change in risk resulting from such amendments, their impacts and the potential support from stakeholders need to be assessed.

5.4 Provisions for the operation of mutual recognition

Significant concern was expressed by all stakeholders as to whether mutual recognition of the authorisation and registration of biocidal products would work effectively. Respondents doubted that MS would trust the assessment of others and that the same principles would be applied by all MS to judge the completeness of a dossier, the efficiency and the potential risks of a product. Furthermore, decisions on risk management measures have been shifted from the decision on Annex I inclusion to the product level and rules for the mutual recognition scheme are missing. Concerns also relate to the level of protection on the national market.

While the authorisation/registration of a biocidal product always takes place at national level, the Commission can react to refusals of mutual recognition by taking decisions binding on all Member States after consultation and a positive opinion on the draft decision of the Standing Committee (Article 4 of Directive 98/8/EC). These provisions might be used as a way to improve mutual recognition. However, stakeholders also suggested other approaches to address their concerns.

[12] VERBAND DER CHEMISCHEN INDUSTRIE e.V. Position:Amendment of the EU Biocidal Products Directive - Improvements necessary in biocidal products legislation. 12 January 2007

CEFIC. Industry Proposal for Product Authorisations under the BPD. Cefic – 07-282, June 2007

One option would be to abandon product authorisation completely and have only the Annex I inclusion procedure. This would be a significant change to the BPD and would mean a loss of control over the biocidal products on the market. A second option would be to identify the product types for which it is likely that mutual recognition may be difficult and to submit them to a centralised procedure. This would lead to a formalised discussion on the authorisation conditions at EU-level and may save resources for all stakeholders. In addition, these discussions could be a process by which the MS harmonise their approaches in general.

Other measures to facilitate the functioning of the system could include

- Development of guidance on how the mutual recognition should work by the Commission and the MS
- The first authorising MS to prepare an evaluation dossier, making the process and decision taking on mutual recognition more transparent and providing reasons for granting the authorisation
- Decision making on risk management measures should not be moved to the product authorisation level but be part of Annex I as far as possible
- Setting up of a data base on biocidal products, including the most up-to-date status of mutual recognition of biocidal products in different MS.

5.5 Conclusions

The study indicates the need, and potential options, for amendments to address the following main unwanted effects of the BPD as indicated by the responding stakeholders:

- Withdrawal of more active substances and biocidal products than predicted
- Removal of potentially non-dangerous and niche market substances
- Postponement of the development of new active substances with potentially lower risks
- Increased risk of impacts on pest control through reduced treatment options
- Significant risks to business, particularly for SMEs, with larger companies gaining commercial advantage (monopoly structure, higher dependence of formulators and users on suppliers)
- Free-riders on the market due to the transition period and lack of enforcement
- Discrimination against EU-industry through circumvention of the Directive by import of treated articles
- Perception of few benefits of the BPD compared to high level of bureaucracy
- Non-harmonised interpretation and implementation of BPD

Many proposals require a more consistent and harmonised procedure for dossier evaluation, data protection, mandatory data sharing and obligatory use of existing vertebrate studies, similar to that currently proposed for the revision of the PPPD. A number of stakeholders have suggested that this can only be achieved through greater centralisation, and REACH has been referred to as a suitable model. The analysis of the potential amendments and policy options proposed by stakeholders indicated that there exist options meriting analysis within an extended impact assessment. Due to the progress of the review programme, some of the proposed amendments would come too late to have any influence on the withdrawal of active substances. They could, however, facilitate the re-submission of applications for inclusion of these substances into Annex I at a later stage. Specific

requirements for potentially non-dangerous and niche market substances could be adopted to facilitate Annex I inclusion, in accordance with Article 11 of the BPD. All improvements concerning product authorisation, such as provisions for frame formulations or mutual recognition, or variations to product authorisations such as minor/major changes, could contribute to the aim of the BPD to harmonise the European biocides market while ensuring a high level of protection to human health and the environment.

Case study 1: Reasons for the withdrawal of active substances and potential measures to reduce the cost

1 Introduction: Objectives of the Case Study and Approach

1.1 Objective

The questions that the case study is intended to answer are:

- What are the real reasons for the withdrawal of active substances?
- What is the contribution of the cost of Annex 1 inclusion to the decision for withdrawal and
- How could the cost be reduced?

The case-study focused on identifying why the biocidal use of certain active substances has not been supported by producers and the views of producers on what measures could be adopted to reduce the costs of Annex 1 inclusion. It aimed to quantify the scale of production of the withdrawn active substances and to discuss in detail the reasons for withdrawal.

1.2 Approach

The case study involved the following work steps:

- More in-depth analysis of responses to the Task 1 questionnaires, identifying the reasons given for withdrawal and suggestions of measures to reduce costs.
- Selection of at least 10 industry participants from questionnaire respondents, covering a range of MS, company size and types and all four PTs (in practice, a larger number was selected to ensure that there were 10 participants at minimum).
- Development of tailored questionnaires to guide discussion with the companies and to ensure consistency of approach in discussions with them.
- Telephone or email contact with potential participants to determine their willingness and ability to provide input. Sending of questionnaire to participants to enable them to prepare for discussion.
- Telephone discussion (or email responses where these were preferred by the participant); supporting information and documentation were sought where possible.

1.3 Consultation participants

Completed questionnaires were received in task 1 from 32 producers (including importers) of biocidal active substances and 33 formulators of biocidal products. From these responses, 20 producers of active substances used for PT 8, 14, 18 and 19, or formulators of these PTs who have joined consortia to defend active substances, were identified and invited to take part in this case study. (One of the companies had not withdrawn an active substance but had entered the market with a new active substance and was able to provide information on the cost of preparing and submitting a dossier). Sixteen of these companies contributed to the case study; including six SMEs, in eight

Member States (including one of the new ones) plus companies based in Switzerland; they covered PT 8, 14, 18 and 19.

2 Reasons for withdrawal of active substances

In the responses to the task 1 questionnaire, the proportion of active substances defended by producers ranged from 0% -100% (median 65%). Responses indicated that companies' decisions on whether to support an active substance were based on comparison between profitability of the active substance and the anticipated costs of compliance with the BPD. In particular, companies defend an active substance because of the size of their current market or the anticipated future market, because it is a core product or a significant part of the company's business.

2.1 Scale of production of withdrawn substances

For reasons of commercial confidentiality, not all of the case-study companies were willing to provide information on the scale of production or the significance to their business of the substances that they did not support. The responses that were received are shown in Table 1. For most companies, withdrawn substances accounted for only a small proportion of their business.

Table 1: Scale of production and significance of withdrawn substances

The substance that was not defended was manufactured at rather small tonnage (one tonne or less); however, one of the defended substances has an even lower tonnage. (SME)
The company manufactures only one active substance. The product is also used for PPPD applications and, while the relevant biocidals market is small, in absolute terms is very attractive to the company. As the company operates in a small market, once having passed the hurdle of the BPD, it will effectively be forming a factual duopoly in the market as, due to the limited market size, no other company will have the possibility to enter the market and recoup the cost of dossier preparation. (SME)
The company's current annual turnover from its active substance is €150,000; the company hopes to increase this to €750,000 through support of the active substance. (SME)
The withdrawn active substance is/was predominantly used in non-biocidal applications with the latter accounting for ca. 1% of turnover. The company has now stopped R&D activities in the biocidal sector. The effect of the withdrawal to the overall production volume is quoted as '*extremely small*'.
No information was provided on the relative importance of the non-supported applications. However, the production/import of biocidal products is only one of many business activities of the company, accounting for less than 1% of its turnover.
The company estimates that not supporting five of its active substances will loose it approximately €2 million in sales per year.

2.2 Reasons why companies did not support active substances

The overwhelming cause expressed in responses to the questionnaire in task 1 as to why producers and importers do not support actives is the higher regulatory costs associated with their notification and authorisation. Financial rather than toxicological, safety or efficacy reasons are behind decisions on the support or withdrawal of actives.

Case-study participants' reasons for not supporting active substances were based primarily on the balance between the (anticipated or actual) costs of supporting a

substance and the anticipated return, together with the significance of the active substance to the company's business. One company provided a rough guide that for 'opportunistic' dossier submissions (i.e. non-strategic products), it would expect a payback of the costs in two to three years, whilst the company would accept significantly longer pay-back times for strategic long-term projects. Examples of the economic reasons are set out in Table 2.

Table 2: Economic reasons why case study companies did not support active substances

The costs of developing the full notification package were not warranted for niche products. Profit margins are such that no return on any investment was foreseen within a reasonable time frame. (SME)
The company decided not to prepare dossiers for certain pheromones, because of the unrealistic data demand and the associated costs. There is significant discrepancy between the potential market for the different pheromone traps and the costs involved in the defence of even one pheromone. (SME)
The company initially notified in 12 of the 23 PTs. To date, it has only submitted dossiers for PT8 for four of the five active substances; there was a lack of data and the cost to obtain these and the resource input required to compile the dossier within the timeframe of the Directive could not be justified commercially. Some active substances were not supported because the EU market for them did not justify the costs required to support them. Changes to the BPD to remove the company's expressed concerns about data protection, free riders and lack of CA harmonisation, although important, would not in themselves have changed the outcome any of the company's decisions.
The cost of compliance is high and support cannot be justified commercially. Profit margins have fallen by 25% or more over the past five years, due to inability to recover the costs associated with the BPD.
Decisions based on financial viability, primarily. Newer chemistry with patent protection or data protection for new studies is favoured for support. Current support for the active under 91/414 usually means less need for additional study costs and availability of DAR for reference with same CA.
Formulators do not have access to data needed to create an active substance dossier and may not support an active substance because the investment is too high to balance the product sales (turnover). The company believes that if the supplier of the active substance is not interested/not supporting/not willing to invest, for formulators an investment of about €1-5 million is not realistic.
The company has notified an active substance as part of a consortium but does not intend to submit a dossier because of the *cost for dossier preparation and review* (the cost was deemed very high) and the *tonnage of the active substance used in biocides* (the active substance of concern is manufactured for chemical synthesis and other key applications, only a very small volume is used for biocidal applications); and the *reluctance of consortium members* (the other consortia members also believe that the costs would be disproportionate to the size of the market for this active substance in biocides).
The size of the global market was an important factor in the company's decision making process; active substances without large potential global markets were not considered for support in the EU. Data protection was considered to be too weak but this did not affect the company's decisions.
The company has opted to defend only those products that have decent growth potential and/or have already generated adequate sales.
The company is supporting all of its active substances with the aim of maintaining and growing its business. However, some of its products with multiple uses will not be supported for all uses and have not been notified under all PTs, a decision purely driven by costs of the process.
The company's decision was based on an economic assessment of whether its turnover was likely to more than repay the investment required within the 10 years of data protection given under the BPD. It also felt that it did not have the workforce required to support more active substances and could not afford to employ the extra staff.

Uncertainty about the BPD requirements, and/or the constraints on staff and expertise, were important in some cases. Non-economic reasons for not supporting active substances are shown in Table 3.

Table 3: Non-economic reasons for not supporting active substances

Other active substances were not supported because the company did not have the manpower to devote to the defence of more than one active substance.

Due to the level of input required for the other dossiers, the company did not have the resources to complete these data gaps. Other reasons for not supporting active substances included a lack of knowledge about the biocidal product in terms of formulation and use patterns and poor communication with the downstream users (formulators) to obtain this information.

Uncertainties about the risk assessment methodology far enough in advance of the dossier due date meant elimination of some smaller/niche actives, because the company was unwilling to commit the large resources needed for dossier preparation, submission fees and defence of dossier with open questions on how the risks will be evaluated.

It has been a challenging task is to know in advance what is required for registration, on efficacy data, for instance. The company feels that today going into a notification process is "*an unknown journey*". This represents a risky commercial scenario that does deter some investment.

The internal skills required to progress such a project are considerable and, although this is not the limiting factor in deciding whether to support BPD registrations, the company has to prioritise these projects and resources against others within its organisation.

Though a capable successful company, we lack the scale to defend active substances using internal resources. To defend an active substance we would at a minimum have to increase staff in human toxicology, environmental toxicology, human and environmental exposure, chemistry, registration/regulatory and analytical services. This is not an economically viable option for a formulator whose marketing, production and distribution are geared towards products. (Formulator).

2.3 Impacts of the BPD on development of new active substances/alternatives

Some of the companies responding to the task 1 questionnaire plan to invest in the development of new active substances and see this as offering new market opportunities. However, most of the businesses consulted are not considering developing new active substances or alternatives, because the expected costs associated with BPD compliance, the time frame for registration and the risk of failing to achieve registration are significant and disproportionate to the market. Overall, the risk for new investment is considered to be unacceptably high and the BPD does not provide incentives to invest in innovation. The development of new actives might be encouraged by European support programmes; the CRAFT projects under the 6th Framework Programme are a positive sign.

The case study companies were asked their reasons for developing, or deciding not to develop new active substances. Only three of the companies indicated that they planned to develop new active substances. The responses are summarised in Table 4.

Table 4: Reasons for decisions on whether to develop new active substances

Supporting new substances

The company is investing in new active substances for the EU market. This is to defend its market share, to retain its customer base and to replace older, less efficacious active substances with newer, more efficacious substances. The BPD would force downstream users to use a more efficacious active substance in place of less efficacious substances produced by competitors.

The company has invested a significant percentage of its revenue in R&D in the last five years. One of the

most important developments underway is of new (for the market) active substances (SME).

The company plans to invest in the development of new active substances, the main reason being the creation of new market opportunities.

Not supporting new substances

At this stage, the company has no plan to invest in research on new active substances; however non-chemical alternatives are being closely examined. Partly due to the BPD, the company's belief is that small companies are now far off being able to develop any novel substances (SME).

The development of new actives is said to be "*outside the financial scope of the company*". The company's expenditure on R&D is now decreasing (SME).

The time between payment of the CA fee and placing a product with a new active substance onto the market was estimated to be 4 to 8 years. The outlay of €2 million plus, with no payback for up to 8 years, in support of a share of a total EU market that might by only €1-2 million per year, was seen as a major barrier to bringing a new active substance to the EU market.

Producers and formulators must focus all their resources, now and in the coming years, on existing substances and products. It is not realistic even to think about investments in new active substances.

The company is reluctant to introduce new active substances to the EU market due to concerns about the lack of data protection under the BPD.

3 What is the contribution of the costs of Annex 1 inclusion to substance withdrawal?

3.1 Overall costs

Respondents to the Task 1 questionnaire indicated that the costs of compliance with BPD are considered much too high and support for active substances can not be justified commercially. Most companies consulted do not expect that the return on investment will balance the costs associated with the required data generation, and the high fees charged by RMS. The costs of compliance are not in line with the market for a particular substance and profit margins are such that no return on investment is foreseen within a reasonable time. Due to the expected cost burden, it has been speculated that even products that are "safer" than those actually supported may be withdrawn.

Table 5 summarises the data provided by the case study companies on the costs of supporting an active substance.

Table 5: Costs to case study companies of supporting an active substance

Company size	Total Cost per Substance	Data generation cost	Dossier completion cost	Fees	Other costs
SME	Estimated €1-1.8 million (but could be as low as €500,000 for some unsupported AS) (e.g. pheromones)	€700,000 - €750,000	Consultant costs €150,000 (plus further €100,000 for products)	€150,000 - €180,000 on average (however, for 2 AS, the company has paid €480,000)	Administrative costs for running a consortium are in the range of € 50 – 70.000 for a period of 3-4 years
Large	For PT08 (4 active substances based on the same key starting chemical substance) >€1.2 million 1.2 man-years have been spent	<€50,000 (phys/chem data, copyright costs, costs to get references)	€480,000 (cost for staff and external consultants) plus €3,500 for admin costs (courier delivery costs, CDs for submissions, photocopying)	€195,000 - €295,000	Travel costs: €5,000 (included in the total) The costs to date for the post-evaluation phase have been ca. €83,000.
	For PT18 >€345,000 for each active substance	>€30,000	Admin costs of up to 100 days of varying expertise: €70,000 assuming an average charge of €700/day	€195,000 - €345,000 Speculated minimum cost €245,000)	These are speculated costs for **withdrawn** uses of the active substances
Large	-	€3 – 4.4 million	-	-	-
SME	Over €1 million for existing AS More than €3 million for a completely new active substance Total of 41 man-months	15 man-months (preparation of list of studies, identification and selection of providers, access to funding, monitoring)	9 man-months (preparation of summaries, IUCLID)	-	Familiarisation with BPD, notification: 7 man-months; evaluating risk of substance not being accepted: 6 man-months; liaison with RMS during evaluation: 1 man-year; application for national registrations in member states: 1 man-year Monitoring of the legal environment: 20 man-days per year.
Large	€2 million plus	(Additional study costs not monitored)	Manpower, consultants (costs not monitored)	€82,000 - €360,000	-

Table 5: Costs to case study companies of supporting an active substance					
Company size	**Total Cost per Substance**	**Data generation cost**	**Dossier completion cost**	**Fees**	**Other costs**
SME	€1.8 million - €3.4 million per substance) (€2 million already spent, €7-15 million further to complete dossiers for 5 AS)	€1.5 - €3 million per AS for 6 missing studies (10,000 animals for all 5 AS)	-	-	-
Large	€3.5-4.75 million	€3 million (average)	€200,000 (1 person-year)	€100,000 - €200,000 per PT	'Millions' since 1992 for contribution to BPD development, tracking, preparation etc
Large	2 person-years	-	1 person-year	-	Further 1 person-year to defend dossier through review to Annex I inclusion
SME	-	Around €20,000	€20,000	€104,000 - €165,000	-
Large	Total of €5.1 million for 7 AS.				
Large	-	-	-	€295,000 - €345,000	-
Large	-	-	> €0.25 million for consultants; €0.5 – 0.6 million for "paperwork"	€0.9 – 1.0 million (for 1 AS with 13 PTs – at the request of the RMS)	-
Large	-	-	-	€100,000+	-
Large	€750,000 (for failed defence)	€500,000 expenditure plus €250,000 administrative time)			-

Table 5: Costs to case study companies of supporting an active substance					
Company size	**Total Cost per Substance**	**Data generation cost**	**Dossier completion cost**	**Fees**	**Other costs**
Large	(€217,000 - €337,000)	Basic efficacy study: €40,000	Consultant fees: €22,000. Internal support and review: €20,000. Expert support in completeness check, evaluation and technical meetings: ca. €30,000-150,000. Copying/sending dossier to each MS following completeness check: €5,000	Up to €100,000	Cost estimates assume: • no phys-chem, tox or ecotox studies are provided on the product; • Doc IIIA is already available (e.g. submitted for a previous product type), otherwise costs will increase (approximate example €100,000 for summarising the available studies - main factor in cost is number of studies to summarise); and • no studies new are needed on the available active substance data package
Large	(€12.5 – 15 million for 5 AS)	Manpower: €240,000		(€280,000 for 5 AS, different PTs)	Plus notification costs for each MS – 2 person-years
SME	€120,000 (new AS) (a further €320,000+ would be required to complete Annex 1 inclusion)	Estimates €320,000 to fill gaps in public domain data	€120,000 (consultants €60,000; management €60,000)	-	-
Large	-	€60,000 - €75,000 (chemistry studies only)	€51,500 (breakdown provided)	-	-

There is considerable variation in the estimates of the total cost, ranging from €120,000 for a new substance and €217,000 for an existing substance to around €5 million per substance. The cost of supporting an active substance is substance-specific, with the costs influenced by a range of factors, analysed in further detail in the remainder of this section. For example:

- The estimate of €120,000 was preparation of a dossier for a new active substance by an SME. As limited funding was available, the dossier relied primarily on public domain data. The completeness check identified data gaps and the company estimated that €320,000 would need to be spent on studies to complete the dossier for acceptance into the evaluation phase. Because there would also be further costs (including fees) during the evaluation phase, the company withdrew the application.
- The estimate of €217,000 - €337,000 for supporting an existing active substance is based on the assumption that no new physico-chemical, toxicological or ecotox studies are required and that study summaries are already available (e.g. submitted for a previous product type or available due to requirements of the PPPD). The estimate of €3.5 million to €4.75 million assumes data generation costs of €3 million; this is considered by the company to be an average figure.
- The estimate of up to €3.4 million per substance (by an SME) includes the amount already spent by the company and the anticipated costs of completing the data package. Around 5-10 years cash flow would be required to cover this investment.

Many companies found it difficult to be precise about the costs of Annex 1 inclusion, because these costs are not accounted for separately within their finance systems. Some external costs, such as the costs of testing undertaken by external laboratories or the fees paid to RMS, are easier to distinguish than the internal time costs of preparing dossiers and supporting them through to Annex 1 inclusion. Table 6 shows one SME company's estimate of the internal manpower requirements of supporting a single active substance.

Table 6: SME company estimate of internal manpower required to support an active substance

Task	**Time required (man months)**
Familiarisation with the BPD and its mechanisms	4
Notification	3
Risk evaluation of substance not being accepted by RMS	6
Preparation of list of studies to be conducted	6
Identification and selection of service providers	3
Access to sufficient funding	5
Monitoring of data generation	12
Preparation of summaries	6
IUCLID	3
(Anticipated) liaising with RMS in evaluation process	12
Application for national registrations in member states	12
Total	**72**

Another (large) company has already invested 1.2 man-years in preparing and submitting dossiers for four active substances.

One participant provided an indication of the staff and skills required to support an active substance for one product type:

- Basic efficacy study: 1 technical manager and 2-3 laboratory staff;
- Dossier preparation: 1 regulatory Manager, 1 product chemistry specialist, 1 toxicologist, 1 operator exposure specialist, 1 analytical method specialist, 1 environmental fate expert, 1 ecotox expert and 1 environmental fate modeller. Assume all have a number of years experience.

Another company indicated the number of staff involved in the registration of its seven active substances; all levels of expertise are involved, especially with technical and regulatory background (University education):

- at headquarters:
  - 4 staff fulltime in Regulatory Affairs;
  - 9 staff part-time in Research & Development;
  - 5 staff part-time in Marketing;
- additional staff in all European countries and in supply chain

3.2 Costs of data generation

Responses to the Task 1 questionnaire indicated that the lack of technical guidance on what kind of testing is needed, or what the possibilities of waiving are, are further concerns (the TGD is not considered user-friendly). Companies are faced with tough deadlines and uncertainty concerning the need fort higher tier testing. Further, it seems that waiving is accepted and handled differently in various EMS.

Data generation was identified as potentially one of the most costly, but also a very uncertain, component of the costs of supporting an active substance through Annex 1 inclusion, accounting for between 5% and 88% of the total. The costs per active substance (identified in Table 6) ranged from €20,000 (SME, for a "low toxicity substance used as a food additive") to up to €4 million. One company estimated that the average cost of data generation would be €3 million per active substance, but in some cases could be higher than this. The key factors determining the costs are:

- the extent of data already available and the number and type of new tests required;
- uncertainty over data requirements;
- the acceptability of data generated outside the EU and non-animal test data; and
- the ability to share data generation costs within consortia.

Testing costs

Breakdowns of the costs of different tests were provided by some companies. For example:

- the most costly element of data generation is animal tests. One SME estimated the cost of six studies (carcinogenicity in the rat and mouse; teratogenicity in the rat and rabbit; two-generation toxicity in the rat and rat metabolism) at €9.5 million to €17 million for five substances. The company was also concerned about the high number of vertebrate animals involved;
- another company indicated that the two-year rat test was the most expensive;
- another SME noted that "*elucidation of what the data requirements actually are, particularly for larger animal testing studies*" is a major hurdle in preparing a dossier;
- however, basic efficacy and physico-chemical data generation can also be costly. One company estimated €40,000 as the cost of a basic efficacy study. A formulator provided a breakdown of the estimated a cost of generating physico-chemical data at just over €70,000 (shown in Table 7).

Table 7: Estimated costs of generating physico-chemical data for a typical aerosol insecticide (PT 18)	
Property	**Estimated cost (€)**
Appearance	1,500
Relative density	600
Storage stability	7,500 (accelerated) 33,000 (long term)
Surface tension and viscosity	650
Particle size distribution	1000
Analytical method for determining the concentrations of the active substance in the biocidal product	7,000 (development) 14,000 (validation)
Discharge rate study (results are used in risk assessment)	2000
Other (weight, can, pressure)	2200
Solubility in water	2750
Total (excluding VAT, administration and overheads)	**72,200**

Uncertainty over data requirements

Several companies indicated that uncertainty over data requirements was a contributory factor to costs and delays. For two SMEs, the completeness check had identified the need for extensive further data, at a cost of €500,000 for one and €7 million to €15 million (for five active substances) for another. Another commented that, because the guidance documents were not specific enough, there was a considerable margin for RMS interpretation. Lack of support from RMS in identifying the data needed left the company insufficient time to collect it. One company commented on, but did not quantify the cost of, the lack of RMS flexibility in reviews of substances with similar chemistry and overlapping data packages, particularly in the case of the substances with the same chemistry in different product types.

Data acceptability

Several participants commented that the acceptability of existing data was a key factor influencing costs. Examples are given in Table 8.

Table 8: Impacts of data acceptability on costs
The acceptability of GLP data generated under test guidelines other than Annex V of Directive 67/548/EEC (e.g. US EPA guidelines) was a critical factor in determining the cost of data generation. Several CAs indicated that US data could be submitted, but that acceptance was not guaranteed. Repeating the tests would add significantly to the costs; there would also be insufficient time to commission and conduct repeat tests during the registration period.
The company had to replace the physiochemical data for the whole group of active substances, at the cost of around €40,000, because the RMS would not accept data from literature that has been used for decades (e.g. from the Merck Index). Because much of the data is based on literature, the company was obliged to pay for the copyright (around €6,400). To add to this, the RMS demanded another set of references, which the company had not considered to be key references and had not submitted. The RMS charged the company €1,300 for obtaining these.
The same company had to repeat some solubility work even though, in its opinion, the data were perfectly good, because they were not fully in line with the requirements. This was despite the fact that, because of the way the active substances are used, the broad based solubility data required was not necessary for the assessment. This extra cost was in the range of €20,000. The company was obliged to hire a consultant analytical chemist for discussions with the RMS because it had difficulty in persuading the RMS to accept some of its chemical arguments. This cost the company another €1,200. Eventually, the company withdrew one of its active substances notified for PT8 due to a lack of efficacy and exposure data, which was estimated to cost around €45,000. Additionally, it was not established whether read-across would be sufficient to satisfy the requirements of the human and ecotoxicology package. If it was not, a further

around €250,000 would have been required to gather these data. A conservative estimate of resource input (scientists and administrative) is at least 0.5 man-year assuming read-across was acceptable.
Another participant indicated that the costs of data generation could be reduced significantly by accepting novel test methods in place of *in vivo* methods, particularly for generic active ingredients for which conventional results have already been generated which would be available for comparison/validation.

Cost-sharing in consortia

The advantages and drawbacks of consortia are discussed further in section 1.4. The availability or lack of consortium partners can have a significant impact on testing costs. For example, a (large) competitor of the SME facing testing costs of €9.5 million to €17 million holds the information that the studies would generate, but it has not proved possible for the SME to negotiate access to this information.

3.3 Cost of dossier completion

Responses to the task 1 questionnaire identified a number of issues related to dossier completion. One common problem was the fact that MS are not always willing to provide support, although one case to the contrary was noted. Contacts in the various CA are often difficult to identify and it is difficult to get binding answers to questions. Considerable differences in the interpretation of the requirements of the BPD between MS sometimes complicate effective dossier preparation. Another concern was the lack of clarity about the evaluation process by authorities.

Companies also criticised the need to provide the same information repeatedly throughout each dossier and that numerous reference lists for each document within a dossier are required. The preparation of study summaries in IUCLID seems difficult for companies to handle. Respondents also indicated that actives with PPPD dossiers should not require separate full BPD dossiers, although environmental effects require separate risk assessment under the BPD, as use conditions will greatly differ. In addition, because the format of PPPD summaries for dossiers is different from IIIA 98/8 documents, and because the respective electronic systems are different (IUCLID versus Caddy), summaries have to be redone. It is estimated that up to 99% of these studies are the same (i.e. the same data).

There was less variation in the estimated cost of dossier completion provided by case study participants compared to the cost of data generation; these ranged from €20,000 to €200,000, with an average of around €100,000. Dossier preparation cost accounted for between 5% and 50% of total cost for supporting an active substance. Three participants provided an estimate of staff time instead of or as well as a cost estimate; for two companies, this was one man-year; for the other it was nine man-months. One participant provided a combined estimate for data generation and dossier preparation cost of €750,000 (€500,000 expenditure plus €250,000 administrative time), another identified professional fees (in-house and for external consultants) at €480,000 and other administrative costs of €3,500.

One company provided a breakdown of the typical cost of the different basic elements of a BPD dossier for a PT 18 active substance. The company comments that the cost is reduced since first preparing dossiers, because of the learning curve. The cost for other PTs could be higher or lower, based on the complexity of the risk assessment. These estimates are probably only reliable for existing products that are well understood from a use and usage standpoint; the assessment of new products would be much more difficult and therefore more costly. As an example, the company recently paid €17,000 for the human risk

assessment of a new product, compared with the estimate in Table 9 of only €14,000. Another company estimated that the preparation of study summaries alone could cost €100,000, depending on the number of studies.

Table 9: Summary of costs of the basic elements of a BPD dossier	
Action	**Estimate (€)**
Completeness check of existing dossier	2500
Data Review, Summaries, Evaluation	
Docs II-B and III-B for each of the following:	
• Identity & Chemistry	2800
• Analytical Methods	700
• Toxicology	2800
• Human health risk assessments	14000
• Environmental Exposures (PECs) & risk assessments	14000
Relevant sections of Document I (overall summary & assessment, incl. completeness, peer review and checking cross-section consistency)	4200
Project management	9800
Product Dossier compilation (difficult to estimate, these are illustrative costs for initial two copies to RMS)	700
Meetings, travel, etc	(not yet known)
Preparation of 26 summary dossiers	(not yet known)
Total (ex VAT)	**51,500**
Note: these estimates do not include internal management time or other overheads	

Several companies had hired consultants to prepare dossiers. In most cases, in-house cost for management of the process was similar to the consultants' fees. One SME quoted a cost of around €150,000, approximately 20 % of the cost of defending one active substance. Another (large) company indicated that consultants cost around €20,000 per PT, for an active substance that could be registered under several PTs. A company which had an extensive database on its active substances, as these are also plant protection products, quoted a similar cost. This company anticipates requiring further support during the completeness check, evaluation and technical meetings, estimated to cost €30,000-150,000. One participant commented that:

"*the turn-around time for several consultants we use is increasing and they have confirmed for me that this is due to capacity constraints, as a result I expect the prices to increase over time simply due to the effects of supply and demand. The product registration/authorisation phase of the BPD in concert with the impact of REACH will place significant additional increases on highly specialised resources that cannot be expanded quickly.*"

Case study companies also commented on other issues affecting the cost of dossier preparation, but were not generally able to specify their financial consequences. The comments are summarised in Table 10.

Table 10: Comments on other factors affecting dossier preparation cost
Availability of guidance: one company commented that, if the recently published official guidelines and rules on multiple dossier submission had been available at the start of this process, there may have been the financial justification necessary for the support of more active substances.
Risk assessment: one noted that there was a lack of knowledge about the biocidal products [in which an active substance is used] in terms of formulation and use patterns, and poor communication with downstream users (formulators) to obtain this information. Another noted that models were often not available and that the lack of emission scenario documents made conducting a risk assessment problematic.
Bureaucratic demands of the dossier submission process and the lack of coordination with the PPPD: One company commented that national registers of biocidal products were much less demanding than the BPD, requiring only around 10% of the resources. The need for multiple indexes, including an index by author which had to be blacked out for the public version, study summaries as well as attachment of the studies themselves and completion of IUCLID (which has a different numbering system to the BPD), added significantly to the cost but did not bring safety benefits. Companies also noted the costs of providing paper copies of dossiers to RMS (estimated by one at €40,000) and, in the case of some RMS, multiple copies of dossiers for the different Ministries/authorities involved.
Lack of coordination between the BPD and the PPPD: an SME argued that there are many borderline cases between the two, yet the data demands are definitely different. Preparation of a BPD dossier is still time consuming and costly, even where there is already a PPPD dossier. Another company indicated that the cost of reformatting Document IIIA, using an available PPPD dossier, was around €35,000 for a single substance. An issue that has been highlighted is the fact that the same substance may be evaluated as a BP and a PPP by different people in the same RMS. This not only increases the bureaucratic requirements but occasionally also results in a discrepancy of opinion which has hindered the registration process.

3.4 Fees

Fees payable to RMS were a significant component of the total cost of supporting an active substance for participating companies, ranging from 5% to 75%. The highest fee cited was €900,000 to €1 million, for a single active substance in 13 PTs. The lowest was €82,000, for an active substance within a single PT.

A potential complicating factor was the method for allocating the costs of the RMS. One company had faced a fee of up to €500,000 for one substance, because the RMS allocated the full costs of developing a leachate test to the substance, when in fact the test would have wider applicability. Following negotiation, this fee was not in fact charged.

The key factors determining the level of fees were the variation in charges between Member States and differences in how single active substances with different PTs were charged. This is addressed in the case study on competent authority harmonisation.

3.5 Other costs

Participants identified a number of other costs associated with the BPD, in particular contributing to the development of and becoming familiar with the requirements. One company estimated that its costs during the development of the BPD had amounted to 'millions'. Another cited 20 man-days per year for monitoring legal developments.

4 How could the cost be reduced?

4.1 Suggestions to reduce cost

Respondents to the task 1 questionnaire made suggestions for amending the BPD to reduce costs. Many of these related to data sharing and protection rules. Others concerned harmonisation of procedures across Europe and simplified procedures, which are addressed

in other case studies. Suggestions included eliminating multiple reviews of the same active substance for multiple PTs, and requiring a single product use dossier per PT. It was also suggested that mandatory duplicate studies and reviews should be eliminated. Removing the requirement for increased animal testing was also proposed; the issue of animal testing was said to be adequately addressed in the REACH Regulation and in the PPPD provisions, but not by the BPD. To assist SMEs, respondents recommended changing the submission format for active ingredients to the OECD mode and providing better advice to applicants (as provided under the PPPD).

Proposals from case-study participants to reduce the cost of supporting active substances included:

- Co-ordination of requirements between the BPD and PPPD
- Improved data sharing and co-operation
- Changes to dossier requirements
- Simplified procedures for niche substances and low risk substances for inclusion in Annex IA
- Harmonisation of fees and procedures between MS.

These proposals are discussed further below.

Co-ordination of requirements between the BPD and PPPD

One company proposed that, if a dossier has been prepared under one Directive, then far less demanding data requirements should apply for the submission of a dossier under the other Directive. This would reduce costs and make the two Directives more transparent.

A company that manufactures plant protection products suggested ways to avoid duplication of work due to the differences in the formats of the summaries for 91/414/EEC and dossier IIIA documents for 98/8/EC:

- use a more pragmatic approach for Document IIIA preparation. For instance acceptance of 91/414/EEC dossiers or Monographs when they exist (as Finland and Sweden do), with only addenda needing to be specific to biocides uses;
- use of existing endpoint lists from 91/414/EEC;
- abandon or reduce requests for IUCLID entries;
- allow the use of the same electronic system for both legislation 91/414 and 98/8 (Caddy/IUCLID);
- use only electronic versions of dossiers;
- RMS evaluation only of risk assessments of the biocide dossier (not document IIIA) when the substance is already on Annex I of 91/414/EEC;
- within a country, the same Ministries and/or authorities should review the same active substance under both BPD and PPPD.

Improved data-sharing and co-operation, and data protection

One company proposed that data-sharing between companies holding data vital for the completion of dossiers should be mandatory. The company argues that a European inventory of studies and their data protection status must be set up, and a precedent case created, to give companies planning security.

Changes to dossier requirements

Many companies suggested greater flexibility in data requirements, such as accepting studies not performed according to the test methods described in Annex V of Directive

67/548/EEC (e.g. US EPA data) and old data sets. While the BPD allows the use of all existing data in principle, industry doubts whether these data really will be accepted and asks for more guidance. Timely, definitive answers to questions on data requirements for products, especially efficacy, would be of major assistance. Definition of an efficacy data set that would be accepted by all MS would go a long way to addressing concerns about data requirements - it would eliminate multiple inquires from industry, ensure money was wisely spent, that authorities received viable data sets warranting review and, very importantly, ensure individual products were tested only once, reducing competition for laboratory time.

One company provided information on the US EPA requirements for dossier preparation, which, allegedly, are much less costly than for the EU (no costs were provided):

- the USEPA does not require preparation of study summaries or such extensive reformatting and presentation of endpoints for chemistry, toxicology or efficacy studies. All studies submitted must follow a particular format and contract laboratories generally deliver study reports in this format, eliminating the need for further manipulation by the submitter;
- it does not require that applicants submit risk assessments - these are instead prepared by US EPA staff; and
- if an applicant has conducted a risk assessment, they are permitted to submit it for review, and all applicants are encouraged to submit reviews or assessments performed or prepared by other governments.

However, one company urged strongly that all product types should have to comply with the same requirements as the first product types have had to, and that the Directive should not be 'watered down'. Another proposed that a series of workshops be set up (including industry, since they do understand how the products are used) with the aim to clearly define detailed tiered risk assessment procedures, in particular for the exposure scenarios and agree higher tier risk refinement options.

Simplified procedures for niche substances and 'low-risk' substances for inclusion in Annex IA

One company proposed that dossier requirements should be reduced for low toxicity active substances, perhaps through the application of waivers for core dossier requirements. A second proposed that low risk, niche market active substances should be fast tracked with slimmed down dossiers. The CAs would decide which active substances qualified for this process, after the submission of draft dossiers, 1 year into the approval process. Clear guidance would be needed from the Commission for this to work. The issue of simplified procedures is addressed in detail under Case study 4.

Harmonisation of fees and procedures between Member States

Several companies called for charging regimes to be harmonised across MS. One company argued that:

- harmonisation would help achieve a common market
- rationalisation would reduce the unintended consequence of biocidal products leaving the market purely on registration costs grounds
- publishing the fees charged would be consistent with better regulation principles.

Another respondent advocated the introduction of a common procedure to challenge requests from CA for extra data, that were not necessarily required to establish risk, but which could give rise to excessive cost. This would help achieve a common market, as currently some CAs take a more risk-based approach to data requirements than others. A

third company suggested that more guidance was needed to ensure the harmonisation of data requirements and product definitions, as in practice there appeared to be differences in interpretation between CAs. This would simplify the process, which would make it more workable for both industry and CA.

One company proposed a limit on the number of separate fees for submissions for an active substance used in a number of product types. A maximum of two product type submissions could be the basis for the fee and the rest could be free of charge for a single active substance. The company stated that such an approach would affect its willingness to defend its active substances. Harmonisation between MS is discussed in detail in Case Study 3.

4.2 Cost-sharing through consortia

Responses to the task 1 questionnaire indicated that consortia are complex because they deal with confidential business information and need to ensure that they comply with European competition law. If consortia work well, they can reduce compliance costs, eliminate duplication of tests and resolve conflicting situations. However, their financial advantages are offset by the resources required to manage the consortia and delays to dossier preparation. It was suggested that mandatory data sharing may ensure that all biocidal markets will remain competitive without undermining the fundamentals of the Directive. It is argued that this will need to be accompanied by clear data compensation provisions (such as the data compensation law in the USA).

Many companies participating in the case study had experience of working in consortia, both under the BPD and other regulatory regimes (in the EU and elsewhere). Some had positive experience; others had experienced problems or a mix of good and bad experiences.

Positive experience

Four case study participants described at least some of their experience of consortia or other industry groupings formed in support of AS in positive terms. One company found that consortia offered good opportunities for cost and data-sharing. Another considered the benefits of participating in an industry association based grouping, not in terms of cost saving but rather in providing a harmonised industry approach to the Commission and CAs, from the production of generic waiver arguments and the ability to lobby the Commission more effectively in support of downstream markets. A third participant found that its industry association acted as an effective umbrella for joint notification of its active substance. A final company, while not having positive experience with BPD consortia, indicated that participation in several US Task Forces in support of one of its active substances resulted in “data generated jointly for US EPA which saved considerable costs.”

Negative experience

Ten of the participants had negative experience with consortia, summarised in Table 11.

Table 11: Negative experiences with consortia operation
Loss of commercially sensitive information. Seven companies quoted this as the over-riding reason for not joining consortia. One company would only participate in a consortium if forced to do so and another had only joined consortia because of pre-existing data sharing agreements from non-EU approval processes
Direct cost savings were too small. Six companies stated that the expected cost savings were too small to outweigh the other disadvantages listed here
Difficulty in reaching agreement and in setting up the consortia. Five companies cited difficulties, mainly due to disagreements over cost sharing and commercially sensitive information
Consortia were **contrary to corporate strategy**. Three companies avoided co-operation with competitors, preferring to control data, to their own competitive advantage
Increased burden of administration. Two companies had concerns about the level of administration required to participate in a consortium. One commented on the highly bureaucratic nature of consortia and on the added complexity imposed by EU antitrust legislation
Difficulty and delays in steering dossier through to approval. One company commented that negotiations within a consortium added delays to the evaluation process. Another stated that the need for an intermediary consultant made a consortium unwieldy and caused delays

4.3 Better communication and cooperation with customers

Most producers responding to the task 1 questionnaire indicated that there is in general a good dialogue with customers. However, only a few customers are willing to provide significant data or information on their use and application of active substances. The main concerns related to confidentiality (particularly with regard to disclosing formulations, since these are the basis of differentiating their products from competitors). Participants in the case study indicated that, in general, co-operation with customers was good and that there was close contact. However, some companies had found customers reluctant to participate and/or lacking knowledge of the BPD and its requirements.

One company carried out a market survey and held discussions with its most important customers. The customers' main concern was whether the company would actually guarantee the Annex I inclusion, which it could not do. Most customers were concerned about the potential for a monopoly in the EU market, due to the fact that only this company and one other are defending the active substances. The company's customer structure is extremely heterogeneous, including several downstream layers of distributors, formulators, representatives etc.

A second company has been involved in extensive collaboration with its customers for most of its active substances. The customers have reportedly driven the company's selection of active substances and helped to define the uses and the rates to support. Other companies indicated that involving the customer in the Annex I listing is not viable. One company had had no direct discussion with customers. It focused on the use of the actives for its own biocidal products/formulations. The views of customers were taken into account indirectly by analysing the market and the sales. There has only been co-operation with customers within consortia, where formulators are participants. Another company contacted all potential customers at the time of notification, but a substantial number of these did not respond. As the registration process is moving forward, the company said some customers now are "waking up" to the importance of the BPD.

5 Summary and conclusions

Responses to the case study indicate that the main reason for the withdrawal of active substances is the balance between the cost of Annex 1 inclusion and the anticipated value to a company of sales of an active substance. Most of the substances not supported by participating companies were of relatively low value, or accounted for only a small proportion of the company's business.

All respondents commented that the cost of Annex 1 inclusion had been a significant factor in their decision not to support existing active substances. Most also indicated that this cost had also reduced their willingness or ability to place new substances on the market, although a minority of respondents envisaged new market opportunities for safer of more efficacious substances. The costs of Annex I inclusion are highest when additional data generation is required, particularly if this involves long-term animal tests. Other significant factors are the cost of preparing the dossier (because of the bureaucratic format of the dossier and the lack of consistency with the PPPD) and the fees payable to RMS, especially where multiple fees are charged for each PT in which an active substance is used. Obtaining Annex I inclusion is made more difficult and costly by the lack of clear guidance and the shortage of models and emission scenario documents for risk assessment.

Participants identified a number of ways in which the costs of Annex I inclusion could be reduced, including changes to dossier requirements and wider acceptance of existing data, co-ordination of requirements between the BPD and PPPD, improved data sharing and co-operation and harmonization of fees and procedures between MS.

Report on Case Study 2: Impact of withdrawn active substances

1 Introduction: Objectives of the Case Study and Approach

1.1 Objective

The purpose of the case study was to analyse the impacts and negative effects of the withdrawal of active substances on pest control, on the level of protection with regard to the environment, human and animal health and in relation to the occurrence of resistance. Another question was whether the concept of essential use applications is appropriate to counteract the negative effects. Potential gaps in the availability of measures for pest control, the reaction of end-users to the withdrawal of substances and the reasons why continuing use of substances without evaluation is required were other issues to be evaluated. Case study 2 focuses on PT8, 14, 18 and 19.

1.2 Approach

The following work steps were carried out in this case study:

- More in-depth assessment of responses from the task 1 consultation concerning impact on pest control and the level of protection as well as applications for essential uses
- Identifying and contacting of companies and CAs that responded to the main questionnaires for interview and commenting
- Collecting opinions of selected stakeholders by a specific questionnaire
- Analysing and evaluating the answers obtained
- Documentation of the findings by writing a case study 2 report.

1.3 Consultation of participants

Several stakeholders who had already contributed to the task 1 questionnaires regarding pest control and the essential use provisions were contacted again. A background document and specific questionnaire were prepared and sent to around 60 potential stakeholders. In total 3 CAs, 4 expert institutes, 7 formulators, one producer as well as 2 user associations and 4 user companies contributed via written comments or telephone interviews. Half of the stakeholders were contacted by phone or e-mail and asked to contribute to the case study. Notes on interviews have been sent to the participants for approval.

2 Analysis of impact of withdrawn active substances

All so-called existing notified active substances are to be evaluated under the review programme during a transition period, ending in May 2010, according to four priority lists. Products containing existing active substances, which have not been notified for that specific product type, had to be removed from the market by 1st September 2006. Of the 964 identified active substances, only 416 have initially been notified for one or more PTs. Currently, 367 different active substances are still included in the review programme for at least one PT, and about 139 substances have been withdrawn. However, 90 of these 139 are still supported for other PTs, which means that 49 formerly notified actives are now withdrawn from all PTs and are definitely out of the review programme.

2.1 Impact on pest control and level of protection

2.1.1 Market analysis

An analysis of existing national biocidal product registers of 13 Member States was carried out in order to describe the current situation and to assess the impact of the BPD on the availability of products. The data indicates that only a rather small part of the approximately 550 existing active substances identified but not defended were previously used in biocidal products on the market. In Sweden, about 70 active substances, in Germany and Portugal up to 180 active substances had to be removed. This corresponds to percentages from about 13% to 33% of all identified but not notified existing actives (n=548). The lower number of non-notified active substances on the market might indicate that the concerned industry tended to identify all possible active substances, to maintain their potential for future applications. This is also confirmed by the fact that the particular mode of action has recently been questioned for some actives (like chromium trioxide, pine tar, acetic acid).

A summary of the most important active substances (in terms of number of products affected), which have not been supported is given in Table 1.

Table 1: Overview of the most important active substances (in terms of number of products) that have been identified, but not notified, and thus withdrawn

	Wood preservatives (PT8)	Rodenticides (PT14)	Insecticides (PT18)	Repellents (PT19)
Only identified, non-notified	Copper sulphate pentahydrate Copper(I) oxide Deltamethrin	Cholecalciferol	Phenothrin Trichlofon Resmethrin Methoprene	Citronella oil Lavender oil Neem Cedarwood oil Eucalyptus oil Methyl-4-hydroxibenzoate
Withdrawn from review programme	2-octyl-2H-isothiazol-3-one Chromium trioxide Diarsenic pentaoxide Dicopper oxide Copper sulphate Deltamethrin Cyfluthrin Fenitrothione	Diphacinone Trimagnesiumdiphosphide Bromethalin	Allethrin Chlorpyrifos 14-dichlorbencene S-Bioallethrin Phoxim Bioresmethrin Methomyl Pirimiphos-methyl Boric acid Fenithrothion Amitraz	Permethrin Piperonyl butoxide Naphthalene Bone oil Australian Tea oil Silicon dioxide

It is estimated that about 8-10% of all biocidal products have been affected by the removal of non-notified active substances. In addition, another 5% of the biocidal products will be removed because active substances they contained have been withdrawn from the review programme. As Table 1 shows, several compounds that are comparable and belong to the same parent compound (like copper sulphate and copper sulphate pentahydrate, or di-sodium octaborate and sodium perborate monohydrate) have only been identified, but not notified, or completely withdrawn. Of course, the market analysis reflects only the status in 2006 and will have to be updated in line with the progress of the review programme.

According to information from a recent expert meeting[13], withdrawn actives in Table 1 for PT 14, like *phenothrin*, and *S-bioallethrin,* are now back in the review process[14].

A closer look at the substances withdrawn from the review programme reveals that they are among the 10 most important actives used in the relevant PTs. For example:

PT 8: *2-octyl-2H-isothiazol-3-one* has been one of the 10 most important actives. The question of whether chromium compounds can be considered as active substances or fixative agents is still being discussed.

PT 14: Here, none of the withdrawn actives were amongst to the 10 most important ones.

PT 18: *Allethrin, Chlorpyrifos* and *Phenothrin* are among the 10 most important actives. A total of 47 substances have been removed from the review programme, while 63 active substances are still defended. *Allethrin* and *Phenothrine* are not included in Annex I of Directive 91/414/EEC, while *Chlorpyrifos* was approved in 2005.

PT 19: *Lavender oil*, *Citronella oil*, and *Permethrin* have been among the 10 most important actives. Essential oils are particularly affected by the BPD, because almost 50 essential oils from plants have not been defended as active substances.

In the following sections, the results of the main consultation performed in task 1 are summarised. This is further elaborated with the answers of the case study participants to the more specific questions in the background paper (in boxes).

2.1.2 Impact on pest control

In the first stakeholder consultation, no straightforward evidence was given on impacts on the performance of pest control and the level of protection that can be directly related to the BPD, mainly because the time since implementation is still too short. However, some stakeholders pointed out that tolerance and resistance of target organisms may become a problem, due to reduced diversity of active substances and hence a lower variety of modes of action.

Do you experience evidence of potential impact on pest control, and for the level of protection resulting from the removal of active substances especially for PT 8, 14, 18 and 19 (regarding resistance of organisms, treatment gaps, threats to health control…)? Please give examples and references.

Competent Authorities

Most of the responding CAs emphasized that the development of resistance against a limited number of active ingredients, especially for pest control (rodenticides, insecticides) and for a group of 'disinfectants', could become a matter of future concern. Others did not see any concern, due to the knock-out effect (complete eradication of a pest population) or argued that industry should be encouraged to use its innovative capacity for the development of new active substances with lower risk potential. For one CA, possible gaps in pest control due to withdrawal of actives have been avoided so far by post-notification (e. g. for *hydrogen cyanide*), but it agreed that it does not know which gaps may arise in

[13] Meeting of the technical expert group "Vorratsschutz und Nagetierbekämpfung" of the Federal Biological Research Centre for Agriculture and Forestry" on 14 and 15 May 2007 in Münster, Germany. The minutes of this expert group meeting are confidential.

[14] There might be still some confusion about the status of several active substances as in the case of S-Bioallethrin and d-Phenothrin that are defended, while their counterparts Bioallethrin = d-trans-Allethrin and Phenothrin have been withdrawn.

the future. Another CA is concerned that not enough *rodenticides* and *disinfectants* may be available in the future to avoid resistance problems, or that *antifouling products* may be authorised for sensitive sea areas (e.g. the Baltic Sea) where they have been restricted or even banned. Although there are concerns, it is expected that these problems can be tackled by further evaluation and negotiations.

One CA believes that it will be possible to maintain an acceptable level of control of rodents (PT 14) with the products containing only those actives that are still in the review programme. Decisions on non-inclusion of active substances by the *Standing Committee on Biocides* will have a greater impact on the availability of actives, since 2 major insecticidal substances will disappear. *Rotenone* disappeared as a piscicide, but its use in Sweden was minimal. It was used, for example, to clear waters that would subsequently be used for fish breeding. However, if there was an emergency, permission for limited use could be granted according to Article 15(1) of the Directive.

One stakeholder consulted by a CA emphasized that the BPD inhibits the marketing and use of low-risk substances. Thus co-notifiers of the pheromones *Tineola bisselliella*, i.e. *(E)-2-octadecenal* and *(E,Z)-2,13-Octadecadienal* and of Ephestia/Plodia, *(Z,E)-tetradeca-9,12-dienyl acetate* withdrew their support because of the data requirements and dossier costs. The situation was said to be even more critical for attractants/potentiators of mosquitoes and other disease-carrying insects. The resources required for authorising *carbon dioxide* and the potentiators *1-Octen-3-ol* and *lactic acid*, which are natural food ingredients, was stated to be too high and jeopardizing further product development.[15]

One CA replied that house mice have developed resistances against anticoagulants in at least 10 MS and alternatives in rodent baits are urgently needed. The non-anticoagulant *Chloralose* has been notified, but its efficacy dependents on ambient temperature. Another substance, *corn cob*, has been examined and found to be not sufficiently effective. As resistance develops only over generations of organisms, potential impacts may not be detectable before 2008/2009. A 'treatment gap' may occur, when numbers of control products available for a specific target pest have fallen below a critical level. An 'Expert Advisory Panel' with members from authorities and industry should regularly monitor the availability of insecticides and rodenticides used in public health control.

Expert Institutes

Expert institutes stated that resistance in rats and mice to first- and to some second-generation anticoagulants is well documented (e.g. Kerins *et al.* 2001, Lodal 2001, Pelz 2001). In response to resistance to first-generation anticoagulants (*coumarin*-derivatives *warfarin*, *coumachlor*, *coumatetralyl*, and the *indane-1,3-dione*-derivatives *diphacinone* and *chlorophacinone*), second-generation anticoagulants (*coumarin*-derivatives *difenacoum*, *bromadiolone*, *difethialone*, *brodifacoum* and *flocoumafen*) have been developed. It is still too early to draw any direct link between the withdrawal of actives and the occurrence of anticoagulant resistance.

One expert confirmed that, after the removal of *cholecalciferol*, only one group of active substances with the same mode of action (*anticoagulants*) is presently available to control rodents. For 3 out of the 8 notified active ingredients, no resistance in rats has been observed, whereas mice seem to show more resistance, to some anticoagulants.. Only one real alternative to *Calciferol* exists, namely *Zn-phosphide*, which is applicable as an acute

[15] In contrast to the above information, the three withdrawn substances mentioned are still in the review program. Also *L(+) lactic acid* (CAS 79-33-4) is supported for PT 1-6, 9, 13, 20, but not for PT19, while *1-Octen-3-ol* was not found in the review list.

toxin to control house mice. *Alfachloralose*, a notified active, can be suitable in certain situations but is restricted at temperatures below 16°C. There are reports and publications available on increasing resistance in pest control, in particular regarding highly effective anti-coagulants. A well known example is the increasing tolerance in Norway rats treated with highly effective actives[16]. Another expert responded that, in big European cities, first generation anti-coagulants no longer work efficiently and controlling moles is also difficult with second generation actives. A third expert stated that the loss of *dichlorvos* (which in fact is supported for PT18) can severely threaten thorough insect control in stores.

Producers and formulators

The wood protection industry expressed concern that the use of *chromium* or *pine tar* is uncertain. It considers that the mode of action of *pine tar* as physical rather than chemical. It is argued that no equivalent or better alternatives are available for specific areas (e.g. wood user class 4), so that customers may move to other materials (like metals, concrete, etc.). According to an expert institute, outdoor wooden surfaces and maritime ropes treated with *pine tar* cannot be treated with any other agent without changing or damaging the wood itself. Therefore pine tar is very important to preserve the national cultural heritage. Essential use derogation has been provided for some MS until 2010 concerning the use of pine tar on historical buildings or objects, but not as a general wood preservative. Formulators applying biocidal products said that adaptation of micro-organisms, and hence resistance, is already a problem in water-based metalworking fluids, if the same actives have been used for several years. An increase in the use of relevant preservatives has been reported by several suppliers of metalworking fluids.

Some companies do not expect an impact on pest control; the application of wood preservatives is not so concentrated in an area that resistance is expected. Soft rot, for example, is controlled by copper in wood with ground contact. In recent decades there was no alternative to this active but no increase of resistance was observed. However, there may be impacts in the future if further substances are withdrawn.

According to one formulator, the list of actives notified in PT18 looks very wide, but not in relation to insecticides suitable to control, for example, flies or cockroaches. Here, 19 *pyrethroid* type actives have been notified, while only 5 *organophosphates* and *carbamates* remain, of which 3 are still uncertain (*azamethiphos*, *propoxur* and *diazinon*). There are also only 5 *neonicotynoids* (insecticides). The company fears that only *pyrethroids* and the much more expensive *neonicotynoids* will be approved for spraying. The consequence may be that end users (of which 95% are individuals not professionals) prefer the cheaper *pyrethroids*, which would promote the development of resistance.

Another company was disappointed that *permethrin* and *piperonyl butoxide* have been withdrawn from PT19, as they are regarded as effective repellents. It was stated that 'delisted' essential oils, such as *citronella*, will still be used but described as 'fragrances' in the formulae, rather than actives. It was stated by another formulator that if *chlorpyrifos*, *malathion* and *DDVP* would be withdrawn, no alternatives to *pyrethroids* would be left to formulators. This would increase the risk of insect resistance and would result in a lack of products for hot weather (*pyrethroids* do not perform at temperatures above 30-32°C).

[16] GILL JE, KERINS GM, MACNICOLL AD: INHERITANCE OF LOW-GRADE BRODIFACOUM RESISTANCE IN THE NORWAY RAT JOURNAL OF WILDLIFE MANAGEMENT 56 (4): 809-816 OCT 1992

Industrial Associations

One association stated that there is no possibility to control ticks in risk areas, e.g. in natural areas, parks, kindergartens or at public events, at low cost as malathion, which is still employed outside Europe, is no longer supported. One consequence may be that certain vector bound pests will spread even more than forecast. Also, the control of mosquitoes by means of hot steam may no longer be economically feasible. Actives based on Bacillus thuringiensis subspecies israelensis cannot be applied in all locations, as mosquito plagues often happen after short-term inundation of pasture land. The WHO expects that tropical diseases may spread further to Europe. This is another reason why the withdrawal of Chlorpyriphos is seen as problematic. Additionally, the fumigation of wood has become impossible due to the ban on methyl bromide, causing difficulties because many wood items are temperature sensitive.

Users

Two professional users explained that, before the BPD, a large choice of first-generation anti-coagulants was available. Now, one trend is to concentrate on and use more second-generation anti-coagulant bait products which, it is believed, will eventually lead to increasing resistance in rodents.[17]

Pest control companies are concerned that products they find very useful, such as *calciferol*[18] (PT14), *hydramethylo*[19]*n, chlorpyrifos, pirimiphos-methyl*, *boric acid*[20] and *citronella* (PT18), are no longer available although many of these (like *boric acid* and oil of *citronella*) have been used for decades without problems. In particular, mole control was stated to be affected, since strychnine has been withdrawn and no alternative products seem available. However it seems that only one MS (UK) applied for an essential use application of strychnine for mole control and mole control might be considered as being within the scope of the PPPD. One user referred to the WHO recommendation of permethrin for use on anti-mosquito nets in Africa to combat malaria (PT19). To combat rodents it was necessary to revert to trapping, since calciferol has been removed.

2.1.3 Impact on environment, human and animal health

Have the most important active substances withdrawn been of particular risk, or do you consider them as having a low risk? Please give examples. What active substances have been or will be used to substitute the actives withdrawn?

Competent Authorities

One CA welcomed the fact that the phase-out of non-supported biocidal products in the Review Programme has removed well-known high-risk substances, such as *arsenic*

[17] Although anti-coagulants of the 1st generation, i. e. Warfarin, Warfarin sodium, Chlorophacinone and Coumatetralyl are supported, and only one active, viz. Diphacinone, has been withdrawn (see: Consolidated Commission Regulation (EC) No 2032/2003). Again it seems that there is still some uncertainty among users about the current progress of the ongoing Review Programme and of the evaluation of active substances.

[18] *Colecalciferol* (CAS 67-97-0) and *Ergocalciferol* = *Vitamin D2* (CAS 50-14-6) have been withdrawn.

[19] For Hydramethylon a company has indicated an interest in taking over the role of participant. http://ec.europa.eu/environment/biocides/pdf/substances_2ndlist_taken_over.pdf

[20] Natural *boric acid* (CAS 11113-50-1) has been indeed withdrawn, although boric acid is supported. A company has indicated an interest in taking over the role of participant.

pentoxide, pentachlorophenol, certain *organic tin compounds* and other "old" pesticides from the market. It believes that this reduces risks to human health and the environment. Occupational health concerns remain, related to the replacement of *di-arsenic pentoxide* as a wood preservative by *creosote oil*, which is more cost-effective in treating transmission poles but also more hazardous. Also wood treatment by more costly *copper based wood preservatives*, which have a shorter effective period, was questioned.

Many CAs were concerned that active substances which have always been assumed to be low-risk (such as essential oils and plant extracts etc.) have been withdrawn without any evaluation. In particular, the phase-out of the common mosquito repellent *citronella oil* has been questioned, although one ingredient (*citriodiol*) has been included in the Review Programme. Also fishery and animal infection supervision authorities have complained about the phase-out of *rotenone*, used to combat a dangerous fish parasite. Derogation for essential use application of roteneone has been granted for Norway.

For PT 8, *CCA*[21] *(mixture of copper-, chromium- and arsenic)* products were of particular risk, according to one CA, but have already been disappearing as the use areas became more limited. It added that a potential low-risk active substance for antifouling products (*capsaicin*) is lost and was not even identified, through a series of mishaps. Another CA stated that *di-arsenic pentoxide*, another substance of concern, has mainly been substituted by *creosote*, which is also a substance of high concern.[22]

It was also stated that rodent baits with *trizinc diphosphide* (which is not supported) have been listed by national authorities as effective and safe for house mice control. As environmental and human risks were evaluated and found acceptable, this active is not thought to be problematic. The most important withdrawn substances in PT 18 include *chlorpyrifos, trichlorfon, pirimphos-methyl, clofenotan, Lindane, dichlorebenzene, chlorpyrifos-methyl*, etc. It was suggested that relevant human and environmental toxicity data should be analyzed, to reveal whether these substances in fact constitute the more toxic /efficacious ones.

One CA replied that most of the 81 active substances notified for PT 8 are not actually on the market in the country. Meanwhile, 50 % of these substances have been removed. Of the 34 actives presented in a national list for wood preservatives, in total 11 actives (e. g. *borates, fluorides*, diff. *copper salts, pyrethroides, arsenic pentoxide, Al-HDO, cyproconazol*) are not supported. This number may increase further during the review process. However, formulators of wood preserving products were stated to have developed new preventive formulations, based on new active substances, during recent years and are thus expected to be able to cope with the situation. Only the rather low number of insecticides with a long service life is considered as critical.

Expert Institutes

Experts from science, the pest control industry, public authorities and environmental and consumer associations concluded, at a meeting organized by the German Environmental Agency in March 2006, that the BPD may trigger problems, especially in areas where quick and efficient control is necessary. Potential treatment gaps may arise if less than four active substances or biocidal products are available for a specific pest control.

The withdrawal of *Chlorpyrifos* was discussed as serious for the control of vector bound infectious diseases, as it is the active most frequently used for PT 18. Other *organo-*

[21] CCA = a chromium / copper / arsenic mixture consisting of 34.2 % chromium trioxide, 24.1 % di-arsenic pentoxide and 13.7 % copperIIoxide has been withdrawn

[22] Creosote has been notified and the dossier is under evaluation..

phosphates have also been withdrawn, so that a whole group of active substances (with a particular mode of action) may not be supported.

Authorities also worry that no acute rodenticide (such as hydrocyanic acid, zinc phosphide) will be available because most supported actives belong to anticoagulants with retarded toxicity. Resistance development amongst rodents, in particular to first generation anticoagulants, has been reported all over Europe[23]. However, in this context the progress of the review programme must be taken into account: the acute toxic *hydrogen cyanide* is now included in the review programme for PT 8, 14 and 18[24], while four actives (*Diphacinone, Trizinc diphosphide, Trimagnesium diphosphide*, and *Bromethalin*) have been withdrawn for PT 14. One expert explained that, for PT 14, 3 of the withdrawn substances have never been relevant. For example, *bromethalin* was never authorized for plant protection, which is considered being an important market.

Producers and formulators

Respondents said that the most important withdrawn actives used in wood pre-treatment are *di-arsenic pentoxide* and *chromium trioxide*, although the latter continues to be used (as a fixative) in many MS despite being identified as a category 1 carcinogen. Most EU suppliers produce alternatives, mainly based on copper, that have been in use for over 10 years. A formulator emphasized that the withdrawal e.g. of copper sulphate was not necessary, because it is not believed to cause particular risks. One common dossier for all copper (II) compounds would have guaranteed the same level of safety and more flexibility to formulators.

Although some of the essential oils, such as *citronella, lavender* or *eucalyptus*, are considered potential allergens, the reasons for not supporting them were believed to be economic rather than based on risk. It was assumed that they will not be substituted, because they will continue to be used but called 'perfumes' or similar, rather than biocidal active substances.

One respondent was concerned about the withdrawal of non-anticoagulant rodenticides, i.e. *trizinc diphosphide,* although this active is notified under 91/414/EEC. The producer decided to renew the agricultural authorisation, knowing that end users in practice still also apply this active for biocidal applications.

There was some uncertainty whether *permethrin* would be supported for PT18. One alternative, *Cypermethrin*, is generally considered more irritant and therefore potentially more problematic. Although no company has submitted a dossier for *Temephos*, this active substance is approved by the US EPA for mosquito larvae control. In three Member States essential use of Temephos has been applied for mosquito control.

One stakeholder pointed out that the best substances for *insect repellents* have not been supported by suppliers, because they are normally sold to the cosmetic industry and the suppliers are unwilling to accept the financial burden for their use as biocide. The risk profile of essential oils, in particular of *Eucalyptus oil*, is assumed to be negligible and the material is accepted even on the "GRAS" list ("Generally Recognized As Safe" list for food additives in US and Australia) as posing no risk to the environment, end users or animals (see: http://www.cfsan.fda.gov/~dms/grasguid.html).

[23] Federal Environment Agency. 2006. How many biocides does man need? – Professional conference at Federal Environment Agency in on 16-17 March 2006 in Berlin UBA-Texte 22/06 http://www.umweltdaten.de/publikationen/fpdf-l/3059.pdf (in German)

[24] see Commission Regulation (EC) 1849/2006

Users

One user regretted that essential oils, like *Lavender oil, Citronella* and *Lemon Eucalyptus,* have been withdrawn from PT19, considering the low concentrations applied on textiles and their inherent low toxicity. This also contrasts to US legislation, where *citronella oil*, four vegetable oils and eleven essential plant oils have been exempted from pesticide registration for mosquito & general insect control[25] . However, any repellent containing more than 10% of essential oils is not approved under US legislation, due to possible skin irritation and other effects, and formulations with over 3% of essential oils require registration.

According to another user, limiting the use of more dangerous pesticides, such as strychnine hydrochloride, to professional or trained users has for years delivered good risk management in his country. It may also be dangerous to assume that products currently being notified will be sufficient to control future pests. It is expected that, because of the loss of *strychnine hydrochloride*, most farming or larger land-owning clients will use *phosphine* generating tablets instead, for which the level of control may be lower than that obtained with strychnine, due to different soil conditions.

2.1.4 Further impact of the withdrawal of active substances

What negative impact have you experienced as a direct or indirect consequence of the withdrawal of active substances from the review programme?

Competent Authorities

One CA is concerned that no analysis of the consequences was carried out by the Commission before the directive entered into force and the phase-out started. According to this CA, unfortunate advice has been given to industry about which substances they should identify or notify and the consequences were not made sufficiently transparent. The early withdrawal of unsupported (only identified) actives is considered disproportionate, since companies could also have notified an active substance and stayed on the market for several years without the intention to submit a full dossier. Chemically nonsensical entries were stated to have appeared between the two lists, due to uncertainty among industry about the chemical identity of active substances. For example, boric acid was notified, but natural boric acid was only identified. Altogether, negative impacts from the phasing out on 1st September 2006 were stated to have been limited. But it was anticipated that the phasing out of products containing active substances withdrawn since then will have considerably more impact. Also, the question of how the non approval for Annex I inclusion of actives that do not pass risk assessment will affect pest control and the level of protection will have to be addressed.

Producers and formulators

For most formulators, the availability of a diversity of active substances is considered to be favourable for effective action on new diseases or reappearance of eradicated pests such as Dengue-fever and bed-bugs. While products for main applications will be still available, there may be less choice and fewer alternatives. Products for small-scale applications and minor uses might disappear, with the consequence of fewer options to act against future epidemics or of gaps in the spectrum of efficacy.

[25] www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_plant-oils.htm

One formulator of PT8 products argued that, as chromium-containing products fix copper to a higher extent than chromium-free products do, the ban on chromium-containing products would cause a higher environmental risk for wood in permanent ground contact. There were also complaints that decisions on insecticides for PT 8 were made very late. *Fenoxycarb* was withdrawn at first but afterwards it was supported for PT8, whereas *Cyfluthrin* was withdrawn for PT8 and is only supported for PT18.

Suppliers of metalworking fluids suspect that the rates of contaminated manufacturing machines will increase, and conditions for workers may become worse, as the incidence of skin and respiratory infections caused by bacteria spores may increase.

One respondent has used *permethrin + pyrethrum* to fight dust mites, mosquitoes and mites. Due to the withdrawal of *permethrin* from PT19, the company had to change its anti-mosquito repellent products. The company was also affected by the withdrawal of *lavender oil* and *eucalyptus oil*, both used as repellents in their formulas, and must now search for natural active substances that are still defended.

Another stakeholder argued that individual substances should not have been withdrawn until the rest of the review process had been completed. This relates in particular to Phenol, which is widely used by medical schools in their anatomy examinations.

Industrial Associations

The fact that many actives are not notified because of the high registration costs, rather than due to possible risks to human health or the environment, is seen particularly problematic. It is expected that the reduction of the spectrum of actives will negatively affect the development of new wood protection products, which may hamper control of future hazards that may not be relevant now. It was also argued that it is a problem that alternatives of many withdrawn actives, e.g. CCA[8] and arsenic compounds, are more expensive. Furthermore, the import of articles treated with non-supported actives was stated as a problem.

Users

For one user, the fundamental impacts will occur when decisions on active substances are made. The whole registration procedure seems very confusing for another user, as parts are changed after having been established, which makes planning rather meaningless, in particular for SMEs.

Negative effects occurred for another company through the loss of the (in their mind) only commercially available insect repellents for general use (e. g. *oil of citronella*), of a whole group of insecticides (*organophosphates*), of an important rodenticide with a different mode of action to anti-coagulants (*calciferol*) and of the only effective product for treating large areas of land infested with moles (*strychnine hydrochloride*).

2.1.5 Potential treatment gaps for future pest control

Do you expect potential gaps in the overall availability of measures for future pest control due to the withdrawal of actives, and what strategies or alternatives would you suggest for end-users to adequately respond?

Competent Authorities

Two of the CAs consulted do not see a need for a special strategy, but advise end-users to use non-chemical control methods where possible, or to use alternative authorised products

that remain on the market. Furthermore, it is also believed likely that new products will be introduced or developed to fill the gaps. The effectiveness of pest control is expected to decrease, however, due to the restricted availability of essential oils. It is not known how end-users will replace these products. One CA pointed out that potential future gaps may arise in the control of insects like mosquitoes, fleas, mites, cockroaches and flies. Ports and animal housing may be the areas most affected. Thus end-users may be advised to discourage the use of insecticides in private environments. Concerning chromates (e. g. CCA salts) it first has to be defined whether CrO_3 can be considered as a biocidal substance. If so, chromate-based wood preservatives will have to be removed from the market, due to the lack of dossiers, and also woods of the user class 4 (steady soil and water contact) will have to be protected by alternative products. It may be difficult to find equally effective substitutes for chromates with the same durability of the treated wood. Leaching of these wood preservatives into the environment during application and service life would have to be considered, besides their eco-toxicity.

Expert Institutes

One expert notes that only ordinary mice traps could be used in Europe for house mice control, if resistance occurs with actives used in baits.

Producers and formulators

One producer was worried that a higher demand for *insect repellents*, due to climate change, could not be met as active substances are withdrawn. Also, when *essential oils* are no longer available for this application, more harmful active substances may be used. Others complained about the uncertain status of *formaldehyde* donors and chromates. A loss of these substances would increase damage to water-based products and wood. The illegal use of substances not included in the BPD Annexes was another aspect of concern.

One formulator does not expect treatment gaps. However, the conclusions of the review programme and the criteria for product authorisation would be decisive. It was stated that it would not make sense to include active substances in Annex I if no relevant products are authorised. One company could see a lack of acutely toxic cheap rodenticides for quick reduction of large rodent populations. Another company fears that no alternatives or strategies are available to replace organophosphates. Instead, organophosphate containing formulations, like chlorpyrifos, sold under Directive 91/414 might be "smuggled" into the BPD pest-control sector. To cover for the loss of repellents, one option may be to change from current product formats e. g. cellulose pad, candle, liquid wick to one relying on UV energy and electricity, one producer suggested. One stakeholder expects numerous gaps for PT 22, and another notes that the fact that essential oils are variable from harvest to harvest may help to limit resistance.

Users

One user said that there will be a risk for the European textile industry that treatment with PT18 and PT19 products will be completed outside of Europe and the treated articles re-imported without limitation or control. Another company expects that the largest international producers will dominate the market and will offer fewer products for professional users and more for amateur use approvals, to offset registration costs. Physical methods, in particular the use of heat, were mentioned as alternatives for withdrawn actives, but with a loss of level of protection, as such methods do not provide protection after the actual treatment is completed, which can result in rapid re-infestation.

2.2 Acceptance of the essential use derogation

2.2.1 Background and provisions of the BPD

The term "essential use" biocide is introduced in Article 4a of Regulation (EC) 2032/2003 and enables MS to apply for an extension of the 1 September 2006 deadline for the withdrawal of undefended active substances. This is possible when MS consider a substance as essential for reasons of health, safety, protection of cultural heritage or as critical for the functioning of society and when there are no technically and economically feasible alternatives or substitutes available that are acceptable with regard to human health and the environment. The MS can keep essential use biocidal products on the market during a transition period up to 2010. However, essential use exemptions are only granted for the specific MS that applies for an essential use. The status (December 2006) of essential use applications is summarised for PT 8 and 18 in the following table:

Table 2: Overview of essential use applications (December 2006)

	CAS	Applicant MS	PT	Main arguments and preliminary decision of COM
Bromfenwinfos	33399-00-7	PL	18	Very important compound used against insecticide resistant pests, especially those that are resistant to pyrethroids; Proposal not to grant an extension of the period.
Cyfluthrin	68359-37-5	PL	8	Widely used as insecticide in most wood protection products; long-term effects for preventive treatment and rapid action for curative treating; Proposal to extend the period until 01.09.2007
Hydrogen cyanide	74-90-8	CZ	8, 18	Alternative fumigant for methyl bromide, the usage of which has been banned (Montreal Protocol). Proposal to extend the period until 14 May 2008 for PT 8 and 18
Methyl Bromide	74 – 83 - 9	UK	8, 18, 20	Control of pests in airplanes; Control of cheese mites in the rind on Cheddar cheese. Proposal to reject the extension applications.
Tar, pine / Pine wood tar	8011-48-1	DK/FI/N/IS	8	Efficacy mainly based on physically blocking the porous structure of wood. The treated wood can resist wood destroying fungi. May have a slight biocidal effect on some fungi species. Proposal to extend the period until 14 May 2010 only for historical buildings and objects.
Temephos	3383-96-8	EL, FR, IT	18	Important resistance management tool for mosquito abatement; Proposal to extend the period until 1 November 2007 for EL, 14.05.2009 for overseas departments of FR but no extension for IT.
Trichlorfon	52-68-6	PL	18	More than 60-70% products for ant control on the Polish market contain trichlorfon; Proposal not to grant an extension of the period.

2.2.2 Results from the stakeholder consultation

Has the essential use provision been successful to support further active substances? Do there exist, next to hydrogen cyanide, other essential use applications for which the applicant or concerned industry intends to support them within the review programme? Why do you support / not support this provision? Please give reasons and arguments? What are the main reasons for you to consider a substance as essential?

Competent authorities

Only two of the CAs that responded to the main consultation have applied for essential use derogations. One MS applied for an active that is widely used within its national health system, but was not granted a derogation by the COM. A derogation for the use of *pine tar* as a wood preservative was granted to some applicant countries. One of these CAs asked for a permanent solution (derogation) based on cultural and historical reasons, but no dossier has been submitted, due to the costs. Three CAs consulted were critical or sceptical about the essential use concept, as it may encourage some industries and MS not to meet the requirements that apply to industry. One CA calls for better guidelines. Five other CAs consulted have not made any requests so far. One CA supports *pine tar* but doesn't consider it as a biocidal product, due to its physical mode of action.

It was also argued that the essential use derogation might be an obstacle to the principles of free and fair competition. All applicants should be equally treated under the BPD and meet the same requirements. However, the provision is also seen as necessary during the transition period, as active substances have been withdrawn before the period has come to an end. The provision should be granted only when there is an absolute need, but high standards of legal security and transparency should be maintained.

According to another CA, no real substitute is available for *pine tar* but applying for Annex I inclusion is not regarded as feasible. A more permanent solution is stated to be needed if *pine tar* will not be excluded from the scope of the BPD. This could e.g. consist of adding a derogation procedure to article 15 of the BPD that addresses the protection of objects of cultural and historical interest, as done in the VOC Directive[26]. Another CA thinks that the time limit on essential uses could become a problem for pest control and heritage protection, if it cannot be prolonged.

Another CA was of the opinion that the derogation process was not handled well by the COM and that there is a lack of guidance, resulting in inconsistency in completing the forms. As no deadline has been given for submission, some industries and MS were stated to have used the derogation to 'get around' the system.[27]

The main issue with *pine tar* in Sweden is that it is burnt off from wood by many individuals or small groups and sometimes also informally sold, which makes ensuring compliance complicated. Producers are not always aware what their substances are used for on the market.

According to one stakeholder, it was felt that the Commission's decisions on the acceptability of a particular cases were not consistent and no indication is seen that any 'essential use' substances[28] will be supported within the review programme.

One CA decided not to object to other MS's applications, as any exposure would be local, and because it holds essential use exemptions under the PPPD. It welcomed the short-term exemptions granted for training of operatives in alternative products. It appears more difficult to support the concept in the longer term, especially because people should be

[26] "For the purposes of restoration and maintenance of buildings and vintage vehicles designated by competent authorities as being of particular historical and cultural value, Member States may grant individual licences for the sale and purchase in strictly limited quantities of products which do not meet the VOC limit values laid down in Annex II.". (ref: Art. 3.3 of Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC)

[27] However, only few essential use derogations have been granted for limited time periods and the possibility for an essential use may also occur later than 1 September 2006. Thus no deadline for submission of applications has been considered.

[28] Comment: except hydrogen cyanide

better informed about alternatives and learn how to use them. The possibility to prolong phase-out periods for more than 12 months, if a problem occurs, would be preferable to granting an essential use exemption. According to another stakeholder, the provision should be adapted to enable low risk active substances, such as essential oils, to remain on the market up to certain concentrations.

One CA considers the provision successful in promoting two substances nationally, one of which was needed in public health and has been notified for further use.

For one CA, an unacceptable risk to health from a harmful organism would be considered as a reason to grant an essential use, including those "preventative" cases where MS need more time for training in the use of alternatives. Cultural heritage (as included in the current definition) should not be considered as essential use. Since the strongest reasons for essential use are health grounds, one would hope that these uses will eventually be permitted. Concern was expressed that the risk assessments required are much more limited than those demanded from industry. If appropriate information is available for risk assessment, the substance would probably have been supported by industry. Therefore, it is better to find alternatives[29] wherever possible or to limit their applications to short-term use, to train up people to be able to use alternatives. Whether an essential use for the longer term can be considered as defensible with a very limited risk assessment is questionable. It is worthwhile mentioning that the PPPD will not grant essential use exemptions for most products containing active substances not included on Annex I of Directive 91/414/EEC from 2008 on.

Another response pointed out that "essential use" – in addition to specific applications for health protection and/or cultural tradition where no alternative exist - should also apply for active substances for which potential market share is too low to offset the costs of dossier preparation. It is suggested that 'essential use' substances should be notified, if of interest to more than a specified number of countries. If no applicant has come forward to promote the dossier, the possibility of other means of financial support should be investigated to meet dossier costs, e.g. by research funding etc.

Expert Institutes

One expert admitted that although the "essential-use" provision is a possibility to keep certain particular actives on the market until 2010, it will not provide a true perspective for industry. It was questioned why successful active substances are taken off the market and suggested that the history of a particular active should deserve more attention. For example, it is not clear why *Chlorophacinone*[30], which has been successfully subjected to the PPPD to control field rodents, should no longer be on the market. Another expert suggests that there could be an essential use of *pirimiphos-methyl*, which has been withdrawn from PT14.

One expert replied that the term "essential" should be related to market effects and specific application fields. It may be a small field of application with little profit that is affected. As with the procedures of the Montreal protocol, the processes should balance "environmental", "economic" and "agricultural" considerations. Ingenious solutions brought forward by SMEs should not have to overcome too many market barriers. At present, the system is perceived as too bureaucratic and favouring global players in obtaining registrations.

[29] However, essential use applications are rejected if alternatives are available.

[30] Chlorophacinone is supported for PT14

Producers and formulators

The results of the main consultation indicate that the concept is not supported by producers, as it is said to undermine the harmonised market and to create different standards regarding data and assessment requirements. It has been suggested that the MS requesting essential use derogations should also be responsible for preparing and financing the dossiers. The concept is partly supported if no or only very few effective alternatives exist, as well as for minor niche markets. *Hydrogen cyanide* is an example of an active that was not notified, but for which an essential use application has been submitted (and granted). In the meantime, this substance is supported by a Czech producer.

One respondent supports the essential use concept to control important but rare pests that cannot be controlled by listed actives. The respondent complained that the essential use concept also supports substances for which adequate alternatives exist. For example, *Cyfluthrin* can not be a candidate for essential use because alternative insecticides are supported[31]. In general, it seems that the concept of essential use is understood quite differently by different MS. One company supports essential use applications for *denatonium benzoate*, but an alternative way forward appears to have been found.

Other companies question whether a governmental agency is able to successfully prepare a complete dossier and to prepare a dossier for an essential use derogation for an active substance. Also, the usefulness of the concept is questioned, as the withdrawal is only postponed, without finding a real alternative (i.e. introduction of a new active) to the active ingredient concerned.

One company replied that a substance is essential when it is the only one known to be efficient against a certain pest at reasonable cost and with reasonable toxicity. For one formulator, the essential use concept could be improved by extending it to several years and by confirming that "alternative" should mean "having the same mode of action".

Users

From the rather few responses obtained, it seems that users do not know how this provision works. As an example, one user commented that the concept does not apply well, as evidenced by the loss of strychnine hydrochloride for mole control. One user emphasized the lack of information and lack of support by local authorities, and another that a legal framework is needed that is harmonized across all MS (although the legal harmonised basis is provided in article 4a of Commission Regulation 2032/2003).

The essential use concept may be very interesting for "cheap" safe products like essential oils, as producers are too small to prepare a BPD – compliant dossier, according to one user. Another user said an essential use should only be granted to the most effective biocidal product for a particular purpose in the MS concerned.[32] Also, cost-effectiveness should be considered, where its use supports an event, practice or other manufactured products unique to that MS's culture (e. g. building materials not used elsewhere).

[31] Comment: Cyfluthrin is supported for PT18 but not for PT19

[32] Comment: This comparison presupposes that at least 2 products are available, in which case the application for essential use of either one of them is not acceptable.

3 Proposals for amendments

3.1 Proposals to reduce negative impacts on pest control and level of protection

According to a Background Paper presented on behalf on the German Federal Institute for Risk Assessment and based on the TMIII 05 discussion to OECD Thought Starter from October 2005 (Version – March 01, 2006), resistance development and management is an integral part of the evaluation process for inclusion of an active into Annex I, but also for the national authorisation and registration of biocidal products. The Technical Notes for Guidance (TNsG) require an evaluation of resistance to an active substance on a "case by case" basis. Like efficacy, resistance is an important criterion to address for Annex I inclusion (Pickardt 2006). However, as the main data on resistance are collected at product level, it is suggested to extend the TNsG (*Technical Notes for Guidance* on *Annex I Inclusion* and *Product evaluation*) from 2002 in this respect to include additional sections where different organisms and application fields are specifically and separately treated. A classification into different organism groups would be preferable. Also, the current versions of both TNsG should differentiate between intrinsic and acquired resistance, since intrinsic resistance does not play a significant role in higher organisms.

Concerning natural repellents, it has been suggested to use a similar approach to the one in the US, where *citronella oil* together with four other vegetable oils and eleven other essential plant oils have been exempted from EPA pesticide registration for mosquito and general insect control (see web-link above: US EPA "Plant Oils Fact Sheet").

The history of a particular active substance should be taken more into account, as shown for *Chlorophacinone* and *essential oils* that have been traditionally applied without any significant harm to man or the environment.

Further, the possibility of different tiers of data requirements is suggested, depending on the end product and risk analysis of exposure levels throughout the product lifetimes.

It is further recommended always to advise end-users to use non-chemical alternative methods of control wherever possible, to keep items or areas clean by normal (non-biocidal) agents (normal detergents), or to use alternative authorised products that remain on the market. A particular need for amendments of the BPD exists for the control of biocide products that are be imported from abroad into the EU market.[33]

3.2 Proposals to improve the implementation of the essential use provision

One CA suggested adding provisions to the Directive regarding environmental protection, if an essential use derogation would be allowed on a European (instead on a national) level as suggested by other stakeholders. In this case, dossier requirements should be more extensive than at present, and the high standards of legal security and transparency within the EC should be maintained.

As the essential use provision is MS-specific, and could only last until 2010, one stakeholder requests a method that would ensure Europe-wide acceptance until the next review period. Also, people should be better informed about finding alternatives and learning how to use them before the end of a phase-out period. An alternative to the essential use provision might be the possibility to set phase-out periods longer than 12 months for active substances withdrawn from the review programme (4th Review

[33] Although import of BPs means placing on the market and is regulated under the same rules as for BPs produced within the EU.

Regulation), if a problem can be foreseen and if it would be preferable to do this rather than to grant further essential use exemptions.

To grant an essential use could also include those "preventative" cases where MS need more time for training in the use of alternative products. But the procedure should be more transparent, especially for rejections, and more guidance should be given.[34]

A producer suggested that this provision should be adapted for essential oils, to allow low risk active substances to remain on the market if not used above certain concentrations in biocidal products. It was also proposed to amend the BPD by granting a permanent derogation for biocidal products that are used for protection of objects of cultural and historical interest.

To further improve the BPD, issues such as "essential /minor substances/other specific biocide categories "should be considered and discussed. According to one CA, it should also be possible to extend the application time if problems may occur. In addition, economic aspects and investigations should be addressed, not only environmental criteria, to keep the market open for ingenious solutions from SMEs.

4 Summary and conclusions

4.1 Impact on pest control and level of protection

No clear evidence of negative impacts on the performance of pest control was obtained in the main consultation that could be directly related to the BPD or the withdrawal of active substances, because the implementation time is too short. Possible effects were stated to be observable only after product authorisation. Effects are also seen as depending on the conclusions of the review programme and the criteria for product authorisation.

There seems to be confusion in the market about the progress of the review programme and of the evaluation of active substances, because some examples of impacts of withdrawn substances in fact referred to substances that are supported.

It is assumed that the knock-on effect and phase-out of unsupported actives has already created much benefit for the environment, human and animal health by removing well known high-risk substances from the market. The general public is believed only to fully benefit after 2010, when all related products will be withdrawn or subjected to evaluation.

It is reported that resistance of target organisms may become a problem, due to reduced diversity of actives and lower availability of modes of action. This seems mainly relevant for PTs against pests (PT14, 18) and for disinfectants. Resistance was reported to be of lesser significance for PTs to protect materials (PT8).

A minimum number of products with different modes of action is stated to be necessary to avoid resistance and to quickly and efficiently control specific pests. Experts concluded that there may be treatment gaps if less than four active substances or biocidal products are available. In particular, the withdrawal of *Chlorpyrifos* is discussed as a serious problem for the control of vector bound infectious diseases, as this substance is most frequently used in PT 18.

There was a broad concern that active substances considered as low-risk (like essential oils and plant extracts) have been withdrawn without further evaluation. How far gaps may arise from this remains to be seen after product authorisation and after the review period.

[34] Comment: There are preparatory documents for all applications explaining the decision of COM and all MS which were not granted a derogation receive official letters explaining the reasons.

The pest control industry is particularly concerned about the removal of traditionally useful products, like *calciferol* (for PT14), *hydramethylon, chlorpyrifos*, *pirimiphos-methyl*, *boric acid*, and *citronella* (for PT18), and that products (with substances like *boric acid* and *citronella oil*) that have been used for decades without problems disappear.

Serious concern is expressed about the future control of commensal rodents (rats and mice), as only one group of actives with the same mode of action (*anticoagulants*) for applications with baits. Resistance in rats and mice to first- and some second-generation anticoagulants is already well documented. Although it may be geographically restricted, it is reported from many countries and can pose a serious problem for pest control. Before entry into force of the BPD, a large choice of first-generation anti-coagulants was available and second-generation anti-coagulants could be used to clear up a resistant rat population, before first-generation *rodenticides* could be used again. But now more second-generation anti-coagulant bait products are now used, which may lead to increasing resistance. Some authorities also worry that no acute toxic rodenticides (e.g. hydrocyanic acid, zinc phosphide[35]) are currently available for quick reduction of large rodent populations, as anti-coagulants kill only after 5 days and during that time rodents still cause damage and are vectors for diseases.

That *permethrin* is notified for PT18 but withdrawn from PT19[36] has been criticised, as the dosage used as an insect repellent is much lower then when used as an insecticide. For this reason it was suggested that, if a product is registered in PT18, it should be also approved in PT19.

The wood protection industry is worried about the future of *chromium* or *pine tar* used to protect wood, and claims that the mode of action is physical and that no alternatives exist. It does not seem possible to anticipate the potential impact, mainly because application is not so concentrated in an area that development of resistance can occur. There is concern that the reduction of the available spectrum of actives may negatively affect the development of wood protection products, and that it may become more difficult in the future to respond to hazards that may not be relevant now.

4.2 Acceptance of the essential use provision

From the responses received, but also from the comments given to submitted essential use applications, it seems that the objectives and purposes of this provision are not well understood by MS and industry. This is evidenced by applications supporting substances for which adequate alternatives exist. Clear and more transparent guidance is requested to increase acceptance of the provision.

Concern is also expressed that the essential use procedure may tighten up EU standards set for biocidal products, and that its short-term perspective cannot meet requirements of resistance management that have to be designed for a much longer perspective.

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Pickardt 2006. Background paper "Considering the potential of resistance in the efficacy and risk evaluation of biocidal compounds" (based on the TMIII 05 discussion to OECD Thought Starter from October 2005)

[35] Although hydrogen cyanide (as Hydrocyanic acid), CO_2 and Aluminium phosphide are supported for PT14.

[36] Although still uncertainty about the current status of permethrin exists, see above.

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Report on Case Study 3: Harmonisation of CA work

1 Introduction: Objectives of the Case Study and Approach

1.1 Objective

The purpose of the case study was to analyse differences and difficulties in the implementation work of the competent authorities (CA) in relation to the interpretation of data requirements (including waiving procedures), assistance and communication with notifiers/applicants during dossier preparation and evaluation, risk assessment, the peer review process for active substances, the potential for mutual recognition and risk management approaches. The case study analyses the need and potential options for further harmonisation and improvement of the CA work. Areas suffering from a perceived or actual lack of harmonisation are described and illustrated with examples. The objective was to obtain a set of potential solutions on how the work of CAs can be harmonised for issues where divergence and problems have been identified, so that notifiers/applicants for authorisation face equal conditions.

1.2 Approach

The case study involved the following work steps:

a) More in-depth analysis of answers to the task 1 questionnaires. Identification of CAs which were indicated as ‘cooperative’ or 'uncooperative' by industry.
b) Listing of issues that need further harmonisation between CAs, description of cases and proposals for improvement identified in the responses, comparison of whether all issues could be acknowledged by the selected CAs.
c) Follow-up interviews with industry respondents (including regulatory consultants) who ‘complained’ about or 'praised' CAs behaviour and performance.
d) Telephone or email contact with CAs to discuss harmonisation issues described in the questionnaires.
e) Discussions with CAs on their experience with 'good' and 'bad' participants – what are their recommendations to participants to improve working relations and speed of evaluation.
f) Drafting of a discussion paper to be submitted to one of the next CA meetings, discussion of content with COM and CAs
g) Consolidation of discussion paper

1.3 Consultation participants

CAs, producers of active substances, formulators of biocidal products and regulatory consultants were identified as potential participants. A background document was drafted and distributed to around 45 potential participants. Half of them were contacted by phone or e-mail asking them to contribute. In total 12 CA, 9 producers, two formulators and one chemical association (German Chemical Industry Association, VCI) contributed via written comments, telephone interviews or at a telephone conference. Notes of the interviews were sent to the participants for approval. Responses from CA represent the personal views of the participants and should not be interpreted as the official agreed view of the respective CA. The identity of CAs and industrial participants is kept anonymous as industry responses also reflect personal views.

2 Analysis of deficiencies in harmonisation of CA work

Task 1 of the study on the impact of Directive 98/8/EC included a market survey and stakeholder consultation. More than 250 responses were received, including 11 from CAs. At the 24th Competent Authorities meeting the state of the review programme was described ("mid term review") and it was noted that the 2010 deadline cannot be met at the current rate of progress, that the specific time limits for dossier evaluation are not respected by the RMS and that the peer review and decision making process takes too much time.[37] Among the reasons cited were the lack of human resources, methodological gaps for the evaluation procedures, incomplete dossiers submitted by industry as well as different quality of Competent Authorities Reports (CARs) and the need to improve the organisation of CA meetings.

The following sections summarise the results from the task 1 stakeholder questionnaires, followed by the specific question posed in the background paper (in boxes) and the responses of the case study participants to these questions.

2.1 Communication with participants

Considering that communication with participants was perceived as essential for improving the process – could you give examples where communication works well and where not and for which reasons? Can you give examples for particularly good or bad evaluation processes (either as a participant having worked with several different Rapporteurs or a CA having worked with different participants) and describe the crucial factors.

All responding CA consider communication with applicants as essential and offer meetings well in advance of the dossier submission deadline where specific issues on data requirements, waiving or read across of data, structuring and formatting the dossier, the different stages of procedure and the timetable are discussed. This enables the identification of any weaknesses in the dossier and problems which may arise during the evaluation process, such as the quality of any waiving arguments. Thus problems can be identified ahead of dossier submission, which gives the RMS time to address these issues, e.g. by consulting colleagues from other MS, without affecting the evaluation deadlines. After dossier submission, applicants should be kept informed of the progress of the dossier through e-mails and telephone calls. Good communication allows questions to be raised and answers to be provided quickly. Early communication of problems encountered during the completeness check allows industry to take action and to provide additional information before the end of the completeness check period.

Some CAs assign a "project manager" to each dossier, who is responsible for coordinating the evaluation and establishes a point of contact. One CA also initiated discussions with a number of participants, in cases where there are several applicants for an active substance but where task forces have not been established. Participants were informed in separate initial meetings that others are interested in the substance and that only one assessment report will be required for the substance. Dossier evaluation of active substances from the lime industry (calcium oxide, calcium dihydroxide, calcium magnesium oxide, calcium magnesium tetrahydroxide) has been cited by one CA as an example of where good

[37] MID-TERM REVIEW OF THE BIOCIDES REVIEW PROGRAMME – STATE OF PLAY AND IDENTIFICATION OF PROBLEMS. 24th CA meeting. Working document CA-March07-Doc.0.1

communication has facilitated the processes. Another example is that obstacles to the process regarding data-sharing have been solved, even amongst fiercely competitive participants, such as the anti-fouling industry.

According to one CA, around 10% of applicants are not very co-operative and hesitate to provide sufficient additional information. Other CAs agree that communication does not work well when the participant has poor knowledge of the requirements and procedures of the BPD, is under-resourced for the dossier preparation and review process or is working on his own without support from others. One CA suggested that disagreements or differences in the interpretations or conclusions between applicants and CAs often cannot be solved bilaterally between the participants, but need to be discussed during the peer review process in the TMs etc., where the participant also has the possibility to table extensive comments and proposals. Finalisation of the CA's report should not be postponed in such cases, with these issues to be solved during the peer review process, but the participants would have favored postponing the submission of the CA's report.

If problems are identified only once the evaluation has started, the applicant has little time to remedy the problems or provide new data or waiving arguments. Where waiving arguments are not straightforward, these have to be discussed with other MS through waiving groups. However, this is a time consuming process. One CA reported that a company which thought that it understood the requirements, following hours of telephone guidance, came for a meeting just 4 months before the submission deadline and submitted a dossier which, to its surprise, was not acceptable. Face-to-face contact is much more effective than telephone or e-mail, and worth the applicant’s time and effort. However, there are very good consultants who give advice to applicants, who do not follow them.

One CA indicated that providing repeated advice to applicants might be unfair to the larger companies or those that hire consultants. Maybe providing advice to SMEs through central bodies (for example the Commission and European sector organisations) should be considered. Other CAs generally offer initial meetings at no cost but charge for any further meeting or work carried out on dossier evaluation.

Producers of active substances gave examples of bad communication with CAs. One company asked for guidance on waiving of data requirements, but the CA was not willing to give comments and referred to the later evaluation process. However, if waiving of data is not accepted in an early stage of the process, the dossier might not pass the completeness check. Even if the RMS agrees on waiving of data, other MS might not accept waiving arguments during the peer review. Clear guidance on waiving possibilities is lacking but MS also should trust each other more.

There are indications from industry that some CAs demonstrated a lack of understanding and expertise and gave no answer at all on specific questions. Feedback from RMS varied from co-operation to rejection of contact requests. It generally appeared that the CAs face uncertainty about data requirements and waiving possibilities. At the TM there is no time for discussion on details and some MS are not prepared to contribute. Many problems could be solved in a harmonized and transparent manner by establishing a central desk which harmonizes and streamlines the evaluation process and which could also act as a decision-making body. The desk might be part of a central agency, but that is not a precondition. Specific issues, notably related to waiving arguments, borderline issues and risk methodology, might be submitted to other MS before the submission of a dossier so that applicants can expect that the answers from the RMS are valid and that no other national rules will be applied during the peer review.

Other producers considered that deficiencies of individual RMS should not be pointed out, but rather that in many fields clear guidance and definitions are not available. These should have been provided by the Commission and MS before the dossiers had to be submitted.

The evaluation process for plant protection products is not considered as a suitable model for biocidal products. Indeed, the peer review of active substances is more centralized through the EFSA (European Food Safety Authority). However, the Draft Assessment Reports (DARs) are also prepared by RMS and the process in total has not been accelerated. The structure and the supply chain of the plant protection industry are also completely different to that of the biocide industry. In the plant protection sector, large producers of active substances also distribute finished products to distributors and end users. Thus active substances and plant protection products are sold at the same time. In contrast, biocidal active substances are usually first sold by smaller producers to formulators. REACH is considered a much better regulatory model than the PPPD.

One producer experienced considerable repeat working because the BPD and RMS require a completely new dossier format, and do not even accept the views that their own in-country colleagues have expressed on the PPPD DAR for the same active substance. No RMS are known to accept PPPD formats.

In some cases, the CA asked for studies that the producer did not believe were required for the BPD. It seemed apparent that the CA knew that those studies had been submitted for the PPPD approval. Another concern has been the change of allocation of the RMS for a specific active substance, because the original CA clearly was not capable of conducting the evaluation. One consortium lost 1.5 years and now faces far higher fees. Communication in English also turned out to be difficult with some CAs from the southern or eastern part of Europe. On the other hand, a formulator of biocidal products indicated that, in general, communication with the Commission (including the ECB) is good or very good, as its websites are updated regularly and are easy to navigate. In the few instances the formulator had contact the Commission, it has been responsive and has provided useful information.

2.2 Data requirements

Responding CAs indicated that they face uncertainty about data requirements. As a consequence, data requirements have been applied differently in different RMS, which is considered unacceptable. It was also indicated that technical guidance is missing (e.g. on analytical methods, identity, technical equivalence, type of exposure scenario to be applied). Data requirements for low and very-low exposure products, in particular, are considered as too high for smaller companies[38]. While the Directive is meant to promote sustainable development of these products, they may in fact be lost from the market. Much of the data required by the Directive is not actually needed for the risk assessment and Article 8(5) ought to be applied more often.[39]

Do you know examples where data requirements or waiving justifications have been interpreted differently by CAs?

[38] However CAs also insisted that data requirements should not depend upon the size of the company, but should depend upon common factors such as the exposure to people and the environment, how the product is used and the properties of the active substances and substances of concern

[39] Article 8 Requirements for authorisation (5) Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information.

One CA indicates that data requirements on reproductive toxicity for anticoagulant rodenticides, for example, have been interpreted differently. Here, some MS do not consider tests with rat and mice as reasonable, while others do. Data requirements and waiving possibilities allow some room for interpretation. This was discussed at the TM, but it seems that different criteria are still applied.

According to another CA, data requirements have been applied differently in relation to the analytical method for sediments and waiving justifications for two-generation reproduction toxicity study on anticoagulant rodenticides. The question of whether core environmental data requirements can be waived has also been changed within the process; from 'environmental core data cannot be waived' to 'not required if no exposure' to 'core data required where relevant'.

One CA complained that some MS request data without knowing how they are going to use them. Discrepancies have been noticed because some RMS follow the guidance on data requirements but focus more on the data used for risk assessment. Some MS are suspected of using the BPD to try and implement national legislation e.g. by requiring exposure data associated with the manufacture of the active substance. The production site should be outside the scope of the BPD (as it does not relate to placing of BP on the market). However, Annex II of the BPD refers to Directive 67/548/EEC, which requires exposure data for the manufacturing site. Thus CAs interpret the requirements differently and some CA consider the production site as not totally out of the scope of the Directive.

Another CA indicated that it evaluated a very low exposure (to both man and the environment) product and considered waiving arguments. The CA does not know whether their arguments are sufficiently strong to be supported by other MS. It considers that removing low exposure products from the market because producers do not submit a large number of new studies, almost all of which might not be necessary for risk assessment, is ridiculous. Uncertainty has been expressed about evaluation of an active substance that is also a nutrient. The applicant discussed a possible risk assessment approach based on the agreed European indices for Average Daily Intake and Recommended Daily dose, but these would involve different risk characterisation methods. When the CA deviates from the guidance, it tries to act reasonably but does not always ask for MS agreement or comments beforehand, since people tend to be more negative and worried about a theoretical case than a concrete proposal.

Producers also indicated that data protection after Annex I listing is considered not to be harmonized. Some MS do not apply data protection rules as strictly as others. Industry is worried about free-riders who might pay data holders for single studies with claimed protected data, write a new dossier and reduce their costs by copying the published dossier. Those competitors would additionally benefit from lower fees, because the effort required for dossier evaluation by CA referring to existing dossiers is also lower. Therefore, a nominative listing of Annex I inclusion of active substances is requested.

2.3 Fees for approval of active substances and authorisation of products

The fact that fees differ between MS could lead to market distortions, potentially preventing submission of dossiers in 'expensive' MS. The range of fees for dossier evaluation of active substances was from 50.000 to 300.000 EUR and those for the authorisation of biocidal products vary between 1.000 to 70.000 EUR per biocidal product.

Similar differences in fees were observed for registration and for the mutual recognition of biocidal products.[40]

Producers have suggested fines for RMS that do not finish the completeness check within 3 months, or do not deliver the draft assessment report by the 12 month deadline. These fines could be reimbursed to the affected industry.

Producers also requested that fee regimes across MS should be harmonised and published, or that standard fees should be charged by a proposed Central Agency, with an upper limit. Fees should never exceed the work required, and tiered approaches for dossier preparation should be considered.[41] Many of them considered that more appropriate charging might make it possible for SMEs to keep their products on the market.

Given that fees differ considerably between Member States and that designated human resources are too scare - what do you suggest to harmonise fees and improve personal capacity of CAs?

CAs agreed that harmonization of fees is a difficult issue, as it is a national matter. Some CAs assume it is impossible to force harmonization and doubt that MS would agree politically to the centralized setting of fees. According to them it is a common misperception that the directive instructs MS to levy fees proportionate to the work carried out on an application. It actually states that fees should cover all the work required under the directive, not just review of an application. They consider that the principle of financing all work through fees charged to industry is not reasonable and hinders the objective of the BPD to harmonise the market. Some CA confirmed that charging the same fee for the first PT and for all subsequent PT is not reasonable, but that in general fees are too low to cover all issues related to the BPD, including the peer-review process. Some CAs charge fees relate to the actual work done and have introduced a comprehensive system of work recording, so that the time spent on various activities can be accurately recorded, ensuring that the final fee represents the cost of the work actually undertaken. Whilst they can give the participant a general estimate of what the fee is likely to be, a more specific estimate of the amount of work needed to carry out the evaluation is made at the completeness check stage.

Other respondents considered that the fee structure should be harmonised centrally and each MS involved should contribute its own resources to achieve harmonisation. In addition to the fees paid by industry, a similar amount should be available for harmonisation of the process. A review of the charging system across MS and the establishment of work recording systems by all MS have been proposed. Several CA indicated that their fees for dossier evaluation of both active substances and biocidal products certainly will have to rise.

In the past it has been very difficult for CAs to obtain a realistic estimate of the number of dossiers to be evaluated from the list of notified active substances, and to plan corresponding personnel resources. Most received far fewer dossiers than expected. Lack of personnel resources in a CA cannot be solved by rapid hiring of new staff, since new staff need training and this also distracts the established staff from their evaluation work.

[40] Fees applied by the Member States, Norway and Iceland for the evaluation of existing active substances within the framework of the Biocides Directive 98/8/EC (CA-Avril06-Doc.15.2)

[41] Although CAs also indicate that it is a common misperception that the Directive instructs MS to have fees proportionate to the work carried out on an application. It actually states that fees should cover all the work required under the directive, not just work carried out on an application.

The efficiency of the work could be improved by organizing more training on the different fields of risk and other assessment of biocidal active substances. The personnel capacity of CAs could be improved indirectly through pressure from the Commission on CAs to deliver on time. That would be time-consuming for the Commission but competition from PPPD and REACH means that biocides always comes third in line for resources.

Among producers, one commented that the fee structure differs considerably within MS but most MS charge fees for dossier evaluation for each PT for which an AS is submitted. Some CAs charge the same amount for each PT, independently of the number of PTs; others charge more for the first PT and less for a subsequent PT. Dossier evaluation of an active substance such as formaldehyde, notified for 13 PTs, is likely to cost up to €1 million. Another issue is the point of time when the fees have to be paid. Some MS require the full amount in advance, when the dossier is submitted. Others require a smaller amount for the completeness check and the full fee when the evaluation starts. There are no rules on whether fees have to be paid back, e.g. if the dossier has not passed the completeness check and is not evaluated. The fees should be reasonable and it is suggested to charge e.g. half of the fees at the beginning and half at the end of the dossier evaluation, when the work has been done. The Commission has asked MS to provide information on fees and fee structure but the responses differ considerably and do not take into account changes.

Participants from industry gave several examples where significant fee increases have been announced; some CAs have increased their fees 2-8-fold. There is no transparency how MS fix their fees.

Some respondents considered that there is no scientific justification to request equal fees for all PTs for which an active substance has been notified, as the main work is done at the first dossier submission when all the basic toxicology and ecotoxicology is reviewed. Fees should only reflect the time needed for the evaluation and resources should focus on the evaluation process. In practice, many other aspects are considered and CA should ask themselves whether these are really necessary for the evaluation of active substances. For this reason, a central agency should harmonize and charge the fees and should distribute them to MS. There should be standard prices for the complete check and generally fees should consider the effort of industry to prepare the dossier. Part of the fees might also be attributed to the central agency for improving harmonization. REACH might serve as an example of how this could work.

The differing fees for product authorization will cause problems because industry will focus on cheaper MS and those will be overloaded, while other MS will be unhappy that they do not receive dossiers on biocidal products, due to their higher costs. The CA with unrealistically high fees might be willing to interfere in the mutual recognition process in order to protect its resources. It is very important to reduce the fees and facilitate the placing on the market of biocide products in all MS by industry. Otherwise the market will be limited and only the big MS with important markets will offer biocide products.

2.4 Evaluation of dossiers and harmonisation of risk assessment

Both producers and formulators are concerned about differences in the quality of dossier evaluation by RMSs. Formulators are concerned that, as with Directive 91/414/EEC, there may be delays for bureaucratic reasons in Annex I inclusion and even in the decision on non-inclusion, due to the lack of appropriate evaluation guidelines for risk assessments. This would have severe consequences for SME formulators.

However, CAs also complain about the poor quality of parts of (but not of all) dossiers that have been submitted, contributing to delays. The justifications for waiving of data

requirements are often found to be not as robust as the applicants thought. Additionally, CAs received multiple dossiers for the same active substances, because participants did not reach agreement on data sharing. Evaluation of several assessment reports is laborious and might lead to conflicting conclusions.

Regulatory consultants seek rapid feedback mechanisms that can re-appraise decisions in the light of new experience. For example, some of the key models and default values used in the risk assessments are regarded as wrong and need to be changed in order to have an evaluation that stands up to scrutiny.

It was suggested by some producers that centralised dossier evaluation would be more pragmatic and quicker. In particular, a Central Agency was proposed that would be the central communication point, staffed with scientific experts, and with responsibility to harmonise data requirements, develop risk assessment models, carry out substance evaluation in a harmonised way, ask for identical and proportionate fees, handle data protection and data sharing issues. Such a Central Agency could also address mutual recognition issues. According to formulators, experience with existing substances risk evaluations should be considered.

While several CAs suggested that the evaluation of data should be better harmonised between MS, a central Agency was not suggested. Instead, CAs recommended improving the evaluation of dossiers by evaluating similar types of active substances at the same time, to solve possible common problems in their risk assessment. Another challenging issue is the need to better harmonise evaluation of data between MS. MS evaluating active substances of the same PTs should co-operate and build working groups with greater technical expertise. Support from the Commission for this is requested.

Producers, as well as formulators, request improved co-operation between CAs. Producers suggested that a Board of Appeal, as will be introduced for REACH, should be set up as an impartial arbiter when there are differences between CA and the industry in dossier evaluation[42]. Several proposals have been submitted by CAs to improve the commenting phase of CA reports, the management of time-frames, the CA and technical meetings and the effectiveness of information flow. Some CAs are concerned whether agreement on risk management approaches for Annex I inclusion of active substances can be reached.

Could you give examples where the methodology of the dossier evaluation and the risk assessment has been applied differently? With what consequences? How could the evaluation of dossiers and the risk assessment be better harmonised?

One CA indicated that, as a first step, the BPD rules for risk assessment are applied. If the preliminary evaluation shows a degree of concern, the common principles of risk assessment for old and new substances, as described in the TGD and REACH RIP[43] should be considered and more detailed assessments carried out. This might lead to different conclusions to those previously reached and may allow the definition of suitable safety measures. However, other MS apply different strategies. For example, the conservative approach of the BPD compares AOEL-values (acceptable operator exposure level) with exposure data and requires safety measures if a level of concern is identified. In other MS, a refinement of the risk assessment for professionals is carried out by including unrealistic risk reduction measures (e.g. assumption of reduced frequency or duration of application,

[42] It should be noted that each participant can complain about decisions of CAs to the Commission. Decisions of the Commission can be challenged at the Court of Justice.

[43] Technical Guidance Document and REACH Implementation Projects

specific material of protection gloves in wood preservation, change of gloves every day). Many CAs indicated that a dummy product can not be the basis for risk assessment of a real product, thereby referring decisions on workplace risks to the risk assessment during product authorisation. This only postpones the necessary discussions to the product authorisation phase and could hinder mutual recognition. Some CAs also indicated that they have had few resources for the peer-review and therefore no experience on different risk assessment approaches.

Other CAs gave examples of distinct approaches for dossier evaluation, most of which have been discussed and resolved at TM or CA-meetings, such as the acceptable affected distance from treated wood construction (the so called safe distance) or differences in the use of environmental emission scenarios (ESD). The need for discussion in small expert groups on interpretation of study results and guidance has been challenged. It would be time consuming and costly if all experts were present at each TM to discuss these issues. On the other hand, the Commission should ensure that proposals for guidance arising from these meetings are not considered as finished documents, because relevant points might have been missed and MS (and industry) not present at the meeting should also have the opportunity to comment on proposals.

Some CAs are concerned that some MS do not respect deadlines and the Commission seems to be unable to do anything about this. Participants who have dealt with MS who have properly applied the principles of the Directive have been effectively disadvantaged, such as by having to remove their products from the market, whilst other MS have not taken equivalent action.

Several CAs agree that a central agency would reduce some of the diverse decisions. However, they assume that it would still have to go through the development steps which always occur when one is putting theoretical procedures into practice. Also, pushing for "more pragmatic and quicker" evaluations contradicts the extensive data requirements. It is not acceptable that CAs should skip through a report and simply accept the summary from the company without any kind of quality check, because this will not lead to a good scientific basis for regulatory decisions. A board of appeal, as will be introduced for REACH, would save time at the TM meetings, which seem to spend a disproportionate amount of time discussing problems between a particular CA and a company of which they have no prior knowledge.

Producers predict difficulties in dossier evaluation of PT6-10 active substances in particular, because few MS have previously had national provisions for those products. There are different standardised leaching tests for impregnated wood, the longer application causing higher leaching rates. Another example from industry is that the time weighted average approach, which is applied for substances with good degradability, has been applied by one CA for Tolylfluanid (CAS 731-271) but not by another CA for very similar applications with Dichlofluanid (CAS 1085-98-9). In particular, exposure scenarios are not described sufficiently and allow a wide range of interpretation for CAs during product approvals. One formulator refers to uncertainty concerning the utility of US EPA and non GLP data on chemistry methods, efficacy, and exposure studies.[44]

[44] Chapter 6 of the TNGs on Data requirements gives guidance on Good Laboratory Practice. GLP principles have to be applied for physical-chemical studies, non-clinical health and environmental safety studies, but need not be applied to the efficacy and exposure studies. These studies should be done to an appropriate protocol and suitable quality assurance standards.
http://ecb.jrc.it/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_DATA_REQUIREMENTS/chapter4-5-6.pdf

2.5 Enforcement and lack of resources of Competent Authorities

Based on the questionnaire responses, it could be concluded that compliance with the BPD is not enforced effectively. This was stated in relation to the control of non-identified as well as non-notified substances in biocidal products. Furthermore, the level of market surveillance and control apparently differs across the EU.

Producers complain that they are aware of substances that can no longer be used since 1 September 2006 that are still on the market, and that many MS do not know what products are on their markets. Enforcement is considered to be vigorous in some MS and negligible in others. Concern is expressed that, in some MS, enforcement responsibility does not lie with the same agency which acts as the reviewing authority. Formulators also indicated that the inspectorates are sometimes from different legal bodies than the regulatory authorities. There is a need for improved communication and training in order to ensure proper enforcement. Regulatory consultants demanded that there should be an obligation for MS to meet deadlines and enforce monitoring of products in their particular country. Industry organisations stated that all MS are required to monitor sales of biocidal products, to ensure that only registered products are being sold. However, it is suspected that MS do not always have the resources to carry out this work.

The evaluation of questionnaires submitted by CAs to the Commission, for the 2nd Composite report on the transposition and implementation of Directive, confirms that enforcement of the withdrawal of biocidal products with non-notified active substances differs considerably between MS.

An overall observation is that CAs have not assigned sufficient resources and competent staff to carry out the work under the review programme of active substances. According to producers, national CAs are considered as having resource problems and differ in their attitudes to giving assistance. MS also differ in their knowledge of the Directive. It is said that the inflexibility and limited expertise of some RMS have both resulted in further slowing down of the process. It has been claimed that some MS do not respect deadlines for evaluations of dossiers attributed to them and the Commission has been asked to put pressure on them to do so.

Formulators commented that authorities lack sufficient resources, which will also create enforcement problems. They demand that the Commission obliges all MS to implement the Directive with the same criteria for all procedures, deadlines, costs etc. Trade organisations fear that timelines are not being met by some MS in the review process. Most CAs agree that they have too few resources, and even more so the Commission and in particular the ECB, to manage all the tasks associated with the Directive

To make enforcement more efficient, producers suggest that independent EU enforcement teams should ensure that all Member States implement withdrawals of substances and actives. Users of biocides also confirm the need for more action to ensure compliance with the implementation of the Directive in the various Member States.

Do you agree that the monitoring and regulation of products which should be withdrawn from the market is not enforced in particular Member States? Could you give more details and examples?

One CA referred to the latest three-year-report on the BPD implementation, which gives an overview of the monitoring situation of withdrawn biocidal products. According to the CA, compliance is controlled by authorities as well as by competitive suppliers of biocides. Another CA states that it is difficult for MS that do not have any existing regulatory

processes in place effectively to control their market. Often it is not known where MS take action – at the source of supply, at the retail outlet, at the point of use or on premises? There is little feedback from other MS at the CA meeting about the action they have taken, and some CAs suspect that many MS have done nothing. One example indicated is the lack of harmonisation on the removal of chromium; some MS took action but many others have taken no steps to remove such products from the market. One CA argues that it does not have the legal basis to take action against biocidal products which had not been regulated previously.

Producers indicated that the withdrawal of chromium trioxide has been enforced differently among MS.[45] In many countries no biocidal registers exist and, therefore, enforcement of market surveillance is not effective. They question how MS can check compliance with the 1st September 2006 deadline if they do not know what is on their market. A mandatory declaration of all the biocidal products present on the national market should be required by all countries and a 'notification number' should be provided and applied to the product label. The current non-enforcement favours non complying companies and is detrimental to the BPD objective of increased safety for human health and environment. The Commission has no power to force MS to comply with the requirements during the transition period. Also, where a CA has taken action based on its national biocide registration system, the CA has no overview of those biocidal products which have still not been regulated. One formulator suggests that the possibility of a centralised programme for product registration/authorisation should be investigated, to increase efficiency. Changing the BPD to a Regulation would provide the Commission with the power to enforce the principle of mutual recognition and require that MS follow the timelines.

2.6 Uncertainty of rules

Although numerous Regulations, Technical Notes of Guidance (TNsG) and other documents have been developed to guide industry and CAs in carrying out their duties, many uncertainties about the rules are still perceived, both by industry and CAs. CAs indicated that they face difficulties concerning the identity of active substances and the correct product types, borderlines between chemical and physical mechanisms, direct and indirect actions of actives or other issues such as treated articles. It was also indicated that some technical guidance is missing (e.g. on analytical methods, identity, technical equivalence, kind of exposure scenario to be applied). Some CAs asked for further guidance concerning product authorisation, frame formulation and mutual recognition.

Considering that lack of agreed guidance documents is complained about in relation to numerous issues. What are the most important ones which should be adopted with priority?

The following key issues which require further guidance were identified by participants:

CA:

- Better description of provisions during the transitional period
- Clarification of borderlines with other regulations

[45] Meanwhile this issue seems to be harmonised, see "Guidance document agreed between the Commission services and the competent authorities of Member States on the role of chromium in wood preservation. (http://ec.europa.eu/environment/biocides/pdf/nfg_cr_040705.pdf)

- Guidance on data requirements, requirements for the efficacy dossier, data protection, mutual recognition and on parallel imports

Producers:

- Borderlines with other regulations (REACH, cosmetics, food contact materials regulations, veterinary medicine)
- Legal rules for participation in consortia[46]
- Update of TNsG on data requirements and waiving possibilities
- Technical guidance for risk assessments (especially human risk assessment for PT 2, 4 and 13)
- Leaching tests or PT 6, 9 10 and 21
- Guidance document on analytical methods
- Guidance on comparative assessments
- Lack of clearly defined models for human exposure and ESD (PT 2, 3, 4, 8, 18, 19)
- Evaluation of dossier documents not linked with IUCLID (retyping of data needed)

Formulators:

- Which active substances will be supported in future (as there are no consequences for strategic notifications)
- Clearly defined PT definitions
- Guidance on frame formulations and mutual recognition
- Future regulations on imports (e.g. from treated articles)
- Efficacy requirements

Users of biocidal products in particular are uncertain about the future status of active substances, including essential use applications.

2.7 Mutual recognition of authorisations

Most producers and formulators consider mutual recognition as being very advantageous, if it occurs as intended. However, industry is worried that mutual recognition may not be applied by all MS and proposes a centralised procedure for product authorisation instead.

Most CA also welcome the advantages of mutual recognition of product authorisations in saving time and resources. However, some anticipate difficulties because of uncertainties over the rules. One drawback relates to problems encountered during the risk evaluation of active substances and agreements among the CAs on risk reduction measures for active substances. Decisions on this have been postponed and shifted to decision making on product authorisation. Integrating clear requirements for risk reduction measures into the Annex I inclusion would ensure a harmonised application in the product authorisation phase and would thus facilitate mutual recognition. In this context, it would be very helpful if the database of biocidal products, planned by the Commission, always included the most up-to-date status of mutual recognition of biocidal products in different MS. However, some CAs also expressed concern that mutual recognition might increase the number of biocides on the market, and that products formerly not approved, or with restricted use, might be introduced onto national markets. Further, lack of harmonisation in evaluation of substances and the "negative listing" now adopted for Annex I decisions are considered as

[46] Comment: It should be noted that legal rules for participation in consortia are outside EU competence.

additional barriers to mutual recognition, because some points of the discussion have been postponed to the authorisation of biocidal product.

The industry is concerned about the practical implementation of mutual recognition of biocidal products in different MS, because national rules and different data requirements might still be applied. For this reason, a centralised authorisation/registration system, comparable to REACH, would be beneficial. If the harmonisation of product authorisation/registration and mutual recognition does not work as foreseen, the most important benefit of the implementation of the BPD for the industry would be endangered. Another practical instrument for improving the harmonisation of biocidal product authorisation within MS would be to establish a common register of biocidal products within the EC.[47]

What has to be done, to ensure that mutual recognition of authorisations will function in future?

One CA indicated that the assessment reports should be expanded to include a description of acceptable and non-acceptable applications and potential risks. The TM are not considered as being an adequate forum for such discussions. It is suggested that discussions should take place in workshops attended by experts from MS. Additionally, a collection of all safety measures considered in the risk assessments of active substances should be made available, in order to evaluate the worst case exposure scenarios and to have an overview of other risk reduction measures that are still available. Mutual recognition is simplified by attributing one authorisation / registration number to each biocidal product, which would apply to all MS. Authorisation or registration should be granted automatically if a CA does not object within certain time period. Some CAs also considered the possibility for MS to impose national requirements as being too wide.

Another CA is worried that mutual recognition will be jeopardised if risk management approaches cannot be agreed at the Community level. CAs should agree on a list of product types (or their sub uses) for which a mutual recognition of authorisation would be acceptable. All MS should trust each other and accept product evaluations carried out by other MS. Several CAs indicated that the broad Annex I inclusion of active substances and shift of decision on risk reduction measures to the product authorization stage will cause problems for mutual recognition. One CA argues that a centralised procedure of product authorisation by a central agency is unlikely to be politically acceptable to MS.

Producers call for a centralised procedure in order to harmonise product authorization and mutual recognition. The industry is worried that additional tests might be required during mutual recognition, e.g. for efficacy testing, due to different national approaches. Additionally, mutual recognition is not applied to provisionally authorised new active substances and CAs are indicated to have different approaches if a biocidal product contains a second active substance currently being evaluated. Industry needs a flexible registration system offering different possibilities, such as main registration, duplicates of registrations, supplemental registrations, secondary registrations (see case study 4). English should be accepted as the standard language by all MS in order to avoid the translation of parts of the dossiers (only the medical data sheet, SDS and label should be translated). Additionally, there should be a clear and EU-wide statement on the acceptability of US EPA methods and non-GLP data for chemistry and efficacy studies.

[47] European Commission Biocidal products register - Vision Document 27/11/2006 (CA-March07-Doc.9.2.3)

3 Proposals for amendments and improvement of harmonisation of the CA work

3.1 Analysis of questionnaires

An in-depth analysis of questionnaires from the stakeholder consultation (task 1) identified the following issues:

- Similar kinds of active substances should be evaluated at the same time so that the substances can be discussed at the same TM.
- The time frame for evaluating a dossier must also take into account management issues, such as change of staff or the impossibility to cover all different issues.
- Harmonisation between MS should already be improved during the evaluation of active substances.
- Co-operation between RMS with active substances in the same PT should be established as routine. The formation of working groups with greater technical expertise is suggested.
- Often the work of MS is done by different people in different departments, which leads to difficulty in decision making. Some MS are not producing any evaluations and the Commission needs to put pressure on them to do so.
- The peer review of DARs could be accelerated, especially at the TM. The proposal that the RMS separates the comments to its CA-report from the peer review into different types (e.g. open for discussion, editorial, and relevant for decision on Annex I inclusion) is welcomed. MS need to think about the end result of their deliberations and should consider whether the issue influences the risk assessment and so affects the Annex I listing.
- Harmonisation of evaluation is urgently needed and this should be mainly the responsibility of the Commission/ECB. The ECB should have much greater resources for the detailed peer review of the CA evaluation reports. The peer review cannot depend solely on the availability of CA resources, which may be entirely taken up by the CAs' own evaluation tasks.
- The working group on "Minor Use products“ (e.g. pheromones) and "other specific categories of Biocides“ (e.g. naturally occurring substances) should start discussions again.
- The PPPD model, with an early compliance check in the inclusion directives, would be very beneficial in the BPD process as well and facilitate a harmonised approach amongst the MS.
- Article 4 (1) of 98/8/EG concerning special requirements MS could impose during the mutual recognition of biocidal products should also address concerns about environmental effects.

- The harmonisation of the BPD with the REACH regulation is requested by CA and industry. Examples are the harmonisation of the data protection period, the use of non-GLP data, the obligation that applicants participate in task forces or the obligation that data from existing studies with vertebrate animals must be shared. REACH has also special provisions for naturally occurring substances or low-risk substances which should be considered when the BPD is revised.[48]
- Industry also recommends future provisions on fees similar to REACH (point 100) which indicates that a Commission Regulation will specify the structure and amounts of fees, including the circumstances under which a proportion of the fees will be transferred to the relevant MS CA. Additionally, a Board of Appeal, as planned for REACH within the Agency, is requested to provide a procedure to address any complains against CAs' decisions which is less onerous and costly than legal complaints to the Court of Justice (REACH introduction point 106).

3.2 Analysis of CIRCA documents

From an analysis of the CIRCA documents, some proposals as to how CA work could be harmonised have been identified, such as a proposal to optimise the procedures for discussion of individual substance.[49]

In March 2007 the Commission presented a working document on possible solutions for the problems identified in the implementation of the Biocides Review Programme [50] Here several recommendations refer directly to the harmonisation of the CA work. In addition to compliance and supervision or time limits, the following items are referred to:

- Better assistance from MS in pre-submission consultations with participants and more flexibility on waiving.
- More direct utilisation of monographs prepared under Directive 91/414/EEC; less thorough evaluation and peer-review in cases where the dossier has already been reviewed under Directive 91/414/EEC.
- Assessment of groups of active substances (as is already done, e.g. in the case of silver compounds and quaternary ammonium compounds).
- Optimisation of the use of the first CAR for subsequent product types (PT)
- Resolution of more issues outside TM, e.g. by smaller, electronic sub-groups; or direct contacts of RMS with MS.

Other proposals, requiring more in-depth discussion before adoption, are described in the original document.

[48] Article 2 (7) a and b of REACH exempts substances included in Annex IV or V from the obligation to register because a) sufficient information is known about these substances and they are considered to cause minimum risk because of their intrinsic properties; or b) a registration is deemed inappropriate or unnecessary for these substances. In Annex V point 7 and 8 several substances which occur in nature are excluded from scope if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC.

[49] KEMI. Thought starter regarding Pt 6.4 Procedures for discussion of individual substance. CA-April06-Doc.6.4

[50] MID-TERM REVIEW OF THE BIOCIDES REVIEW PROGRAMME – PRELIMINARY IDEAS FOR POSSIBLE SOLUTIONS. CA-March07-Doc. 0.2

3.3 Proposals for amendments from participants

The German Chemical Association (VCI) suggests in its position paper[51] that, when amending the Biocidal Products Directive, the new legislation should be given the status of an EU Regulation (like REACH) which would apply equally in all MS. This would contribute significantly to the harmonisation of the Single Market and, consequently, make matters easier for all parties involved. Generally, a more centralised procedure should be introduced for active substance reviews and product authorisations. A central agency, as created under REACH, would be needed for this purpose. Charges should be fixed by a central agency. The list of legislation mentioned as exemptions should be updated and also the Manual of Decisions; the EU borderline documents should be made binding, and foodstuffs and feeding stuffs should be excluded from the scope of the Directive. Further aspects of the position paper of the VCI have been considered in the case study report on simplified procedures (frame formulation, minor/major changes of formulations) or do not directly refer to the case studies (general data requirements, data protection, reduced data requirements for minor uses or niche products, biocide-containing articles and materials).

4 Summary and conclusions

4.1 Communication with participants

Both CAs and industry gave examples of good and bad communication with participants. Meetings with applicants before dossier submission are considered to be essential for improving the process by discussing data requirements, methodology (e.g. exposure scenarios to be applied) and waiving possibilities.

Some CAs are considered as more co-operative than others and communication with some CAs was indicated as being difficult because they are not accustomed to using English. The allocation of an active substance has changed from one RMS to another because the first RMS clearly had no capacity to evaluate the dossier.

Some applicants lacking experienced staff or consultants, who contacted the CA too late (e.g. 4 months before the deadline for submission of the dossier), have not been successful with their dossier. Similarly, dossiers elaborated by a single person often did not pass the completeness check. The establishment of task forces should be encouraged by CA through discussion with different applicants.

An early completeness check of the dossier offers the opportunity for missing data to be provided in time. The consideration of dossiers submitted under 91/414/EEC is recommended. Differences in the interpretation of data requirements often cannot be solved bilaterally between the participant and the RMS, but need to be discussed during the peer review process. Waiving arguments should be discussed with other MS through the waiving groups, because any decision of the RMS could be cancelled during the peer-review and this causes uncertainty. Better guidance on waiving is urgently requested.

Better advice to SMEs from central bodies (the Commission and European sector organisations) might be considered in order to provide support.

A desk or board of all MS has also been suggested, where specific issues, notably related to waiving arguments, borderline issues and risk methodology, might be submitted to other MS before the submission of a dossier, so that applicants can expect that the answers from the RMS are valid and that no other national rules will be applied during the peer review.

[51] VERBAND DER CHEMISCHEN INDUSTRIE e.V. Position: Amendment of the EU Biocidal Products Directive - Improvements necessary in biocidal products legislation. 12 January 2007

The proposals of the Commission from the mid term meeting concerning electronic committees might be step in this direction. REACH is often mentioned as a suitable regulatory system which may solve some of the problems observed in the BPD.

4.2 Data requirements

CAs and industry provided several examples of where data requirements have been interpreted differently. However, most issues have since been solved in TM or CA-meetings and many the differences have been described in CIRCA documents.

There is still uncertainty concerning the question of whether core data can be waived or not. Waiving of data requirements for very low exposure (both to man and the environment) products has been challenged by one CA.

When requesting additional data, CAs should consider why they want these data. Exposure data associated with the manufacture of the active substance have been requested by CAs, but manufacturing is essentially outside the scope of the Directive.

Industry doubts that data protection after Annex I listing will be harmonised, although Article 12 describes the rules, and several industrial participants would have welcomed a case study on data protection. One producer indicated that data protection rules cause extensive unnecessary vertebrate animal testing. In at least one case, waiving of data for existing vertebrate studies submitted under PPPD has not been granted, due to a missing letter of access from the data holder. Under REACH, the use of the existing data would have been enforced by data sharing and cost compensation rules.

4.3 Fees for approval of active substances and authorisation of products

The fee structure is being revised in several MS. Participants agree that charging the same fee for the first PT and all subsequent PT is not reasonable. Fees should be used for carrying out the work involved in implementing the BPD and not for other purposes.

It also appears that fees in general are too low to cover all issues related to the BPD. There are estimates that about half of the effort related to the BPD is related to the evaluation of dossiers and half to the harmonisation of the process, including peer review.

While industry requires that fees should cover only dossier evaluation, some CA refer to the text of the BPD, which states that fees should cover all the work required under the Directive, not just work carried out on an application. However, it is suggested that the principle of re-financing all work to be done with fees charged to the industry is not reasonable and hinders the objective of the BPD to harmonise the market. The fee structure should be harmonised centrally and each MS involved should contribute with own resources to achieve harmonisation. Some CAs indicated that they have few resources to participate in the peer review, other indicated that this kind of work will be limited in future and this will downgrade harmonisation.

Another issue is the point of time when fees have to be paid. Some MS require the full amount in advance when the dossier has been submitted and reject dossiers if the fee is not received in time. Others require a smaller amount for the completeness check and the full fee when the evaluation starts. Industry suggests that, for example, half of the fees should be charged at the beginning an half at the end of the dossier evaluation.

Differing fees for product authorisation will cause problems, because the industry will focus on cheaper MS and those will be overloaded, while other MS will be unhappy that they do not receive dossiers on biocidal products due to their higher costs.

4.4 Dossier evaluation and risk assessment

Several examples of distinct approaches to dossier evaluation were reported by industry and CA. Some related to very detailed aspect of the risk assessment. Again it seems that most of these issues have been discussed at CA-meetings and TM and harmonisation has partly been achieved. It has been claimed that guidance documents which would improve harmonisation are still missing. CAs and industry are concerned that some RMS do not respect deadlines and the Commission seems to be unable to enforce these.

Discussion between experts is essential for better harmonization. It would be time consuming and too costly for all experts to be present at each TM. There are other options for discussion between experts working on the same issues, e.g. websites.

The objective to push for "more pragmatic and quicker" evaluations is questioned by CAs, because harmonisation of evaluations and the quality check will be downgraded, which is contradictory to requiring detailed, ambitious and expensive data form applicants. It will not lead to a good scientific basis for regulatory decisions.

A central agency, as for REACH, might improve harmonisation of dossier evaluations and reduce some of the diverse decisions. However, some CAs assume that experts from MS would still have to go through the development steps which always occur when putting theoretical procedures into practice.

4.5 Enforcement

There is clear evidence that the enforcement of the withdrawal from the market of active substances not supported by industry has been different among MS. However, little information is available from the CA input to the 2nd composite report. Only MS with complete registers of biocidal products are able to survey their market effectively. Existing national biocide registers often only consider part of the PTs. There is broad acceptance that a European product register would facilitate market surveillance and would also improve mutual recognition of biocidal products.

4.6 Lack of resources in the competent authorities to implement and enforce all requirements

Lack of resources is a complaint of most of the CAs. Several CAs indicated that they will have to focus on their tasks as RMS and will reduce their effort for peer review. Some CAs confirmed that it was very difficult to obtain a realistic estimate of the number of dossiers to be evaluated from the list of notified active substances. Far fewer dossiers have been submitted than expected. Lack of resources amongst CAs is directly related to the amount of fees, as far as these are really directed to the respective authorities involved.

4.7 Uncertainty of rules

Among the guidance documents which should be elaborated/updated with high priority are:

- Human health exposure
- Human risk assessment for PT 2, 4 and 13
- Borderline issues to other directives
- ESD on PT 2, 3, 4, 8, 18, 19

- Leaching tests or PT 6, 9 10 and 21
- TNsG on data requirements
- Guidance document on analytical methods
- Position paper on situ generation of biocides
- Regulations on imports (e.g. from treated articles)
- Efficacy requirements

Surprisingly, frame formulations were not mentioned as a key area for guidance by most CAs, perhaps because there are still 2 years until the first product authorisations (see case study 4).

Participants agree that clarifying and enhancing existing guidance will reduce the number of inquiries received by the authorities.

4.8 Mutual recognition of authorisations

There is clear evidence that mutual recognition is at risk through national specific requirements on product authorisation and because part of the discussion on risk evaluation/risk mitigation measures of active substances has been postponed to product authorisation. Industry and some CAs consider Article 4 of the Directive as too wide, because MS are allowed to impose conditions on placing biocidal products on the market. Other CAs request consideration of further aspects to be included, in order to maintain the level of protection achieved through national product authorisation regimes. According to industry and some CAs, a centralised procedure of product authorisation by a central agency might be a solution. Other CAs consider this as not being politically acceptable. It was suggested that an authorisation or registration granted by a MS should apply to all MS automatically if MS do not object within a certain time period. Industry suggests that a guidance document should support harmonisation and generally MS are asked to trust each other.

A description of acceptable and non-acceptable applications should be developed and the decision criteria should be reported in the assessment reports, with the aim of facilitating the future authorization of biocidal products. Similar approaches are envisaged under REACH, where acceptable exposure levels are identified. All issues should be openly discussed by experts and a collection of all decisions should be provided. The TM are not considered as being an adequate forum for such discussions. It is suggested that discussions should take place in workshops attended by relevant experts from MS.

The industry is also concerned that mutual recognition is not applied to provisionally authorized biocidal products containing active substances not listed yet in Annex I or IA (e.g. new active substances) according to Article 15 of the Directive.

English should be accepted in order to omit the translation of parts of the dossiers (only medical data sheet, SDS and label should be translated). There should be a clear and EU-wide statement on the acceptability of US EPA methods and GLP efficacy and chemistry studies.

Report on Case Study 4: Simplified procedures

1 Introduction: Objectives of the Case Study and Approach

1.1 Objective

The purpose of the case study was to analyse the concept of frame formulations and low risk biocidal products and to outline possible modifications of the concept to reduce uncertainties and make it more practicable and useful. The analysis includes models of simplified procedures used in national authorisation schemes and other regulatory fields. The evaluation of procedures for commodity substances has not been assessed in detail.

1.2 Approach

The case study involved the following work steps:

- More in-depth analysis of answers to task 1 questionnaires
- Evaluation of other legislation/approaches with frame formulation concepts
- Development of a background paper outlining the concerns of industry and solutions suggested by CAs and industry
- Telephone or email contact with participants
- Documentation and reporting

1.3 Consultation participants

CAs, producers of active substances and formulators of biocidal products were identified as potential participants. Several stakeholders who responded to the task 1 questionnaires by commenting the concept of simplified procedures were contacted and additional information was received. A background document was drafted and distributed to around 60 potential participants. Half of them were contacted by phone or e-mail asking for further contributions. In total 12 CAs, 7 producers, 7 formulators as well as 6 national and 6 chemical associations contributed via written comments, telephone interviews or during a telephone conference. Interview notes have been approved by the participants. Responses from CAs represent the personal views of the participants and should not be interpreted as the official agreed view. The views expressed by industry participants also reflect personal opinions. The anonymity of all participants has been preserved.

2 Analysis of simplified procedures

The Biocidal Product Directive (BPD) includes several provisions, notably the simplified procedures for basic substances, low risk products, and frame formulations, which are intended to deliver time and consequently cost savings. Based on the main issues identified in the stakeholder consultation, the case study focuses on frame-formulations and low-risk products.

2.1 Frame-formulation

2.1.1 Provisions of the BPD

In the definitions of the BPD, the term 'frame-formulation' is used for a group of biocidal products that have the same use and user type, and that contain the same active substances with the same specifications. Their compositions must present only limited variations from a previously authorised biocidal product, which must not affect their level of risk or their efficacy. In this context, *"a variation can be defined as a reduction in the percentage of a particular active substance, and/or an alteration in the percentage composition of one or more non-active substances, and/or the replacement of one or more pigments, dyes, perfumes by other compounds presenting the same or a lower risk, but which do not decrease its efficacy"* (Article 2 (1) i).

In addition, the use of frame formulations is referred to in Annex VI, paragraph 9:

"It is known that many biocidal products present only minor differences in composition and this should be taken into account when evaluating dossiers. The concept of "frame formulations" is relevant here."

Frame formulations should also be considered in the context of Annex VI, paragraph 12:

".....The administrative burden, especially for small and medium sized enterprises (SMEs), shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment."

According to the Technical Notes for Guidance (TNsG) on Common principles and practical procedures for the authorisation and registration of products (final draft July 2002)[52] the concept of frame formulations:

- reduces the complexity of the authorisation system by permitting products to be authorised in ranges of colours and fragrances without the need for specific data on every formulation variation. This reduces the amount of data needed and the need for multiple assessments on virtually identical products; and
- does not compromise human or environmental safety or the efficacy of a product resulting from their use. This is because there will have to be an assessment completed on a dossier of one formulation within this frame and all other formulation variations only represent minor differences from that which the dossier supported.

In addition there is a provision in the BPD for the communication of frame formulations to applicants under Article 3, which states that: "Member States shall, on request, or may, on their own initiative, and where relevant, establish a frame formulation and communicate it to the applicant when issuing an authorisation for a particular biocidal product." However, a detailed frame formulation may only be communicated to the party(ies) whose products originally established the frame formulation, so that issues of confidentiality and data protection are not compromised.

The TNsG specify several examples of how the concept of frame formulations could work in practice. Varying the concentrations of the active substance, solvents (low odour kerosene, water), pigments and other inert non-active substances such as calcium carbonate or sodium sulphate is allowed within a frame formulation. Depending on the type of ingredient, the concentration range for variations is ± 0.1-2.5%. Different classification or labelling requirements of the formulation are not permitted within one frame formulation,

[52] http://ecb.jrc.it/documents/Biocides/

regardless of the class of ingredient which causes the change. Therefore the concept of frame formulations is directly linked to the Preparations Directive (1999/45/EC). Notably, the examples given in the TNsG (including e.g. variations in solvents) are beyond the current definition of frame formulations, which allow only an alteration in the percentage of pigments, dyes, and perfumes.

Several guidance documents on the principles of frame formulations have been developed by CAs and are currently discussed in technical meetings:

Table 1: Documents of CAs on frame formulations

Reference	Document	Title
Au-TMIII05	 Appendix (a) Appendix (b) Appendix (c)	*Concept on frame formulations* A statistical framework for the interpolation of the acute toxicity Interpolation of corrosive and irritant effects on skin and eyes Determination of sensitising effects
CA-Dec05-Doc.6.5	Testing of Frame Formulations	Testing of Frame Formulations
UK-TMI06	TMI06TOX-item6-frame-formulation-general.doc	Frame formulations – their purpose under BPD
NL_TMI06	TMI06TOX-item6-frame-formulation-general-NL-com.doc	Proposal for further explanation of the concept "frame formulation"
AT draft distributed to UK and (Sept. 06)	TMII06GEN-item10-frame-formulation.doc	Frame formulations – their purpose under BPD
SE_TM I 07	TMII07GEN-item9-antifoulants-frame-formulation-SE-com.doc	Swedish comments on CEPE's "Frames Position Document"

The Austrian CA drafted a document on testing of frame formulations which was commented on by UK and NL. A consolidated version was distributed to the contributors but, to date, this document has not been accepted at technical meetings.

The interpretation of Article 2.1 (j) of Directive 98/8/EC is crucial. Industry and some CAs interpret the text strictly, in such a way that only pigments, dyes and perfumes can be replaced within a frame. Any expansion to other chemical classes of non-active substances would require an amendment of the Directive. However, one CA assumes that changes resulting in a reduced risk of a formulation within a frame are covered by the definition in the Directive, which states that *"…a variation is the allowance of a reduction in the percentage of the active substance* ***and/or alteration in percentage composition of one or more non-active ingredients*** *and/or the replacement of dyes, perfumes by others compounds presenting the same or a lower risk, but which do not decrease its efficacy"*. According to them, the first subparagraph refers to the subsequent part of the sentence not affecting the level of risk associated with them and their efficacy. On the other hand, the second subparagraph indicates that the risk could be lower.

2.1.2 Results from the stakeholder consultation

The international Association for Soaps, Detergents and Maintenance Products (A.I.S.E.) agrees that the possibility to submit dossiers on frame products is a practical tool that should be used extensively to simplify the procedure for product authorisation. It reduces complexity, the amount of data to be generated (including animal test data) and

assessments whilst also minimising cost and resources for regulators and applicants for product authorisation. The procedure could be optimised by allowing changes in the non-active components whilst respecting the main rule being that the level of classification should always be maintained (or reduced) for equivalent efficacy.[53] When the applicants are not the owners of the frames and of the supporting data packages, but wish to refer to an already authorised frame formulation, they are obliged to make arrangements ("letter of access") with the authorisation holder ('owner') of the original frame product.

The European Council of Paint, Printing Inks and Artists' Colours Industry (CEPE) also sent a position document on frame formulations which essentially supports the A.I.S.E approach.[54] Again it is suggested that the substitution 'rule' should be extended to all non-active substances. Additionally, the concept of setting a theoretical worst case product is supported. As part of a risk assessment, leaching rates should be tested with this worst case product rather than with the 'mother' product with the highest biocide concentration, because the leaching rate depends not only on the concentration of the active substance but also on the formulation (e.g. the resin concentration). Furthermore, CEPE proposed that the hazard classification for the establishment of a frame should be based on the classification calculated by using the conventional method of the preparations directive (1999/45/EC). Alteration of the concentration of a raw material or substitution of a raw material should be acceptable, if the overall classification of the product, compared to the 'mother', is not more severe as a result.

The European Chemical Industry Council, CEFIC claims that the concept of frame formulations should allow the widest possible concentration variations for the active substances and other non-active ingredients, as long as use and product-type are the same, classification of risk[55] is the same or less severe, restrictions of the user-type (e.g. amateur use / professional use only) are the same or more severe, and an equivalent level of efficacy is met. Additionally, the ownership of data and data protection should be an integral part of the concept of frame formulations and public access to information on frames should be limited in the same way as for individual product formulations.[56]

In the statements of CEFIC and A.I.S.E an example is given showing how they would define frame formulations. Here other inert ingredients are considered and usually "0" has been defined as the lowest allowed limit concentrations for non-active substances.

The evaluation of questionnaires from formulators of biocidal products indicates that most respondents consider the concept of frame formulations as beneficial or even as the only solution to reduce the costs of product authorisation and to spread them amongst more parties. However, there was a high degree of uncertainty about the future rules and several formulators were not aware of the concept at all. Generally, the development of specific guidelines was requested. However, several formulators expressed concern about frame formulations, which leave producers of active substances (potential owners of frame formulations) in a strong position, while small and medium size formulator companies will be in a weak position. Some formulators are concerned that suppliers of active substances may refuse to provide access to data for frame formulations based on their active substances, since they have their own frame formulations. In this case, a formulator would not only require a letter of access for data on the active substance but also for the frame formulation.

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53 A.I.S.E. comments on frame formulations, July 11, 2006

54 Frames Position Document CEPE, 10 October 2006

55 It remains unclear whether "classification of risks" refers to the hazard classification according to the Preparations Directive (1999/45/EC) or to a risk based approach.

56 Cefic Position on Frame formulation , 14th June 2006

Additionally, greater flexibility with non-active substances such as detergents, defoamers, solvents, dispersants, corrosion inhibitors, etc is requested.

Several formulators stated that the concept of frame formulations is inappropriate and suggested a similar approach to that for cosmetics or suggested a registration scheme similar to that used in the United States for minor formulation amendments of pesticides (see below). One stakeholder suggested a concept including multiple product registrations (with differing concentrations of an active substance). For example, for a repellent with two different concentrations of an active, e.g. 10 and 20%, the 20% dossier would require chemistry, toxicology and efficacy data and the 10% concentration only data on efficacy and chemistry to some extent. Hence, risk assessments on the 20% product would adequately cover also the 10% product.

The possibility of "bridging" reference data from other registrations or authorisations was also considered as essential for frame formulations. As an example, toxicology data from products with higher concentrations and efficacy data from products with lower concentrations should be accepted.

2.1.3 National provisions on frame formulations within authorisation of biocidal products

Labelling of blue stain inhibiting paints and varnishes in Germany

The voluntary registration and evaluation of blue stain inhibiting paints and varnishes in Germany follows an agreement of the German Paint Industry Association (VdL) and the Deutsche Bauchemie e.V. with the German Environmental Agency, the Federal Institute for Risk Assessment (BfR), and the Federal Institute for Materials Research and Testing (BAM). The use pattern consists of the preventive treatment of wood against blue stain used in outdoor applications, including windows. The procedure follows the VdL-Guideline 05[57]. In principle, 13 different frame formulations have been described, which are distinguished between water-based and solvent-based products as well as by the content of binders, while the content of the active substances is maintained at a fixed concentration. Additionally, the amount of application (ml/m^2) and the kind of application (coating, dipping, spraying in closed systems, flowing) are indicated for each frame formulation. These frame formulations have been evaluated by authorities based on active substance dossiers provided by the producers. The frame formulations usually belong to the manufactures and are granted to formulators through a letter of access (there is no information available about data protection periods but it seems that data protection is unlimited). Additionally, maximum concentrations (between 1 and 3%) of ingredients such as dispersants, surfactants, emulsifiers, defoamers, stabiliser, filming aids, decalcifiers, preservatives (bactericide), solvents, thickening agents etc. have been defined which are generally allowed within the frame, while dyestuffs and pigments are not considered.

Applicants have to provide details of the composition and a technical data sheet for their products and to refer to a specific frame-formulation together with a letter of access. The authorities have to approve the conformity of the products without further testing. If products contain active substances at lower concentration than specified in the frame formulations, their efficacy has to be proven. It should be noted in this context that only a very narrow selection of all wood preservatives are covered by this example.

[57] VdL-Richtlinie Bläueschutzmittel, Verband der deutschen Lackindustrie, Frankfurt a. M., Januar 2002 http://www.zoom-web.com/lackpubli2000/pdf/VDLRL05-102.pdf

Voluntary labelling of wood protection agents not used for construction purposes (RAL GZ 830)

The Quality Assurance Association for wood protection agents in Germany defines voluntary labelling requirements for wood preservatives not used for construction purposes within the German Institute for Quality (RAL). The criteria have been published in the official health publication bulletin.[58] More than 200 wood preservatives have been approved for this label. In some cases, the producers of the active substance are the owners of a reference formulation being evaluated in detail. An applicant referring to a reference formulation declares the full composition of his formulation as placed on the market (which is kept confidential from the public, the competitors and also the RAL) and submits it together with a safety data sheet, product label and technical data sheet, evidence of efficiency, safety data sheets of all ingredients as well as a letter of access for the reference product, to the authorities involved. The authorities evaluate the conformity of the product to the reference product case-by-case. Although no strict criteria on frame formulations exist, the industry association has retrospectively evaluated the range of different non-active substances and their concentrations which have been approved by authorities to conform to a reference product. Here narrow variations of the active substance (< 0.2%) and broader variations of the concentrations of binders (12-30%), solvents (up to 100%) and additives (< 5%) have been attributed to the same reference formulation. The respondent concluded that a workable concept on frame formulations should be manageable for small and medium-sized companies and suggested the following provisions:

- Possibility of the replacement or change in concentration of all non active substances up to an upper limit, provided that the classification and labelling of the formulation is equal to or less stringent than for the reference product.
- This upper limits can be derived for specific functional groups (i.e. binders, solvents, additives, pigments)
- Frame formulations should consider toxicity, ecotoxicity and exposure of humans and the environment.
- The confirmation of efficacy should be clarified separately, if necessary after consultation with the authority.

Labelling of wood protection agents for construction purposes

Wood protection agents used for masonry and timber construction in Germany require an approval by the "Deutsches Institut für Bautechnik" (DIBt), which is an institute of the Federal and Laender Governments. According to an administrative agreement, minor changes of a formulation that do not require a new approval of the wood protection product, have been defined as follows:

- Change of concentrations of inert agents (thickening agents, pigments, emulsifiers, and other additives) up to a maximum of 15% of the absolute value of the reference product.
- Exchange of inert agents by other agents with identical function.
- Change of the producer/supplier of the biocidal active substance. The technical properties of the active substance must be identical.

[58] http://www.holz-schuetzen.de/5_aktuell/files/qicf2236.pdf

UK Control of Pesticides Regulations

The UK has had a regulatory system for a number of biocidal product types (e.g. rodenticides, antifouling paints, wood preservatives, but not disinfectants) for 20 years. Frame formulations are used on a 'case-by-case' basis as a tool to enable regulation of a range of products with the same main ingredients, but small changes in pigment or perfume content. The UK approach was presented in a paper to the biocides technical meeting (TM I 2006).

National authorisations of biocidal products in Sweden

The previous application of the frame formulation concept in Sweden included the replacement of any non-active ingredient and the acceptance of formulations with the same or lower risk. Formulation changes could not involve higher concentrations of active substances. The Swedish position has been provided in comments to the Commission.

2.1.4 Other regulations on frame formulations

Cosmetics Directive (76/768/EEC)

The Cosmetics Directive[59] makes no reference to frame formulations. However, Article 7.3 of the Cosmetics Directive specifies that Member States may require information on substances used in cosmetic products for the purpose of prompt and appropriate medical treatment in the event of difficulties.

The European Association of Poison Centres and Clinical Toxicologists (EAPCCT) and the European Trade Association representing the interests of the cosmetic, toiletry and perfumery industry, COLIPA, have developed a system of frame formulations to be used for the notifications required under Article 7.3 of the Cosmetics Directive. The frame formulations detail the types of ingredients and their maximum concentrations for most cosmetic products introduced on the European market. In 2000, a list of about 110 different frame formulations of cosmetics was published in which mainly the type and maximum levels of ingredients are defined.[60] Similarly, Annex VI of the Cosmetics Directive contains a list of preservatives allowed for use in cosmetics and their permitted maximum authorised concentration, limitations and requirements. However, the provisions of the Cosmetics Directive are not comparable to that of the BPD because, among other factors, no authorisation of products is required and the purpose of frame formulation focuses on information to be provided to the poison centres.

US EPA Pesticide registration notice on minor formulation amendments

The US EPA published a Pesticide Registration Notice 98-10 to producers, producers, formulators and registrants of pesticide products which refers to the subject of "Notifications, Non-Notifications and Minor Formulation Amendments".[61]

The registration note distinguishes between applications for amendments (alternate formulation), minor changes which can be indicated by notification and changes that need not be reported to US EPA.

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[59] http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1976/L/01976L0768-20060809-en.pdf

[60] European Association of Poison Centres and Clinical Toxicologists (EAPCCT) and European Trade Association representing the interests of the cosmetic, toiletry and perfumery industry (Colipa). Cosmetic Frame Formulations. January 2000 http://www.vsi.gov.lv/doc_upl/frame_formulations_jaun.doc

[61] http://www.epa.gov/opppmsd1/PR_Notices/pr98-10.pdf

a) Any change of the concentration of the active ingredient(s) requires a new application.

b) A change of the nominal concentration of any inert ingredient might be indicated by notification, provided that the nominal concentration falls within the certified limits for that ingredient. However, for certain product types, such as antifoulants, changes of inert ingredients are not permitted by notification, because such changes may affect the release rate of these products. Other examples are products used for the control of vertebrate animals (because odour, taste and dye are usually crucial to product effectiveness), including baits used to control insects and other vertebrates.

   Additionally, the Registration Notice describes accelerated reviews of amended registration applications for certain minor formulation amendments such as the addition, deletion or substitution of one or more colorants or fragrances in a formulation provided that the total percentage of changed colorant does not exceed 1% by weight. Similar procedures are defined also for other inert ingredients. Minor formulation amendments do not require confirmatory efficacy data, except for aerosols.

Canadian Regulatory Directive DIR2001-04 on Notification/Non-notification

Regulatory directive DIR2001-04[62] defines certain minor changes to control products registered under the Pest Control Products Act (PCP Act) in Canada. The directive distinguishes between:

a) minor changes that are acceptable when they have been notified to the Pest Management Regulatory Agency (PMRA) by the submission of a notification letter,

b) minor changes where the PMRA does not need to be informed, and

c) changes that require amended registration

A change of the nominal concentration (within certified limits) of a formulant considered as inert by EPA, or the introduction of a new source of an inert formulant, requires an amended registration under the previous Canadian PMRA-process, while under the EPA process only a notification is required.

Manual on the development and use of FAO and WHO specifications for pesticides

One industrial stakeholder suggested the adoption of a similar procedure on frame formulations to that described in the Manual on the development and use of FAO and WHO specifications for pesticides.[63] The FAO/WHO specifications are intended for quality assurance and risk management. With regard to the active ingredient of a pesticide, a tolerance range is defined which takes into account manufacturing, sampling and analytical variations. For example, if the declared content is ≤ 25g/l, the tolerance allowed is ± 15% of the declared content. (The PPPD indicates the same difference between the stated and the actual content of the active substance in a PPP.) Technical concentrates or formulations will be considered to comply with the specification if the average analytical result lies within the tolerance range of the declared content. While it should be noted that the tolerance ranges are not designated as frame formulations but define acceptable deviations from the declared content in analytical surveillance, industry suggested that the

[62] http://www.pmra-arla.gc.ca/english/pdf/dir/dir2001-04-e.pdf

[63] http://www.fao.org/ag/AGP/AGPP/Pesticid/Specs/Pdf/Manual_update%202006.pdf

concept might serve as a model for acceptable range of variance for biocide registration or authorisation.

Recently **CEFIC** has finalised a document on product authorisations under the BPD.[64] This distinguishes between

1. Initial product authorisations (first authorisation of a biocidal product in a MS)
2. Subsequent product authorisations
   - Duplicate authorisation of the same product under a different commercial name.
   - Supplemental authorisation where the authorisation holder allows another company to apply with another trade name.
   - Secondary authorisation by another company which refers to an existing product authorisation via a letter of access.
3. Changing of an authorisation
   - Minor changes of a formulation might be indicated to MS by simple notification, if companies wish to substitute one of the inert materials such as a solvent or have an additional or different site of production.
   - Major changes in composition of a biocidal product are deemed too important to be supported by the initial data set and some additional studies or bridging studies are required.

Additionally, US EPA rules on waving and "bridging" of data have been submitted which have been considered in an analysis of amendments to reduce the data requirements for Annex 1 inclusion (see main report).

2.1.5 Reponses to specific questions

a) Do you support the request on a greater flexibility with non-active substances in frame formulations? If yes, for which ingredients and under which conditions?

Most CAs support a greater flexibility for non-active substances in frame formulations in general. However the following questions/preconditions were mentioned:

- What are the data requirements for non-active ingredients? Should there be a set of core data requirements?
- The identity of the BP should be guaranteed by an unambiguous numbering as a precondition for efficient surveillance of biocidal products. A centralised EU numbering system for frame formulations and specific products is asked for.
- There are limitations on flexibility for ingredients of particular concern for occupational exposure, such as solvents.
- The mutual recognition of BPs should only be valid for real products but not for frame formulations

One CA indicated that there are no scientific reasons why only pigments, dyes and perfumes should be allowed to vary whilst other non-active ingredients should not. In many cases a variation in pigments, dyes or perfumes would require a change in other non-

[64] CEFIC. Industry Proposal for Product Authorisations under the BPD. Cefic – 07-282, June 2007

active ingredients e.g. solvents. A discussion on the range of allowed variation for any type of ingredient (active or non-active) is regarded as necessary. Another CA supports a greater flexibility for all inert co-formulating agents which do not affect efficacy, toxicology and ecotoxicology. In contrast, other CAs do not support greater flexibility on frame formulations because, in their opinion, this could cause more problems during the review of applications and related data.

The lack of guidance is mentioned by most CAs. The existing concepts should be discussed and analysed and an agreement on a guidance document should be obtained before product authorisation starts in 2008. Some CAs state that the practical implementation of the concept cannot be determined from the draft guidance documents. However, another CA finds the discussion on frame formulations to be disproportionate. It is of the opinion that the percentages of all "non-active substances" can be changed under the existing definition on frame formulations (see chapter 2.1.1). The same CA also does not accept the concept of defining and authorising a theoretical worst case product, since the mother frame must represent an actual product (see Article 3.4).

The producers support greater flexibility of frame formulations or another simplified approach to streamline the product registration process. Flexibility on the concentration of all ingredients, except biocide actives and substances of high concern, is requested. It should be possible to substitute or vary the concentration of any of the non-active substances, provided the level of efficacy is maintained and the classification is the same or less severe. Biocidal products should be classified according to the normal rules for classification of preparations.[65] If it is demonstrated that the risks of the frame formulation are acceptable, all products fitting into the frame and having an equal or less severe classifications should be acceptable.

The provisions of the PPPD are considered as more flexible and more pragmatic. A distinction between minor and major changes of a formulation has been introduced and in general lower concentrations of ingredients are always allowed.[66] The bridging of data from other sources is an accepted principle.

Antifouling paints typically contain between 10 and 15 different raw materials in addition to pigments, dyes and perfumes, all of which are used as frequently as pigments and colorants.

A.I.S.E believes that the high end of the frame formulation should represent the worst case for hazard and exposure. It is also noted that the safety of all non-active ingredients will be assessed under REACH (if they are produced/imported in amounts of more than 10 t/y and per actor), which was not in place at the time of the BPD's adoption.

The German Chemical association (VCI) submitted a position paper on amendments to the Directive which has been translated into English.[67] Concerning frame formulations, the position paper proposes the following solutions:

- The frame formulation concept should enable as much flexibility as possible, especially for changes not concerning active substances.

[65] This represents a partial shift of the concept of frame formulation as defined in the BPD from a risk based approach to a hazard-based approach, because classification of preparations e.g. does not consider exposure or user types.

[66] The concept of minor or major changes of pesticides is known from North American countries. There is no information available whether and how this concept is applied within the PPPD.

[67] VERBAND DER CHEMISCHEN INDUSTRIE e.V. Position: Amendment of the EU Biocidal Products Directive - Improvements necessary in biocidal products legislation. 12 January 2007

- Property rights to protected data should become an integral part of the frame formulation concept. The applicant, as the owner of a frame formulation, should be required to present a letter of access when referring to protected data of third parties.
- Public access to established frame formulations should be limited, because - similar to many individual formulations of biocidal products –the composition with regard to non-active substances in particular can constitute confidential business information.
- National authorisation fees – also in connection with frame formulations – should be imposed in a clear and transparent manner, reflecting the real workload in the processing of applications for product authorisation.
- Preferably, a pragmatic concept for frame formulations should be adopted at EU level to ensure a harmonised approach in all Member States. For this purpose, the VCI proposes to amend the Biocidal Products Directive (see 4.1).

The VCI suggests that frame formulations could be used to support an active substance for listing in Annex I or could be taken as a biocidal product or for the first national authorisation.

b) Do you support the worst-case product/use approach covering all biocidal products within one frame with the same or lower classification of risks, user-type restriction (e.g. authorisation for consumer use automatically includes professional users), exposure level to humans and the environment (e.g. authorisation for spray application includes dipping application)

Most CAs in principle support the worst-case product/use approach covering all biocidal products within one frame, with the same or lower classification of risks and user-type restriction. However there are several concerns about the concept:

- Frame formulations could not be applied for products with different application methods, as these may imply different exposure times and concentrations. This could increase the risk of resistance and enhanced chronic exposure to man and the environment. Furthermore, different use instructions (e.g. spray or dipping) would be required.
- Authorisation for consumer uses should not automatically include professional uses, as differences in application and exposure patterns could lead to deviations in the related risk assessment and characterisation. Thus user type restrictions need to be maintained, since the consumer use risk assessment may have been based on short term exposure and acute endpoints, whilst professional use is more likely to be considered as repetitive/chronic exposure and so different toxicological endpoints may be required in the risk assessment.
- A variation of the type of ingredient may affect the risk without altering the hazard classification (e.g. endocrine disruptors) and the change in ingredients may also affect the exposure/risk assessment (e.g. resins increasing solubility of active substances in antifouling paints).
- Frame formulation should be based on a real product and not on a dummy product since the definition refers to “a previously authorised product”
- The definition should preferable refer to “risk” instead of “classification”. This also relates to the user-type restrictions: Usually but not always an amateur is at higher

risk than a professional user. An example would be amateurs carrying out an activity once a year but a professional doing so many times during the year.

Another CA is unsure how a worst-case formulation could really be established without obtaining data on other formulations that are intended to be part of the frame. The worst case approach appears to be an approach where chemistry and toxicology (for man and the environment) would be required on the 'worst-case' product(s) and chemistry and efficacy on the 'best-case' product, assuming both products have the same or lower classification. Products within this range/frame could then be authorised by the use of read-across/bridging justifications with minimal further data required.

A formulator does not consider that the worst case approach works and does not agree with the concept that risk assessment for consumer use necessarily covers professional use, because it is very likely that the product labels will be different. A.I.S.E supports the worst case approach provided that read across is permitted for all biocidal products falling under the frame.

c) Do you see the need for a guidance document on frame formulations? If yes, which of the documents listed above (or their combination) would you suggest to be a proper basis?

According to CAs, the development of guidance documents has been delayed and no agreement on a combined document has been achieved to date. Other CAs agree that there would be the need for a guidance document, but all draft guidelines available so far consider only the possibilities that the Directive already allows and none stands out as a particularly good basis for guidance. Some CAs did not participate in the discussion on guidance documents, but favour an amendment of the Directive instead. A guidance document on frame formulations would be essential and some CAs suggest that elements from the US EPA guidance could be considered. One CA suggested the following work steps:

a) define what a frame formulation is, and to what extent simplified testing strategies and read-across/bridging justifications are included;
b) address what types of ingredients can be varied, and by how much, based on the testing of a single representative product;
c) establish when simplified testing strategies can be used to set up a frame formulation, clarify how to determine which formulation to test and how to read-across/bridge to other products;
d) outline what the applicant needs to do, in terms of process and data requirements, to establish a frame formulation and to seek authorisation of a product within a frame formulation;
e) clarify what the CA would need to do, in terms of procedures to assess and establish a frame formulation and to grant authorisation to a product/products within a frame formulation.

One CA suggests using the proposal NL_TMI06 as a starting point for discussion. Another CA recommends a practical approach by agreeing on which elements can be replaced and whether the risk can be lower or only the same, instead of drafting a long guidance document.

Also, producers request a clear definition and a process description on frame formulations. Some do not consider existing drafts as user-friendly, in particular for SMEs which have

little experience in applying the complicated rules on hazard evaluations described. After inclusion of active substances into Annex I, the authorisation of BPs will start and binding rules on frames should be ready. One suggestion is that the Commission centralize the management of procedures under the BPD, as it is envisaged under REACH. Industry supports the approaches of CEPE, A.I.S.E and CEFIC, which are considered as essentially covering the same principles. Additionally, it is indicated that PT-specific guidance should be developed and other concepts such as minor changes of a formulation indicated by simple notification should be considered. For example the MS should set lower fees for simplified ("accelerated") reviews of "similar authorisation cases" in line with re-authorisation cases.

d) Do you expect that formulators might not be able to apply for their own frame formulations because the supplier of active substances might combine their letter of access for the active substance with another letter of access for a frame formulation owned by the producer/supplier? If yes, please describe your worries.

The general view of CAs is that, although it cannot be excluded that producers might use frame formulations for controlling their distribution chain, this is not seen as a major problem. Formulators can submit their own product data to obtain a product authorisation or establish a frame formulation and it seems unlikely that a producer would risk potentially losing customers by not submitting or granting access to data. However, the generation of overlapping frame formulations which are confidential to different owners, and based on data protected for different time periods, will create a complexity that needs to be considered if the EU establishes a central system for handling product authorisation and frame formulation information. Legal or contractual issues should be considered if producers or suppliers try to restrict the market access of formulators.

Some respondents do not accept that producer / suppliers could grant formulators access to their data only if they use an established frame formulation. This might be a reaction to concern over data protection on the active substances.

A central agency could combine several requests for authorization of frame formulations and approve these all in one go to all applicants.

Other formulators see no problem in this context. For producers it would not be wise to limit data access as, typically, formulators have specialised skills in formulating and producing innovative products and have access to other distribution channels.

One industry participant was worried that Member States could establish frame formulations based on the work of individual companies or industry associations. A.I.S.E considers that it is important to prevent the obligatory application of a frame formulation for other formulators. Otherwise, there is a risk that the supplier of the active substance will apply for a wide frame formulation and then limit access to this frame formulation in such a way that all formulators of comparable products would be dependant upon a letter of access to this frame formulation.

e) What are your suggestions on data protection and confidentiality with regard to frame formulations?

Most CAs suggest to apply normal rules and procedures and always to check the need for a letter of access and article 19 rules on confidentiality/non-confidentiality. Another CA believes that there is still some confusion over the difference between ‘data protection’ and ‘confidentiality’. Data on frame formulations should be treated as confidential in the same

way as for any other product. The CA is doubtful whether a frame formulation should receive data protection. It has also been argued that it is difficult for CAs to ignore their knowledge and experience from other dossiers in their decisions in favour or against a biocidal product.

Producers propose that the data protection period of frames should be the same as data protection granted for biocidal products (10 years). All data submitted by industry and marked in the dossier as confidential should be kept as strictly confidential. Obviously, such details should not be accessible to the general public. The frame formulation itself, which would probably be a list of ranges of the different ingredients in the product, should only be accessible to the authorities. There are some concerns amongst industry that confidential data will be made available to competitors, together with study reports for which the data protection period has expired. Producers are worried that formulators might submit a letter of access for data on an active substance, but change the supplier after product authorisation. It seems that some CAs indicated they do not require a new letter of access if the supplier changes. While Article 14 of the BPD on new information requires that changes in the source of the active substance shall immediately be notified to the competent authority, this is not connected automatically with the need for a new letter of access.

Article 12 of the BPD regulates the use of data held by competent authorities. This does not exclude the possibility that MS might apply national rules on data protection for BPs previously authorised under national regimes. As a consequence, all studies submitted previously in at least one MS would lose data protection post 2010. However, this issue has already been addressed in a general note on data protection and an amendment of Article 12(1) has been proposed.[68]

A.I.S.E notes that, if the applicants are not the owners of the frames but wish to refer to an already authorised frame formulation, they are obliged to make arrangements ("letter of access") with the authorisation holder of the original frame product.

One industrial participant indicated that the US EPA's re-registration program uses a "batching" system for product data. In this system the EPA inspects existing product formulations and determines which can be grouped for purposes of data generation.

2.2 Low-risk substances (inclusion in Annex 1A)

2.2.1 Provisions of the BPD

The BPD defines low-risk biocidal products as those which contain only active substance(s) listed in Annex I A and which do not contain any substance(s) of concern.

Under the conditions of use, low-risk biocidal products shall pose only a low risk to humans, animals and the environment (Article 2 (1b). Low-risk biocidal products are registered and not authorised and data requirements for dossiers are significantly reduced (applicant, identity, intended uses, efficacy data, analytical methods, classification, packaging and labelling and safety data sheet). However, the advertising of a biocidal product may not mention terms such as 'low-risk biocidal product' Article 22 (2)).

An active substance cannot be included in Annex IA if it is classified according to Directive 67/548/EEC as carcinogenic, mutagenic, toxic for reproduction, sensitising, or as

[68] European Commission. General Note on Data Protection in the framework of Directive 98/8/EC 04.07.2005 http://ec.europa.eu/environment/biocides/pdf/guidance_data_protection_rev.pdf

bioaccumulative and not readily degradable. Where appropriate, the entry of an active substance in Annex IA shall refer to the concentration ranges in which a particular substance can be used (Article 10 (1)). In the TNsG on Annex I inclusion, several criteria for the inclusion of active substances in Annex IA are defined.[69]

The TNsG on Product Evaluation specify data requirements for low-risk products. Here it is stated that risk is related to both hazard and exposure. "Low risk" is not the same as "low hazard". For example, a low-risk product can be hazardous provided that it only gives rise to insignificant exposure. However, the dossiers for inclusion of an active substance into Annex IA are the same as those for Annex I, because the active substance has to be fully evaluated in order to demonstrate that it indeed meets the criteria for inclusion into Annex IA.

2.2.2 Results from the stakeholder consultation

According to the responses of producers, the concept of low-risk substances does not work: few substances are expected to qualify, criteria are not clear and only the assessment shows whether the concept applies (and thus the full dossier is submitted only to find out that it is not needed).

The responses to the questionnaires from formulators also indicate that industry does not see real advantages in the concept of low risk products as set out in the BPD. It is noted that the definition refers to biocidal products, but the assessment is based on active substances, not considering the exposure to the biocidal product. Although many formulators indicate that product development is always driven by “low-risks”, some assume that only non-effective active substances will be “low risk” compounds.

The possibility to develop low-risk products will be determined (and limited) by the active substances included in Annex IA and cannot be predicted. However, as many allegedly low-risk actives such as essential oils, pheromones and other insect attractants have been withdrawn from the review programme, the options for developing low-risk products have been reduced. Therefore, some formulators are focusing more on waiving of data requirements for active substances they consider low-risk than on simplified procedures for biocidal product registration.

As no precise criteria for “low risk” products exist, all data for the active substances have to be submitted. Reduced product data sets and lower fees for products using actives from Annex 1A would serve to stimulate investment in lower risk products.

Additionally it has been noted that Article 20 of the BPD on labelling precludes label claims which identify products as “low risk”. According to one formulator, permitting claims highlighting the relative safety profiles of “low risk” products would be a positive driver for more investment and innovation in this area.

Most Competent Authorities do not expect difficulties with low-risk product registration and see the major hurdle as the inclusion of active substances in Annex IA. Some CAs agree that applicants still have to supply large amounts of data, simply to show that a particular substance is ‘low risk’, and that this seems to negate any advantages of being

[69] TNsG on Annex I inclusion - Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB. Final draft April 2002 http://ecb.jrc.it/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_ANNEX_I_INCLUSION/Web_April_2002.doc

considered a 'low risk' product.[70] Moreover, several CAs are considering promoting low-risk products with reduced registration fees.

Because many potential low-risk active substances have been withdrawn from the review programme, some CAs suggested avoiding unnecessary testing through acceptance of most of the studies derived from literature.

Up to now only one active substance, carbon dioxide, will be included in Annex IA for PT 14 (rodenticides) and can thus be used in low risk products. The assessment report refers to a specific ready-to-use application in mousetraps. Waving of data requirements has been accepted because negligible exposure to water is expected and natural carbon dioxide concentration in ambient air will not be elevated under normal conditions. Most data have been derived from the literature and no data ownership is claimed for most studies, with the exception of efficacy tests with the mouse trap prototype and a validation of the analytical method for the detection of carbon dioxide. However, carbon dioxide seems to be a specific case and cannot be directly compared with other active substances. Carbon dioxide could also have been a candidate for commodity substances. Therefore, an analysis of the evaluation of other active substances for which an inclusion into Annex IA has been or will be requested would be useful.

2.2.3 Questions to be answered

a) Producers: Do you intend to apply / have you applied for inclusion of an active substance into Annex 1A?

Most producers do not intend to apply for Annex IA inclusion because they consider all active substances to be classified as dangerous. Customers might think that actives listed on Annex IA are less efficient than those on Annex I. One formulator considers the concept as misleading, because it refers to products but the definition is based on hazards of ingredients not taking exposure into consideration. Furthermore, all authorised or registered biocidal products will have been assessed and concluded to not pose unacceptable risks to humans and the environment.

b) Competent authorities: Did you receive any requests for the inclusion of existing or new active substances into Annex IA?

Most CAs have not yet received applications for Annex IA, and they do not consider Annex IA inclusion as a very important issue. Although data requirements for active substances are seen as ambitious, they are regarded as necessary to judge that the substance indeed qualifies for low risk products. The time frame for the registration of low risk products does not allow a more thorough evaluation. Potential candidates for Annex 1A might be natural substances (e.g. pheromones and essential oils) and essential elements (e.g. vitamins and metals). Also, some competent authorities find it confusing that low risk could also result from low exposures and that the requirements for low risk substances only relate to low degrees of hazard.

c) Would you accept specific labelling claims for "low risk" products?

Most CAs do not agree with specific labelling claims for 'low risk' biocidal products. The term is considered non-specific (low risk to who or what?) and comparative (low risk compared to what?) and it might mean that users are less aware of the risks. Article 20(3)

[70] However, registration of low-risk products is far less expensive than product authorisation. Thus the advantage is not at the stage of inclusion of actives into Annex IA but at the stage of product approval.

specifies that labelling must not mention 'low-risk biocidal product'. One CA reported bad experiences in the past when biocides have been claimed to have lower risk. However, two CAs support specific labelling, if Member States agree on a common approach and wording. Products that have lower risks could also be promoted by including them in a positive list.

Producers also do not consider specific labelling claims as reasonable. One formulator argues that with the existing labelling system, REACH and GHS it will not be possible to develop a low risk product, whether it contains an active ingredient or not. Solvent based impregnations have e.g. to be marked with Xn, R65, so it can never be a low risk product. A.I.S.E indicates that when granted an authorisation, products would all have been assessed and their risks deemed to be acceptable.

d) Would you suggest that data requirements for active substances intended to be included into Annex IA inclusion should be modified? What prerequisites or conditions should be defined to identify potential Annex IA active substances?

Most CAs did not support reducing data requirements for active substances intended for Annex IA inclusion because the evaluation of active substances will be the only decision basis for the approval of low risk products. Only after the evaluation process can it be determined whether an active substance qualifies for low risk products or not. One CA suggests that the waiving possibilities should be highlighted more for such substances. However, data submission should ensure that an appropriate evaluation can be carried out. Endpoints critical to show that the active substance has no hazards should be supported by robust data, but other endpoints could be waived or submitted based on literature data or extrapolations. Another CA sees no specific need for waiving of data. In contrast, it asks that waiving should be applied carefully, because the registration of low risk products does not include any evaluation except of efficacy. Active substance may be perceived as being low risk, but that does not prevent the CAs or the Commission from taking regulatory decisions based on the same scientific basis as decisions taken for other active substances.

However, a case study participant responsible for market surveillance of biocides proposed exemptions for low-risk or no-risk biocidal products He proposes including agreed low-risk active substances into a new annex without any further testing requirements, because often they are produced in small quantities and will not be cost-effective if they have to be authorised or registered. Therefore, he fears that many of them will be substituted by other biocidal products, irrespective of possible hazardous properties. A combination of the low risk concept with that for basic substances has also been proposed.

3 Proposals for amendments on simplified procedures

3.1 Frame formulations

The formulator, also representing the European Council of Paint, Printing Inks and Artists' Colours Industry (CEPE) suggested replacing of article 2(j) by

> "*…a variation is the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more non-active substances by others presenting the same or a lower risk, and which do not decrease its efficacy.*"

The German Chemical association (VCI) submitted a position paper on amendments to the Directive which has been translated into English. Concerning frame formulations the VCI proposes to amend Article 2 (j) of the Directive on frame-formulation as follows:

> *"Specifications for a group of biocidal products having the same use and user type. This group of products must contain the same active substances of the same specifications, and their compositions must present only variations ~~from a previously authorised biocidal product~~ which do not affect the level of risk associated with them and their efficacy. In this context, a variation is an omission of an active substance, the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more ~~pigments, dyes and perfumes~~ non-active substances by others presenting the same or a lower risk, and which do not decrease its efficacy as stated in the product claim."*

In this context the VCI, also proposes the inclusion of a definition of "minor changes" and "major changes". In addition to frame formulations, an application should be made for a change in composition. Reasons behind minor or major changes can be that e.g. labelling of a non-active substance ("coformulant") has become more stringent, that a new coformulant offers technical advantages or is less costly to purchase. Neither the Biocidal Products Directive nor the Review Regulations include the possibility of a procedure for minor or major changes.[71]

The European Council of Paint, Printing Inks and Artists' Colours Industry (CEPE) also submitted a position paper on how to amend the definition of frame formulations following discussions held in TM meeting 07:

> *"Specifications for a group of biocidal products having the same use and user type. This group of products must contain the same active substances of the same specifications, and their compositions must present only variations from a previously authorised biocidal product which do not **increase** the level of risk associated with them **or affect** their efficacy. In this context, a variation is the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more **non-active substances** by others presenting the same or a lower risk, and which do not decrease its efficacy **as stated in the product claim.**"*

According to CEPE, by allowing the substitution of any non-active substances, products containing different non-active substances within a colour range (including, but not exclusive to, plasticisers, thixotropes or fillers) can continue to be registered as one product. Without the proposed amendment to the Directive, such products would have to be split into two or more frames multiplying registration costs for industry, increasing the administrative work load of the competent authorities and, potentially, leading to increased animal testing; all of which the frames concept was conceived to minimise.[72]

3.2 Low-risk substances

Other than the general comment that low-risk active substances should require a reduced data package, for instance by waiving core data if scientifically justified, no specific

[71] Although Article 14 of the BPD in principle allows changes in the source or composition of the active substance or changes in composition of a biocidal product while Article 7 allows modifications and extensions of uses of authorisations.

[72] CEPE Proposed Amendment to 98/8/EC regarding Frames. Brussels, June 2007

proposals for amendments to the Directive have been submitted To promote low-risk biocides, it has been suggested to generate relevant data in research projects. The extension of eco-labelling to low-risk biocide products could enhance advertising. However this issue seems not to be a priority.

4 Summary and conclusions

The whole issue of frame formulation and other simplified procedures is considered as very complex and some CAs indicate that the initial attempts by the Commission and MS to try and put together a 'harmonised' view have to date not been very successful. The responses of the participants to the questions in the background document are very detailed and a full technical/procedural discussion is not possible within the context of this case study, given the timescale.

4.1 Frame Formulations

According to the participants' contributions to the case study on simplified procedures, the following conclusions can be drawn:

- A higher degree of flexibility in variations of the concentrations of non-active substances in frame formulations is broadly accepted by CAs and urgently required by industry, acknowledging that variations must not results in higher risks or affect the efficacy. There is no clear legal interpretation of whether or not this is possible with the current definition.
- There is uncertainty among CAs about data requirements for non-active ingredients in frame formulations.
- CAs and industry ask for a European register of biocidal products, potentially also including frame formulations, to facilitate mutual recognition and market surveillance. The identity of a specific biocidal product should be non-ambiguous, e.g. by assigning numbers for each product in a frame. The existence of a frame could be made publicly available via the register.
- Some participants suggest establishing a frame for varying concentrations of active substances (minor/major changes of a formulation).
- Most CAs require that mutual recognition is not applied to frame formulations. Industry prefers that frame formulations do not necessarily refer to a previously authorised product.
- The worst case product/use approach is partly supported by CAs and broadly supported by industry. The user type restrictions should be maintained because of differing exposure and risks. Some CAs require the worst case approach to refer to an actual product.
- Guidance on the frame formulation concept is urgently requested. Up to now no substantial progress has been achieved. This might be due to uncertainty in the legal interpretation of the definition and/or because some CAs refused to participate in discussions because they first require an amendment of the Directive concerning greater flexibility on non-active substances.
- The draft documents are mostly regarded as not practicable or too complicated to serve as basis for a guidance document. The standard rules for classification and labelling should be applied.

- It was regarded as possible and unwelcome, but not very likely, that producers would use frame formulations to control their markets.
- There is agreement that data on frame formulations should be treated as confidential. This may be problematic if multiple dossiers are submitted. A letter of access should always be requested.
- Other proposals simplifying product authorisation relate to lower fees for simplified ("accelerated") reviews of "similar authorisation cases" and minor changes in composition
- An electronic consultation group could be set to discuss problems related to frame formulations and similar issues

To make progress with the guidance development, a small working group of CAs and industry representatives could be set up to agree on definitions and terminology, principles of approach, data requirements and data protection. All results should be summarised in guidance document, which should be presented to all MS for approval. A similar group could also be established to look at other simplified procedures.

4.2 Low risk substances

Simplified procedures for low risk products, containing active substances included in Annex IA of the Directive, seem not to be of particular interest to CAs and industry. Although several CA have received applications to include active substances in Annex IA, industry usually considers these actives as less efficient in biocidal products.

Some CAs and industry consider specific labelling claims for “low risk” products as acceptable, but most do not agree to such an amendment.