

CA-March07-Doc.9.2.1 –final - revised after 25<sup>th</sup> CA meeting

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EUROPEAN COMMISSION

DIRECTORATE-GENERAL

ENVIRONMENT

Directorate B - Protecting the Natural Environment

ENV.B.3 - Biotechnology, Pesticides and Health

**HARMONISED TIMELINES AND PROCEDURES TO BE FOLLOWED BY  
MEMBER STATES, THE COMMISSION AND INDUSTRY FOLLOWING  
INCLUSION OF AN EXISTING ACTIVE SUBSTANCE INTO ANNEX I OR IA**

**Introduction**

At the 18<sup>th</sup> CA-Meeting, industry requested clarification of the timescales for action following decisions on Annex I or IA inclusion. Industry also submitted a proposal on possible procedures and timescales, which was distributed for the meeting (Reference CEFIC 05-240).

At the 19<sup>th</sup> CA-Meeting, the Commission presented a document (Reference *CA-Jul05-Doc.6.1*) setting out a framework of the legal provisions as contained in Directive 98/8/EC. In particular, Article 16(3) only requires the Member States to ensure that, following the decision by the Commission to include or not to include an active substance into Annex I or IA, authorisations or, where relevant, registrations for biocidal products containing the active substances and complying with the provisions of the Directive are granted, modified or cancelled as appropriate.

The article does not give the Commission the power to adopt legal measures that would oblige the Member States to require submission of dossiers for product authorisation or to withdraw products for which no dossiers have been submitted by a given date. Any such actions must come from the Member States themselves.

The Commission can only set out an overall timeframe by which all products have to be authorised in accordance with the Directive.

During the discussions at the 19<sup>th</sup> and 20<sup>th</sup> CA meetings, Member States agreed that they should all act in a harmonised way to set deadlines by which:

- i. applications for authorisation should be received,
- ii. unauthorised products be removed from the market,
- iii. authorisations be granted.

This document sets out guidelines in order to promote harmonised actions by the Member States following a decision on inclusion of an active substance into Annex I or IA.

It is important to note that further to the adoption of these guidelines, Member States might have to adapt their national legislation or administrative acts to be able to take the actions and respect the timelines suggested in these guidelines.<sup>1</sup>

For more concrete information and possible derivations in the different Member States please refer to the annexes of this document.

## **1. Procedures to facilitate harmonised actions by Member States following the decision not to include an active substance into Annex I or IA**

When a decision is made not to include an active substance in Annex I or IA for a given product-type, products of that type and containing that active substance<sup>2</sup> will have to be phased out of the EU market within 12 months after the publishing of the decision in the Official Journal of the European Union, unless otherwise decided in the specific non-inclusion decision.<sup>3</sup>

## **2. Procedures to facilitate harmonised actions by Member States following adoption of a decision to include an active substance into Annex I or IA**

### 2.1. Existing biocidal products

'Existing biocidal products' refers in the context of this note for guidance to those products which will have already been placed on the market of the relevant Member State (as opposed to the EU market as a whole) at the date of inclusion of the substance into Annex I or IA<sup>4</sup>. The concept of "existing biocidal product" is therefore seen at Member State level.

#### 2.1.1 Submission of application

Member States should stipulate that companies wishing to continue to place an existing biocidal product on the market will have to submit, by the date of inclusion of the active substance in Annex I or IA<sup>5</sup>, for the biocidal product containing the relevant active substance:

- an **application for authorisation** complying with the requirements of Article 8 of the Directive;
- an **application for mutual recognition**<sup>6</sup> in accordance with Article 4 of the Directive;

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<sup>1</sup> The actions and timelines set in this document shall apply *mutatis mutandis* to registration of low-risk biocidal products, except that the time for registering a product already registered in another Member State shall be 60 days.

<sup>2</sup> This covers both products containing only that active, and products containing that active substance and other active substances.

<sup>3</sup> In accordance with Article 4 of Regulation (EC) No 1451/2007.

<sup>4</sup> Products where only the source of the active substance changes by switching to a supplier who has a complete dossier for the active substance should be considered as existing biocidal products.

<sup>5</sup> Except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances. For the first inclusions of active substances, Member states may have taken different approaches, as indicated in annex I of the present document.

<sup>6</sup> The submission should include all required data and information other than those parts that can only be submitted following the authorisation/registration of the product in the first Member State (for instance, copy of the first authorisation...). These remaining items must be submitted within 2 months

- or a letter of intention that an application for mutual recognition will be submitted within 60 days of obtaining a first authorisation in another Member State<sup>7</sup>.

Applications for mutual recognition would not be rejected if the Member State was to receive within the relevant deadline<sup>8</sup> in a first step the following information<sup>9</sup>:

- A covering letter confirming that an application is made for mutual recognition of authorisation for the product.
- A filled in paper copy of the application form generated via the Register for Biocidal Products (R4BP)
- One electronic copy of the summary dossier for the product as submitted to the first member state.

The rest of the information would be submitted in a second step, once the first authorisation would have been granted.

Those products, for which an application for either authorisation or mutual recognition has been made in due time, can then remain on the market in accordance with existing provisions in the Member States, while the applications are evaluated.

Member States should stipulate that, within 6 months of this deadline to apply for authorisation or mutual recognition, all products, for which no application will have been submitted, will be removed from their market.<sup>10</sup>

#### 2.1.2 Completeness check of the dossiers:

Member States should stipulate that, within 3 months of having received the application, they will verify that the submitted dossiers are complete and that the active substance corresponds to the one included into Annex I or IA.

#### 2.1.3 Evaluation of the dossiers:

Member States should stipulate that, once a dossier has been considered to be complete, they then have 12 months to complete the evaluation and decide whether to authorise the biocidal product or not. This will be done in accordance with the common principles as established in Annex VI to the Directive. The date of the product authorisation will be made available to the other Member States and the Commission via the Register for Biocidal Products (R4BP).

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of the decision being taken on the application for a first authorisation/registration of the product in a first Member State (or “Reference Member State”).

<sup>7</sup> See SK.

<sup>8</sup> See table in annex.

<sup>9</sup> Following Member States have confirmed that they would accept such an approach: CH, DE, DK, EE, EL, FI, FR, IE, NL, NO, PL, PT, SI, UK.

<sup>10</sup> The 6-month deadline for the phasing out of products not supported should refer at least to the first placing on the market. For subsequent storage and stocks, Member State may grant a period of grace in accordance with the provisions of Article 7(3) of the Directive.

#### 2.1.4 Negative conclusions

In the case, where, for a product for an application for mutual recognition was made, a Reference Member State comes to the conclusion that a dossier submitted is not complete or, after evaluation, that an authorisation cannot be granted, it shall immediately and before taking a final decision consult the Concerned Member States.

The purpose of such a consultation would be to ensure that all Concerned Member States can support the negative conclusions of the Reference Member State and that they can take the necessary steps to withdraw products from the market within the same timeframe.

It shall be noted that this is only a consultation, without prejudice of the decision to be eventually taken by the Reference Member State.

In the event that the Reference Member State decides to refuse to grant an authorisation, companies which had submitted an application for mutual recognition will then be in the impossibility to transmit the copy of the authorisation within 2 months of the decision on their application being taken. Consequently, in the absence of the different elements requested in Article 4(1) of the Directive, the applications for mutual recognition should be declared incomplete, rejected and the products for, which the applications were made, removed from the market.

#### 2.1.5 Phasing-out

Member States should stipulate that, when a decision is made that a dossier is not complete or that an authorisation can not be granted, the product shall be removed from their market within 6 months of the decision being made.<sup>11</sup>

#### 2.1.6 Mutual recognition:

Within two months of having obtained a first authorisation in the Reference Member State, companies shall submit a certified copy of the first authorisation granted in the Concerned Member States in accordance with Article 4 of Directive 98/8/EC. Concerned Member States shall evaluate and decide on the mutual recognition of the first authorisation within 120 days from the date of receipt of the certified copy.

Companies should be advised to submit the certified copies of the first authorisation at the same time so that the applications for mutual recognition can be processed in parallel in the Concerned Member States and that arising issues can be discussed within the same 120-day period.

Member States should stipulate that, if within the 2 months following the granting of a first authorisation, the certified copy of this authorisation has not been submitted to them, for a product for which an application for mutual recognition was made, the product concerned will be removed from their market within the next 6 months<sup>12</sup>.

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<sup>11</sup> See footnote 10.

<sup>12</sup> See footnote 10.

## 2.2. New biocidal products

'New biocidal products' refer in the context of this note for guidance to those products which will not have already been placed on the market of the relevant Member State at the date of inclusion of the active substance into Annex I or IA for the relevant product type.

For products with more than one active substance, 'New biocidal products' refer to those products which will not have already been placed on the market of the relevant Member State at the date of inclusion of its last active substance into Annex I or IA for the product type.

Dossiers for new products can be submitted at any time. Placing on the market of a Member State can start after successful evaluation of the dossier by the Member State. Once the first authorisation is obtained, companies can ask for mutual recognition in all other Member States where they wish to place the product on the market.

### **3. Additional measures to facilitate harmonised actions by Member States following inclusion of an active substance into Annex I or IA**

- Companies will have to generate their application forms through the Register for Biocidal Products (R4BP) – administered by the Commission and accessible via internet, or when relevant, via systems developed by Member States.
- All products, for which an application will have been made, will be listed in the R4BP and the main milestones of the authorisation and mutual recognition procedures made available through the R4BP.
- In order to facilitate the evaluation, it would be preferable for companies to request the first product authorisation in (one of) the Member State(s) who was Rapporteur for the active substance(s) concerned, if the companies already place or intend to place their products on the market in these Member States<sup>13</sup>. The assessment will be made in the light of conditions existing in the Member State (for instance, local conditions may be important for some product types, such as PT08, PT21 etc...).
- Assessment reports and summary dossiers of authorised products, which will be subject to mutual recognition, should be made available in English and posted on restricted CIRCA.
- These timelines and procedures are without prejudice of any quicker actions that the Member States or the Commission may decide to take in individual cases in order to protect the environment, animal or human health.

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<sup>13</sup> It shall be noted that this is an advice to companies, which are however free to choose the Member States where they want to apply to obtain a first authorisation on the basis of which they can then apply for mutual recognition in other Member States.

## ANNEX I

### Post-Annex I procedure

#### Deadline for the submission of applications for product authorisation or for mutual recognition<sup>14</sup>

2 years after date of adoption of decision <small>(e.g. 20.12.2008 for sulfuryl fluorid)</small>	2 years after date of publication of decision <small>(e.g. 30.12.2008 for sulfuryl fluorid)</small>	2 years after date of coming into force of decision <small>(e.g. 19.1.2009 for sulfuryl fluorid)</small>	Date of inclusion <small>(e.g. 1.1.2009 for sulfuryl fluorid)</small>	other
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AT			X	
BE			X	
BU				
CH			X	
CY			X	
CZ				See below
DE	X			
DK			X	
EE			X <sup>15</sup>	
EL			X	
ES			X	
FI		X <sup>16</sup>		
FR			X	
HU		X <sup>17</sup>		
IE		X		
IS				
IT				See below
LT				
LU			X	See below
LV				See below
MT			X	
NO			X	
NL			X	
PL		X		
PT			X	
RO				
SE				See below
SI			X	
SK			X	
UK				See below

<sup>14</sup> In grey, Competent Authorities which have not yet responded.

<sup>15</sup> The proposed deadline for submitting an application for mutual recognition is the date of inclusion. The modification of the national regulation is however still under process.

<sup>16</sup> FI is going to change the deadline for the submission of applications for product authorisation or for mutual recognition into "date of inclusion" as soon as possible.

<sup>17</sup> The modification of the national regulation is however under process, the proposed deadline for submitting an application for product authorisation or for mutual recognition is the date of inclusion.

## ANNEX II

### Post-Annex I procedure

**Further details on what information is expected and when, as well as explanations on specific national provisions are provided hereafter.**

#### **AT:**

In Österreich wurden mit der BiozidG-Altwirkstoffverordnung, BGBl II Nr. 353/2008 jene Rechtsvorschriften erlassen, die

1. die Verfahren der Antragstellung auf Zulassung/Registrierung von Biozid-Produkten/Biozid-Produkten mit niedrigem Risikopotential mit einem bereits in Anhang I/IA aufgenommenen Wirkstoff, der vorher ein alter Wirkstoff war und in Anhang II der EU-Verordnung Nr. 1451/2007 aufgelistet ist, und
2. die Verfahren der Antragstellung auf gegenseitige Anerkennung der Zulassung/Registrierung dieser Biozid-Produkte/Biozid-Produkte mit niedrigem Risikopotential in Österreich im Detail regeln.

Auf den gegenständlichen Fall kommen für das Antragstellung auf gegenseitige Anerkennung Ihres Biozid-Produktes folgende Bestimmungen dieser BiozidG-Altwirkstoffverordnung zur Anwendung: § 2 Abs.1 Z 2, Abs.2 und Abs.3.

Damit wird hinsichtlich des Zeitpunktes der Einbringung Ihres Antrages, des Datenumfanges und der Abfolge der Einbringungen Folgendes festgelegt:

- Einbringung der schriftlichen Mitteilung, dass Ihre Firma bis spätestens 4 Monate vor dem 31.12.2010 einen Antrag gemäß § 13 des BiozidG (= österr. Biozid-Produkte-Gesetz, BGBl. I Nr. 105, 2000; als Kopie beige geschlossen) stellen wird, bei der österreichischen Behörde bis spätestens 1.1.2009; diese Mitteilung ist unbedingt erforderlich, damit Ihr Produkt vorläufig bis zur Einbringung des vollständigen Antrages gemäß § 13 des BiozidG in Österreich weiterhin in Verkehr gebracht werden darf
- dieser schriftlichen Mitteilung sind anzuschließen:
  - (a) Angaben gemäß § 13 Abs.1 Z 1 und Z 4 BiozidG sowie gemäß Anhang IIB Abschnitte I und X der Biozid-Produkte-Richtlinie (= dieser erforderliche Datenumfang sollte von dem auf der letzten PA&MRFG-Sitzung besprochenen "Summary Dossier" des Wirkstoffes - übermittelt auf einer CD-ROM - ausreichendst umfaßt sein)
  - (b) Nachweis, dass Ihr Biozid-Produkt in Österreich bereits vor dem 1.1.2009 in Verkehr gebracht worden ist (= zu erbringen z.B. durch Lieferschein/Rechnung betreffend die Lieferung/Verkauf dieses Biozid-Produktes an einen österreichischen Abnehmer vor dem 1.1.2009)
- es gibt keine Formvorschrift für die schriftliche Mitteilung, eine firmenmäßige Zeichnung ist aber erforderlich (= kann eine Abschrift der R4BP-Eingabe mit firmenmäßiger Zeichnung sein; die Absichtserklärung, dass Ihre Firma bis spätestens 4 Monate vor dem 31.12.2010 einen Antrag gemäß § 13 des BiozidG in Österreich stellen wird, ist anzufügen)
- nach erfolgter (Erst-) Zulassung in 1. EU-Mitgliedstaat muss bis spätestens 4 Monate vor dem 31.12.2010 ein vollständiger Antrag gemäß § 13 des BiozidG bei der österr. Behörde eingebracht werden
- erst mit der Eingabe dieses vollständigen Antrages gemäß § 13 des BiozidG sind auch die Gebühren für das Verfahren der gegenseitigen Anerkennung der Zulassung

gleichzeitig zu entrichten; sie betragen derzeit: € 3.910,- bis € 6.910,- (als Kopie beigeschlossen).

**BE:**

### ***I. General Remarks***

The applicant is required to have a permanent office in the European Community (cfr art 4 royal decree 22/5/2003).

When the applicant has this permanent office in Belgium and he is a legal person he has to make use of the Dutch, French or German language depending on the location of his permanent office, at least for the A form and for the R4BP:

- applicant established in Flemish region : Dutch language required (by default of the Dutch version of the official R4BP, the Dutch version of form B1, part 1 has to be used (Ministerial decree of 3 september 2008, published on 08-09-2009; see on the website [www.moniteur.be](http://www.moniteur.be) or on our website [www.biocide.be](http://www.biocide.be); législation / wetgeving)
- applicant established in Walloon region : French language required
- applicant established in Brussels region : Dutch or French language required
- applicant established in German community : German language required

A natural person can use his own language, Dutch, French or German, independently of the location of his permanent office in Belgium.

The labelling proposal and the proposal of the directions for first aid as well as the safety data sheet for the product have to be in Dutch and in French. For the other information not given in the form A or R4BP we accept an English version.

An applicant established in another member state of the EC can use one of our national languages for the A form and for the R4BP form and apply the same rules as above for the information not specified in the A and R4BP form.

The data (paper and data on electronic support) should be send to the following address :

Federale Overheidsdienst Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu,  
Directoraat-generaal Leefmilieu  
Dienst Risicobeheersing  
Victor Hortaplein 40, bus 10  
B-1060 Brussel

The electronic data can also be send by e-mail to : [info.gestautor@health.fgov.be](mailto:info.gestautor@health.fgov.be)

In case of questions, an e-mail can be send to [info-biocides@health.fgov.be](mailto:info-biocides@health.fgov.be)

## ***II. Application for an authorisation of an existing biocide based upon one single active ingredient which has been included in Annex I/IA of Directive 98/8:***

The application has to be made by the actual authorisation holder of the existing product. Only in that case the Minister can grant a prolongation of the existing authorisation for the period necessary for the treatment of the application. The application should be introduced at the latest at the date of inclusion of the active ingredient in Annex I, IA of Directive 98/8 and should include the following documents:

1) a covering letter (= form A) , as well as form B1, part 2 (Ministerial decree of 3 september 2008, published on 08-09-2009). For Form A and B1 see on the website [www.moniteur.be](http://www.moniteur.be) or on our website [www.biocide.be](http://www.biocide.be); législation / wetgeving. The covering letter (Form A) should be signed by the actual authorisation holder of the existing product.

2) the application form generated via the "Register For Biocidal Products (R4BP)", a tool set up by the European Commission. The R4BP is available at: <https://webgate.ec.europa.eu/env/r4bp/>. Once you filled in the R4BP, you have to make a print-out of the form, sign it and send it to the address, mentioned on Form A.

3) one electronic copy of the dossier according to the requirements of Directive 98/8/CE, Annex IIB-IIIB. These requirements are more detailed in the Technical Notes for Guidance on Data Requirements (see <http://ecb.jrc.ec.europa.eu/biocides/>) We would recommend the use of IUCLID 5 for the study summaries. In addition a proposal for the label in French and Dutch, a safety data sheet for the product in French and Dutch and an instruction leaflet for first aid in French and Dutch are required. This leaflet has to be in accordance with the requirements of the Poison Control Center (see [www.biocide.be](http://www.biocide.be) ; toelatingsaanvraag; [Instructies voor het vermelden van eerste hulp maatregelen \(.WORD\)](#) and [Instructies eerste hulp \(.EXCEL\)](#) or in the French version : demande d'autorisation ; [Instructions pour la rédaction des premier soins \(.WORD\)](#) et [Notice premiers soins \(.EXCEL\)](#))

4) one original paper copy of a certificate of analysis of the content of the active ingredient in the requested product. This analysis should be performed by an independent laboratory, except if the laboratory is GLP recognised for performing analyses at the moment of performing the analysis with the requested product.

5) a Letter of Access from the owner of the data which has been used for the annex I inclusion if the applicant doesn't own the data himself. This LOA should authorise the Belgian authority to use the data for the purpose of granting an authorisation to the applicant for the authorisation of the biocidal product for which he did held an authorisation before the annex I inclusion of the active substance concerned.

6) the fee of €1000,00 for an application for authorisation. You can find the necessary information (nr for bank transfer, BIC,IBAN) on form A. This fee should be payed before sending the application; a copy of the bank transfer has to be added to the dossier. As mentioned on Form A, the bank transfer should mention as reference "KB 14/1/04, art 9§1" as well as the name of the product.

### ***III. Application for mutual recognition of an authorisation for a existing biocide based upon one single active ingredient which has been included in Annex I/IA if Directive 98/8:***

An application for mutual recognition has to be made by the actual authorisation holder of the existing product. Only in that case the Minister can grant a prolongation of the existing authorisation for the period necessary for the treatment of the application.

An application for mutual recognition has to include the following documents:

**In a first step**, at the latest at the date of inclusion of the active ingredient in Annex I,IA of Directive 98/8 :

1) a covering letter (= form A) , as well as form B1, part 2 (Ministerial decree of 3 september 2008, published on 08-09-2009). For Form A and B1 see on the website [www.moniteur.be](http://www.moniteur.be) or on our website [www.biocide.be](http://www.biocide.be); législation / wetgeving. The covering letter (Form A) should be signed by the actual authorisation holder of the existing product.

2) the application form generated via the "Register For Biocidal Products (R4BP)", a tool set up by the European Commission. The R4BP is available at: <https://webgate.ec.europa.eu/env/r4bp/>. Once you filled in the R4BP, you have to make a print-out of the form, sign it and send it to the address, mentioned on Form A.

3) one electronic copy of the summary dossier which you have sent to the first member state (the rapporteur member state for the product). In default of the summary dossier, one electronic copy of the dossier according to the requirements of Directive 98/8/CE, Annex IIB-IIIB. In addition a proposal for the label in French and Dutch, a safety data sheet for the product in French and Dutch and an instruction leaflet for first aid in French and Dutch are required. This leaflet has to be in accordance with the requirements of the Poison Control Center (see [www.biocide.be](http://www.biocide.be) ; toelatingsaanvraag ; [Instructies voor het vermelden van eerste hulp maatregelen \(.WORD\)](#) and [Instructies eerste hulp \(.EXCEL\)](#) or in the French version : demande d'autorisation ; [Instructions pour la rédaction des premiers soins \(.WORD\)](#) et [Notice premiers soins \(.EXCEL\)](#))

4) the certified copy of the application form received by the first member state (Reference Member State)

5) a Letter of Access from the owner of the data which has been used for the annex I inclusion if the applicant doesn't own the data himself. This LOA should authorise the belgian authority to use the data for the purpose of granting an mutual recognition to the applicant for the mutual recognition of the authorisation for the biocidal product for which he did held an authorisation before the annex I inclusion of the active substance concerned.

6) the fee of €500,00 for a application for mutual recognition. You can find the necessary information (nr for bank transfer, BIC,IBAN) on form A. This fee should be payed before sending the application ; a copy of the bank transfer has to be added to the dossier. As mentioned on Form A, the bank transfer should mention as reference "KB 14/1/04, art 9§1" as well as the name of the product.

**Within 4 months** after the application for mutual recognition, the proof that the first application has been assessed as complete by the Reference Member State. **After the**

**first authorisation has been delivered**, the certified copy of the authorisation act. Once we received this document, the 120 days period, as foreseen in the Directive for treatment of the application for mutual recognition, starts.

Remark : This deadlines and procedures however only apply in the context of the post-Annex I procedure for products currently authorised and placed on the market in Belgium and will allow the Belgian authority to grant an temporary extension of the existing authorisation. For the others an application for mutual recognition can only be accepted after the first post annex I authorisation has been delivered.

**BU:**

We will be accepting applications in Bulgarian language. 3 electronic copies and 3 paper copy are needed.

**CH:**

We ask for a notification of intention the latest on the date of inclusion of the active substance. This is a form to be downloaded from internet. The company must indicate among others in which country it will apply for the first authorization (or registration) and promises with its signature to apply for a mutual recognition the latest two months after the first authorization has been granted in an European or EEA country. We do not require other documents, though most of the companies have sent us a copy of the R4BP form.

A dossier for a mutual recognition required in Switzerland is the one foreseen in the BPD. Though, as we do not have access to not published data, we may ask in some cases for a copy of the documents IIA and IIIA related to the active substances.

We accept dossiers in one of the three national languages (German, French and Italian) or in English.

**CY:**

Our service, accepts application forms in English language.

## **CZ:**

In the Czech legislation, products - on the basis of national notifications - can be placed on the market until the end of the transition period (14 May 2010 to be extended to 14 May 2014) or, in the case of products containing substances included in Annex I until the date of compliance with Article 16(3), as stipulated in the Annex I inclusion..

We however recommend via our web pages that applicants submit applications for a first authorisation by the date of inclusion of the active substance in Annex I (e.g. 1 January 2009 for wood preservatives containing sulfuryl fluoride). In case of application for mutual recognition, we recommend the applicants to submit the application no later than 120 days before the date by which the product notified in accordance with the national provisions is to be removed from the market.

Regarding mutual recognition, a complete data set containing a covering letter, the application form generated via the R4BP (1 copies in print and 4 electronic copies), proof of the payment of the fee, 1 electronic copy of the summary dossier and 1 copy of authorization issued by the Reference Member State (we need certified translation of the authorization into Czech) is to be submitted. MSDS and proposed labelling is required in Czech.

Once a dossier has been considered to be complete, it shall be evaluated within 9 months.

If the documentation is incomplete, the clock can be stopped and applicant asked to provide the remaining data.

## **DE:**

Article 28 (8) of the German Chemicals Act provides for rules on the interim arrangement for both new and existing biocidal-products, which contain existing active substances for which the decision for Annex I inclusion was reached. According to this provision the interim arrangement only applies if an application for authorization, registration or mutual recognition has been filed at the latest 24 month after the date the inclusion directive has been published in the Official Journal.

For a product containing more than one active substance for a given Product Type (PT), the deadline for submission of an application is the date of inclusion of the last active substance. For instance, for a wood preservative with two active substances (AS1 and AS2, decision of inclusion of AS1 is taken before AS2), the application for authorization has to be filed until the date of inclusion of AS2 by the latest.

Provided that this application was filed in due time, the product may still be placed on the market for the time of the subsequent procedures (product authorization, registration and the following mutual recognition procedure). The time period has to be in accordance with the date given in the inclusion directive according to Article 16 (3) of Directive 98/8/EG.

The German transposition of the BPD – as well as the BPD itself – does not foresee the possibility to reject applications on the ground that the dossier submitted is incomplete. In such a case the missing data would have to be requested and the administrative proceedings would be suspended.

For application of mutual recognition the following documents/forms are required:

The application shall include all required information for mutual recognition as described in Article 4 (1) of Directive 98/8/EC, except the certified copy of the first authorization. Furthermore the following documents have to be submitted:

1. Print out of the R4BP application form with date and signature in German (we are only able to accept the application form in our language).

2. Second part of application form in German. Only for courtesy reasons a version in English is available. Furthermore, the English version should facilitate the completion of the German version. Additionally, the following documents have to be filled in, if necessary:

- Authorization for communication with date and signature
- Confirmation, that the dossier versions are identical (electronic and paper copy) with date and signature
- Letter of access with date and signature

3. A proposal for the classification and labelling, the safety data sheet, and the copy of the label of the product also have to be submitted in German.

4. Submission of 2 electronic (on CD-ROM) and 1 paper copy of the summary dossier (Doc. I -III). The paper copy is needed for administrative reasons.

The above mentioned documents are available in German as well as in English (courtesy translation) from the Federal Institute of Occupational Safety and Health (BAuA). Contact: [chemg@baua.bund.de](mailto:chemg@baua.bund.de) <<mailto:chemg@baua.bund.de>>

In a second step the following documents have to be submitted:

- Certified copy of the authorisation granted by the reference member state
- Certified copy of the reference member states authorisation assessment report

#### **DK:**

We at present will require the following - in a first step - for this first application for mutual recognition:

- A covering letter confirming that an application is made for mutual recognition of authorization for the product.
- A filled in paper copy of the application form generated via the R4BP
- One electronic copy of the summary dossier for the product as submitted to the first member state.

Additional information will be required in a second step where the full application for mutual recognition will be submitted. These will, for instance, include:

- Fees for handling the application to be paid

- A summary dossier, where the first member state has filled in the evaluation boxes, in English
- Other part of application form covered by R4BP (not yet available, in English or Danish)
- A certified copy of the first authorization (in Danish or English) and an assessment report as foreseen being made by the first member state in English
- Label proposal and instruction leaflets in Danish

In addition we may request for all studies submitted by the applicant in an electronic form according to Article 8 of the BPD.

We want 3 electronic copies (CD) and one paper copy.

## **EE**

As the modification of the national regulation is still under process, the proposed actions for mutual recognition are:

In a first step the following information will be submitted:

- A filled in and signed paper copy of the application form generated via the R4BP in Estonian or English.

In a second step the full application for mutual recognition will be submitted. These will, for instance, include:

- Fees for handling the application to be paid
- The summary dossier in accordance with BPD
- certified copy of the first authorisation (in Estonia or English) and the assessment report (in English)
- label proposal, SDS and instruction leaflets, all in Estonian.

We want one electronic copy (CD) and one paper copy.

All answers above are given based to the proposal of the new Biocidal Act, so we can not be 100% sure that it will be in force as such.

## **EL:**

### **1. For the 1<sup>st</sup> Authorisation in Greece, are required the followings:**

1) The administrative part in Greek, containing a covering letter in paper to explain the purpose of the submission and the application form in paper (generated via the R4BP).

2) The Assessment Report (a synthesis of Doc.I and Doc.II of the biocidal product dossier) can be in Greek or in English. In case where the Assessment Report is in Greek language an English version will be needed for a mutual recognition and we agree to review the draft translation provided by the applicant.

3) A summary of the main product characteristics (SPC)

- 4) A list, as Annex to the Assessment Report, of the studies reviewed.
- 5) A proposal for the classification and labeling, the safety data sheet, and the copy of the table of the product also have to be submitted in Greek
- 6) Fees for handling the application to be paid

The MS will make the Decision and grant the authorisation to the applicant.

## **2. For the mutual recognition:**

An application for mutual recognition would not be rejected if the Member State was to receive until the date of Inclusion of the a.s **in a first step** the following information:

- A covering letter in paper in Greek or maybe we can accept also an English version confirming that an application is made for mutual recognition of authorisation for the product.
- A filled in paper copy of the application form in Greek generated via the R4BP
- One electronic copy and one paper copy of the summary dossier for the product, as requested in Article 4 of the Directive and already submitted to the Reference Member State.

The rest of the information would be submitted **in a second step**, once the first authorisation would have been granted.

- A certified copy of the authorisation granted in whatever MS and an official translation in Greek.
- An electronic copy and one paper copy of the Assessment Report of the Reference member state.
- A proposal for the classification and labeling, the safety data sheet, and the copy of the table of the product also have to be submitted in Greek.
- A Safety data Sheet for the product as well as for all inerts in Greek.
- Fees for handling the application to be paid

### **ES:**

The application form must be sent in Spanish language, and we have some additional information requirements that do not appear in the generated by R4BP form.

### **FI:**

For a product already placed on the Finnish market for a given Product Type (PT), the deadline for submission of an application is two years after date of coming into force of the inclusion directive of the last active substance. (Note: The deadline will be changed as soon as possible to the date of inclusion.). Procedures after Annex I inclusion and related deadlines are implemented by the Ministry of the Environment Decree 20/2008 as amended.

The application, in accordance with Chemicals Act 1998/1999 and related Decrees, consists of:

- an application for authorisation/registration or
- an application for mutual recognition of authorisation/registration.

The content of the dossier (studies, risk assessment etc.) depends on the kind of application (authorisation, registration, mutual recognition etc.) and is specified in the Ministry of The Environment Decree 518/2000 as amended and application guideline which will be available at [www.environment.fi/biocides](http://www.environment.fi/biocides) and <http://www.valvira.fi/en/chemicals/biocides> .

This dossier shall be accompanied by:

- The application form generated from the *Register for Biocidal Products* (R4BP) of the EU Commission (part 1 of the applications form)
- A specific FI application form (part 2 of the application form). It is given upon request from [syke\\_kem\\_biosinfo@ymparisto.fi](mailto:syke_kem_biosinfo@ymparisto.fi) and [biocides@valvira.fi](mailto:biocides@valvira.fi). It will be available also at: [www.environment.fi/biocides](http://www.environment.fi/biocides) and <http://www.valvira.fi/en/chemicals/biocides>.
- A proposal for the Classification and Labeling, the Safety Data Sheet, and the copy of the label of the product in Finnish and Swedish.

Application for mutual recognition of authorisation/registration takes place in two steps: notice of intention and formal application.

For the notice of intention following shall be submitted at the deadline of application at latest:

- A cover letter indicating that an application for product authorisation is being made in another Member State and mutual recognition of that product will be sought in FI
- Copy of the R4BP form, printed and signed (part 1)
- One electronic copy of the summary dossier.

For the formal application for mutual recognition following is submitted within two months of the first authorisation granted:

- Copy of the official authorisation granted by the reference Member State, where relevant translation into Finnish, Swedish or English
- Copy of the Product Assessment Report by the reference Member State, preferably in English
- A specific FI application form (part 2)
- Summary dossier (Doc I-III)
- Copy of the proposed label and Safety Data Sheet.

Additional studies and information considered essential to the assessment may be requested.

All documents shall be submitted either in Finnish, in Swedish or in English. However, proposal for the Safety Data Sheet and the proposed label must always be available in Finnish and in Swedish. One paper copy and two electronic copies (CD or DVD) are required.

Fees are according to the Decrees 1207/2006 (SYKE) and 36/2009 (Valvira). The applicant will be invoiced by the CAs.

Applications shall be submitted to the designated CA:

PT 8, 10-12, 14-17, 21, 23	PT 1-7, 9, 13, 18-20, 22
<b>Finnish Environment Institute (SYKE)</b> Chemicals Division  P.O. Box 140, FI-00251 Helsinki register office: <a href="mailto:kirjaamo@syke.fi">kirjaamo@syke.fi</a> biocides: <a href="mailto:syke_kem_biosinfo@ymparisto.fi">syke_kem_biosinfo@ymparisto.fi</a> <a href="http://www.environment.fi/biocides">www.environment.fi/biocides</a>	<b>National Supervisory Authority for Welfare and Health (Valvira)</b> Chemicals P.O. Box 210, FI-00531 Helsinki register office: <a href="mailto:kirjaamo@valvira.fi">kirjaamo@valvira.fi</a> biocides: <a href="mailto:biocides@valvira.fi">biocides@valvira.fi</a> <a href="http://www.valvira.fi/en/chemicals/biocides">http://www.valvira.fi/en/chemicals/biocides</a>

In case no application is submitted before the deadline, the first placing on the market will be forbidden 6 months after the deadline. A period of grace for subsequent storage and use may be granted.

In case application is rejected due to incompleteness of the dossier, the first placing on the market will be forbidden 6 months after the rejection. A period of grace for subsequent storage and use may be granted.

#### FR:

For a product already placed on the French market for a given Product Type (PT), the deadline for submission of an application is the date of inclusion of the last active substance.

→ For instance, for a wood preservative product PT08 put on the French market with 2 active substances (AS1 and AS2, decision of inclusion of AS1 is taken before AS2), the submission of the dossier can be made from the date of transposition of the inclusion directive of AS2, until the date of inclusion of AS2, at the latest.

This application, in accordance with articles R522-14 and following of the FR Environmental Code and the Decree of 19 may 2004 modified (“*arrêté du 19 mai 2004 modifié relatif au contrôle de la mise sur le marché des substances actives biocides et à l’autorisation de mise sur le marché des produits biocides*”), consists in :

- either an application to demand the Authorization as defined in articles R.522-15 to R.522-21 of the FR Environmental Code, and article 2 of the Decree of 19 may 2004 modified,
- or, if a demand of authorization is submitted in another Member State where the product is also put on the market (called “Reference Member State”), an application to demand the Mutual recognition as defined in articles R.522-26 to R.522-27 FR Environmental Code, and article 4 of the Decree of 19 may 2004 modified. In such case, the assessment of the dossier would be put on hold until a decision is taken by the Reference Member State.

The content of the “technical” dossier (studies, risk assessment etc...) depends on the kind of demand (authorization, registration, mutual recognition etc....) and is specified in the Decree of 19 may 2004 modified.

For a demand of mutual recognition, the “technical” dossier consists in the summary dossier foreseen article 4 of the Decree of 19 may 2004 modified (similar to article 4, paragraph 1 of directive 98/8/EC).

It is accepted that this “technical” dossier is submitted either in French or in English. It shall only be submitted in electronic format (CD or DVD).

This “technical” dossier shall be accompanied by:

- 1) A letter from the applicant written in French, to explain the purpose of the submission (ie demand for authorization, demand for mutual recognition, registration of a low risk product etc....). It has to be in paper form.
- 2) The application form generated from the *Register for Biocidal Products* (R4BP) of the EU Commission, in French version. It shall be noted an electronic system for the application of authorization of biocidal products is being developed in France, and in the future, applicants will have to pass through this system for any application in France. This system will then communicate with the R4BP.
- 3) A specific additional FR application form, explaining the status of the product in France. It is given upon request to [biocides@developpement-durable.gouv.fr](mailto:biocides@developpement-durable.gouv.fr).
- 4) A proposal for the Classification and Labeling, the Safety Data Sheet, and the copy of the label of the product also have to be submitted in French. A copy of the letter of access in French shall also be submitted.

This application shall be sent to :

- One copy to MEEDDAT (Competent Authority on biocides): Ministère de l'Écologie, de l'Énergie, du Développement Durable et de l'Aménagement du Territoire, DGPR/SPNQE/DPCPDA, Bureau des substances et préparations chimiques, Grande Arche, 92055 LA DEFENSE Cedex
- One copy to AFSSET : Agence Française de Sécurité Sanitaire de l'Environnement et du Travail, A l'attention de Monsieur JUVIN - Pôle biocides, 253 avenue du Général Leclerc, F-94701 MAISONS-ALFORT cedex

Fees are fixed in the Decree of 24 June 2004 modified (*«Arrêté du 24 juin 2004 modifié fixant le montant de la rémunération due au titre de l'autorisation de mise sur le marché des substances et produits biocides »*), and shall be paid to AFSSET :

- In case of an application to demand the Authorization, 2.500 euros shall be paid at the submission for the completeness check of the dossier. If the dossier is declared as complete, the dossier will be assessed and the remaining part of the fee will have to be paid later (according to the provisions of last paragraph of article 1 of the Decree of 24 June 2004 modified). Several fees are defined in function of the amount of work needed, from 16.000 to 37.000 euros, with the “basic” fee of 32.500 euros. For products to which the “frame formulations” concept may apply, the question of the establishment of a frame formulation shall be discussed.
- In case of an application for Mutual recognition, the fee will have to be paid when the Reference Member State would have taken a decision on the dossier. The fee is 4.000 euros for a “standart product”, 1.800 euros for a “low risk product”.

In case no dossier is submitted for a product before the deadline, all placing on the market will be forbidden 6 months after the deadline for submission of the dossier, and their use 12 months after the deadline for submission

In case the dossier is declared uncompleted and rejected, all placing on the market will be forbidden 6 months after the decision, and use forbidden 12 months after the decision, unless otherwise specified.

For any question on the procedure to follow for the authorization of biocidal products, please contact : [biocides@developpement-durable.gouv.fr](mailto:biocides@developpement-durable.gouv.fr) .

## **HU:**

For the first authorisation the following is required:

- Covering letter stating that the applicant would like to apply for product authorisation.
- One electronic and one paper copy of the dossier as stated in the BPD, accepted in Hungarian or English.
- Fee for product authorisation has to be paid according to our fee regulation *1/2009. (I.30.) EüM rendelet*.

Mutual recognition of the first authorisation

1. In the first step the following is required:

- A covering letter confirming that an application is made for mutual recognition of authorisation for the product
- A filled in paper copy of the application form generated via R4BP. At the moment English version is only available, but in the future the Hungarian is preferred.
- One electronic copy of the summary dossier for the product as submitted to the first Member State.

2. In the second step of mutual recognition the following is required:

- Covering letter that the first authorisation has been granted.
- Certified copy of the first authorisation granted in the Reference Member State. Certified Hungarian translation is required if it is not in English.
- Fee for mutual recognition has to be paid according to the fee regulation *1/2009 (I.30.) EüM rendelet*.
- One electronic and one paper copy of the Assessment Report.
- One paper copy of the summary dossier for the product as submitted to the first Member State.

Label proposal, Safety Data Sheet and using instructions only accepted in Hungarian.

## **IE:**

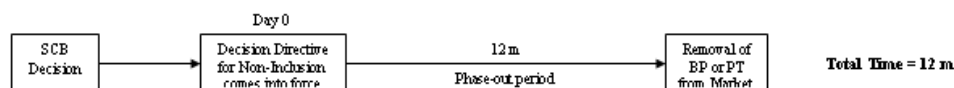
**Upon publication of a Decision Directive for Inclusion/Non-inclusion:**

The Irish CA informs notification holders, of the relevant biocidal product(s) that contain the active substance and associated product-type (PT) combination, that products will need to be either supported for Product Authorisation/Registration or Mutual Recognition as per an inclusion decision, or that the products are revoked from the market as per a non-inclusion decision.

For support of a product based on an inclusion decision, the PCS distinguishes between products containing a single active/PT combination, multiple actives/single PT combination and multiple actives/PT combinations.

For revocation of a product based on a non-inclusion decision, the PCS distinguishes between a full product revocation and a product-type revocation. Following entry into force of the non-inclusion the notification holder of the relevant product has a period of 1-year to use existing stocks of the product.

**Non-Inclusion**

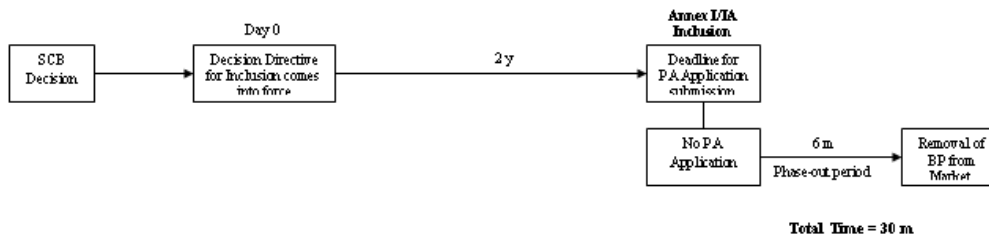


From 2 months of the date of the above letter informing of an inclusion decision, the PCS requires a letter of intent (that can be emailed) from the authorisation holder of the relevant biocidal products as to whether they will support the product(s) authorisation or mutual recognition.

Within the period between entry into force of an inclusion Directive and the date of inclusion into Annex I of Directive 98/8/EC the PCS are willing to liase (via email or face-to-face) with applicants regarding specifics of their product application/mutual recognition.

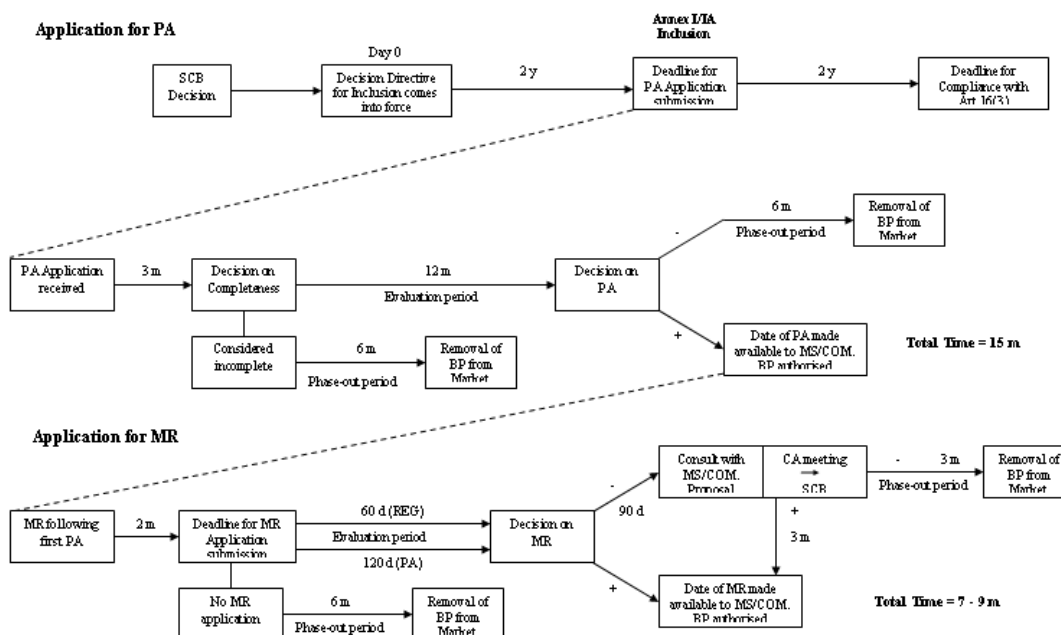
**Inclusion**

**No application submission**



The deadline for submission of an application for Product Authorisation (PA) or Mutual Recognition (MR):

Date of Inclusion (as stated in the specific Decision Directive), e.g. Sulfuryl Fluoride deadline = 01/01/09.



General data requirements for Product Authorisation (PA) or Mutual Recognition (MR):

**For MR of authorisation:**

Following the completeness check of the reference MS or before, the PCS requires:

Copy of Summary dossier (1x electronic copy, 1x paper copy), which includes:

- R4BP application form
- Annex IIA/IIIA sections (either equivalent data or LoA)
- Annex IIB/IIIB sections (either equivalent data or LoA)
- Confidential section

Draft Irish label (1x electronic copy, 1x paper copy)

SDSs for the active substance and co-formulants

Following authorisation by the reference RMS, the PCS requires:

Copy of reference MS evaluation report in English (1x electronic copy, 1x paper copy)

Certified copy of the first authorisation granted in English (1x electronic copy, 1x paper copy)

Fee for mutual recognition (€2500.00<sup>18</sup> as of 01/0109)

**For product authorisation:**

Required by all applicants:

<sup>18</sup> here is an additional re-occurring annual fee of €300.00 that comes into effect from 01/09.

Fee for product authorisation (€5000.00<sup>19</sup> as of 01/01/09)

Completed application form (1x electronic copy, 1x paper copy), which includes:

- Export file of the R4BP
- Similar information, necessary for national authorisations, that is not present in R4BP (incl. SDS and draft Irish label). NB: The PCS is still developing an application form in line with the PA&MRFG discussions on this issue.
- Full composition
- Checklist information on active substance and biocidal product
- Reference list
- Relevant LoA

Required by the Applicant that secured Annex I Inclusion:

Summary dossier (Electronic ×1, Paper ×1), which include:

- Annex IIA/IIIA updated sections
- Annex IIB/IIIB updated sections
- Confidential updated section

Required by Applicants that did not support Annex I Inclusion:

Summary dossier (Electronic ×1, Paper ×1), which include:

- An equivalent Annex IIA/IIIA dossier satisfying requirements of the EU review.
- An equivalent Annex IIB/IIIB dossier satisfying requirements of the EU review.
- Or a notarised LoA from the primary data holder for the data pertaining to the active substance and/or biocidal product.

\* Please note that for authorisation/mutual recognition of a biocidal product containing more than 1 active substance, the product will be evaluated and subsequently authorised following inclusion in Annex I of the last active substance contained in the product. However, at the inclusion date of the preceding active substances the applicant is required to provide either:

- A notarised LoA, for either the active substance and/or product data, from the primary data holder.
- Equivalent data for the active substance/biocidal product (reference list, study protocols, provisional reports, final reports).

***For product registration:***

Required by all applicants:

Fee for product registration (€2000.00<sup>20</sup> as of 01/01/09)

Completed application form (1x electronic copy, 1x paper copy), which includes:

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<sup>19</sup> There is an additional re-occurring annual fee of €300.00 that comes into effect from 01/09.

<sup>20</sup> There is an additional re-occurring annual fee of €300.00 that comes into effect from 01/09.

- Export file of the R4BP
- Similar information, necessary for national authorisations, that is not present in R4BP (incl. SDS and draft Irish label). NB: The PCS is still developing an application form in line with the PA&MRFG discussions on this issue.
- Full composition
- Checklist information on active substance and biocidal product
- Reference list
- Relevant LoA

Required by the Applicant that secured Annex I Inclusion:

Summary dossier (Electronic ×1, Paper ×1), which include:

- Annex IIA/IIIA updated sections
- Annex IIB/IIIB updated sections (as per Article 8 (3) of Directive 98/8/EC)
- Confidential updated section

Required by Applicants that did not support Annex I Inclusion:

Summary dossier (Electronic ×1, Paper ×1), which include:

- An equivalent Annex IIA/IIIA dossier satisfying requirements of the EU review.
- An equivalent Annex IIB/IIIB dossier satisfying requirements of the EU review (as per Article 8 (3) of Directive 98/8/EC).
- Or a notarised LoA from the primary data holder for the data pertaining to the active substance and/or biocidal product.

Additional Information:

It is hoped that by the end of the year the PCS will have available online:

- A full database of all biocidal products authorised in Ireland
- Application information for national authorisation and EU dossier evaluation.
- Pay structure information
- Annex I Inclusion/non-inclusion information
- Contact information

**IT:**

In Italy, we can accept the submission of a request of authorisation of product containing substances included in Annex I until two-years after the date of publication of the inclusion decision, if the product is already on the market with or without authorisation (free).

There is however also the possibility to submit the request after this date, and until the date of compliance with Article 16(3), when all these last existing products on the market must be revoked if they are then still under evaluation.

If there is a request of authorisation of a new product containing substances included in Annex I (also according mutual recognition), we can accept the submission at any time and we can grant an authorisation from the date of inclusion of the active substances in Annex I.

In any case, we accept the application only in Italian.

## LU:

Currently, the deadline for submission of an application may go up to 6 months after the date of inclusion of the (last) active substance.

However, the modification of the national legislation, by which the deadline will be set to the date of inclusion, is under process. Therefore, the proposed deadline for submission of an application for mutual recognition is the date of inclusion of the active substance.

Please note that labelling, instructions for use and safety data sheets must be in at least one of the following languages: German; French.

### Requirements for MR are:

#### 1<sup>st</sup> Step:

- A covering letter confirming that an application is made for mutual recognition. (French, German and English accepted). Please specify if the product is already placed on the market.
- A filled in paper copy of the application form generated via the R4BP (register for biocidal products) (French, German - English also accepted).
- One (1) electronic copy of the summary dossier for the product (French, German, English acceptable). This dossier consists in a summary of the dossier as required in Article 8(2)(a) and Annex II B, Section X of directive 98/8/EC.

An application can only be accepted as complete if the following information is submitted in a 2<sup>nd</sup> step (once the first authorisation has been granted):

- Certified copy of the first authorisation (If not in German or French, the additional submission of an English translation, together with the original authorisation, is requested)
- Acknowledgment of receipt or copy of the bank transfer order. Amounts of Fees are provided in the “*Règlement grand-ducal du 7 juin 2007*”. LINK: <http://www.legilux.public.lu/leg/a/archives/2007/0092/2007A1784B.html>
- Label, instructions leaflet, Safety Data Sheet

### Mail address:

#### **Direction de la Santé**

Division de la Pharmacie et des Médicaments  
Allée Marconi – Villa Louvigny  
L-2120 Luxembourg

## LV:

In Latvia we can not accept the application for product authorisation and mutual recognition before official date of inclusion of active substance in Annex I of Biocidal Directive 98/8/EC. Therefore, Latvian Environment, Geology and Meteorology Agency can start accept the documentation after the date of inclusion, in case of sulfuric acid after 1.1.2009.

In Latvia we have the legal requirement to submit product dossier in national language for Latvian companies. If the applicant is international company the dossier can be submitted in other language. Competent Authority, however, in this case may request a translation with a notarial certificate approving it. Usually we do not require that for English and Russian languages, i.e. languages for which we have sufficient expertise and experience.

**MT:**

We will be accepting applications in English as well as in Maltese since both languages are official languages in Malta.

**NL:**

An announcement (with the R4BP form), is needed to know that for products already authorised in the Netherlands an application for authorisation (mutual recognition) based on the EU dossier will be submitted to Ctgb. In case Ctgb does not receive such an announcement, we can conclude that the authorisation holder is not planning to notify this product anymore in the Netherlands.

Actual applications for the mutual recognition of authorisations have to be submitted to Ctgb within 2 months after authorisation of the product by the Reference Member State. For this application for authorisation the application form must be used that is officially decreed in the Netherlands by Ctgb. That is a bilingual form in Dutch and English and (at this moment) not the R4BP form.

**NO:**

At present, NO will require the following to be submitted:

- A covering letter confirming that an application is made for mutual recognition of authorization for the product. This should preferably be signed by the one presently responsible for placing on the Norwegian market.
- A filled in paper copy of the application form generated via the R4BP (in future no printout is needed)
- One electronic copy of the summary dossier for the product as submitted to the Reference Member State.

We will at this point of time not require:

- Other part of application form not covered by R4B (not yet available)
- Label proposal and instruction leaflets and SDS in Norwegian (if already available they could be submitted electronically or on paper copies now).
- Fees for handling the application to be paid.

This have to be submitted/fulfilled together with a copy of the first authorization and an assessment report as foreseen being made by the Reference Member State. This will have to be submitted at the latest 8 weeks after the first authorization has been given.

In general we accept all part of a product dossier to be submitted in either English or Norwegian (except label proposals, proposal for instruction of use and a copy of the SDS. These documents all have to be in Norwegian).

**PL:**

**In the first step we require:**

1. a covering letter signed by person who is responsible to represent the applicant. This letter should be in Polish language or if it is in other language then require sworn translation into Polish.
2. a filled in 1 paper copy of the application form generated via the R4BP (only in Polish language)
3. one electronic copy and 1 paper copy of the summary dossier (can be in Polish or English)

**In the second step we will require:**

1. certified copy of authorization granted by Reference Member State with sworn translation into Polish language;
2. electronic copy of assessment report of Reference Member State
3. proposal for classification, labelling and instruction leaflet (if needed) in Polish language according to art.20 BPD
4. Safety data Sheet (in Polish)
5. Evidence of payment concerning submission of the application. The fee for a demand of MRP has been fixed to 6250zł for authorization and 2500zł for registration of low risk biocidal product (the Regulation of Minister of Health of January, 12 2007 concerning charging activities related to authorization for the placing of biocidal product on the market (Official Journal No. 8, item.62).  
On the evidence of payment title of charge shall be given (e.g 6250zł - *'payment concerning the placing of biocidal product (name of product) on the market'*)

Payment shall be transmitted to the bank account:

Narodowy Bank Polski  
00-950 Warszawa; Plac Powstańców Warszawy 4  
PL30 1010 1010 0094 1022 3100 0000  
Kod BIC – NBPLPLPW

All copies should be certified by Polish consul or by “apostile”

Poland also confirms that deadline for submission of application is two years after the date of coming into force of the inclusion Directive.

**PT:**

**A - Biocidal Products PT8/Wood Preservatives**

Application for Mutual Recognition in Portugal, following a decision on inclusion of an existing active substance into Annex I or I-A of the Decree Law n° 121/2002 from 3rd May

Documents to submit to the Portuguese Competent Authority Direcção-Geral de Agricultura e Desenvolvimento Rural (DGADR):

## 1. Note of intention<sup>21</sup>:

Within 2 years from entry into force the inclusion directive<sup>22(2)</sup>, the Company that wants to continue to place the existing biocidal product on the market has to submit in a first step the documents below (1.1 to 1-3)

1.1-A cover letter in Portuguese language, signed by a person responsible in the Company, confirming that an application is made for mutual recognition of authorisation for the product.

1.2-Print out of the first part of the application form fulfilled in the site of the registration for the Biocidal Products (R4BP): <https://webgate.ec.europa.eu/env/r4bp/>

1.3-One electronic copy of the summary dossier (Doc I-III) of the product as submitted in the Reference Member State

1.4-Letter of access for the active substance dossier

## 2. Formal application:

Within two month of having obtained the first authorization for the product in the Reference Member State (RMS) the Applicant shall submit to the Portuguese Competent Authority (DGADR) the documents below (2.1 to 2.6)

2.1-one certified copy of the granted authorization in the Reference Member State (RMS)

2.2-The assessment report from the RMS in English or Portuguese language

2.3-Print out of the second part of the application form fulfilled in the common register for biocidal products (R4BP) in the site <https://webgate.ec.europa.eu/env/r4bp/>

Dated and signed by a person responsible in the Company

2.4-Safety data sheet in Portuguese

2.5-Copy of the proposed label, in Portuguese

2.6-Evidence of the payment of the fee<sup>23</sup> (Portaria n°702/2006 de 13 de Julho)

## **B - Direcção Geral de Veterinária (DGV) Portuguese Competent Authority to Veterinary Biocidal Products for the application will require:**

1. For the notice of intention (only for products already in the market at the date of inclusion):

- A cover letter indicating:

(1) that an application for the product authorisation is being made in another member state;

(2) the intention of submit a mutual recognition for that product in Portugal.

- Copy of the R4BP.

2. For the formal application:

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21 For products with more than one active substance, the deadline shall be the one set out in the last inclusion decision relating to its active substances

22 Until the date of inclusion of the active substance in the Annex I or I-A

23 1500 to 2100 euros depending on the work

- Application form in Portuguese;
- Certified copy of the official authorisation granted by the reference member state;
- Certified copy of the reference member state authorisation assessment report;
- Proof of payment (the applicant has until 10 day after the application form);
- 4 electronic copies and 1 paper copy of the summary dossier of the product;
- If necessary we may request 4 electronic copies and 1 paper copy of all the studies submitted by the applicant;
- Label proposal and instruction leaflets in Portuguese;
- Safety Data Sheet in Portuguese

**C - General Directorate of Health (DGS) is the Competent Authority for all biocidal product types, excluding PT 8 and Veterinary Biocidal uses.**

In case we do not receive a submission related to a product already placed on the Portuguese market, DGS will conclude that the product authorisation holder does not intend to continue with this product on the market and will inform him that, in accordance with the provisions of Article 7(3) of the Directive (in Portugal, article 14.º of Decreto-Lei n.º 121/2002), a period of grace of 6 months after the date of inclusion of the active substance will be granted, for storage and stocks phasing-out. After this deadline the products are considered as removed from the market.

For a product, already placed on the Portuguese market, containing more than one active substance for a given Product Type (PT), the deadline to submit an application is the date of inclusion of the last active substance in the product to be included in the BPD Annex (I or IA).

If a biocidal product containing all active substances included in one of the BPD Annexes already exists on the Portuguese market, to be able to remain on the market while applications are evaluated, the companies have to submit till the deadline mentioned above, the following:

1 - For the application to demand the mutual recognition of an **authorisation**, the following elements must be submitted, on electronic form (1 CD or DVD) and 1 paper copy, to Director General of Health - General Directorate of Health – Alameda D. Afonso Henriques, 45 – 1049-005 Lisboa:

- A covering letter from the Applicant, written in Portuguese language, dated and signed.
- Print out of the R4BP application form, dated and signed (can be in Portuguese or English).
- The summary dossier, as described in article 4 paragraph 1 of Directive 98/8/CE (in Portugal, article 22.º, paragraph 1 and 2 of Decreto-Lei n.º 121/2002, de 3 de Maio) or a letter of access, dated and signed (if this is the case).
- A certified copy of the first authorisation and the assessment report from the Reference Member State.

The proposal for the Classification and Labelling, the Material Safety Data Sheet, and the copy of the label of the product have to be submitted in Portuguese. Other information in this dossier can be accepted in Portuguese or English.

The fee related to a demand of mutual recognition of an authorisation has been fixed to 1.539 EUR, at the moment, by point 6, table I of the annex of rectified Portaria n.º 702/2006, of 13 July 2006, and must be paid in advance, after the request from our Financial Department

Applications for mutual recognition of an authorisation will be put on hold until the certified copy of the first authorisation, to be granted by the Reference Member State, is received by DGS. The application will only then be considered as complete.

2 - For the application to demand the mutual recognition of a **registration**, the following elements must be submitted, on electronic form (1 CD or DVD) and 1 paper copy, to Director General of Health - General Directorate of Health – Alameda D. Afonso Henriques, 45 – 1049-005 Lisboa:

- A covering letter from the Applicant, written in Portuguese language, dated and signed.
- Print out of the R4BP application form, dated and signed (can be in Portuguese or English).
- Information, as described in article 4, paragraph 1 and article 8, paragraph 3 of Directive 98/8/CE (in Portugal, paragraph 1, article 16.º and paragraph 3, article 22.º of Decreto-Lei n.º 121/2002, de 3 de Maio) or a letter of access, dated and signed (if this is the case).
- A certified copy of the first registration and the assessment report from the Reference Member State.

The proposal for the Classification and Labelling, the Material Safety Data Sheet, and the copy of the label of the product have to be submitted in Portuguese. Other information in this dossier can be accepted in Portuguese or English.

The fee related to a demand of mutual recognition of a registration has been fixed to 1.539 EUR, at the moment, by point 6, table I of the annex of rectified Portaria n.º 702/2006, of 13 July 2006, and must be paid in advance, after the request from our Financial Department.

Applications for mutual recognition of a registration will be put on hold until the certified copy of the first registration, to be granted by the Reference Member State, is received. The application will only then be considered as complete.

#### **SE:**

The Swedish Competent Authority is developing procedures for applications for product authorisation largely in line with the Gentlemen's agreement. Information on application forms, fees and language requirements can be found on our website ([http://www.kemi.se/templates/Page\\_3213.aspx](http://www.kemi.se/templates/Page_3213.aspx)). In the absence of a European harmonised approach to formal compliance control of products, we are implementing a procedure of our own based on co-operation with applicant companies. Information on this procedure is provided in information to applicant companies. In the meantime, we will continue to work for a harmonised approach.

#### **SI:**

If the product is already placed on the Slovenian market companies have to submit, in order to prolong the stay on the market, before the date of inclusion of the active substance in Annex I:

- Application for the authorisation or
- A letter of intention for mutual recognition.

The letter on intention covers in the first step:

- A covering letter confirming that an application is made for mutual recognition of authorization for the product in Slovenian language. Other documentation can be in Slovenian or English.
- A filled in paper copy of the application form generated via the R4BP
- One electronic copy of the summary dossier for the product as submitted to the first member state.

Additional information: a declaration stating that the applicant agrees with the withdrawal of the biocidal product from the market when fails to submit the application for the issue of the mutual recognition of the authorisation within two months of the first issuance of the authorisation.

In the second step we will require:

- The summary dossier in accordance with BPD
- certified copy of the first authorisation and the assessment report
- label proposal, SDS and instruction leaflets, all in Slovenian
- Fee to be paid.

## SK

“Existing biocidal product” in Slovakia refers in the context of this document to those products which have already been placed on the market of the Slovak Republic in accordance with transitional provisions of Article 33, paragraph 2 of the Act No 217/2003 Coll. transposing Directive (EC) 98/8/EC. As a basic requirement, these products:

- must bear a valid registration number on the product label at the date of inclusion of the active substance into Annexes I or IA
- and at the same time they must be listed in the [SK On-line Registry of Biocidal Products](#).

If any applicant wishes to continue to place an existing biocidal product on the market of the Slovak Republic, the SK CA recommends to submit by the inclusion date at the latest (except for products containing more than one active substance, for which the deadline shall be the one set out in the last inclusion decision relating to its active substances):

- either an **application for authorisation** complying with the requirements of Article 4 of the Act No 217/2003 Coll. (Article 8 of the Directive 98/8/EC) [to one of the competent authorities](#) for implementation of Directive (EC) 98/8/EC in the European Union
- or a **letter of intention**<sup>24</sup> for placing an existing biocidal product on the market of the Slovak Republic based on the procedure of mutual recognition according to

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<sup>24</sup> In accordance with Article 4(1) BPD the applicant shall submit a certified copy of the first authorisation granted. Since this Article does not contain any specific provisions related to handling of incomplete applications, the CCSP is obliged to follow the deadlines in accordance with the national Act on State Administrative Procedures. As a consequence, the CCSP cannot wait until the first authorisation in one of the EU MS is granted and hold the incomplete application for more than 60 days. This will result in the decision on rejection of the application for mutual recognition. Due to this fact, the CCSP

Article 10 of the Act No 217/2003 Coll. (Article 4 of the Directive 98/8/EC) to the Centre for Chemical Substances and Preparations. The applicants are recommended to use a [standardized form for letter of intention](#) which is placed on the CCSP web page.

The CCSP accepts applications in SK or EN languages. The applicants are also advised to use the European Register for Biocidal Products (R4BP) .

Starting March 2009, detailed instructions in SK and EN languages with all necessary links to the related EU web pages are placed on the CCSP web page: <http://www.ccsp.sk/biocides/pages/englishbio.html>

For more specific information the applicants are advised to use the CCSP electronic Help-Desk: <http://helpdesk.ccsp.sk/> .

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proposes to amend the existing version of the document on the post-Annex I procedure by adding the words “or a letter of intention” to the second bullet point of Article 2.1.1 Submission of application. This will avoid possible misunderstandings in the future and at the same time it will enable the CCSP to meet the harmonized time frames as proposed by the above mentioned document.

## UK:

The Biocidal Products Directive is implemented in the UK in the Biocidal Products Regulation (BPR).

For products already on the market which contain existing active substances, the BPR (Schedule 13) defines transitional arrangements. These allow the applicant to submit authorisation applications up to 3 months after the date of inclusion in Annex 1. The applicant must request a Certificate of Exemption (CoE), which exempts their product from the requirements of BPR, to take advantage of this 3 month window. The CoE lasts until a decision on the authorisation is made (but not exceeding 3 years).

Prior to an active entering Annex 1 the company should inform us of their intention to make an application for mutual recognition within 3 months of the first authorisation being granted (a “notice of intention”). Once we have this they are issued with a CoE.

For the notice of intention we would expect to receive:

- A cover letter indicating that an application for product authorisation is being made in another Member State and mutual recognition of that product will be sought in the UK
- Copy of the R4BP form (part 1)

When the formal application for mutual recognition is made we expect to receive:

- Copy of the official authorisation granted by the reference Member State (we receive this just as evidence that the authorisation is given. We do not anticipate expecting a version in English as all relevant information will be in the Product Assessment Report).
- Copy of the Product Assessment Report by the reference Member State
- Copy of R4BP form (part 2). Until R4BP is fully operational we have our own application form for the applicants to use.
- Summary dossier (Doc I-III; on CD)
- Copy of the proposed label (and Safety Data Sheet)

Additional studies and information considered essential to the assessment may be requested on an ad-hoc basis. The applicant will be invoiced at some stage during the evaluation.

We prefer to receive all documentation in electronic form (including e-mail where appropriate) wherever possible, and documents should be in English.

## ANNEX

