This document has not been updated since April 11, 2014. It may contain inaccurate information and broken links. A revision is in progress and the document will be updated shortly.

Guidance on applying for authorisation of biocidal products

- according to Swedish rules

This document is available on the Swedish Chemicals Agency website

www.kemikalieinspektionen.se/en/
Updates
KemI continuously updates this guidance document. Dates and major changes will be reported here.

<table>
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<tr>
<td>2014-04-11</td>
<td>page 35, revision regarding mosquito repellants</td>
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<tr>
<td></td>
<td>page 42, text amendment as the Public Health Agency of Sweden has taken over the responsibility for So-licencing,</td>
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<tr>
<td></td>
<td>page 53, added link to the Public Health Agency of Sweden</td>
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<tr>
<td>2013-09-02</td>
<td>Updates and revisions throughout the document with respect to the new EU Biocidal Products Regulation and the new fees for biocidal products, which are valid from 1 September 1, 2013</td>
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<tr>
<td>2013-03-08</td>
<td>page 23, updated information with respect to that a new regulation concerning charges for pesticides will enter into force, Fees for Pesticides (2013:63) Ordinance</td>
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<tr>
<td>2013-01-30</td>
<td>page 15, text amendment regarding the exemption for product type 19</td>
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<td>page 17, Figure 2 is updated with “application according to the Biocidal Products Regulation”</td>
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<tr>
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<td>page 18, updated information about transitional provisions</td>
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<tr>
<td>2012-10-03</td>
<td>page 27-29, the ID for several application forms has been added. The ID is searchable on the KemI website</td>
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<td>page 47, text amendment regarding guidelines for Class 3 (section 9.3.1.1) and distinction between Class 1 and 2 (section 9.3.1.2)</td>
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<tr>
<td>2012-05-09</td>
<td>Section 3.1.5.3, Exemption for special reasons is removed as KemI according to the Environmental Code only has the authority to grant exemptions in individual cases where &quot;exceptional reasons&quot; exist</td>
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<tr>
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<td>page 20, text amendment regarding notification of additional name</td>
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<td></td>
<td>page 39, link to guidance document on exposure estimates for animals</td>
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<td></td>
<td>page 40, updated text on residual concentrations in exposed food, feedstuffs or food-producing animals</td>
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<tr>
<td></td>
<td>page 47, additions concerning biocidal products that are not suitable to be placed in Class 3</td>
</tr>
<tr>
<td></td>
<td>page 47, additions concerning the distinction between Class 1 and 2</td>
</tr>
<tr>
<td>2011-11-11</td>
<td>Original document</td>
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1 Introduction

This guidance document is intended to be used as an aid for those who plan to apply for authorisation according to Swedish rules for placing a biocidal product on the Swedish market or for those who plan to apply for renewed authorisation, an extended area of use or other changes in conditions for a biocidal product that has already been authorised. Guidance is also given on applying for exemptions and notifications of additional names for biocidal products.

The document also contains information about the rules applicable to biocidal products that are currently exempt from the requirement for authorisation.

Continuous work is in progress on harmonisation of the authorisation procedure for biocidal products in the EU, and certain requirements and conditions described in this document may consequently change. This guidance will be updated as work continues, and the Swedish Chemicals Agency (KemI) therefore recommends you to use the electronic version of the guidance available on the KemI website www.kemikalieinspektionen.se.

This guidance document does not provide guidance for the application for authorisation of biocidal products in accordance with the rules of the new Biocidal Products Regulation (Regulation (EU) No 528/2012) which is valid from 1 September 2013. More information about the new Regulation can be found on the European Chemicals Agency ECHA’s website and will also be published on the KemI website.

2 General information about biocidal products

2.1 What is a biocidal product?

A biocidal product is defined in the Environmental Code (1998:808)\(^1\) as a chemical or biological pesticide which is intended to prevent or deter animals, plants or microorganisms, including viruses, causing damage or detriment to human health or damage to property. Examples of biocidal products that can be mentioned are wood preservatives, repellents, rodenticides and antifouling paints for boats.

Products that are used to protect plants are not regulated as biocidal products, but rather as plant protection products.

There are 22 different types of biocidal products, see Table 1 below. The new EU Biocidal Products Regulation includes 22 product types instead of the 23 previously included in the Biocidal Products Directive. Product type 20 in the Directive, \(^1\) Biocidal products are defined in Chapter 14 in the Environmental Code and include both chemical and biological products. In this guidance the active substance refers to both chemical substances and microorganisms, including viruses or fungi.
preservatives for food or feedstocks, has been deleted. Product type 20 in the Regulation is the former product type 23, control of other vertebrates. Also the names of the product types and their descriptions have in some cases been changed. For more detailed descriptions of the product types see Annex V to the EU Biocidal Products Regulation (Regulation (EU) No 528/2012).

Table 1. List over the 22 product types listed in the EU Biocidal Products Regulation (Regulation (EU) No 528/2012)

<table>
<thead>
<tr>
<th>Product type</th>
<th>Description of product type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main group 1: Disinfectants</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Human hygiene</td>
</tr>
<tr>
<td>2</td>
<td>Disinfectants and algaecides not intended for direct application to humans or animals</td>
</tr>
<tr>
<td>3</td>
<td>Veterinary hygiene</td>
</tr>
<tr>
<td>4</td>
<td>Food and feed area</td>
</tr>
<tr>
<td>5</td>
<td>Drinking water</td>
</tr>
<tr>
<td><strong>Main group 2: Preservatives</strong></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Preservatives for products during storage</td>
</tr>
<tr>
<td>7</td>
<td>Film preservatives</td>
</tr>
<tr>
<td>8</td>
<td>Wood preservatives</td>
</tr>
<tr>
<td>9</td>
<td>Fibre, leather, rubber and polymerised materials preservatives</td>
</tr>
<tr>
<td>10</td>
<td>Construction material preservatives</td>
</tr>
<tr>
<td>11</td>
<td>Preservatives for liquid-cooling and processing systems</td>
</tr>
<tr>
<td>12</td>
<td>Slimicides</td>
</tr>
<tr>
<td>13</td>
<td>Working of cutting fluid preservatives</td>
</tr>
<tr>
<td><strong>Main group 3: Pest control</strong></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Rodenticides</td>
</tr>
<tr>
<td>15</td>
<td>Avicides</td>
</tr>
<tr>
<td>16</td>
<td>Molluscicides, vermicides and products to control other invertebrates</td>
</tr>
<tr>
<td>17</td>
<td>Piscicides</td>
</tr>
<tr>
<td>18</td>
<td>Insecticides, acaricides and products to control other arthropods</td>
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<tr>
<td>19</td>
<td>Repellents and attractants</td>
</tr>
<tr>
<td><strong>Main group 4: Other biocidal products</strong></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Control of other vertebrates</td>
</tr>
<tr>
<td>21</td>
<td>Antifouling products</td>
</tr>
<tr>
<td>22</td>
<td>Embalming and taxidermist fluids</td>
</tr>
</tbody>
</table>
2.2 Legislation on biocidal products

The Swedish Chemicals Agency is the authority responsible for evaluating and making decisions regarding authorisation of biocidal products in Sweden. The requirements for authorisation are contained in Chapter 14 of the Environmental Code (1998:808) and in the EU Biocidal Products Regulation (EU) No 528/2012. The Biocidal Products Regulation came into effect on 1 September 2013, at which date the Biocidal Products Directive 98/8/EC was revoked. At the same time, certain Swedish rules had to be amended or revoked. EU regulations apply directly without first having been implemented into Swedish regulations. In some cases, transitional provisions apply.

The purpose of the EU Biocidal Products Regulation is to harmonise the internal market for biocidal products in the EU and ensure a high level of protection for humans, animals and the environment. During a transitional period the Member States may however continue to apply their national rules. Therefore, the requirements for product authorisation may differ between the countries during this time.

Biocidal products whose active substances have been authorised within the EU are regulated by the EU Biocidal Products Regulation. More information about the new Regulation can be found on the European Chemicals Agency ECHA’s website and will also be published on the KemI website.

The procedure for evaluating biocidal products according to older, national provisions is regulated in the Biocidal Products Ordinance (2000:338) and the Swedish Chemicals Agency’s Pesticides Regulations (KIFS 2008:3).

2.3 Evaluation of active substances in the EU

Biocidal products may contain chemical substances or microorganisms, including viruses or fungi, as active substances. All the formal requirements and the main principles of risk assessment are the same for the two types of active substances, although certain details differ. Special account must be taken of the biology of the microorganisms, which differentiates the assessment of biocidal products containing these from those containing chemical substances.

[2 Articles 8-10 Biocidal Products Ordinance (2000:338)]
[3 Chapter 4, Article 9-12 KIFS 2008:3]
The Biocidal Products Directive introduced a work programme for the review of all active substances in biocidal products on the market on 14 May 2000. Existing active substances were identified in the first phase⁴. Some of these⁵ were notified for evaluation by stakeholders, who presented documentation as a basis for the evaluation. The deadline for notification of active substances to the work programme was 28 March 2002. After this date, biocidal products containing non-notified active substances were recalled.

Notified active substances are currently being reviewed and evaluated in a particular order by competent authorities (CA) in so called Rapporteur member States in the EU. The RMS writes a report (CA-report) and recommends a decision to be taken to approve or not approve the substance. Authorised active substances are included in a list published by the European Commission.

Official CA-reports are published on the European Commission website for biocides.

Official documents to CA meetings and other working parties within the process of evaluation of active substances and the implementation of EU legislation are also published at the European Commission website CIRCABC.

2.3.1 Active substances evaluated in the work programme

Steps to find out what active substances are examined in the work programme are:

Step 1 – Search for the active substance in Annex II to Regulation (EC) No 1451/2007 (substances to be examined). Take note that the substance must have been notified in the product type to which the biocidal product belongs.

Step 2 – If the active substance in the product is included in Annex II, consult the European Commission website for biocides to see if there is a Commission decision to allow or not allow the substance for use in biocidal products. The decision makes it clear what applies to products containing the substance. The decisions are included in a list electronically published by the European Commission.

If a product contains an active substance that is not included in Annex II or if there is a decision that the substance is not allowed to be used in biocidal products, the biocidal product is not allowed to be placed on the Swedish market. This also applies to products which at present are exempted from the requirement for approval.

2.3.2 Decision to approve an active substance in accordance with the EU Biocidal Products regulation

For an active substance to be approved, it must have been evaluated with regard to effects on health and the environment. If an active substance is approved, the Commission adopts an implementing regulation. This regulation gives the approval date and when it expires, and any conditions for biocidal products containing the

⁴ The active substances contained in biocidal products on the market on 14 May 2000 were identified as “existing substances”. Deadline for this identification was 28 March 2002. See Article 3.1 Regulation (EC) No 1896/2000

⁵ See the list of notified substances in Annex II, Regulation (EC) No 1451/2007
active substance. The implementing regulations are published in the Official Journal of the European Union, EUT. The European Commission website for biocides contains a list of all the active substances for which a decision to approve the substance has been taken.

2.3.3 Decision not to approve an active substance according to the EU Biocidal Products

Decisions on non-approval of an active substance are published in the Official Journal of the European Union, EUT. After twelve months from the day the decision was published, biocidal products containing such an active substance are no longer allowed to be placed on the market for the product types concerned, unless otherwise stated in the decision. The Swedish Chemicals Agency may grant respite for use, storage, sale and disposal of remaining stocks.

2.3.4 New active substances

When active substances that are not identified as “existing substances” are to be used in biocidal products they are referred to as “new active substances”. Before a new active substance may be used in a biocidal product it must also be evaluated by the Member States. Applications for evaluation of such a substance are submitted to any chosen Member State. Applications may be submitted by companies, Member States or other stakeholders. The procedure is the same as for existing substances. Anyone wishing to have a new active substance evaluated by Sweden should contact the Swedish Chemicals Agency.

2.4 Which biocidal products require authorisation?

The principal rule in Sweden is that all biocidal products must be authorised to be placed or used on the Swedish market.

One condition for authorisation of a biocidal product is that the active substances in the biocidal product are among the substances included in the EU work programme for existing substances. It is therefore important to find out whether the active substances in a product are included in the programme.

Step 1 – Search for the active substance in Annex II to Regulation (EC) No 1451/2007 (substances to be examined). Take note that the substance must have been notified in the product type to which the biocidal product belongs.

Step 2 – If the active substance in the product is included in Annex II, consult the the European Commission website for biocides to see if there is a Commission decision to allow or not allow the substance for use in biocidal products. The decision makes it clear what applies to products containing the substance. The decisions are included in a list electronically published by the European Commission.
If a product contains an active substance that is not included in Annex II, or if there is a decision that the substance is not allowed to be used in biocidal products, the biocidal product is not allowed to be placed on the Swedish market. This also applies to products which at the present situation are exempt from the requirement for authorisation. Note that there is another exemption for certain repellents and attractants, see Table 2.

The type of evaluation required for a biocidal product depends on how far the assessment of the active substance/microorganism has progresses in the EU. See Figure 1 to find out if the application for authorisation should be made in accordance to the EU Biocidal Products Regulation or according to Swedish rules.

Certain product types are, however, at present exempt from the requirement for authorisation. These product types are listed in Chapter 4 of KIFS 2008:3 and in Table 2. However, authorisation requirements apply to certain products in the exempted product types.

One condition for using the exemption from the requirement for authorisation is that the active substances in the biocidal product are among the substances included in the EU work programme for existing substances. The exemption from the requirement for authorisation only applies until the active substance in an exempted product type is approved according to the EU Biocidal Products Regulation.

Biocidal products that today do not need to be authorised before being placed on the market are nevertheless regarded as biocidal products and have to be labelled in accordance with the rules for biocidal products with effect from 1 July 2011, see Chapter 10.2. Please note that other laws and regulations that apply to chemical products also apply to all chemical biocidal products (no matter if they need to be authorised or not), see Chapter 11.5.

Biocidal products whose active substances were not on the market before 14 May 2000 (i.e. “new active substances”) and are being evaluated as active substance but are not yet approved according to the EU Biocidal Products Regulation may be granted temporary authorisation in Sweden.

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6 In order to make gradual phase-out possible, the products exempted from the requirement for authorisation were nevertheless offered for sale and transferred until 31 December 2010 and used up to 31 December 2011, despite they contained active substances not included in the work programme.

7 Chapter 4, Article 4 a-c KIFS 2008:3
Table 2. Product types at present exempt from the requirement for authorisation and a description of the products not covered by the exemption

<table>
<thead>
<tr>
<th>Exempt product types</th>
<th>Biocidal products that must be authorised to be placed at the Swedish market. I.e. products within the product type NOT covered by the exemption(^8)</th>
</tr>
</thead>
</table>

**Main group 1: Disinfectants**

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<tbody>
<tr>
<td>1</td>
<td>Human hygiene</td>
</tr>
<tr>
<td>2</td>
<td>Disinfectants and algaecides not intended for direct application to humans or animals</td>
</tr>
<tr>
<td>3</td>
<td>Veterinary hygiene</td>
</tr>
<tr>
<td>4</td>
<td>Food and feed area</td>
</tr>
<tr>
<td>5</td>
<td>Drinking water</td>
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</table>

**Main group 2: Preservatives**

<p>| | |</p>
<table>
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<tr>
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<tbody>
<tr>
<td>6</td>
<td>Preservatives for products during storage</td>
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<tr>
<td>7</td>
<td>Film preservatives</td>
</tr>
<tr>
<td>9</td>
<td>Fibre, leather, rubber and polymerised materials preservatives</td>
</tr>
<tr>
<td>11</td>
<td>Preservatives for liquid-cooling and processing systems</td>
</tr>
<tr>
<td>12</td>
<td>Slimicides</td>
</tr>
<tr>
<td>13</td>
<td>Working of cutting fluid preservatives</td>
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</tbody>
</table>

**Main group 3: Pest control**

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>19</td>
<td>Repellents and attractants</td>
</tr>
<tr>
<td></td>
<td>See information below regarding the exemption from the requirement for authorisation for some attractants and repellents</td>
</tr>
</tbody>
</table>

**Main group 4: Other biocidal products**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>20</td>
<td>Control of other vertebrates</td>
</tr>
<tr>
<td>22</td>
<td>Embalming and taxidermist fluids</td>
</tr>
</tbody>
</table>

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\(^8\) Chapter 4, Article 4 KIFS 2008:3
The 14 May 2010, a new exemption from the requirement for authorisation and use of certain biocidal products in product type 19 (repellents and attractants) whose active substances consist solely of food or feed was implemented in the Swedish Chemicals Agency’s Regulations (KIFS 2008:3) by the amended regulation KIFS 2010:2. The exception was the basis of Article 6, Regulation (EC) No 1451/2007. What is meant by human or animal consumption in the application of the exemption is provided in Article 6, Regulation (EC) No 1451/2007 and reads:

"any edible substance or product of plant or animal origin, whether processed, partially processed or unprocessed, which is intended or reasonably expected to be ingested by humans or animals; this category does not comprise extracts or individual substances isolated from food or feed"

This means that certain biocidal products containing active substances consisting solely of food or feed no longer need to be authorised by the Swedish Chemicals Agency before they can be sold. This exemption applies to biocidal products intended to attract or repel harmful organisms. This exemption applies to edible substances and products which are of plant or animal origin, and that humans and animals can be expected to eat. Foods that are unsuitable, unfit or harmful is not covered by the exemption. For the exemption to apply, it is for the individual to prove that:

- The amount of the active substance in the product, used at a specific time, reasonably can be ingested by a person or an animal at that same time, for example by referring to food on the market where the active substance is in the corresponding amount.

The products concerned are for example marketed as repellents against such as mosquitoes and gnats. The products are often based on different kinds of oils, spices, etc. Although they are excluded from the authorisation requirement, they are still considered under common EU rules for biocidal products and included in product type 19, according to the Biocidal Products Directive. The packaging of these products must be labelled accordance with KIFS 2005:7 or Regulation (EC) 1272/2008, and the Chapter 4, Article 6 third paragraph KIFS 2008:3 as of July 1, 2011.

The manufacturer has the responsibility to see to that the products do not present a danger to health or the environment. However, without an evaluation of an application it is not possible for KemI to ensure that such products have no adverse side effects or how effective such products really are. These are matters that KemI normally assess when the products are evaluated for authorisation, based on the data submitted by the applicant.

Note that for products covered by this exemption to the requirement of authorisation, the active substances must not be notified and under review in the EU work programme.
### 3 Choice of product authorisation

Use the figure and text below to find out the right choice of product authorisation depending on how far the assessment of the active substance has progressed in the EU.

*Please note that for some biocidal products, the rules for biocidal products does not apply, e.g. food or feed used as repellents or attractants. Please see Article 2 in the Biocidal Products Regulation (Regulation (EU) nr 528/2012).

** Please note that Annex I to the new Biocidal Products Regulation does not correspond to Annex I in the Biocidal Products Directive (98/8/EC).

*** All active substances must be in the work programme for use in the relevant product type. If the active substance is being evaluated as a so called new active substance, there can in some cases be a possibility to apply for a temporary authorisation. Special rules can also apply for some in situ generated biocidal products, please see Article 93 in the Biocidal Products Regulation (regulation EU (nr) 528/2012).

**** Please see the rules for exemption in Chapter 4, Section 4 KIFS 2008:3

Figure 1. Flowchart for type of application for authorisation of biocidal product depending on the status of the active substance in the work programme.
When all the active substances in a biocidal product have been authorised according to the EU Biocidal Products Regulation, applications for a product authorisation shall be made according to that regulation. Applications of this type will not be described in more detail in this guidance document, see instead the guidance for applications for authorisation of biocidal products according to the Biocidal Products Regulation on the KemI website.

If the biocidal product requires an authorisation and contains active substances included in the EU work programme for active substances, but which has not yet been authorised in accordance with the EU Biocidal Products Regulation, applications for a new authorisation or a re-authorisation of the product shall be made according to previous Swedish rules. Applications according to Swedish rules are dealt with in this guidance document. There are also a number of other application matters that are addressed in this guidance document, such as changes of conditions, exemptions and notifications of additional names.

### 3.1 Transitional provisions

As from 1 September 2013, an application for product authorisation or mutual recognition of a biocidal product in accordance with the EU Biocidal Products Regulation shall be submitted by the date of the last authorised active substance in order for the biocidal product to be allowed to remain on the market. If no application is submitted at the latest on this date, the product may be supplied on the market no longer than 180 days after the date of authorisation of the active substance that was last authorised. Available stocks may be disposed of and used no longer than 365 days after the same date.

If the date for inclusion of the active substance in a biocidal product has taken place before 1 September 2013, relevant biocidal products already authorised in Sweden according to Swedish rules may remain on the Swedish market as long as the authorisation is valid, however no longer than the last date for decisions on reauthorisation in accordance with the EU Biocidal Products Regulation.

### 3.2 Different types of applications

KemI can only issue authorisations according to Swedish rules until the day before date for inclusion of the active substance in the product. This means that an application for new or renewed authorisation of a biocidal product according to Swedish rules must be submitted to KemI no later than 12 months before the inclusion date to enable the Agency to handle it in time.

#### 3.2.1 New authorisation

The documentation described in Chapter 5 has to be submitted with the application, and the data requirements and guidance documents applicable at the time of application must be followed. An authorisation issued according to Swedish rules applies only in Sweden and cannot be mutually recognised in other EU Member States.
3.2.2 Temporary authorisation

Biocidal products whose active substances were not on the market before 14 May 2000 (“new substances”) and are being evaluated as active substance but not yet authorised according to the EU Biocidal Products Regulation may be granted temporary authorisation. However, such a temporary authorisation may be valid for no longer than three years. The conditions to be met for temporary authorisation are that KemI, after evaluation, has to consider the active substance to fulfil the requirements set for an active substance to be authorised according to the EU Biocidal Products Regulation, and that the assessment of the product shows that the risks to the environment and health are acceptable. The same requirements apply to applications for authorisation of a biocidal product whose active substance is a “new substance” as for an application for authorisation for a product containing all the active substances authorised according to the EU Biocidal Products Regulation.

3.2.3 Renewed authorisation

KemI sets the same requirements for documentation and risk assessment in applications for renewed authorisation as in applications for a new authorisation. For documentation requirements, see Chapter 5. The data requirements and guidance documents applicable at the time of application for renewed authorisation have to be followed unless KemI has indicated otherwise. If a change of conditions for the biocidal product has to be made in conjunction with an application for continued authorisation, this must be highlighted in the application form.

Unless otherwise indicated by KemI, an application for renewed authorisation should, as a rule, be submitted to KemI approximately two years before the authorisation expires so that uninterrupted authorisation can be anticipated. It is generally stated in the relevant decision on authorisation when an application for continued authorisation has to be submitted at the latest.

3.2.4 Changes of conditions

For applications for all types of changes of conditions the application form for change of conditions for a biocidal product should be used, see Chapter 5. The form must be signed and submitted in original form. Attach also necessary documentation.

3.2.4.1 Change regarding conditions of use

In general, a new assessment of the product is triggered by a change regarding conditions of use. Examples of this type of changes of conditions are:

- Change of packaging conditions.
- New or more extensive area of use.
- Change of dosage and method of application.
- Change in composition of ingredients in the preparation. Documentation showing how the change affects the formulation, classification, directions for

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9 Article 55.2 EU Biocidal Products Regulation (EU) No 518/2012
use and other conditions is needed. If the change has too great impact, this may mean that it cannot be implemented under the applicable authorisation. The application for change will in this case be regarded as a new product application.

- Change in ingredients of the preparation for which labelling is mandatory or which are of toxicological/ecotoxicological relevance
- Minor change in concentration of active substance. Major changes to the concentration of active substance are not covered by changes of conditions and require a new product application.

3.2.4.2 Other changes

Other changes of conditions which as a rule do not require a new assessment of the product are, for example:

- Change of authorisation holder. A signed letter from the old authorisation holder certifying that the latter wishes to transfer the product and a letter from the new authorisation holder certifying that they wish to be the authorisation holder are required. In addition, a registration certificate for the new authorisation holder/company may be required (see Chapter 5.11).
- Change of representative. A letter of appointment from the authorisation holder is required (see 5.10), as well as a registration certificate for the new representative (see Chapter 5.11).
- Changes of address and change of company name. New registration certificate is required (see Chapter 5.11).
- Change of name of product. Note that a biocidal product must not be given a name that can be considered misleading with regard to the product's composition, mechanism of action or other characteristics or can lead to confusion with another pesticide\(^\text{10}\).

3.2.5 Exemptions

KemI can grant an exemption in the individual case, i.e. grant exemptions from the authorisation requirement for pesticides\(^\text{11}\). An exemption can only be permitted if there are special reasons and is not to be used as a substitute for authorisation.

A decision on exemption has to be associated with the conditions needed with respect to protection of human health or the environment or pursuant to the EU Biocidal Products Regulation. An application may be made for exemption by anyone who wishes to use or place a biocidal product on the Swedish market. Exemptions are always granted for a limited time. Use the application form for exemptions for

\(^\text{10}\) Article 10 Biocidal Products Ordinance (2000:338)

\(^\text{11}\) Article 55 and 56 EU Biocidal Products Regulation (EU) No 518/2012
biocidal products when applying for exemption, see Chapter 5. The form must be signed and submitted as the original. Attach also necessary documentation.

### 3.2.5.1 Exemption for research and development purposes

An exemption must be applied for if anyone wishes to use a biocidal product that is not authorised in Sweden for research and development purposes, for example efficacy tests, and the trial results in a release to the environment\(^\text{12}\). Scientific trials must not be a covert use, and exemptions are therefore normally not granted for large-scale trials. A description of the trial, information about the quantity of the product to be used and information on the toxicity of the substance must be submitted with the application.

### 3.2.5.2 Exemption for limited and controlled use for a maximum of 120 days

Exemptions may be granted for limited and controlled use for a maximum of 120 days if it appears necessary because of an unforeseen danger that cannot be counteracted in any other way. The applicant must state in the application why the exemption is applied for, what area of use the application covers, the number of repeated treatments, the time of treatment and possible waiting period. Information on the quantity of product to the use, information on the toxicity of the substance and a risk assessment for intended use must also be submitted with the application.

### 3.2.6 Notification of additional name

Notification of additional name must be submitted to the Swedish Chemicals Agency for an approved product to be released on the market under a different name than the one stated in the approval. Section 7 of the Biocidal Products Ordinance (2000:338) gives details on the content of the notification. Notification of the additional name must be reported by the company that will be responsible for placing the biocidal product on the market in Sweden under the proposed additional name. When an additional name has been notified, the product may be released on the market under this name also by other parties than the company that notified it, but the notifying company is the only one allowed to withdraw the name.

For notifications of additional names, use the application form for notification of additional names for biocidal products, see Chapter 5. The original form must be signed and submitted. Attach also necessary documentation.

A confirmation of additional name will always be sent to the notifier, whether it is the holder of the product authorisation or another company. The additional name is entered into a register which is accessed through the Swedish pesticides register that can be found on the KemI website.

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\(^{12}\) Article 56 EU Biocidal Products Regulation (EU) No 518/2012
4 To apply

KemI prefers applications and document to be sent as electronic documents on CD or similar medium. However, application forms, letters of appointments and permissions to use documentation (“Letters of Access”) must always be received on paper and signed. For more information on application forms, see Chapter 5.

Applications and associated documentation should be sent to:

Address:
Swedish Chemicals Agency
Pesticides and Biotechnical Products
Box 2
SE-172 13 Sundbyberg
Sweden

Studies and documentation already available at KemI need not be submitted again. However, applications must contain clear references to the previous applications for which the documentation has already been submitted. Further information on what documentation is required for the different types of applications can be found in Chapter 5 and 6.

4.1 Fees

KemI’s fees for application matters and annual fees are governed by the Ordinance (1998:940) on Fees for Pesticides (2013:63) Ordinance (in Swedish) and are summarised on the KemI website.

4.1.1 Application fees

Anyone applying for authorisation of a pesticide shall pay an application fee. The same applies in the case of renewal of authorisation, amendment of a product authorisation, parallel trade permit, extension of authorisation for minor uses and application for a derogation to use or sell pesticides.

When your application has been filed at KemI, this will be confirmed by a letter or a decision on application fee and an invoice. The letter provides details on the amount to be paid and how to pay it. Please do not pay the fee until you have received this letter or invoice. In most cases, we can not start handling your matter until we know that the correct fee has been paid.

4.1.2 Annual fee for pesticides

The person who has had a pesticide authorised, or the person who represents the holder of an authorisation during the term of the authorisation (“permanent representative”) has to pay an annual fee. An annual fee shall also be paid by those who have received a parallel trade permit for a plant protection product or a biocidal product.

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13 KemI accepts format compatible with Microsoft Office and Adobe Acrobat
The annual fee shall be paid every year from the calendar year following the year when the product was authorised until the calendar year when the authorisation ceases to apply.

The Swedish Chemicals Agency sends out a request for accounting of sales values for the previous year. Information on the sales value of chemical and biological plant protection products and biocidal products should be reported separately. Thereafter, the Swedish Chemicals Agency sends a decision on annual fee including an invoice based on the reported sales values.

4.2 Applicant/authorisation holder/representative

4.2.1 Applicant/future authorisation holder

Under Article 8 of the Ordinance (2000:338) on biocidal products, an application for authorisation or amendment of an authorisation has to be made by the person or on behalf of the person who is responsible or will be responsible for the product first being placed on the market in Sweden. The person who is responsible for first placing of a product on the market is thus the person who is to be stated as the applicant in an application, and who in a decision on authorisation will be the future holder of the authorisation. The future holder of the authorisation has to have a permanent office in a country in the EU or the European Economic Area (EEA: EU + Norway, Iceland and Liechtenstein).

If the intended holder of an authorisation is a company outside the EEA, any of the following parties can be responsible for the application (i.e. be responsible for the product first being placed on the market in Sweden):

- A branch office, i.e. a departmental office with independent administration: first paragraph of Article 2 of the Foreign Branch Offices Act (1992:160).
- A representative resident in the EEA with responsibility for the activity pursued in the EU: second paragraph of Article 2 of the Foreign Branch Offices Act (1992:160); but the representative then becomes the holder of the authorisation and responsible for the product first being placed on the market in Sweden.
- A subsidiary (separate legal entity) with a permanent office in the EEA; but the subsidiary then becomes the holder of the authorisation and responsible for the product first being placed on the market in Sweden.
- A commission agent (someone who carries out legal actions on behalf of another but in his own name; Government Bill 2008/09:88, p. 29); but the

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14 Note that in the EU commission’s joint database for applications for authorisation and mutual recognition in accordance with Biocidal Products Directive, R4BP, the term applicant is used to name the individual whom in behalf of the company submits the application, while the one who is supposed to hold the authorization is called future registration holder.
commission agent then becomes the holder of the authorisation and responsible for the product first being placed on the market in Sweden.

4.2.2 Representative

The applicant may conduct its case through a representative. The representative then represents the person who is responsible or will be responsible for the product first being placed on the market in Sweden. A representative may be a temporary representative for the actual application procedure or a permanent representative who represents the holder of an authorisation during the term of the authorisation until the holder decides that that the relationship is to cease.

A representative must always verify his authorisation through written letter of appointment in original form from the applicant, see Chapter 5.10. If the representative’s rights are limited, this has to be apparent in the letter of appointment. Otherwise KemI will assume that the representative represents the applicant in everything that relates to the application and the authorised product and all communication on the part of the authority takes place with the representative. If there is contradictory information on who KemI is to communicate with, this information is to be checked. If there is a representative who has verified his authorisation with granted letter of appointment, KemI will communicate with the representative, otherwise with the applicant. To summarise, a representative can wholly or partially conduct the applicant’s case and, for example, receive documents and decisions (note: in this context also decisions with acknowledgement of service) depending on which rights are contained in the letter of appointment from the applicant.

The authorisation holder is always the one who is responsible or will be responsible for the product first being placed on the market in Sweden. If it is intended that the assignee (representative) will actually be responsible for the product first being placed on the market, the assignee has to hold the authorisation. The assignee is then not a representative in the matter within the meaning of the Administration Act (1986:223) but must itself be stated as the applicant.

5 Application documents and data requirements

All application forms are available on the KemI website.

- For application of authorisation or renewed authorisation of a biocidal product or registration of a low-risk biocidal product the following are available:
  - “Application for authorisation of a biocidal product according to Swedish rules”: This form is common to both chemical biocidal

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15 Article 9 the Administration Act (1986:223)
products and the biological biocidal products where the active substance is a microorganism, including viruses or fungi.

- Associated A, B and C forms: These forms differ depending on whether the application applies to a chemical biocidal product or a biological biocidal product where the active substance is a microorganism, including viruses or fungi.

- Special forms are used for changes of conditions, exemptions and notifications of additional names for biocidal products.

- Applications for authorisation of pesticides where nematodes, insects and arachnids are used are made in the form of a letter based on the data requirements described in Chapter 7.3.

Confidential information may be submitted on the application forms and need not be placed in a separate Annex. However, if placed in a separate Annex, clear references must be made in the applications forms.

Note that clear reference must be made to the studies and documents that underlie the information on which the application is based. All studies on which an application is based must be available at KemI. Studies and documentation already available at KemI need not be submitted again. However, applications must contain clear references to the previous applications for which the documentation has already been submitted. In cases where the applicant refers to another party’s documentation also a permission (“Letter of Access”) showing that the applicant has the right to use or refer to the documentation of another party must be submitted, see Chapter 5.9.

When reference is made (through Letter of Access, see Chapter 5.9) to studies that underlie the evaluation of an active substance (sometimes called the “BPD dossier”), these studies must also be submitted to/present at KemI in their entirety (i.e. document IV\textsuperscript{16}). Submission solely of summaries of these studies (i.e. document III\textsuperscript{17}) can only be accepted if at least a draft of the competent authority report is available (“Draft CAR"\textsuperscript{18}).

5.1 Application for authorisation of a biocidal product according to Swedish rules (MIP-0001-E)

This form is common to both chemical biocidal products and the biological biocidal products where the active substance is a microorganism, including viruses or fungi.

The formal parts of the application should be filled in, such as the name of the biocidal product, what active substances it contains and what product type it belongs to. Information on the applicant and any representative should also be filled in, as

\textsuperscript{16} The part of the Competent Authority’s Report (CA-report) or the submitted dossier which consists of studies/reports in its entirety

\textsuperscript{17} The part of the Competent Authority’s Report (CA-report) or the submitted dossier which consists of summaries of studies/reports

\textsuperscript{18} CAR = Competent Authority Report
well as which documentation is available on the biocidal product and its active substances.

Note that a biocidal product must not be given a name that can be considered misleading with regard to the product’s composition, mechanism of action or other properties or can lead to confusion with another pesticide.19

This form must be signed by a person who has the right to represent the company and has to be submitted as a paper original.

5.2 A-form (information on active substance in the chemical or biological biocidal product)

In the A-form information on the active substances contained in the biocidal product is to be filled in. If certain information is not provided, because it is not considered necessary from the scientific point of view or is not technically possible to obtain, clear reasons for this are to be stated instead. Clear references to the documentation where the stated properties/values are described are to be given in the form.

If the product contains more than one active substance, one A-form per active substance should be filled in and submitted.

There are references in the form to the applicable guidance documents.

5.3 B-form (information about the chemical or biological biocidal product)

In the B-form information on the chemical or biological biocidal product is to be filled in. If certain information is not provided, because it is not considered necessary from the scientific point of view or is not technically possible to obtain, clear reasons for this are to be stated instead. Clear references to the documentation where the stated properties/values are described are to be given in the form.

There are references in the form to the applicable guidance documents.

5.4 C-form (risk assessment of the chemical or biological biocidal product)

In the C-form a quantitative health risk assessment and environmental risk assessment for the chemical or biological biocidal product is to be filled in. A quantitative risk assessment is a method used to estimate the risk of an adverse impact of a natural or synthetic chemical/microorganism, including viruses or fungi, on humans, animals or the environment. Information on exposure to the product is needed to be able to do this in practice. As measured data are rarely available, the exposure is instead estimated using mathematical models. Mathematical models for human exposure can be found on the European Commission Joint Research Centre.

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19 Article 10 Biocidal Products Ordinance (2000:338)
website\textsuperscript{20}. The latest version of the exposure models is from 2007 and should primarily be used. Another exposure model for humans is ConsExpo (Consumer Exposure), which is on the RIVM website\textsuperscript{21}. This exposure model is principally used for non-professional use of biocidal products. Mathematical models for environmental exposure can also be found on the European Commission Joint Research Centre website\textsuperscript{22}. Clear references to the documentation from which the effect values used are taken must be given.

There are references in the form to the applicable guidance documents. The guidance documents that exist are not fully adapted to biological biocidal products, but the fundamental principles are the same for chemicals and microorganisms, including viruses or fungi, for use in biocidal products.

5.5 Application for change of conditions for biocidal product (MIP-0010-E)

This form is common to both chemical and biological biocidal products. Information on the name and registration number of the approved product, as well as information on the change of condition applied for should be filled in. Information on the applicant and available necessary documentation for the change of condition should also be stated in the form.

5.6 Application for exemption for biocidal product (MIP-0002-E)

This form is common to both chemical and biological biocidal products. The form is intended to support applications for all kinds of exemptions. Hence, not all of the fields are applicable for all types of exemptions.

5.7 Notification of additional name for a biocidal product (MIP-0003-E)

This form is common to both chemical and biological biocidal products. The name of the authorised biocidal product and its registration number, the applicant and the desired additional name should be stated. Documentation showing that the product to be placed on the market under the additional name is essentially identical to the authorised product must be submitted and references should be given in the form.

The company wishing to market a biocidal product under an additional name must show in its notification that (according to Article 7 of Ordinance (2000:338) on biocidal products):

\begin{itemize}
\item Mathematical models for human exposure, from both 2007 and 2007, are found under the Technical Notes for Guidance (TNsG) on human exposure
\item National Institute for Public Health and the Environment, The Netherlands
\item Mathematical models for environmental exposure are found in part 2, Chapter 3 in the TGD (Technical Guidance Document): \url{http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/doc/tgd/tgdpart2_2ed.pdf}
\end{itemize}
• The composition and active substance of the product, with the same concentration, are identical to those of the authorised biocidal product. Only very small differences may be permitted.
• The product is produced using the same method as the authorised biocidal product.
• The product has the same function and characteristics as the authorised biocidal product.
• The product fulfils the same safety requirements as the authorised biocidal product.
• The product has a name that cannot lead to confusion with the biocidal product already authorised or otherwise be considered misleading with regard to its composition, mode of action or other characteristics or be capable of causing confusion with another pesticide.

If the biocidal product is identical to the biocidal product already authorised, i.e. it is only to be re-labelled, only documentation verifying this needs to be submitted. This may, for example, be a document where the authorisation holder certifies that it is the authorised product that is placed on the market under the additional name.

5.8 Reference list
For KemI to be able to apply the rules on data protection in the Ordinance (2000:338) on Biocidal Products, the right of ownership or the right to use or refer to the studies on which the application is based must be clear. The applicant must therefore attach a list of the studies to which the applicant refers in the application. This is also specified as a data requirement in both the A- and B-forms.

When referring to a CAR (Competent Authority Report) for an active substance, and the underlying studies, it must be specified to which version of this report the reference is being made. In this case no separate reference list needs to be submitted beyond that contained in the CAR.

In case the documentation to which the applicant refers is owned by someone other than the applicant, written permission is also required, see Chapter 5.9.

5.9 Permission to use another party’s documentation (Letter of Access, LoA)
Applicants who do not themselves own documentation used in support of applications shall submit permission, known as a Letter of Access, showing that they have the right to use or refer to another party’s documentation23. All documentation used in support of an application shall be sent to or be present at KemI.

23 Article 17 Biocidal Products Ordinance (2000:338)
To facilitate the handling of applications for authorisation of biocidal products and make the procedure more efficient, the following requirements are laid down for such permissions:

- The original of the permission must be sent to KemI.
- The permission must be dated.
- The permission must be signed by a person who is entitled to represent the company. Documentation verifying the right to sign may be requested.
- It must be made clearly stated which studies that are covered by the permission by attaching a reference list of protected studies.
- If the party granting permission wishes to restrict the period of time within which KemI may use the documentation, this should be clearly stated in the permission. Please note that the period of validity of the product authorisation is not affected by such a restriction.
- Note that applications may be refused if the applicant has not shown that he is entitled to use the documentation.

KemI wishes to emphasise that the permission may form the basis for the issuing of a product authorisation, but that revoking the permission does not mean that the decision on authorisation is revoked. An authorisation is a positive administrative decision which can only be revoked under certain conditions, stated in the legislation\(^2^4\). KemI cannot revoke an authorisation on the grounds of a contract clause between the granter of permission and another party such as “this permission is only valid for such time as a valid contract exists between X and Y”.

As indicated above, the applicant must therefore attach a list of protected studies informing KemI which studies are covered by the written permission. Note that this list must be attached to the permission and the application in addition to the reference list where the applicant has to specify all the studies on which the application is based, see Chapter 5.8. When referring to a CAR (Competent Authority Report) for a substance, it must be specified to which version of this report the reference is being made. In this case no separate reference list needs to be submitted beyond that contained in the CAR.

### 5.9.1 Data protection rules

Studies and reports on which a product application is based can be given data protection, provided that certain criteria are fulfilled. The rules on data protection are described in Articles 12–18 of the Ordinance (2000:338) on Biocidal Products.

Documentation that is protected may not be used by another party without permission from the owner of the documentation, known as a Letter of Access. For further information on such permissions, see Chapter 5.9.

\(^2^4\) Article 33 Biocidal Products Ordinance (2000:338) and Chapter 24, Article 3 Environmental Code (1998:808)
Studies that have been submitted to KemI for the first time to support an application under national rules receive data protection until the transitional period expires. If these studies also have been submitted to support authorisation of the active substance according to the EU Biocidal Products Regulation, the Commission has described in a guidance document how the rules on data protection can be interpreted (http://ec.europa.eu/environment/biocides/pdf/data_protection_guidance.pdf). Note that this document is not legally binding and merely represents guidance. Only a court of law can finally decide how the rules on data protection are to be interpreted.

5.9.2 Public access and confidentiality

The principle of public access to official documents means that the public have a right of access to government activities. This means that everyone, Swedish and foreign citizens, has the right to study official documents of public authorities provided they are not subject to confidentiality (the Secrecy Act (2009:400)). KemI therefore cannot make any promises to companies issuing Letters of Access that the applicant will not be allowed to read or copy the documentation. A confidentiality assessment will not be conducted until KemI receives a request to release a public document. The sections and documents which KemI judges to be covered by confidentiality under the Secrecy Act (2009:400) will not be released. Note that the right to read or copy a public document does not mean that the applicant has the right to use or refer to it in his application. This is why the permission to use another party’s documentation (“Letter of Access”) is such an important aspect in the consideration of authorisation.

For further information on the principle of public access, see the Swedish Government website.

5.10 Letters of appointment

In cases where applicants communicate with KemI through some other party representing them (representative, consultant etc.) in an application matter, this has to be verified by a letter of appointment from the applicant.

A letter of appointment must be given in writing. The law also accepts verbal letters of appointments, but that would unreasonably complicate the administration at KemI. A letter of appointment needs not be witnessed on this context, but must be signed by the applicant and submitted in original form.

If the representative’s rights are limited, this has to be apparent in the letter of appointment. KemI will otherwise assume that the representative represents the applicant in everything concerning the application. For further information on representatives and applicants, see Chapter 4.2.

If the right to hold a product authorisation is transferred to another holder, new letters of appointments must be drawn up if the old representative is to remain in place. Nor can a representative appoint another representative to act in its place, unless this is explicitly apparent from the letter of appointment.
A letter of appointment is normally applicable until it has been revoked. A letter of appointment may be revoked at any time. A written letter of appointment must be revoked in writing.

The following requirements have to be met by a letter of appointment:

- It must contain information on the applicant’s name and address.
- It must contain information on the representative/consultant’s name and address.
- It must be signed by the applicant and submitted in original form.

### 5.11 Registration certificates

Registration certificates are required from all companies that are not, or have not been, an authorisation holder/permanent representative or notifier of additional name for an authorised biocidal product in Sweden over the past years. A new registration certificate can also be required if there have been changes since the last product authorisation or if a long time has passed since a registration certificate was submitted.

### 5.12 Other information

In connection with the national application forms, with data requirements and risk assessments, KemI advises applicants as far as possible to make use of documents compatible with Microsoft Word. Applications and documentation submitted to KemI must be written in Swedish or English. However, for particulars intended to be reproduced in Swedish in labelling, safety data sheets etc., Swedish is a requirement.\(^\text{25}\)

The following requirements must be met for applications:

- It must be clearly apparent what studies that form the basis for the risk assessment.
- All the studies which are used in the risk assessment and have not been evaluated at EU level must be attached.
- A summary of the new studies must be included.

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\(^{25}\) Chapter 4, Article 14 KIFS 2008:3
6 Clarification of certain data requirements for chemical biocidal products

All the data requirements in the application forms must be met in the application. In cases where a generally accepted method or guidance is not available, it is the duty of the applicant to himself devise a method and argue for its validity.

In addition to the explanations given in the application forms, some clarifications are given below on certain data requirements for chemical biocidal products where KemI has often noted deficiencies in applications received.

6.1 Information on active substance and/or the chemical biocidal product

6.1.1 Composition of the product (B-form, B2.3)

Full particulars of composition must be stated. If the biocidal product contains formulants that are mixtures and for which the applicant does not have the full composition (e.g. solvents, emulsifiers), it is the responsibility of the applicant to ensure that the manufacturer of the formulant submits full composition of this ingredient to KemI. Function and any classification according to CLP (or KIFS 2005:7) for all the substances in the product must also be stated.

All the substances contained in the product must primarily be stated with ISO/IUPAC name, CAS No or EC No and concentration (% by weight).

6.1.1.1 Addition of fragrance(s) to the product

Fragrances often consist of various essential oils. Many of these are also expected to have repellent and attractant properties for insects and consequently to be capable of contributing to the effectiveness of certain products.

If fragrance(s) is or are used in a product to endow them with a pleasing scent, it must be possible for the applicant to justify the choice of fragrances and their concentrations if necessary. The concentration of fragrance(s) must be reasonable, and it must also be possible where necessary to show that the product is also sufficiently effective without the addition of fragrance.

If a fragrance or fragrances is or are used in a product to repel or attract insects (product type 19), the fragrance is defined as an active substance, with the same data requirements as for other active substances, as the fragrance in itself is necessary to the effectiveness of the product.

6.1.2 Use of the product (B-form, B3)

State the area of use applied for and make sure that this is in agreement with the product type applied for, the proposed label and directions for use in Swedish, and with the use described in the risk assessment (C-form).
6.1.2.1 Effectiveness (B-form, B3.7)
To show that the product is effective for the intended purpose, information from practical trials (tests, field studies) relevant to the area of use applied for must be attached to the application. Resistance-generating properties must also be stated in the application.

6.1.3 Proposed classification, labelling and packaging (B-form, B4)
A draft label in Swedish must be submitted with the application. The proposed label must reflect the area of use applied for and the risk assessment of the product. It should contain risk information and safety instructions and other prescribed labelling text.26

Rules on the labelling of chemical biocidal products are contained in Annex 2 and Chapter 4, Article 6 in KIFS 2008:3. Note that the provisions in KIFS 2005:7 on classification and labelling of chemical products and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) also apply to chemical biocidal products. KIFS 2005:7 will successively cease to apply and be replaced by Regulation (EC) 1272/2008, which entered into force on 20 January 2009. The new rules are being introduced gradually and KIFS 2005:7 and the CLP Regulation will apply in parallel during the period until 1 June 2015. Detailed information on the transitional provisions in CLP can be found on the KemI website, see also Chapter 10.

Draft instructions for use containing clear directions on how the biocidal product is to be used must also be submitted to the application.

The package sizes proposed in the application must be compatible with the planned dosage and use on which the risk assessment is based. Products with a typical seasonal use should have package sizes adapted so that they can be consumed during one or a few seasons. For further information on guidelines for packaging, see also Chapter 9.3.1.1.

Information on what types of packages that are to be offered for sale and what closures these packages have must fulfil the general requirements specified for chemical products27 and be submitted to KemI.

6.1.4 Reference list (A-form, A20; B-form, B14)
A reference list stating all the studies cited in the application must be attached. The reference list must be updated by the applicant if new material has been added to the application. For further information on reference lists and the right to use studies for an application, see Chapter 5.8-5.9. The attached health and environmental risk assessment of the product (the C-form) must be based on the studies stated in the A-form and B-form.

26 Chapter 4, Article 6 KIFS (2008:3), KIFS (2005:7) and Regulation (EC) No 1272/2008
27 Chapter 2 KIFS 2008:2
6.2 Physical, chemical and technical properties of the product (B-form, B8)

Note that both the density and the viscosity of liquid products must be stated. State the reference for each result and note that the studies must be available to KemI.

6.3 Analytical methods

6.3.1 Analytical methods for active substance (A-form, A3)

Validated analytical methods to determine the identity and concentration of active substance in the technical product (i.e. the active substance in the form in which it is added to the biocidal product) must be submitted. Descriptions of the analytical methods and the results of these must be submitted to/present at KemI. State the reference in the A-form.

Analytical methods to identify and determine the concentration of the active substance in soil, water, air and biological material must also be attached to the application.

6.3.2 Analytical methods for biocidal product (B-form, B10)

Validated analytical methods for the concentration of active substance in the biocidal product must be submitted together with the application. Descriptions of the analytical methods and the results of these must be submitted to/present at KemI. State the reference in the B-form.

6.4 Risk assessment of the chemical biocidal product

The risk assessment must be in agreement with the area of use applied for and the instructions for use/label of the product.

6.4.1 Health risk assessment

A quantitative assessment of the health risk of the biocidal product means that a calculated exposure is related to the reference value that is not expected to produce any health effects in any exposure group (AEL, Acceptable Exposure Level). If the exposure/reference value ratio is more than 1, there is a risk of negative health effects.

Health risk assessments must be done for all areas of use applied for and for all envisaged users of the product, known as the primary exposure group. In applicable cases, health risk assessments must also be done for those groups that can normally be foreseen to be exposed to the product after use, the so called secondary exposure group, e.g children who crawl on treated surfaces.

An estimate of exposure can be made on the basis of exposure studies on the specific product or from exposure models developed for biocidal products at EU level. Existing exposure models for biocidal products include ConsExpo (Consumer Exposure) and BEAT (Bayesian Exposure Assessment Tool), which can be
downloaded for example via the Technical Notes for Guidance (TNsG) on Human Exposure 2007 available on the European Commission Joint Research Centre website. The exposure level for the product must be calculated on the basis of the planned area of use, application technology and directions for use. Body weight must be stated as 60 kg for adults, 15 kg for children and 10 kg for infants in all types of exposure models. Note that the acute value generated in ConsExpo should be used in the risk assessment. The chronic value of exposure generated is an annual mean, which does not correctly describe the situation when exposure occurs sporadically.

AEL is normally calculated on the basis of a zero-effect value, NOEL (No Observed Effect Level), from the toxicological study deemed as most relevant. This decision should be made on the basis of the envisaged pattern of use for the product applied for, e.g. the exposure period in the study should be comparable with how the product is to be used, but also on the basis of the most sensitive animal species tested if the toxicological studies are conducted on several different species. The NOEL value is then divided by an assessment factor (AF), which is based on the difference that may exist between animal species and between individuals, which in turn generates the AEL level. Extra assessment factors may also need to be applied to compensate for particular uncertainties or noted serious effects in the studies.

For a more detailed description of how to do a health risk assessment, refer to guidance documents, such as TGD (Technical Guidance Document) and TNsG (Technical Notes for Guidance) on the European Commission Joint Research Centre website.

### 6.4.2 Environmental risk assessment

A quantitative environmental risk assessment means that an estimated concentration of a substance in the environment (PEC, Predicted Environmental Concentration) is related to the concentration not expected to produce any toxic effects on any organism (PNEC, Predicted No Effect Concentration). If the PEC/PNEC ratio is more than 1, the risk of effects in the environment is regarded as unacceptable.

The concentration in the environment is estimated on the basis of the product's distribution patterns using measured data or mathematical models. The basic rule is that the concentration is to be calculated in all the compartments of the environment where the product ends up. This usually means that the concentration is calculated for water entering sewage treatment plants, surface water, sediments, soil and groundwater, and where applicable also for marine waters and sediments, as well as air.

PNEC is normally calculated from effect values, EC50/LC50 or NOEC (No Observed Effect Concentration) for the most sensitive species tested. The effect value is divided by an assessment factor (AF) that is based on the reliability and availability of studies to obtain the PNEC. The assessment factor has to compensate for the possibility of more sensitive species and more sensitive life stages than those tested.

For a more detailed description of how to do an environmental risk assessment, refer to guidance documents, such as TGD (Technical Guidance Document), TNsG.
6.4.3 Specific Swedish requirements and rules for health and environmental risk assessments

Below follows a review of specific clarifications and Swedish rules for some different product types that cannot be found in the guidance documents mentioned above.

6.4.3.1 PRODUCT TYPE 8 Wood preservatives

Environment
In the use of timber structures in direct contact with water in the marine environment (i.e. if the wood is to be classed as M²⁸), a risk assessment of the marine environment, among other things, must be attached to the application in accordance with prevailing guidance. If exposure of the Baltic Sea environment is concerned, an extra assessment factor (AF) is applied, AF=2 for organic substances and AF=3 for metals. This assessment factor is based on differences between an actual marine environment and the brackish water environment of the Baltic Sea. For a more detailed justification of this extra assessment factor, refer to the document Baltic Sea Risk Assessment, see Annex 1, Chapter 14.1. In the environmental risk assessment of metals, it is important to take account of abiotic factors in the environment that affect bioavailability. pH, hardness, ion exchange capacity and concentration of dissolved or particulate organic material are generally important parameters to take into account, but how much they effect bioavailability varies between different metals. Sweden’s watercourses and lakes are in general substantially more acidic (lower pH) and have lower hardness than is regarded as applying in general to the EU. Swedish conditions are to be taken into account when calculating bioavailability, for example by using the “biotic ligand model” (BLM).

6.4.3.2 PRODUCT TYPE 18 Insecticides

General
PBO (piperonyl butoxide) is a synergist and is used in various insecticides to enhance the effect of the product by inhibiting the enzyme systems in the target organism that break down the active substance (usually pyrethrins). As a result, a pesticide can be made considerably more effective. Because of its properties and how PBO can influence the efficacy of a product, applicants are requested to justify the concentration of PBO in the product applied for, in relation to the submitted efficacy studies on the product, and to provide an account of how PBO affects the health and environmental risk assessment. KemI will take account of this when assessing the risk of products containing PBO.

²⁸ Wood impregnated according to class M is for use in timber structures that are at risk from attacks by marine pests, for example ship worms, and for constructions that are exposed to extreme stress or for those constructions specific safety standards imposes, i.e. risk-class 5 according to European Standard EN 335. Examples of uses are quays, foundation piles and cooling towers.
Today KemI applies the practice that products against cockroaches and bedbugs should not be placed in authorisation class 3 (for further information about authorisation classes, see 9.3.1). This is based on the risk of the development of resistance to the active substance as cockroaches and bedbugs are insects that are very difficult to control. Such insects should not be controlled by amateurs as special knowledge and strategies are required to control these organisms.

**Environment**

The exposure scenario for insecticides used in livestock buildings includes a calculation of $\text{PEC}_{\text{soil}}$ after manure has been spread on arable land and grassland. The volume of manure that may be spread is calculated on the basis of the maximum permitted quantities of phosphorus and nitrogen that may be added to the soil through manure. The exposure scenario document (ESD) also presents various countries’ standard values for permitted quantities of phosphorus and nitrogen, including a Swedish value for the permitted quantity of nitrogen. In Sweden it is, however, (generally) the concentration of phosphorus in manure that decides how large a volume of manure may be spread.

$\text{PEC}_{\text{soil}}$ is therefore calculated for products to be used in Sweden on the basis of the acreage on which manure is spread for the phosphorus ratio: a maximum of 110 kg total phosphorus/ha/five-year period may be spread, which is equivalent to 22 kg phosphorus/ha/year. Inputs of phosphorus and nitrogen to Swedish arable land and pastureland are governed by SJVFS 2004:62.

Calculation of $\text{PEC}_{\text{sewage treatment plant}}$ and $\text{PEC}_{\text{surface water}}$ after mopping of floor surfaces is included in the model for exposure to insecticides used indoors. The default surface area mopped in a standard EU home according to the guidance document for insecticides is 30% (bathrooms/kitchens). The remainder is considered to be surfaces that are only dry-cleaned (wall-to-wall carpet) and pesticide spread on this fraction of the surface area does not go to sewage treatment plants or surface water but goes with vacuum cleaner bags to landfills or refuse incineration. As wall-to-wall carpets are unusual in Sweden, KemI considers that 100% of the floor surface in the home should be regarded as a realistic worst case in the exposure calculations.

**6.4.3.3 PRODUCT TYPE 19 Repellents and attractants**

**General**

For the product to be allowed to be labelled “Reduces the risk of tick bites”, there must be effectiveness studies that verify this claim.

**Health**

Pending EU-wide decisions for approval of active substances in midge repellents, KemI did apply the practice that these products should not be used on children below the age of 3 years. This strict age restriction has now been removed. However, it is still the responsibility of the applicant to demonstrate in the risk assessment that the use is safe and does not cause an unacceptable risk for the age groups included in the area of use of the product.

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20 Swedish board of agriculture’s regulation (SJVFS 2004:62) about environmental concerns in agriculture with regard to plant nutrition
Environment
There is no applicable guidance at present for the environmental risk assessment of repellents and attractants. Environmental risk assessment can be done using ESD, for example for PT 1, PT 2 and PT 18.

6.4.3.4 PRODUCT TYPE 21 Antifouling products

Environment
The MAMPEC model (Marine Antifoulant Model to Predict Environmental Concentrations) has been developed to calculate the concentration in the environment of active substances in antifouling products. This model contains a number pre-defined scenarios, for instance for an EU harbour and an EU marina, which are used for the evaluation of active substances at EU level. In the national evaluation of products, KemI has judged that the scenarios need to be adjusted as Swedish conditions differ from the standard scenarios with regard to abiotic conditions (e.g. salinity and tides) but also with regard to number and size of boats. A description of these Swedish scenarios is contained in the document Risk assessment of antifouling products – estimation of exposure to the environment, see Annex 2, Chapter 14.2.

If the area of use of the Baltic Sea is applied for, an extra assessment factor (AF) is applied in the calculations, AF=2 for organic substances and AF=3 for metals. This assessment factor is based on differences between an actual marine environment and the brackish water environment of the Baltic Sea. For a more detailed justification of this extra assessment factor, refer to the document Baltic Sea Risk Assessment, see Annex 1, Chapter 14.1.

6.5 Animal health

From 1 September 2011, applicants for products intended to be applied directly on animals or in the vicinity of animals must also contain a consideration of the risk posed to animals from the biocidal product. KemI does not make demands for new studies to be performed, but assessments should be done on the basis of existing toxicological information for the active substance/product and with the same principles as are applied in the assessment of health risks to humans.

The assessment should, however, take particular note of:

- whether the value for dermal absorption also is relevant to the type of animal concerned
- whether there is a difference between types of animal that may be significant for the toxicological assessment, i.e. is there information suggesting that the active substance may be particularly toxic to the type of animal concerned
- relevant values regarding weights, skin surface area etc. for the type of animal concerned

Some guidance on exposure estimates for animals can also be found in the guidance document “Guidance on Estimating Livestock Exposure to Active Substances in
Biocidal Products”, which is available via the European Commission's website for biocidal products (DG Environment).

Note that KemI requires this assessment for applications for new authorisation and renewed authorisation of biocidal products according to Swedish rules. The requirements may be changed in the case of authorisation of biocidal products according to the EU Biocidal Products Regulation.

### 6.6 Residual concentrations in exposed food, feedstuffs or food-producing animals

Since the use of some biocidal products could lead to a risk of unwanted residues of active substances in food or feed, the applicant for applications where the product is intended to be used for example:

- in storage spaces for feedstuffs and foods
- for the treatment of feedstuffs and drinking water
- in the vicinity of or directly on animals that can be involved in food production
- for the treatment of materials which may come into contact with food-producing animals, feedstuffs and foods

must submit an assessment showing that use of the product does not lead to residual concentrations in foods that may pose a risk to the consumer.

An Acceptable Daily Intake (ADI value) shall be calculated from the toxicity studies that refer to the active substance in the product. The ADI value is assessed according to accepted guidelines, i.e. it must cover all relevant toxicological effects. The ADI value is the reference value for the assessment if the residual concentration from the biocidal product is safe from a consumer perspective. The assessment shall also take into account if the substance used in other areas such as medicines, feed additives, pesticides and/or cosmetics. The total exposure of a substance shall not exceed the ADI value.

For guidance on exposure estimates for livestock, see the guidance document "Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products" which is available via the European Commission's website for biocidal products (DG Environment). For guidance on the assessment of MRLs (Maximum Residue Limits) please refer to the guidance document "Risk characterisation and assessment of Maximum Residue Limits (MRLs) for Biocides" at the European Medicines Agency's (EMA) website.

Product groups that may primarily come into consideration for this assessment are those used for the following:

- Treatment of livestock buildings (principally PT 3*, 18 and 19**). PT 21 may also be relevant with regard to products for fish and shellfish cultivation.
• Treatment of feedstuffs and drinking water for storage spaces (principally PT 4*, 5*, 6* and 20*).
• Treatment of materials that foods or food-producing animals may come into contact with (principally PT 4*, 5* and PT 8).
• Direct treatment of animals that may be involved in food production (principally PT 3*, 18 and 19**).

* No requirements for authorisation apply to these products at present
** Certain products in PT19 are exempt from requirements for authorisation

The authority responsible for food matters in Sweden is the National Food Agency (SLV). In connection with the consideration of Swedish authorisations for concerned biocidal products, SLV makes an assessment based on the residual concentrations data and exposure estimates submitted by the applicant and the limit values (MRLs) that exist in the EU. If necessary, SLV sets waiting periods (time from treatment with biocidal product until time of slaughter, milking or similar) for meat, milk and eggs. In other cases, other protective measures are proposed. It is SLV that decides whether the submitted residual concentration studies are sufficient to enable an assessment of residual concentrations for an application. Any supplements and communication with the applicant are, however, coordinated from KemI.

7 Data requirements and risk assessment for biological biocidal products

7.1 Microorganisms, including viruses and fungi
The data requirements for microorganisms, including viruses and fungi, are specified in the application forms for these biological biocidal products, see Chapter 5.

7.2 GMOs - Genetically Modified Organisms
If an application for product authorisation applies to genetically modified organisms, there must be a risk assessment in accordance with Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

7.3 Nematodes, insects and arachnids
Nematodes, insects and arachnids for use as pesticides are governed by Chapter 14, Sections 6 and 13 of the Environmental Code (1998:808).

If it is clearly proven in entomological literature that the species concerned occurs in the Swedish fauna, KemI considers that from the environmental perspective there is no obstacle to use nematodes, insects and arachnids for biological control. A species
that is only found in cases that may be related to performed biological control or other similar activities is not considered to be naturally occurring.

In the risk assessment of organisms KemI assumes that all organisms are able to spread. Even if an organism has poor ability to spread, KemI does not rule out the possibility that it may become established in the Swedish environment when used outdoors. Tropical/subtropical organisms are however, considered to lack adaptations to survive in a temperate climate and are not considered to be capable of surviving a winter in Sweden. They are therefore regarded as acceptable from the point of view of risk by KemI.

When used outdoors, the number of individuals released is substantially greater than indoors. This increases the risk of the species becoming established. In the case of planned outdoor use, account should therefore be taken to this in assessing the risk of establishment.

Alien species are primarily assessed on the basis of their ability to become established in Sweden, according to the following template:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the species naturally occurring in the Swedish fauna?</td>
<td>Yes</td>
<td>Low risk</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Go to point 2</td>
</tr>
<tr>
<td>2. Which climate requirements does the species have?</td>
<td>Temperate</td>
<td>Go to point 4</td>
</tr>
<tr>
<td></td>
<td>Mediterranean</td>
<td>Go to point 3</td>
</tr>
<tr>
<td></td>
<td>Tropical/subtropical</td>
<td>Low risk</td>
</tr>
<tr>
<td>3. Can the species withstand temperatures below 0° for more than 24 hours?</td>
<td>No</td>
<td>Low risk</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Go to point 4</td>
</tr>
<tr>
<td>4. Host/prey spectrum</td>
<td>Polyphage</td>
<td>High risk</td>
</tr>
<tr>
<td></td>
<td>Oligophage/monophage</td>
<td>Judgment in every specific case</td>
</tr>
</tbody>
</table>

An assessment is not, however, given once and for all but may need to be updated when an authorisation is reviewed. The diffusion of species changes constantly and problems may be encountered in distinguishing natural invasions from those caused by humans.

In those cases where an alien species appears capable of becoming established in the Swedish environment, the basic principle is that the species must not be used for biological control. However, account can be taken of whether the species has a clearly limited number of host organisms and whether it can be proven that it only attacks organisms that occur for example in livestock buildings but lack the ability to survive outside in the absence of “food”. It must also in such cases be assessed whether the normal prey of the species (i.e. the species which is to be controlled) has closely related species with a similar lifestyle in the Swedish environment or whether there are reasons to suspect that there is a risk of some other species being attacked. A mono/oligophage species may attack new prey in an alien environment. If there is
a risk of symbiosis between the alien species and any species occurring in Sweden, this must be included in the assessment.

8 The handling process

8.1 Order of priority
As a rule, the order of priority is determined by the date on which the application fee was paid. KemI may, however, if this makes the handling process more efficient, change the order of priority for example making it possible to deal with several biocidal products with the same active substance at the same time.

8.2 Overview of the handling process
As soon as the application fee has been paid and any letters of appointments have been granted, a case team is appointed consisting of a health risk assessor, an environmental risk assessor and a chemist, and handling of the case can begin. In the first stage it is checked whether certain fundamental formal requirements are met. Among other things, a check is made that the applicant has permission to use the documentation on which the application is based, that the area of use is clearly described and that the product composition is complete.

If the fundamental requirements are met, a check is made that other documentation in the application is complete, i.e. that there is documentation that meets the data requirements in the application forms and in cases where certain documentation is lacking there is acceptable justifications. If the documentation is considered to be complete, a detailed evaluation is made of the documentation for the active substance and product as well as of the applicant’s risk assessment of the product. A proposal is then made for a decision. In certain cases it may appropriate to obtain information from other parties before the final decision is taken. In these cases the matter is sent for comments.

8.3 Opportunities to make additions to applications
Applicants are normally given opportunities to make additions to their application. Through a supplementary information letter, KemI gives notice of what deficiencies that have been identified. The letter also states a deadline by which the supplementary information must be submitted to KemI. The period granted for supplying supplementary information is normally around four weeks. If the supplementary information is not received within the time stated or if the supplementary information is not complete, the application may be rejected.

During the handling process, the applicant may also be contacted directly by the case officer to clarify specific questions.
9 Decisions

All decisions can be appealed within three weeks from the date on which the applicant has received the decision (see Chapter 9.4 for further information).

9.1 Positive decisions

9.1.1 New authorisation/renewed authorisation

In the event of approval, the decision contains information about the period of validity of the authorisation, see Figure 2. An authorisation may apply for a maximum of five years or, if there special reasons, 10 years. At the present situation the authorisation periods are adapted to the EU’s work programme for active substances, which means that the decision may apply for a period of more than 5 years.

In the decision the name of the product is written as stated in the application form. Consequently this is the name that must appear on the packaging. The decision also contains conditions for the authorisation, for example area of use and special risk management measures (for further information on conditions in decision, see Chapter 9.3).

Figure 2. Detail from decision document with period of validity and date of application for renewed authorisation.

When a biocidal product has been authorised in Sweden, it is given a Swedish registration number. The registration number is linked to the biocidal product and its authorisation decision as well as any condition imposed with the authorisation.

No other use beyond that stated in the area of use in the decision is permitted. This is due to the fact that KemI has assessed the application on the basis of the documentation submitted together with the application. No other uses have been assessed. It is essential that the risks of use are evaluated and found acceptable for a product to be approved and be used. Use in other ways may pose unacceptable risks. Note that it is a criminal offence to use a pesticide in an incorrect manner, for example for an area of use other than that covered by the authorisation.

Regarding decisions on renewed authorisation where the decision contains new or changed conditions that affect the product’s labelling see Chapter 10.3 for further information.

When a biocidal product has been authorised it is entered into the Swedish pesticides register, which is accessible through the KemI website. For further information, see Chapter 11.4.

30 Article 10, Law (2010:742) about modifications in the Environmental Code
9.1.2 Changes of conditions
Regarding decisions on changes of conditions or renewed authorisation, the decision may contain new or changed terms that affect the product’s labelling, see Chapter 10.4 for further information.

9.1.3 Additional names
If the notification of an additional name is accepted by KemI, the notifier receives a communication on this matter from KemI. The additional name is entered into a register which is accessed through the Swedish pesticides register on the KemI website.

Information on how products with additional names are to be labelled can be found in Chapter 10.3.

9.2 Negative decisions
In the event of complete or partial rejection, the decision contains the reasons why the whole or parts of the application cannot be accepted.

Following rejection of an application for renewed authorisation, KemI decides for how long the product may be sold or used. For further information on prohibition of sale and prohibition of use, see Chapter 11.3.

9.3 Conditions in decisions
The conditions in the decisions are to be regarded as an external framework for the instructions that are to appear on the product’s package or alongside the package. The person who is responsible for the product’s labelling must ensure that the information stated on the package is in agreement with the area of use in the decision. The text on the package needs not to be identical to the area of use in the decision, but it must under no circumstances go beyond what is stated in the decision.

Further conditions beyond the area of use may occur in the decision. This may be conditions that are to be apparent from the labelling or directions for use of the product, for example details on what organisms that are intended to be controlled, where control may take place, maximum number of treatments and restrictions on who may use the product.

9.3.1 Authorisation classes
Biodical products must always be assigned to one of the following authorisation classes:

- Class 1: Product for professional use only, by someone with a special licence.
- Class 2: Product for professional use only.

31 Chapter 4, Article 6 and Annex 2 in KIFS 2008:3
32 Article 25 Biocidal Products Ordinance (2000:338)
• Class 3: Product that may be used by anyone.

A code is also added to the labelling of a biocidal product for professional use in Class 1 to show which authority that grants licences and determines the knowledge requirements that must be satisfied before a person is allowed to use the product.

• AV: Other activity, for example use of wood preservatives and antifouling products. The Swedish Work Environment Authority is the licensing authority.

• So: Measures taken against vermin and pests in accordance with Chapter 9, Section 9 of the Environmental Code (1998:808). The Public Health Agency of Sweden is the licensing authority. Please note that the Public Health Agency of Sweden (Folkhälsomyndigheten) has taken over the responsibility from the National Board of Health and Welfare (Socialstyrelsen) starting 1 January 2014. Licences granted by the National Board of Health and Welfare before 2014 are still valid in accordance with what has been granted.

If requirements for particularly extensive knowledge are stipulated, KemI indicates this with the additional symbol X (for example SoX).

9.3.1.1 Guidelines for Class 3

Biocidal products must not be placed in Class 3 if they have any of the following characteristics:

• Classified as toxic (R23, R24, R25, R39, R48), highly toxic (R26, R27, R28, R39) or carcinogenic, toxic to reproduction, mutagenic in Category 1 or 2.\(^{33}\)

Biocidal products are not in general placed in Class 3 if they have any of the following characteristics:

• Products subject to several or far-reaching conditions for use. This may, for example, apply to requirements for waiting periods or personal protective equipment.

• Carcinogenic, toxic to reproduction or mutagenic in Category 3 or highly corrosive.

• Products that cause serious damage to eyes and require risk phrase R41.

• Causing sensitisation (R43) unless it can be shown that exposure is negligible.

• Harmful by inhalation, in contact with the skin and if swallowed (R20-22).

• Danger of serious damage to health by prolonged exposure (R48).

• May cause harm to breastfed babies (R64).

• Are persistent, mobile or potential bioaccumulative.

\(^{33}\) Chapter 4, Article 11 KIFS 2008:3
• For use against insects that are difficult to control, such as cockroaches and bedbugs, see 6.4.3.
• For use to control rats chemically.

Package size and concentration of active substance are taken into account in allocating to an authorisation class. KemI generally recommends that products in Class 3 are marketed as ready-for-use products in packages of a size adapted to be consumed during one or a few seasons. The purpose of this is to limit the risk in the handling of biocidal products, for example prolonged storage of chemicals in the home, and to prevent unnecessary “overuse” of the chemicals.

9.3.1.2 Distinction between Class 1 and 2
This distinction between Class 1 and 2 is principally concerned with the health aspects, although environmental properties are also taken into account. Common to Class 1 products is that they make greater demands on the user’s knowledge than Class 2 products. Biocidal products are in general placed in Class 1So/AV if they have any of the following characteristics:

• Very high acute toxicity.
• Highly corrosive.
• Carcinogenic, toxic to reproduction or mutagenic in Categories 1 or 2.
• Use of the products requires distinct specialist knowledge. Examples are rodenticides that:
  o are used to control rats chemically
  o contain the second generation of anticoagulants (difenacoum, bromadiolone, difethialone, brodifacoum and flocoumafen).

9.3.2 Conditions for risk management
In order to manage risks to the health or the environment observed in the risk assessment of a product, the applicant can propose restrictions in use leading to reduced exposure. If risk-limiting measures have been adopted in the risk assessment of the product (such as protective equipment or limited number of applications), these risk-limiting measures or equivalent must be clearly apparent from the labelling. This is important so that the risk assessment corresponds to the actual use of the product.

The rules of the Swedish Work Environment Authority also apply to products for professional use, both overarching rules for chemicals in general34 and specific rules for the handling of pesticides35. For more detailed information, see Swedish Work Environment Authority (www.av.se).

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34 Swedish National Board of Occupational Safety and Health regulations (AFS 2000:4) on Chemical hazard in the working environment
35 Swedish National Board of Occupational Safety and Health regulations (AFS 1998:6) on Pesticides
9.3.2.1 The “STOP principle” or “the escalation of action”\textsuperscript{36}

The “STOP principle” for risk reduction is based on the Swedish Work Environment Authority’s regulations where personal protective equipment is recommended as a last measure to deal with identified risks in the working environment. Risks that have been identified shall be eliminated or reduced to an acceptable level with application of the following principles in the order shown:

1. Hazardous chemical substances are replaced by substances that, when handled as intended, pose a lesser risk to health and safety. For example, on the KemI \texttt{website} there is a tool for risk reduction of chemicals (PRIO) in which it is possible to:
   - Search for substances and obtain information on their characteristics posing a hazard to the environment and health.
   - Obtain information on prioritised health and environmental characteristic.
   - Identify substances contained in chemically characterised substance groups and product types
   - Obtain help in developing routines for purchasing, product development, risk management etc.

2. Working methods, processes and technical devices are chosen and designed so that the risk in handling is reduced.

3. Protective measures are taken at the source of risk so that no one is exposed to the risks associated with handling.

4. The work is performed at a particular place or time. Only personnel needed for this work are present.

5. Personal protective equipment is used.

9.3.2.2 Conditions relating to personal equipment

If the composition/design of the product requires personal protective equipment for handling, this must be clearly stated in the labelling. Type and material of protective equipment must also be specified. For products in Class 3 and that may be used by anyone, it cannot be assumed that personal protective equipment will be used. Hence, it is not an acceptable risk management measure to require protective equipment in the use of such products in order to reduce systematic exposure to an acceptable level\textsuperscript{37}.

9.3.2.3 Conditions relating to waiting period

Where appropriate, waiting periods must be observed for food-producing animals that have been exposed to biocidal products, see Chapter 6.6.

\textsuperscript{36} Article 10 AFS 2000:4, ”STOP” comes from the principals: Substitution (1), Technology (2), Organisation (3 and 4), Protection (5)

\textsuperscript{37} TNsG on Human Exposure, 2007.
9.3.2.4 Conditions for re-entering treated spaces
Exposure leading to risks for the user can be reduced by setting a condition for use according to which a minimum number of hours/days must pass after treatment before people or animals may enter the space again. As the protection may be aimed at persons other than those who have carried out the treatment, an information responsibility is attached to the decision whereby others who may come into contact with treated products must be informed about the treatment and any safety information applicable to them. This is also something that must be apparent from the product labelling 38.

9.3.3 Other conditions
Kemi can make an authorisation dependent on additional conditions, for example that certain documentation must be submitted or that the company by a certain date must replace an inactive substance in the formulation of relevance from a health or environmental protection.

9.4 Appealing decisions
Decisions may be appealed to the Land and Environmental Court at Nacka District Court.

Written appeals should be made to the Land and Environmental Court, Nacka District Court, but be sent to Kemi.

Address:
Swedish Chemicals Agency
Pesticides and Biotechnical Products
Box 2
SE-172 13 Sundbyberg
Sweden

The appeal must be received by the Swedish Chemicals Agency within three weeks from the day when the applicant took note of the decision. Kemi then forwards the appeal to the Land and Environmental Court.

10 Labelling

10.1 Authorised products
When a biocidal product is placed on the Swedish market, the package must be labelled in accordance with the provisions of Chapter 4 Section 6 and Annex 2 of KIFS 2008:3. For biological pesticides where the active organism consists of nematodes, insects or arachnids, the provisions of Chapter 2 Section 3 and relevant parts of Annexes 1 and 2 of KIFS 2008:3 are applicable. Information in the labelling must be in agreement with corresponding information stated in the decision on

38 Point j, Annex 2 KIFS 2008:3
authorisation. The labelling for biocidal products placed on the Swedish market must be in Swedish. See also Chapter 6.1.3.

Note that the provisions of KIFS 2005:7 on the classification and labelling of chemical products and Regulation (EC) No 1272/2008 on the classification, labelling and packaging of chemical substances and mixtures (CLP) also apply to biocidal products.

KIFS 2005:7 will successively cease to apply and be replaced by Regulation (EC) 1272/2008, which entered into force on 20 January 2009. The new rules are being introduced gradually and KIFS 2005:7 and the CLP Regulation will apply in parallel during the period until 1 June 2015. Detailed information on the transitional provisions in CLP can be found on the KemI website, but in general:

- By 1 December 2010 companies must have classified substances in accordance with CLP.
- By 1 June 2015 companies must have classified mixtures in accordance with CLP.

As substances at present have to be classified and labelled in accordance with CLP, it is important to note that there is a difference between products that consist solely of one substance and products that are a mixture.

10.2 Products that are exempt from the requirement for authorisation

Biocidal products that today do not need to be authorised before they are placed on the Swedish market must nevertheless be labelled according to the rules for biocidal products in Annex 2 to KIFS 2008:3, except for the information stated in points b, d, e and k of the Annex. In addition, information must be provided on the area of use for which the biocidal product is intended. For further information on the labelling of biocidal products, see Chapter 10.1.

10.3 Products with additional names

Products placed on the market under additional names must be labelled in the same way as the authorised product, see Chapter 10.1.

10.4 New labelling of product

When a decision on renewed authorisation or change of conditions is granted and the conditions to which the decision is subject affect the labelling of the product, the general practice is that the product placed on the market by the holder has to have the new labelling from the time when the decision has entered into force, unless KemI has decided a different date. In the latter case, this date will be stated in the decision.
If the applicant considers itself to need a different set up time for new labelling of the product, the applicant is encouraged to submit reasons for this and to propose the date from which the new labelling is to start to apply.

11 Other information

11.1 Demarcation issues

There are products that end up in a grey area where the demarcation between the rules for biocidal products and other regulatory frameworks may be complex. Several guidance documents have been produced to make it easier to draw the line and to clarify what formal requirements should be met by a particular product. There are guidance documents on the European Commission’s website for biocidal products that describe the demarcation of biocidal products and other types of products, for example medicinal products and cosmetics. In order to be able to make an assessment of equivalence in the EU, the European Commission together with the Member States has also produced a document, the “Manual of Decisions”, which among other things, deals with demarcation issues. It should be noted that the documents contain guidelines and none of the interpretations made there have been tested in law.

Some of the demarcation issues that have been discussed at KemI is described below.

11.1.1 Products against surface growth

KemI considers that products intended to prevent or remove surface growth on wood, stone, concrete, brick and masonry are to be regarded as biocidal products. This is the case regardless of whether the product has a lasting long-term effect or not. This assessment has been made in accordance with the definition of a chemical pesticide, as such a product is intended to prevent or obstruct plants or microorganisms to cause damage to property, and is not a plant protection product. This interpretation has also received support from competent authorities in the other Member States of the EU.

In accordance with previous practice, KemI has made the assessment that these biocidal products belong to product type 8 (wood preservatives) and/or product type 10 (preservatives for building stone) depending on which surface is to be protected. Therefore, KemI has had products authorised against mould and algae on building materials, as well as externally on wood, concrete and brick, since the 1990s.

In discussions at an EU meeting of competent authorities for biocidal products (CA meeting) at the end of December 2009 it was, however, established that products against growth on surfaces that do not have a long-term effect should belong to product type 2 (private area and public health area disinfectants and other biocidal products). Products belonging to this product type are at present exempt from the
requirement for authorisation in Sweden in accordance with current transitional provisions. KemI will continue to apply this new interpretation.

Products that have a long-term effect will, however, continue to be regarded as belonging to product type 8 or 10 depending on what material is to be treated.

11.1.2 Products to be used on animals
A product used on animals against vermin or insects can be regarded as either a biocidal product or a veterinary medicinal product.

For such biocidal products must therefore no claims of secondary effects, for example that the products prevent or limit diseases that may result from attacks by vermin, exist on the marketing (for example on packages and in directions for use).

Products against insects or vermin that are to be marketed with such claims on secondary effects should instead be regarded as veterinary medicinal products. Questions and applications for authorisation should be addressed to the Swedish Medical Products Agency, which deals with applications for the authorisation of veterinary medicinal products.

For further information, see also guidance on demarcation on the European Commission website on demarcation for biocidal products.

11.2 Revocation

11.2.1 Revocation of applications in progress
An applicant may revoke an application at any time during its processing. Such a request must be made in writing to KemI. The authority will then conclude the work in progress.

11.2.2 Revocation of authorisation
The holder of an authorisation for a pesticide may submit a request for authorisation of the product to cease at any time. Such a request must be made in writing to KemI. The authorisation will then cease to apply at the end of the year immediately following the year in which the request was received by the authority.

KemI can also take the initiative for a decision to revoke the authorisation for a product. This may be relevant for example if a decision is taken in the EU not to authorise an active substance according to the EU Biocidal Products Regulation and the period of authorisation for the product in Sweden extends beyond the date when the product may no longer be placed on the market. If it emerges that a product no longer fulfils the conditions for authorisation, KemI may also revoke the authorisation.

For information on prohibition of sale and prohibition of use, see Chapter 11.3.

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39 Chapter 2, Article 7 KIFS 2008:3
11.3 Prohibition of sale and prohibition of use

When an authorisation has ceased, a time limit is usually granted for sale and transfer by parties other than whoever held the authorisation, which generally expires one year after the authorisation has ceased. The time limit granted for use normally expires a further year later. Note that this is merely practice and that a decision must be made for each individual product to introduce periods for sale and use, which are listed in Annex 3 to KIFS 2008:3.

For pesticides that have been authorised in Class 3 (for use by anyone) no last date for use is usually stated. Chapter 2 Section 8 of KIFS 2008:3 states that products may be offered for sale and used by others than the previous authorisation holder if the product is included in Annex 3. This means that those pesticides for which there is no last date for use may only be used during the time they are included in Annex 3. Annex 3 only lists those products whose authorisation ceased some time during the past five years. Pesticides whose authorisation ceased beforehand may thus no longer be used.

11.4 The Swedish pesticides register

The Swedish Chemicals Agency’s pesticides register on the KemI website contains information on authorised and previously authorised pesticides. In the register there is information on areas of use, special conditions etc. Note, however, that all the conditions stated in the decision document sent to the holder/representative do not appear in the public pesticides register. For example, packaging conditions (e.g. package size) as well as detailed instructions for use do not appear in the register. Further information about the register can be found on the KemI website.

Products no longer authorised are highlighted in red in the register. For information on prohibition of sale and prohibition of use, see Chapter 11.3.

The register of products that may be sold under additional names is also accessed from the homepage of the pesticides register.

Note that exemptions for biocidal products are not today entered into the pesticides register (the exemptions listed apply to plant production products).

11.5 Other laws and regulations

Many of the laws applicable to chemical products also apply to pesticides. A report of the activity, for example, must be made to the products register and a product report may also be appropriate. For further information, see www.kemikalieinspektionen.se/en/

11.5.1 Activity report

A report of activity must be submitted to the chemical products register at KemI, as soon as possible but no later than when the activity is initiated, by companies that:

- professionally manufacture or import into Sweden chemical products or biotechnical organisms,
• for further transfer in their own name pack, re-pack or change the name of chemical products or biotechnical organisms,
• for further transfer make preparations (mixtures) of chemical products or biotechnical organisms,
• on their own account transfer to a commercial agent the task of making a product notification,
• manufacture or import into Sweden pesticides that are notifiable.

The reporting obligation is determined by the product’s code number in the Customs Tariff as appearing in the Chemical Products and Biotechnical Organisms Ordinance (2008:245). A notification of activity must be presented irrespective of how much of a notifiable product the company manufactures or imports into Sweden. The notification must contain particulars of the company such as name, address, corporate identity number and preferably who is the contact point.

11.5.2 Product report
A product report must be made to the chemical products register at KemI by companies that:

• professionally manufacture or import into Sweden chemical products or biotechnical organisms,
• for further transfer in their own name pack, re-pack or change the name of chemical products or biotechnical organisms,
• for further transfer make preparations (mixtures) of chemical products or biotechnical organisms,
• manufacture or import into Sweden pesticides that are notifiable.

The reporting obligation is determined by the product’s code number in the Customs Tariff as appearing in the Chemical Products and Biotechnical Organisms Ordinance (2008:245) and if the annual volume is at least 100 kg per product. A product report must be presented no later than 28 February in the year after manufacturing or importing has commenced.

12 Links and references

12.1 Relevant statutory texts
Swedish National Board of Occupational Safety and Health Regulations (1998:6) on Pesticides

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Ordinance (1998:940) on Fees for Examination and Supervision under the Environmental Code

Ordinance 2013:63 on Fees for Pesticides (in Swedish)

The Biocidal Products Ordinance (2000:338)

The Swedish Chemicals Agency’s Regulations (KIFS 2005:7) on Classification and Labelling of chemical products

The Swedish Chemicals Agency’s Chemical Products and Biotechnical Organisms Regulations (KIFS 2008:2)

The Swedish Chemicals Agency’s Pesticides Regulations (KIFS 2008:3)

The Secrecy Act (1980:100) or www.riksdagen.se

Information on classification and labelling and the new CLP Regulation that will replace the current Dangerous Substances and Dangerous Preparations Directive can be found at www.kemikalieinspektionen.se/en/.

Information on which active substances that are included in the EU’s work programme, which substances have been included and which substances have been excluded can be found at: http://ec.europa.eu/environment/biocides/

12.2 Other authorities and institutions

The Swedish Work Environment Authority
http://www.av.se/

ECHA (European Chemicals Agency)
http://echa.europa.eu/

European Commission’s website on Biocidal Products (DG Environment)
http://ec.europa.eu/environment/biocides/index.htm

European Commission Joint Research Centre:

Swedish Poisons Information Centre
http://www.giftinformationscentralen.se/intro.asp?CategoryID=6414

National Food Agency
http://www.slv.se/en-gb/

Medical Products Agency
http://www.lakemedelsverket.se/english/
12.3 Guidance documents

Guidance document on data requirements for active substances and biocidal products (TNsG on Data Requirements):
European Commission Joint Research Centre

Guidance document for human exposure estimation (TNsG Human Exposure):
Europeiska kommissionen Joint Research Centres webbplats

Guidance document for risk assessment of biocidal products according to the uniform principles in the biocides directive (TNsG on Product Evaluation):
European Commission Joint Research Centre

Guidance document from OECD for microbial pest control products:
http://www.oecd.org/document/7/0,3343,en_2649_34383_32286855_1_1_1_1,00.html

Guidance document from OECD for biological pesticides:
http://www.oecd.org/document/8/0,3343,en_2649_34383_31962760_1_1_1_1,00.html

13 Glossary

The KemI website contains a glossary listing words, abbreviations, terms etc. that are found in texts on the website and in this document.

14 Annexes

14.1 Annex 1: Risk assessment Baltic sea

14.1.1 PNEC_Baltic Sea

The TGD (Technical guidance Document)\(^{40}\) provides guidance for the extrapolation of a PNEC based on freshwater data to the marine environment. When $PNEC_{freshwater}$ is calculated with the AF-method from an EC50/LC50- or a NOEC value for the most sensitive species an additional AF=10 is applied to derive the $PNEC_{marine}$ if no

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additional information from marine taxa is available. This additional factor is assumed to cover both that the greater species diversity in marine areas may make the sensitivity distribution broader and that the low species diversity in certain areas (i.e. the Baltic Sea) makes the ecosystem extra vulnerable. In the case when information is available for additional marine taxa (as specified in the TGD) no extra AF is needed to derive the PNEC\textsubscript{marine}. But in order to take into account the sensitivity of the Baltic environment KemI is of the opinion that an additional AF is needed to derive a PNEC\textsubscript{Baltic} in this case.

Despite the lack of guidance for extrapolating the PNEC\textsubscript{marine} from a PNEC\textsubscript{freshwater} derived with the SSD-method, the same approach as for the AF-method has been used in some EU risk assessments i.e. the PNEC\textsubscript{marine} has been derived from the PNEC\textsubscript{freshwater} with an extra AF=10 and in this case the sensitivity of the Baltic can be assumed to be covered. But if the PNEC\textsubscript{marine} is derived from a SSD with only marine species KemI is of the opinion that an extra AF is needed to derive a PNEC\textsubscript{Baltic} based on the previously discussed differences between the truly marine environment and the Baltic Sea.

14.1.2 Factors that apply for all pollutants in the Baltic Sea

Low species diversity

The Baltic Sea is classified as a Particularly Sensitive Sea Area (PSSA) by IMO (International Maritime Organisation, 2004). The Baltic Sea is a brackish sea with low species diversity. The number of macroscopic animal species in the Stockholm archipelago is less than 10\% of the number at Öresund. The low species diversity increases the dependency on individual keystone species to maintain ecosystem function. These include bladder wrack and mussels\textsuperscript{41,42}, which both belong to the species most sensitive to copper.

Osmotic stress

The flora and fauna in the Baltic Sea is made up of species of both marine and limnic origin that live under osmotic stress, which means that less energy is available to general fitness related traits such as growth and tolerance to pollutants. This is illustrated by a significantly smaller body size in Baltic Sea populations of for example the blue mussel, Mytilus edulis, and the shore crab, Carcinus maenas, compared to populations in Skagerrak and the North Sea. Moreover, the higher level of osmotic stress in the Baltic Sea may also make these populations extra sensitive to additional stress in the form of pollutants. Indications of such an extra sensitivity have been described for blue mussels and gammarids\textsuperscript{43, 44}. Together with the


eutrophication of the Baltic Sea, the poor mixing and long turnover of water it makes the Baltic Sea to a multi-stressed environment, a type of environment that has not been risk assessed in the VRAR-Cu\textsuperscript{45}.

14.1.3 Factors which are more specific for copper (or other metals)

Increased bioavailability

According to the TGD the effects assessment must use, where possible, data relevant to the environmental compartment that is considered. Most of the studies used for the marine effects assessment in the VRAR Cu were conducted at a salinity of 20-35 \% which is not representative for the Baltic Sea. The salinity is 5-8 \% in the major part of the Baltic Sea and Gulf of Bothnia but decreases to only 2-3 \% at some locations. At lower salinities copper bioavailability can be higher for example due to the lower Ca\textsuperscript{2+} concentration in the Baltic, which increases cell permeability. A lower Ca\textsuperscript{2+} concentration also reduces the competition between copper ions and Ca\textsuperscript{2+} at the cell membranes. Hence the same concentration of dissolved copper (assuming constant DOC concentration) will have a greater toxic effect in brackish than marine water.

Sensitive keystone species

The blue mussel, \textit{Mytilus edulis}, and the bladderwrack, \textit{Fucus vesiculosus}, are both keystone species in the Baltic Sea, and among the species that are the most sensitive to copper.

This means that although the blue mussel and bladderwrack are represented in the SSD this is by their marine conspecifics and not the Baltic Sea populations. Baltic Sea populations of the same species are experiencing osmotic stress and have been shown to be more sensitive to toxicants (see above).

Based on these arguments KemI has considered it appropriate to use an additional AF=2 for organic substances and an AF=3 for metals when deriving the PNEC\textsubscript{Baltic} from the PNEC\textsubscript{marine} except when PNEC\textsubscript{marine} has been derived from the PNEC\textsubscript{freshwater} with an extra AF=10.

DOC in the Baltic Sea

The concentration of dissolved organic carbon is typically higher in the Baltic Sea than in marine waters and the PNEC is normalised accordingly. A value of TOC=4.6


mg/l has been reported in KemI rapport nr 2/06\(^{46}\) (average of all values at all stations) and this value is used for DOC when normalising PNEC for the Baltic Sea. For comparison, it is worth mentioning a number of other studies where TOC has been measured in the open sea. In 2006 Alling and co-workers measured TOC at 11 different stations in the Baltic Sea. Average concentrations ranged from 3.6 mg/l in the Baltic Proper to 4.0 mg/l in the Bothnian Bay. These values are in line with the values presented by Skoog et al. where the TOC measured ranged between 3.8 and 4.1 mg/l\(^{47}\). Furthermore the average DOC concentration measured in surface water in the eastern Gotland basin is appr. 3.8 mg/l\(^{48}\). The risk assessment presented here concerns the coastal environment, rather than the open sea. Since higher DOC concentrations are expected in the archipelago or in coastal environments than in the open sea, the value from the KemI report No 2/06 of TOC=4.6 mg/l is used as DOC.

### 14.2 Annex 2: Risk assessment of antifouling products – environmental exposure assessment

The MAMPEC (Marine Antifoulant Model to Predict Environmental Concentrations) model has been developed for the calculation of environmental concentrations of active substances in antifouling products. Default scenarios representing an EU harbour and an EU marina incorporated in the software are used in the evaluation of active substances under the BPD (98/8/EG). For the evaluations for Swedish registrations of antifoulants these scenarios need to be adjusted as the conditions in Sweden differ both regarding abiotic environmental factors e.g. salinity and tidal water but also in the number and size of boats and ships in harbors and marinas. Therefore in 2008 additional scenarios were developed: one harbor and one marina scenario representative of the Swedish west coast and one harbor and marina representative of the east coast i.e. the Baltic Sea. Due to a limited database, it is hard to develop representative type scenarios for the Swedish coastline. Hence, the work has been limited to existing harbours and marinas representing high traffic cases for Swedish conditions. The input data is presented briefly below, but is described more in depth in a report by Ambrosson\(^{49}\) (2008, in Swedish). In 2009 some changes in the scenarios were made. Input data for temperature in marina scenarios, sea level fluctuations (tide at the west coast), wind speed and wind direction have been extracted from the data bases of the Swedish Meteorological and Hydrological Institute. Both ”Environment” and ”Emission” need to be changed for the Swedish scenarios.

\(^{46}\) KemI rapport nr 2/06, Kemiska ämnena i båtbotterfärger –en undersökning av koppar, zink och Irgarol 1051 runt Bullandö marina 2004.


The resulting marina PECs should be corrected with factor of 0.92 as on average 8\% of the vessels are out at sea.

In MAMPEC you have the option to define a background concentration for the modeled substance. But even if you define a background concentration MAMPEC (2.5) still assumes the background concentration in the harbor basin to be zero (0) (a bug in the model). KemI has, for this reason, when modeling the PEC of copper, set the background concentration to 0 and added the dissolved concentration afterwards in order to calculate the PEC.

The values of dissolved copper that are used in the MAMPEC model are presented in the table below.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Totalt</th>
<th>Dissolved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Göteborgs harbour</td>
<td>1.3(^{50})</td>
<td>0.46**</td>
</tr>
<tr>
<td>Oxelösunds harbour</td>
<td>-</td>
<td>0.60(^{51})</td>
</tr>
<tr>
<td>East coast marina</td>
<td>1.08*</td>
<td>0.69**</td>
</tr>
<tr>
<td>West coast marina</td>
<td>-</td>
<td>0.51(^{52})</td>
</tr>
</tbody>
</table>

* Average value of reference station calculated from Kylin 2006\(^{53}\)

** Value is estimated in MAMPEC using scenario specific conditions, e.g. total copper

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14.2.1 West Coast Harbor – Gothenburg harbor
For the evaluation of antifoulants in Class 2 for use on the Swedish west coast.

Environment

Calculation of exchange volume
Emission

Needs to be completed with product-specific information on leaching rate
14.2.2 East Coast Harbour – Oxelösunds harbour
For the evaluation of antifoulants in Class 2 for use on the Swedish east coast.

Environment
Calculation of exchange volume

Emission
Needs to be completed with product-specific information on leaching rate.
14.2.3 West Coast Marina

For the evaluation of antifoulants in Class 3 for use on the Swedish west coast

Environment

Calculation of exchange volume

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total difference</td>
<td>5.23 m</td>
</tr>
<tr>
<td>Salinity difference tide</td>
<td>0 kg/m³</td>
</tr>
<tr>
<td>Non-tidal daily water level change</td>
<td>0 m</td>
</tr>
<tr>
<td>Fraction of time wind perpendicular</td>
<td>0.999</td>
</tr>
<tr>
<td>Average wind speed</td>
<td>0.5 m/s</td>
</tr>
<tr>
<td>Flush (W)</td>
<td>0 m³/s</td>
</tr>
<tr>
<td>Max. density difference flush</td>
<td>0 kg/m³</td>
</tr>
</tbody>
</table>

Harbour lay-out data, used for density flow exchange

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth MSL in harbour entrance</td>
<td>3 m</td>
</tr>
<tr>
<td>Exchange area harbour mouth, below mean sea level</td>
<td>1600 m²</td>
</tr>
<tr>
<td>Height of submerged dam</td>
<td>0 m</td>
</tr>
<tr>
<td>Width of submerged dam</td>
<td>0 m</td>
</tr>
</tbody>
</table>
Emission

Needs to be completed with product-specific information on leaching rate
14.2.4 East Coast Marina
For the evaluation of antifoulants in Class 3 for use on the Swedish east coast

Environment

Calculation of exchange volume
Emission

Needs to be completed with product-specific information on leaching rate
West Coast Harbor – Gothenburg harbor
For the evaluation of antifoulants in Class 2 for use on the Swedish west coast.

Environment

Calculation of exchange volume