

The text the Swedish Chemicals Agency reproduces here is a translation of the Swedish text contained in the Swedish Code of Statutes

In any matters of dispute, the Swedish text only shall apply.

The Biocidal Products Ordinance (2000:338)

issued 18 May 2000.

The Government stipulates the following:

Introductory provisions

Section 1

This Ordinance contains provisions about biocidal products. With respect to pesticides which are not biocidal products, the provisions in the Ordinance on Plant Protection Products (2006:1010) apply.

The provisions in this Ordinance apply in addition to the provisions in

1. the Chemical Products and Biotechnical Organisms Ordinance (1998:941),

2. the Ordinance on Deliberate Release into the Environment of Genetically Modified Organisms (2002:1086),

3. Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC, and

4. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

Ordinance (2006:1049).

Section 2

Terms used in this Ordinance have the same meanings as in Chapter 14 of the Environmental Code. Otherwise, for the purposes of this Ordinance, the following meanings apply:

Biocidal Products Directive: Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, most recently amended in Commission Directive 2006/50/EC;

Biocidal product: a chemical or biological pesticide as defined in Chapter 14 of the Environmental Code, which is not a plant protection product as defined in the Ordinance on Plant Protection Products (2006:1010);

Low-risk biocidal product: a biocidal product which does not contain any active substances other than those listed in Annex IA to the Biocidal Products Directive and which does not contain any potentially dangerous substance;

Basic substance: a chemical substance which is included in Annex IB to the Biocidal Products Directive and which is not primarily used as a pesticide but which is used, to a limited extent, as a biocidal product either directly or diluted with an ordinary dilution agent in a chemical product which is neither sold for use as a pesticide nor contains any other substance which gives cause for concern from a health or environmental protection perspective;

Substance of concern: a substance which is not an active substance but which is capable of having a detrimental effect on humans, animals, or the environment and which is present in or formed in a biocidal product in a concentration which is high enough to give rise to such an effect;

Active substance: a substance or micro-organism, including viruses or fungi, which has a general or specific effect on, or against, organisms whose presence is undesirable or harmful to humans, for human activities, for products which humans use or produce, for animals, or for the environment;

Frame-formulation: a specification for a group of biocidal products with the same field of application and the same user category. *Ordinance (2006:1049).*

Section 3

The Swedish Chemicals Agency may issue regulations concerning exemptions from the provisions concerning pesticides in the Environmental Code and from the provisions in this Ordinance, if such exemptions are required with reference to the Biocidal Products Directive. *Ordinance (2006:1049).*

Authorisation or registration requirements

Section 4

The Swedish Chemicals Agency shall review matters concerning authorisation of biocidal products pursuant to Chapter 14, Section 14 of the Environmental Code. *Ordinance (2006:1049).*

Section 5

The Swedish Chemicals Agency may, in addition to the provisions in Section 3, issue regulations concerning exemptions or, in individual cases, issue exemptions from the authorisation requirement in respect of:

1) low-risk biocidal products, where the authorisation requirement is replaced by a registration requirement;

2) basic substances which are used as biocidal products;

3) use for research and development purposes;

4) limited and controlled uses for a maximum of 120 days, if the measure appears necessary due to an unforeseen risk which cannot be controlled in any other way;

5) biocidal products whose active substance was not on the market prior to 14 May 2000 and which has not yet been reviewed for inclusion in Annex I or IA to the Biocidal Products Directive, if the authorisation requirement is replaced with a temporary authorisation requirement in pursuant to the provisions in Article 15.2 of the Biocidal Products Directive;

6) biocidal products whose active substances were on the market prior to 14 May 2000 but which have not yet been included in Annex I or IA to the Biocidal Products Directive, if the authorisation requirement is replaced with a temporary authorisation requirement in accordance with the transitional measures set forth in Article 16 of the Biocidal Products Directive; or

7) if there otherwise exists special cause and an exemption is consistent with the Biocidal Products Directive.

In applying items 5) and 6), an active substance shall be deemed to be on the market only if it is on the market for uses other than scientific or applied research, or development activities. Regulations or exemptions pursuant to item 6) require that the active substance is present in a biocidal product intended for such other uses.

Ordinance (2006:1049).

Section 6

With respect to regulations or exemptions as referred to in Section 5, the Swedish Chemicals Agency shall apply the following provisions in the Biocidal Products Directive:

- 1) Article 3.2 concerning the conditions for allowing, and the obligation to allow, low-risk biocidal products and basic substances to be placed on the market;
- 2) Article 17 concerning the conditions for use of biocidal products for research and development purposes;
- 3) Article 15.2 concerning dossiers and the assessment of biocidal products and their active ingredients in connection with the granting of temporary authorisation pursuant to Section 5, item 5).

If an exemption is granted, it shall be consistent with the conditions necessary for the protection of human health or the environment, or for compliance with the Biocidal Products Directive. *Ordinance (2006:1049)*.

Section 7

No new authorisation is required for the placing of a biocidal product on the market under a new name if the product is essentially similar to a product already authorised under this Ordinance, provided that the similar product

- 1) contains the same active substance in the same strength as the authorised product;
- 2) has been produced using the same method as the authorised product;
- 3) has the same function and properties as the authorised product;
- 4) fulfils the same safety requirements as the authorised product does;
- 5) has a name which cannot be confused with authorised product's name or which otherwise would contravene Section 10; and
- 6) has been reported to the Swedish Chemicals Agency with all the documentation necessary to prove that requirements 1-5 have been fulfilled.

The Swedish Chemicals Agency shall maintain a register of the names reported pursuant to the first paragraph. *Ordinance (2006:1049)*.

Conditions for authorisation**Section 8**

Applications for authorisation, or for an amendment to an authorisation, shall be made by or on behalf of the party that is or will be responsible for initially placing the product on the Swedish market. The applicant must have a permanent office in a country within the European Union or the European Economic Area. *Ordinance (2006:1049)*.

Section 9

The Swedish Chemicals Agency may issue further, detailed regulations about the conditions for authorisation which shall apply pursuant to Chapter 14, Section 14 of the Environmental Code regarding the product's composition, mode of action and its other properties, as well as the need for it for pest control purposes *Ordinance (2006:1049)*.

Section 10

A biocidal product may not be authorised if its name may be regarded as misleading with respect to its composition, mode of action or its other properties, or if it may lead to confusion with another pesticide. *Ordinance (2006:1049)*.

Dossier requirements

Section 11

Applications for authorisation shall include a dossier about the product and its active substance.

The Swedish Chemicals Agency may issue regulations governing dossiers and samples as required in the Biocidal Products Directive, or as otherwise required in order for the Agency to carry out their assessment. *Ordinance (2006:1049)*.

Use of dossiers submitted by other applicants

Section 12

The following shall apply in respect of active substances which were not on the market prior to 14 May 2000:

Information in the dossier attached to an application for authorisation may be used for the benefit of other applicants only if a period of fifteen years has elapsed since the active substance was first included in Annex 1 or 1A to the Biocidal Products Directive.

Section 13

The following shall apply in respect of biocidal products which contain an active substance that was not on the market prior to 14 May 2000:

Information in the dossier attached to an application for authorisation may be used for the benefit of other applicants only if a period of ten years has elapsed since the product was first authorised in any country within the European Union or the European Economic Area.

Section 14

The following shall apply in respect of active substances which were on the market prior to 14 May 2000, and in respect of biocidal products which contain such an active substance:

Information in the dossier attached to an application for authorisation may be used for the benefit of other applicants only after 13 May 2010.

If the information is protected pursuant to provisions in laws or other ordinances, and such protection expires prior to 14 May 2010, the provisions of the first paragraph shall not preclude the use of such information after the earlier date.

The following shall apply in lieu of the first paragraph in respect of information which has been submitted for the first time in order for an active substance or a new product type for that substance to be listed in Annex I or IA to the Biocidal Products Directive:

The information may be used for the benefit of other applicants only if a period of ten years has elapsed since the active substance was listed in Annex I or IA to the Biocidal Products Directive.

Section 15

The following shall apply in respect of additional information about an active substance referred to in Sections 12 or 14 and which has been submitted for the first time in order to amend the conditions for listing or for a continued listing in Annex I or IA to the Biocidal Products Directive:

The information may be used for the benefit of other applicants only if the protection period stipulated in Sections 12 or 14 has expired and a period of five years has elapsed since the date of the decision about conditions or a continued listing which was prompted by the new information.

Section 16

The following shall apply in respect of information about a biocidal product which has been submitted for the first time in order to amend the conditions for authorisation, or in order that an active substance continue to be listed in Annex I or IA of the Biocidal Products Directive:

The information may be used for the benefit of other applicants only if the protection period stipulated in Sections 13 or 14 has expired and a period of five years as elapsed since the new information was submitted.

Section 17

The provisions in Sections 12-16 shall not apply if the applicant has permission to use the information from the original applicant or from someone whose right to grant such permission can be attributed to the original applicant. *Ordinance (2006:1049)*.

Section 18

The provisions in Sections 12-16 shall not preclude the use of the information by the European Commission, its advisory scientific committees, or the Swedish Chemicals Agency with respect to matters regarding a refusal to list an active substance in Annex I, IA, or IB to the Biocidal Products Directive, or to remove a substance from the Annexes.

Use of information in matters regarding the authorisation of products similar to previously authorised products**Section 19**

The Swedish Chemicals Agency may, in lieu of requiring a dossier, accept an applicant's reference to information which was submitted with a previous application that led to the authorisation of a biocidal product, if the applicant demonstrates that the new product is similar to the previous one and contains the same active substances with the same degree of purity and type of impurities.

The first paragraph may not be applied in contravention of the provisions in Sections 12-17.

Section 20

In connection with the authorisation of a biocidal product, the Swedish Chemicals Agency may establish a frame formulation. The Inspectorate shall establish a frame-formulation if the applicant requests it.

In lieu of demanding a dossier, the Swedish Chemicals Agency may apply the frame formulation as a basis for subsequent authorisations of biocidal products. This is on condition that the later product, in comparison with the previously authorised product,

- 1) has the same field of application and user category; and
- 2) only differs in that the strength of the active substance is lower than in the earlier product; and that the content in terms of non-active substances, pigments, colouring agents or scents only varies or has been changed to an extent which does not raise the risk level or lower the effectiveness of the product.

Notification of decisions concerning applications for authorisation as described in the second paragraph shall be made within 60 days of the date on which the application was received.

The second paragraph may not be applied in contravention of the provisions in Sections 12-17. Further, it shall be applied on condition that the applicant has proved his or her authority to use the frame formulation as a basis for his or her application.

Mutual recognition

Section 21

A biocidal product which is authorised or registered in a country within the European Union or European Economic Area shall be authorised or registered at the request of an applicant, if the product's active substance is included in Annex I or IA to the Biocidal Products Directive and fulfils the requirements in the list.

When the Swedish Chemicals Agency has received an application as referred to in the first paragraph, it shall make a decision regarding authorisation within 120 days or regarding registration within 60 days.

The first paragraph may not be applied in contravention of Sections 12-17, or of provisions for the protection of human health or the environment which apply as a consequence of Sweden's membership of the European Union.

Section 22

Notwithstanding the provisions in Section 21, the Swedish Chemicals Agency may decide temporarily to refuse authorisation or registration. In such cases, the provisions set forth in this Section shall apply.

If the Swedish Chemicals Agency considers that a product is not a low-risk biocidal product, and that the registration in another country therefore cannot be recognised, the following shall apply:

The Agency shall immediately notify the authority responsible for checking the dossiers pertaining to the product and attempt to reach an agreement with that authority about what conditions the product should be subject to. If the authorities cannot reach an agreement within 90 days, the matter shall be referred to the European Commission for resolution.

If the Swedish Chemicals Agency considers that the product does not fulfil the conditions referred to in Section 9, and that the authorisation or the registration in another country therefore cannot be recognised, or can only be recognised subject to further conditions, the following shall apply:

The Agency shall refer the matter to the European Commission for resolution. The Agency shall also notify the other countries in the European Union and the European Economic Area. The referral and the notification shall contain a report of the Agency's assessment. The report shall also be handed over to the applicant.

Section 23

Notwithstanding the provisions in Section 21, the Swedish Chemicals Agency may decide to refuse authorisation or registration of biocidal products which are intended for controlling birds, fish, or vertebrates other than rodents. Any such decision must be justifiable and may not counteract the purposes of the Biocidal Products Directive.

Section 24

Notwithstanding the provisions in Section 21, the Swedish Chemicals Agency may make an authorisation subject to special conditions, if such conditions are consistent with Article 4 of the Biocidal Products Directive.

The Swedish Chemicals Agency may issue further, detailed regulations regarding such conditions as referred to in the first paragraph.

Conditions to which an authorisation shall be subject

Section 25

When a biocidal product is authorised, its properties in terms of hazards to human health and the environment shall be evaluated in light of the field of application. On the basis of such an evaluation, the product shall be classified as follows.

Class 1: Products for professional use only, requiring a special permit.

Class 2: Products for professional use only.

Class 3: Products that may be used by anyone.

Section 26

To ensure compliance with the regulations referred to in Section 9, the Swedish Chemicals Agency may, following consultation with other concerned government authorities, decide that the authorisation shall be subject to special conditions in addition to current regulations governing handling, classification, packaging, labelling and other product information. These special conditions shall be stated in the authorisation.

Term of validity of the authorisation

Section 27

Authorisation may be granted for a fixed term only. Chapter 14, Section 14 of the Environmental Code states that this term may not exceed ten years.

If an active substance in a biocidal product is listed in Annex I or IA to the Biocidal Products Directive, authorisation may only be granted for the period of time, as specified in the Annex, during which it will be included there.

Section 28

The term of validity of an authorisation may be extended provided the conditions for authorisation in Section 9 remain fulfilled. The Swedish Chemicals Agency may decide to extend an authorisation for the period of time required for a review of the fulfilment of the conditions. *Ordinance 2006:1049*.

Obligation to notify regarding new information

Section 29

Notification about adverse effects as referred to in Chapter 14, Section 23 of the Environmental Code shall be made to the Swedish Chemicals Agency.

Anyone who has placed an authorised or registered biocidal product on the market, or has obtained an authorisation or registration of such a product, shall further be obliged immediately to notify the Swedish Chemicals Agency in the event of new information emerging with respect to:

- 1) the composition of a biocidal product;
- 2) the origin or composition of an active substance;
- 3) the development of resistance;
- 4) the way in which the product is packaged; or
- 5) other circumstances which may have a bearing on continued authorisation.

The Swedish Chemicals Agency may issue further, detailed regulations regarding the obligation to notify.

Review, modification and cancellation of an authorisation

Section 30

An authorisation may be reviewed if there is information indicating that any of the conditions referred to in Section 9 is not fulfilled.

In connection with a review, the Swedish Chemicals Agency may request the information necessary for its review. The Agency may decide to extend an authorisation for the period of time required for the review and for the submission of the requested information.

Section 31

An authorisation may be modified with respect to conditions for use if the modification is justified from a health or environmental perspective in light of new scientific and technical knowledge.

A modification may also be made if the applicant for authorisation requests it and states the reasons for the modification.

A modification may be granted only if the conditions referred to in Section 9 continue to be fulfilled.

Section 32

An authorisation may be modified with respect to a product's field of application. A broadening of the field of application may not be granted in contravention of the conditions which pertain to the active substance pursuant to Annex I or IA to the Biocidal Products Directive.

A modification may be granted only if the conditions referred to in Section 9 continue to be fulfilled.

Section 33

An authorisation shall be cancelled if:

- 1) the conditions referred to in Section 9 are no longer fulfilled;
- 2) inaccurate or misleading information was submitted regarding the circumstances upon which the authorisation was based; or if
- 3) an active substance in the product has been removed from Annex I or IA to the Biocidal Products Directive.

An authorisation may also be cancelled if the applicant for the authorisation requests it and states the reasons for the cancellation.

Section 34

In connection with the cancellation of an authorisation, the Swedish Chemicals Agency may decide that remaining stocks of the product may be appropriated, stored, placed on the market, and used for a specified period of time. In determining the duration of that period, the reason for the cancellation shall be considered.

The decision may not lead to a product being placed on the market or used in contravention of other regulations applicable to the product.

The Swedish Chemicals Agency may issue further, detailed regulations regarding the application of the first paragraph.

Active substances

Section 35

The Swedish Chemicals Agency shall carry out the tasks incumbent on Sweden under the provisions of the Biocidal Products Directive regarding the listing of active substances in Annex I, IA or IB to the Directive.

The Swedish Chemicals Agency may issue such regulations and decisions as are necessary in order to carry out the tasks referred to in the first paragraph.

Section 36

The Swedish Chemicals Agency may issue such regulations as result from decisions to include or remove substances from an annex to the Biocidal Products Directive.

Section 37

The Swedish Chemicals Agency may issue regulations regarding conditions for allowing an active substance to be placed on the market.

Cooperation on information

Section 38

Anyone intending to apply for authorisation of a biocidal product whose active substance is included in Annex IA or IB to the Biocidal Products Directive shall, before animal testing is carried out, inquire of the Swedish Chemicals Agency if a similar product has already been authorised, and, if that is the case, try to reach an agreement as described in the second paragraph.

All reasonable measures shall be taken, by whoever has had a biocidal product authorised and whoever intends to apply for authorisation of a similar product, to reach an agreement as to how the information about the authorised product and its active substance may be used jointly for both products. The purpose of such an agreement shall be to avoid unnecessary repetitions of animal tests. Provisions governing the authorisation of animal tests are included in the Animal Protection Ordinance (SFS 1988:539). *Ordinance 2006:1049.*

Section 39

The Swedish Chemicals Agency may issue further, detailed regulations regarding the application of Section 38.

Packaging and product information

Section 40

The Swedish Chemicals Agency may issue such regulations about packaging and labelling as are necessary with regard to the protection of human health or the environment, or as a result of the Biocidal Products Directive. *Ordinance 2006:1049.*

Section 41

Biocidal products and active substances intended for use in biocidal products may not be placed on the market unless they are packaged and labelled in accordance with the regulations referred to in Section 40. *Ordinance 2006:1049.*

Section 42

Whoever places a biocidal product on the market or intends to transfer such a product shall inform the buyers and users of the product that it must be used in a safe way. The information shall contain a recommendation always to read the label on the product's packaging and other product information before using a product.

The information shall be presented in such a way as to be clearly distinguishable from other information.

Section 43

Repealed through Ordinance (2006:1049).

Production, storage and transportation in certain cases**Section 44**

The fact that a biocidal product has not been authorised under the provisions in Chapter 14 of the Environmental Code and in this Ordinance may not be used as a basis for obstructing its production, storage or transportation, if it has been authorised in another country within the European Union or the European Economic Area and is intended for use in that country.

The first paragraph notwithstanding, the Swedish Chemicals Agency may issue regulations on what anyone producing, storing or transporting biocidal products must observe in order for the supervisory authority to be able to control that the preparation is not placed on the market in contravention of the regulations on authorisation.

Ordinance 2006:1049.

Use**Section 45**

In the application of the general rules of consideration in Chapter 2, Sections 2,3 and 6 of the Environmental Code, the following in particular should be observed regarding the use of biocidal products:

- 1) that they are used in a way which is consistent with the conditions for authorisation referred to in Section 9 of this Ordinance; and
- 2) with the conditions referred to in Section 26 of this Ordinance; and
- 3) with the labelling requirements referred to in Section 40.

By combining physical, biological, chemical, or other methods, the use of biocidal products shall be limited to what is absolutely necessary. *Ordinance 2006:1049.*

Expertise requirements, etc. in certain cases**Section 46**

A biocidal product classified in Section 25 as a Class 1 product may only be used by a person who fulfils special expertise requirements.

With respect to biocidal products classified in Section 25 as Class 2 products, the Swedish Chemicals Agency may stipulate that the preparation may only be used by a person who fulfils special expertise requirements.

Regulations about special expertise requirements may be combined with a requirement that the person using the product must have attained a certain age.

Section 47

Detailed regulations about what expertise is required and about age limits for use shall be issued by the authority charged, pursuant to Section 48, with reviewing matters concerning permits. The authority shall consult with the Swedish Chemicals Agency before issuing a regulation.

Permits for use

Section 48

A biocidal product classified in Section 25 as a Class 1 product may only be used with a special permit. A permit shall apply for a fixed term.

The matter of permits shall be reviewed by National Board of Health and Welfare in the case of measures to control vermin and pests, in accordance with Chapter 9, Section 9 of the Environmental Code, and by the Swedish Work Environment Authority in the case of other activities. *Ordinance (2000:969)*.

Section 49

The authority charged, under Section 48, with reviewing matters concerning permits may issue detailed regulations about the conditions for such permits. Such regulations shall cover conditions which are material for the fulfilment of the provisions in Section 45 or the regulations referred to in Section 46. The authority shall consult with the Swedish Chemicals Agency prior to issuing a regulation.

Exemptions from bans

Section 49 (a)

The Swedish Chemicals Agency may, in individual cases and if particular cause exist, and following consultation with the Swedish Environmental Protection Agency, the Swedish Board of Agriculture and the Swedish Forest Agency, grant exemptions from the ban on spreading pesticides from aircraft as laid down in Chapter 14, Section 18, second paragraph of the Environmental Code.

Any such exemption shall be subject to conditions necessary from a health and environmental perspective. *Ordinance (2006:1049)*.

Temporary limits and bans

Section 50

If there is reason to suspect that an authorised biocidal product or a product which the Swedish Chemicals Agency is charged with authorising constitutes an unacceptable risk to human health or the environment, the Agency may temporarily limit or ban the use or sale of that product.

If the Agency issues such a decision, it shall immediately notify the European Commission and the other member states within the European Union.

With respect to registered low-risk biocidal products and products which the Agency is charged with registering, the first paragraph shall apply correspondingly.

Ordinance (2006:1049).

Supervision and fees

Section 51

Provisions regarding supervision and fees are laid down in the Environmental Code (Supervision) Ordinance (1998:900), the Environmental Code Fees (Reviews and Supervision) Ordinance (1998:940) and the Chemical Charges Ordinance (1998:942).

Appeals, penalties and forfeiture

Section 52

Provisions regarding appeals, penalties and forfeiture are laid down in Chapter 19, Section 1 and Chapter 29 of the Environmental Code. *Ordinance (2006:1049)*.

Section 53

Repealed through Ordinance (2006:1049).

Information exchange within the European Union, etc.**Section 54**

With respect to announcements, notifications and other information to the European Commission and the other countries in the European Union or the European Economic Area, the Swedish Chemicals Agency shall carry out the tasks incumbent on Sweden under the following provisions of the Biocidal Products Directive:

- 1) transitional measures;
- 2) provisions regarding the furnishing of information about applications and providing access to dossiers;
- 3) provisions regarding information exchange in respect of decisions in matters of authorisation, registration, exemption and revocation, and of lists of authorised and registered products;
- 4) provisions regarding the sharing of information which comes to light during the scrutiny of an application for authorisation;
- 5) provisions regarding the sharing of information about such adverse effects and other new facts as referred to in Section 29;
- 6) provisions regarding deviation from labelling requirements;
- 7) provisions regarding the reporting of supervisory measures and any cases of poisoning caused by biocidal products.