

*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 Plant Protection Ordinance (2006:1010)**

issued on 14 June 2006.

The Government stipulates the following:

### **Introductory provisions**

#### **Section 1**

This Ordinance contains provisions about plant protection products. With respect to pesticides which are not plant protection products, the provisions in the Biocidal Products Ordinance (2000:338) 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.

#### **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:

*Integrated control:* a rational application of a combination of biological, biotechnical, physical, chemical, or cultivation or plant breeding measures which reduces the use of chemical plant protection products to the minimum needed to keep the population of harmful organisms at a level where it does not cause economically unacceptable damage or loss;

*Harmful organisms:* plant or plant-product pests belonging to the animal or plant kingdom or consisting of viruses, bacteria or mycoplasma, or other pathogens;

*Active substances:* substances or micro-organisms, including viruses, which have a general or specific effect on harmful organisms or on plants, plant parts or plant products;

*Plants:* living plants and living plant parts, including fresh fruits and seeds;

*Plant products:* products of plants which are unprocessed or have only been subjected to a simple treatment such as grinding, drying or pressing;

*Plant protection products:* chemical products, biotechnical organisms and chemical or biological pesticides according to the definitions in Chapter 14 in the Environmental Code, which, in the form they are delivered to the user, are intended to

- protect plants or plant products from harmful organisms or prevent the effects of such organisms,
- affect the life processes of plants in other ways than as nutrition,
- preserve plant products to the extent that the chemical product, the biotechnical organism or the pesticide is not covered by special community provisions about preservatives,
- destroy unwanted plants, or
- destroy plant parts or inhibit or prevent unwanted growth in plants;

*The Plant Protection Products Directive:* the Council of Ministers' directive 91/414/EEC of 15 July 1991 about placing plant protection products on the market, most recently amended through the Commission's directive 2006/45/EC.

### **Section 3**

The Swedish Chemicals Agency may issue regulations about 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 Plant Protection Products Directive.

### **Approval requirements**

#### **Section 4**

The Swedish Chemicals Agency shall review matters concerning the approval of plant protection products pursuant to Chapter 14, Section 14 of the Environmental Code. If necessary, the authority shall consult with the Swedish Board of Agriculture and the Swedish Food Administration.

#### **Section 5**

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

- 1) use for research and development purposes;
- 2) 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;
- 3) plant protection products whose active substance was not on the market prior to 26 July 1993 and which has not yet been reviewed for inclusion in Annex I to the Plant Protection Products Directive, if the approval requirement is replaced with a temporary approval requirement under the provisions in Article 8.1 of the Plant Protection Products Directive;
- 4) plant protection products whose active substance was on the market prior to 26 July 1993 and which are included in the work programmes referred to in Article 8.2 of the Plant Protection Products directive, but for which decisions on inclusion in Annex 1 to the Plant Protection Products directive have not yet been taken, if the approval requirement is replaced with a requirement pursuant to the aforementioned Article; or
- 5) if, in cases other than those listed in items 1-4, there exists special cause and an exemption is consistent with the Plant Protection Products Directive.

Chapter 14, Section 16 of the Environmental Code states that such regulations or decisions may include a requirement for notification in advance of any sale or use of a chemical product or a biotechnical organism.

#### **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 Plant Protection Products Directive:

- 1) Article 22 regarding conditions for the use of plant protection products for research and development purposes;

2) Article 8.1 regarding dossiers and assessments of plant protection products and their active substance in connection with the issuing of a temporary approval pursuant to Section 5, paragraph 1, 3; and

3) Article 8.3 regarding dossier requirements before an approval issued pursuant to Section 5, paragraph 1, 4 is reviewed under Article 8.2 of the Plant Protection Products directive. 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 Plant Protection Products Directive.

### **Section 7**

No new approval is required for the marketing of a pesticide which is essentially similar to a product already approved under this Ordinance, provided that the similar product

- 1) contains the same active substance in the same strength as the approved product;
- 2) has been produced using the same method as the approved product;
- 3) has the same function and properties as the approved product;
- 4) fulfils the same safety requirements as the approved product does;
- 5) has a name which cannot be confused with the approved product's name or which otherwise would contravene Section 11; and
- 6) has been reported to the Swedish Chemicals Agency with all the documentation necessary to prove that requirements 1-5 have been fulfilled.

### **Section 8**

Even if an approval is revoked pursuant to this Ordinance, the Swedish Chemicals Agency may decide that a product which has been submitted under Section 7 may continue to be placed on the market during the remainder of the term of validity stated in the approval decision, if

- 1) the revoked approval refers to a product which is still approved in another country in the European Union or the European Economic Area;
- 2) the revocation was not due to the effects of the product or to other properties which are significant from a health or environmental protection perspective; and
- 3) the conditions that apply for approval of the product's active substance in the European Union or the European Economic Area do not amount to a geographical limitation which rules out any use of the product in Sweden.

## **Conditions for approval**

### **Section 9**

Applications for approval or for an amendment to an approval 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.

### **Section 10**

The Swedish Chemicals Agency may issue further, detailed regulations about the conditions for approval which shall apply pursuant to Chapter 14, Section 14 of the Environmental Code regarding the plant protection product's composition, how it acts and its other properties, as well as the demand for it for pest control purposes

### **Section 11**

A plant protection product may not be approved if its name may be regarded as misleading with respect to its composition, how it acts and its other properties, or if it may lead to confusion with another pesticide.

## **Requirements for dossiers, etc.**

### **Section 12**

Applications for approval shall include a dossier about the product and its active substance. If the active substance is listed in Annex 1 to the Plant Protection Products Directive and the applicant demonstrates that he or she has access to the complete dossier about the substance, the application need only, as far as the active substance is concerned, include that part of the dossier which is necessary in order to:

- 1) identify the active substance; and
- 2) verify that the active substance does not differ essentially, in terms of degree of purity and the type of impurities, from the composition which was declared in the dossier that formed the basis of the inclusion in Annex 1 to the Plant Protection Products Directive.

### **Section 13**

The Swedish Chemicals Agency may issue such regulations regarding dossiers and samples as are necessary with reference to the Plant Protection Products Directive, or which are otherwise necessary in order for the Agency to complete its review.

## **Use of dossiers submitted by other applicants**

### **Section 14**

In the processing of applications for approval of plant protection products, information in the dossier accompanying an application for approval may not be used in a way which benefits other applicants

- 1) where the information concerns an active substance which was on the market on or prior to 26 July 1993: until ten years have elapsed since the day of the Swedish Chemicals Agency's decision of approval,
- 2) where the information concerns an active substance which was not on the market on or prior to 26 July 1993: until ten years have elapsed since the active substance was first listed in Annex 1 to the Plant Protection Products Directive;
- 3) where the information concerns an active substance and has been submitted for the first time in order for it to be listed in Annex 1 of the Plant Protection Products Directive, in order to amend the conditions which apply to such a listing, or in order for it to continue being listed in the Annex: until the protection period referred to in 1 or 2 has expired and at least five years have elapsed since the day of the decision regarding amended conditions or a continued listing which was issued in reference to the new information; and
- 4) where the information concerns things other than the product's active substance and
  - a) where the active substance has been listed in Annex 1 to the Plant Protection Products Directive: until ten years have elapsed since the product, subsequent to its listing in Annex 1, was first approved in any of the countries within the European Union or the European Economic Area; or
  - b) where the active substance has not been listed in Annex 1 to the Plant Protection Products Directive: until ten years have elapsed since the product was first approved in Sweden.

### **Section 15**

The provisions in Section 14 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.

## **Tests and analyses requirements**

### **Section 16**

The tests and analyses needed in order to fulfil the requirements for approval shall, when it is required under Annex 2 or 3 to the Plant Protection Products Directive, be carried out by an institution accredited for such tasks under the Technical Conformity Assessment Act (1992:1119).

## **Mutual recognition**

### **Section 17**

When considering an application for approval of a plant protection product which is approved in another country within the European Union or the European Economic Area, the Swedish Chemicals Agency shall, if the applicant requests it,

1) refrain from requiring repetitions of those tests and analyses which were carried out in connection with the earlier approval; and

2) approve the product, if the active substance is listed in Annex 1 to the Plant Protection Products Directive and the product was assessed for the earlier approval by applying the uniform principles referred to in Annex 6 to the Plant Protection Products Directive.

The first paragraph may be applied only if the applicant provides written documentation to corroborate that the agricultural and plant protection conditions, as well as climatic and other environmental conditions relevant to the use of the product, are similar in the areas in question.

The first paragraph may not be applied in contravention of the provisions in Section 14.

### **Section 18**

The Swedish Chemicals Agency may make approval under Section 17 subject to special conditions, if such conditions are consistent with Article 10.1 of the Plant Protection Products Directive.

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

### **Section 19**

If the Swedish Chemicals Agency requires a test or an analysis to be repeated, or refuses to approve a plant protection product, despite the fact that the applicant has requested that Section 17 be applied, the Agency shall notify the European Commission of the decision and the reasons for it.

## **Conditions to which approval shall be subject**

### **Section 20**

When a plant protection product is approved, 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 commercial use only, requiring a special permit.

Class 2: Products for commercial use only, by persons who fulfil special expertise requirements, unless the Swedish Chemicals Agency decides otherwise in connection with the approval.

Class 3: Products for general use.

### **Section 21**

To ensure compliance with the regulations referred to in Section 10, the Swedish Chemicals Agency may, following consultation with other relevant government authorities, decide that approval 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 approval.

## **Term of validity of the approval**

### **Section 22**

Approval 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 the product is listed in Annex 1 to the Plant Protection Products Directive, approval may only be granted for the period of time, as specified in the list, during which it will be included there.

### **Section 23**

The term of validity of an approval may be extended provided the conditions for approval in Section 10 remain fulfilled. The Swedish Chemicals Agency may decide to extend an approval for the period of time required for a review of the fulfilment of the conditions.

## **Obligation to notify regarding new information**

### **Section 24**

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 had a plant protection product approved, or has had a widening of the product's field of application approved pursuant to Section 27, shall furthermore notify the Swedish Chemicals Agency immediately of any changed circumstances that have a bearing on the approval. The Swedish Chemicals Agency may issue further, detailed regulations regarding the obligation to notify.

## **Reconsideration, amendment and revocation of approval**

### **Section 25**

An approval may be reconsidered if there is information indicating that any one of the conditions referred to in Section 10 is not fulfilled.

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

### **Section 26**

An approval may be amended with respect to conditions for use if it is justified in light of new scientific and technical knowledge.

An amendment may also be made if the applicant for approval requests it and states the reasons for the amendment.

An amendment may be granted only if the conditions referred to in Section 10 continue to be fulfilled.

### **Section 27**

Public or scientific institutions in the agricultural area, agricultural organisations and professional users may apply to have the field of application of a previously approved plant protection product widened to include other applications than those covered by the approval. The field of application may be widened if the proposed application is of moderate extent and if it is in the public interest. The Swedish Chemicals Agency may issue such further regulations about conditions for a widening as are needed under Article 9.1 of the Plant Protection Products Directive.

**Section 28**

An approval shall be revoked if the conditions referred to in Section 10 are no longer fulfilled or if inaccurate or misleading information was submitted regarding the circumstances upon which the approval was based.

An approval may also be revoked if the applicant for approval requests it and states the reasons for the revocation.

If an approval is revoked, the Swedish Chemicals Agency shall immediately notify:

- 1) whoever has had the plant protection product approved;
- 2) whoever has submitted a similar product pursuant to Section 7 or has had such a product registered pursuant to Section 55; and
- 3) whoever has had a widening of the product's field of application approved pursuant to Section 27.

**Section 29**

In connection with the revocation of an approval, 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 revocation 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 30**

In Sweden, an application for an active substance to be listed in Annex 1 to the Plant Protection Products Directive shall be submitted to the Swedish Chemicals Agency.

**Section 31**

The Swedish Chemicals Agency shall carry out the tasks incumbent on Sweden under the provisions of the Plant Protection Products Directive regarding the listing of active substances in Annex 1 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 32**

The Swedish Chemicals Agency may issue such regulations as result from decisions to list or remove substances from Annex 1 to the Plant Protection Products Directive.

**Section 33**

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

**Cooperation on information****Section 34**

Anyone intending to apply for approval of a plant protection product whose active substance is listed in Annex 1 to the Plant Protection Products Directive shall, before animal testing is carried out, inquire of the Swedish Chemicals Agency if a similar product has already been approved, 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 plant protection product approved and whoever intends to apply for approval of a similar product, to reach an agreement as to how the information about the approved 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 approval of animal tests are included in the Animal Protection Ordinance (1988:539).

### **Section 35**

The Swedish Chemicals Agency may issue further, detailed regulations regarding the application of Section 34.

## **Classification, packaging and labelling**

### **Section 36**

The Swedish Chemicals Agency may issue such regulations about classification, packaging and labelling as are necessary with regard to the protection of human health or the environment, or as a result of the Plant Protection Products Directive.

### **Section 37**

Plant protection products and active substances intended for use in plant protection products may not be placed on the market unless they have been classified, packaged and labelled in accordance with the regulations referred to in Section 36.

## **Production, storage and transportation in certain cases**

### **Section 38**

The fact that a plant protection product has not been approved under the provisions in Chapter 14 of the Environmental Code and in this Ordinance may not be used as a basis for barring its production, storage or transportation, if it has been approved 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 plant protection 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 regarding approval.

## **Use**

### **Section 39**

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 plant protection products:

- 1) That they are used in a way which is consistent with the conditions for approval referred to in Section 10 of this Ordinance; and
- 2) with the conditions referred to in Section 21 of this Ordinance;
- 3) with the labelling requirements referred to in Section 36; and
- 4) that the principles for good plant protection practice are applied, and, where possible, the principles for integrated control.

## **The application of plant protection products**

### **Section 40**

A plant protection product which is particularly harmful to pollinating insects may not be used to treat plants during the part of the day when bumble-bees and bees are active in the area of cultivation.

If there are special reasons, the Swedish Board of Agriculture may issue regulations about exceptions, or, in individual cases, decide to grant an exemption from the restriction referred to in the first paragraph.

The Swedish Board of Agriculture may issue regulations about the obligation for the user to maintain records when such plant protection products as referred to in the first paragraph are applied commercially.

### **Section 41**

The Swedish Environmental Protection Agency may issue further regulations about the application of plant protection products, including requirements for permits and notification for particular areas.

### **Section 42**

The Swedish Chemicals Agency may, in individual cases and if special reasons exist, grant exemptions from the ban in Chapter 14, Section 18, paragraph 2 of the Environmental Code, and from the ban in Chapter 14, Section 19 of the Environmental Code, if it is necessary for purposes of scientific review.

Any such exemption shall be subject to the conditions necessary from a health and environment perspective.

The Swedish Chemicals Agency shall consult with the Swedish Environmental Protection Agency, the Swedish Board of Agriculture and the Swedish Forest Agency prior to making a decision about exemption from the ban in Chapter 14, Section 18 of the Environmental Code.

### **Section 43**

The Swedish Forest Agency may, in individual cases, grant exemptions pursuant to Chapter 14, Section 20, paragraph 1 of the Environmental Code

## **Expertise requirements, etc. in certain cases**

### **Section 44**

A plant protection product classified in Section 20 as a Class 1 product 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 45**

The authority charged, under Section 47, with reviewing matters concerning permits may issue regulations about what expertise is required, and about age limits for use.

The authority shall consult with the Swedish Chemicals Agency before issuing a regulation.

### **Section 46**

If such regulations as referred to in Section 45 include the requirement that users of a plant protection product shall have received specific training, the Swedish Board of Agriculture may issue regulations to the effect that the County Administrative Board shall be charged with providing the training, and about how the County Administrative Board shall do so.

## **Permits for use**

### **Section 47**

A plant protection product classified in Section 20 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

1) in the case of activities mainly concerning agriculture, forestry or horticulture, by the Swedish Board of Agriculture;

2) in the case of measures to control vermin and pests, pursuant to Chapter 9, Section 9 of the Environmental Code, by the Swedish Board of Health and Welfare; and

3) in the case of activities other than those listed in 1) and 2), by the Swedish Work Environment Authority.

The Swedish Board of Agriculture may issue regulations to the effect that permits reviewed by it under Paragraph 2, 1) shall instead be reviewed by the County Administrative Board.

### **Section 48**

The authority charged, under Section 47, with reviewing matters concerning permits may issue detailed regulations about the conditions for such permits. The regulations shall cover conditions which are material for the fulfilment of the provisions in Section 39 or the regulations referred to in Sections 41 and 45. The authority shall consult with the Swedish Chemicals Agency prior to issuing a regulation.

## **Temporary limits and bans**

### **Section 49**

If there is reason to suspect that an approved plant protection product or a product which the Swedish Chemicals Agency is charged with approving constitutes a 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.

## **Certain goods treated with plant protection products**

### **Section 50**

Grains, potatoes or other seed which has been treated with plant protection products may only be used for sowing purposes.

The Swedish Board of Agriculture may issue regulations to the effect that

1) such seed as referred to in the first paragraph may only be stored in certain types of packaging; and

2) packaging which has been used to store such seed as referred to in the first paragraph may not be used for other purposes, or may only be used for certain other purposes.

### **Section 51**

Conifer plants treated with a plant protection product in the form of a chemical pesticide which is not approved under this Ordinance may not be imported into Sweden.

If there are special reasons, the Swedish Chemicals Agency may, in individual cases, grant exemptions from the ban in the first paragraph.

## **Supervision and fees**

### **Section 52**

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 53**

Provisions regarding appeals, penalties and forfeiture are laid down in Chapter 19, Section 1 and Chapter 29 of the Environmental Code.

## **Information exchange within the European Union, etc.**

### **Section 54**

With respect to announcements, notifications and other information to the European Commission and the other member states 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 Plant Protection Products Directive:

- 1) transitional provisions;
- 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 approval, exemption and revocation, and of lists of approved products;
- 4) provisions regarding the sharing of information which comes to light during the scrutiny of an application for approval;
- 5) provisions regarding the sharing of information about such adverse effects as referred to in Section 24;
- 6) provisions regarding deviation from labelling requirements; and
- 7) provisions regarding the reporting of the results of supervisory measures.

### **Section 55**

The Swedish Chemicals Agency shall maintain a register of the names submitted pursuant to Section 7.

## **Transitional provisions**

1. This Ordinance enters into force on 1 October 2006, when the Ordinance on Pesticides (1998:947) ceases to apply.
2. Older regulations continue to apply for decisions issued before the entry into force.