

The official Swedish wording of the text reproduced here has been published in the Swedish Code of Statutes (SFS) 1998:942, amended by 2000:120, 2000:760, 2001:1, 2005:31, 2006:271, 2006:1042, 2007:22, 2008:254 and 2008:1408.

The Chemical Charges Etc. Ordinance (1998:942)

[In any dispute relating to this Ordinance, the Swedish text only shall apply]

The Government prescribes the following.

Section 1 According to this Ordinance, charges shall be paid for the examination and supervision of the Swedish Chemicals Agency with regard to chemical products, biotechnical organisms and other products as provided in Chapter 14 of the Environmental Code.

Further provisions on charges for the activities of the Swedish Chemicals Agency are provided in the Charges on the Examination and Supervision Under the Environmental Code Ordinance (1998:940). *Ordinance (2008:254).*

Chemical Charges

Section 2 Chemical charges take the form of *annual charges* and *product charges*. The charges shall be paid annually per calendar year by whoever professionally manufactures or imports to Sweden more than one tonne in total of such chemical products that shall be reported to the products register under the Chemical Products and Biotechnical Organisms Ordinance (2008:245).

If the Swedish Chemicals Agency, as provided in the Chemical Products and Biotechnical Organisms Ordinance, having consented in a particular case the duty of reporting being discharged to a commercial agent in the place of the person manufacturing or importing the products to Sweden, the agent shall be liable for the charge.

Chemical charges according to paragraph one shall not be required for anyone paying an annual charge as provided in Section 6 or 7. *Ordinance (2008:254).*

Section 3 Chemical charges shall be paid preliminary and finally.

Preliminary charges are calculated on the basis of particulars in the products register the preceding year or on a preliminary statement by the person liable for the charge. The preliminary paid amount shall be reduced from the final charge.

Section 4 The annual charge is calculated on the total amount of chemical products obliged to be reported according to the following table

Quantity (tonne)	Annual charge (SEK)
1–4	1,300
5–9	4,000
10–49	8,000
50–99	13,000
100–999	20,000
1,000–4,999	30,000
5,000–9,999	40,000
10,000–49,999	50,000
50,000–99,999	60,000
100,000 or more	75,000

Section 5 Product charges shall be determined to an average value depending on the number of products obliged to be reported.

The charge is calculated using the following formula

$$\frac{\text{starting value} - \text{end value}}{k^n} + \text{end value}$$

The starting value is SEK 1,000 and the end value is SEK 350.

n is the number of products obliged to be reported, whereby products with the same function and composition or which are reported under a common denomination, are treated as one product.

k is the value 1.003.

Charges for approval and supervision of plant protection products and biocidal products

Section 6 For the examination and supervision of the Swedish Chemicals Agency with regard to chemical pesticides according to the Plant Protection Products Ordinance Ordinance (2006:1010) and the Biocidal Products Ordinance (2000:338), application charges and annual charges shall be paid according to the following table:

<i>Type of matter</i>	<i>Application charge SEK</i>
1. On application for approval,	
a) for each product	10,000
b) for each active substance not contained in another approved product	30,000
2. On application for a change of condition	
a) with respect to name, size of package or non-active substance	1,000
b) in other respects	5,000
3. On application for continued approval	6,000
4. On application for exemption	3,000

The annual charge shall be paid for each approved product. The annual charge each calendar year amounts to 2.6 per cent of the value of the sale of the product in the year before that to which the annual charge pertains, but shall not exceed SEK 200,000. The minimum annual charge is SEK 2,000.

The application charge shall be paid by the applicant. The annual charge shall be paid by the person who has had a pesticide approved or by the person acting in his place. *Ordinance (2006:1042)*.

Section 7 For the examination and supervision of the Swedish Chemicals Agency with regard to biological pesticides according to the Plant Protection Products Ordinance (2006:1010) and the Biocidal Products Ordinance (2000:338), application charges and annual charges shall be paid according to the following table:

<i>Type of matter</i>	<i>Application charge SEK</i>
1. Application for approval concerning	
a) microorganisms	
- for each pesticide	5,000
- for each active organism not contained in another approved pesticide	15,000
b) genetically modified organisms	
- for each active organism not contained in another approved pesticide	23,000
c) nematodes, insects, arachnids	
- for each pesticide	3,000
- for each active organism not contained in another approved pesticide	8,000
2. Application for a change of condition	
- with respect to name or size of packaging of the pesticide	1,000
- in other respects	2,000
3. Application for continued approval with respect to	
a) microorganisms	3,000
b) genetically modified microorganisms	4,500
c) nematodes, insects, arachnids	1,500
4. Application for exemption with regard to	
a) microorganisms	1,500
b) genetically modified microorganisms	2,000
c) nematodes, insects, arachnids	1,000

The annual charge shall be paid for each approved pesticide. The annual charge each calendar year amounts to 1.8 per cent of the value of the sale of the product in

the year before that to which the annual charge pertains, but shall not exceed SEK 200,000. The minimum annual charge is SEK 2,000.

The application charge shall be paid by the applicant. The annual charge shall be paid by the person who has had a pesticide approved or by the person acting in his place. *Ordinance (2006:1042)*.

Section 7 a A charge shall be paid also for the administrative treatment and evaluation required on application being made for an application for approval according to Section 6 or 7 referring to a pesticide that contains an active substance included in Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, last amended by Commission Directive 2008/108/EC, or Annex I or IA to the European Parliament and Council Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market, last amended by Council Directive 2008/86/EC, and the applicant does not have a permit to refer to the documentation that forms the basis of inclusion in the Annex.

The charge shall be paid as an application charge and be established as a final examination charge. Provisions on payment of application charge and establishment of final examination charge are contained in Section 8 j. *Ordinance (2008:1408)*.

Section 7 b For an application as referred to in Section 7 a, the application charge for each file with documentation (dossier) is:

1. SEK 1,100,000 if the application pertains to a plant protection product containing a chemical substance or a microorganism that is included in Annex I to Directive 91/414/EEC,
2. SEK 850,000 if the application pertains to a biocidal product containing a chemical substance or a microorganism that is included in Annex I or IA to Directive 98/8/EC. *Ordinance (2008:1408)*.

Particular charges for examination of active substances in plant protection products

Section 8 A charge shall be paid for

1. the administrative treatment and evaluation required on application being made for the inclusion of an active substance in Annex I to Council Directive 91/414/EEC and in connection with an application for prolongation of a decision being made on such inclusion, and
2. the further evaluation required after inclusion of a substance in Annex I to Directive 91/414/EEC owing to the procedure according to Commission Regulation (EC) No. 1095/2007 of 20 September 2007 amending Regulation (EC) No. 1490/2002 on laying down further detailed rules on the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 45/2000 and amending Regulation (EC) No. 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC.

The charge shall be paid as an application charge and be established as a final examination charge. Provisions on payment of application charge and establishment of final examination charge are contained in Section 8 j. *Ordinance (2008:1408)*.

Section 8 a For an application as referred to in Section 8, the application charge amounts to:

1. SEK 6 750 000 for each documentation dossier, if the application is made by several applicants jointly and pertains to a chemical substance,
2. SEK 4 500 000 for each documentation dossier, if the application pertains to a chemical substance and is not a joint application as referred to in 1.
3. SEK 3 000 000 for each documentation dossier, if the application is made by several applicants jointly and pertains to a microorganism, and
4. SEK 2 000 000 for each documentation dossier, if the application pertains to a microorganism and is not a joint application as referred to in 3.

Ordinance (2008:1408).

Particular charges for examination of active substances in biocidal products

Section 8 b A charge shall be paid for the administrative treatment and evaluation required in connection with an application for inclusion of an active substance or an additional product type in Annexes I, IA or IB to Directive 98/8/EC and in connection with an application to extend a decision on such inclusion.

The charge shall be paid as an application charge and be established as a final examination charge. Provisions on payment of application charge and establishment of final examination charge are contained in Section 8 j.

Ordinance (2008:1408).

Section 8 c For an application as referred to Section 8 b §, the application charge is

1. SEK 5 700 000 for each file with common documentation (dossier) if the application is made by several applicants jointly and pertains to a chemical substance for inclusion in Annex I or IA,
2. SEK 3 800 000 for each file with documentation (dossier), if the application pertains to a chemical substance for inclusion in Annex I or IA and is not a joint application as referred to in 1,
3. SEK 3 000 000 for each file with common documentation (dossier), if the application is made by several applicants jointly and pertains to a microorganism for inclusion in Annex I or IA,
4. SEK 2 000 000 for each file with documentation (dossier) , if the application pertains to a microorganism for inclusion in Annex I or IA and is not a joint application as referred to in 3,
5. SEK 420 000 for each file with common documentation (dossier), if the application is made by several application jointly and pertains to a substance for inclusion in Annex IB, and
6. SEK 280 000 for each file with documentation (dossier), if the application pertains to a substance for inclusion in Annex IB and is not a joint application as referred to in 5. *Ordinance (2008:1408).*

Particular charges for evaluation after inclusion of an active substance in an Annex

Section 8 d A charge shall be paid for the administrative treatment and evaluation required following a decision on inclusion of an active substance in Annex I to Directive 91/414/ECC or Annexes I, IA or IB to Directive 98/8/EC, for which Sweden has been a rapporteur Member state. The charge shall be paid by the applicant or by the person acting in his place.

The charge for each file amounts to SEK 1 000 000. It shall be paid in the same way as an application charge before the administrative treatment starts and be established as a final examination charge. Provisions on payment of application charge and establishment of final examination charge are contained in Section 8 j.

Ordinance (2008:1408).

Particular charges for evaluation of changed conditions for active substances in plant protection products and biocidal products

Section 8 e An application charge shall be paid for the administrative treatment and evaluation required in connection with an application for a change of conditions for inclusion in Annex I to Directive 91/414/EEC or Annex I, IA or IB to Directive 98/8/EC.

The application charge amounts to SEK 200 000.

Provisions on payment of application charge are contained in Section 8 j.
Ordinance (2008:1408).

Particular charges for co-reporting of active substances in plant protection products and biocidal products

Section 8 f An application charge shall be paid for the administrative treatment and evaluation required in connection with the execution of tasks by the Swedish Chemicals Agency that are incumbent on Sweden as being a co-reporting Member state according to Directive 91/414/EEC or 98/8/EC or their amendments in connection with application for inclusion of an active substance or an additional product type to be included or an application for an extension of a decision to include a substance in an Annex to any of the directives.

The charge shall be paid as an application charge and be established as a final examination charge. Provisions on payment of application charge and establishment of final examination charge are contained in Section 8 j.

Ordinance (2008:1408).

Section 8 g In a matter referred to in Section 8 f and relating to an active substance in a plant protection product, the application charge amounts to, unless otherwise follows by Section 8 i, an amount that is in proportion to the distribution of work agreed upon with the reporting Member state, however, not exceeding

1. SEK 3 375 000 for each file with common documentation (dossier), if the application is made by several applicants jointly and pertains to one chemical substance,
2. SEK 2 250 000 for each file with documentation (dossier), if the application pertains to a chemical substance and is not a joint application as referred to in 1,
3. SEK 1 500 000 For each file with common documentation (dossier), if the application is made by several applicants jointly and pertains to a micro-organism, and
4. SEK 1 000 000 for each file with documentation (dossier), if the application pertains to a microorganism and is not covered by a joint application as referred to in 3. *Ordinance (2008:1048).*

Section 8 h In a matter as referred to in Section 8f and which concerns an active substance in a biocidal product, the application charge amounts to, unless otherwise follows by Section 8, an amount that is in proportion to the distribution of work agreed upon with the reporting Member state, however, not exceeding

1. SEK 2 850 000 for each file with common documentation (dossier), if the application is made by several by several applicants jointly and pertains to a chemical substances,
2. SEK 1 900 000 for each file with documentation (dossier), if the application refers to a chemical substance and is not a joint application as referred to in 1,
3. SEK 1 500 000 for each file with common documentation (dossier), if the application is made by several applicants jointly and pertains to a micro-organism,
4. SEK 1 000 000 for each file with documentation, if the application pertains to a microorganism and not is not covered by a joint application referred to in 3. *Ordinance (2008:1408).*

Section 8 i If the handling of matters of the Swedish Chemicals Agency only covers the time after the reporting Member state having submitted its evaluation to the European Food Safety Agency (EFSA), the application charge amounts to SEK 700 000 instead of what is stated in Section 8 g and 8 h.

Payment of application charge and establishment of final examination charge

Section 8 j An application charge according to Sections 7 a–8 i shall be paid when the handling of matters starts or at the later point of time decided by the Swedish Chemicals Agency in individual cases.

When the matter is finally decided upon, the Swedish Chemicals Agency shall determine the final examination charge. The examination charge shall be equal to the cost of handling and examination, but must not exceed the application charge.

In the decision on settling the examination charge, the Swedish Chemicals Agency shall account for the costs and how they were determined. If the application charge exceeds the examination charge, the Swedish Chemicals Agency is responsible for repaying the difference to the applicant. *Ordinance (2008:1408)*.

Section 9 Annual charges according to Sections 6-7 shall be paid for each calendar year starting in the year when the approval was granted and up to and including the year when the approval expires.

Annual charges shall be paid not later than the 31 March in the year to which the charge pertains.

Section 10 The holder of the approval of a pesticide shall pay the cost of an investigation ordered by the Swedish Chemicals Agency to verify the composition of the pesticide.

Charges for examination in other cases

Section 11 The Swedish Chemicals Agency may issue regulations on charges for

1. examining matters on deviations according to Article 5 in the European Parliament and Council Regulations (EC) No 648/2004 of 31 March 2004 on detergents, and

2. examining matters according to the Chemical Products (Handling, Import, and Export Prohibitions) Ordinance (1998:944) relating to the area of enforcement the Swedish Chemicals Agency is responsible for according to the Enforcement and Supervision Ordinance (1998:900) in accordance with the Environmental Code. *Ordinance (2008:254)*.

Common Provisions

Section 12 For charges according to this Ordinance, the provisions in Sections 9-12 of the Charge Ordinance (1992:191) apply, unless otherwise prescribed.

Other charges than annual charges for pesticides and application charges shall be paid after debiting by the Swedish Chemicals Agency.

Provisions on the account of charges are contained in the Charge Ordinance.

Section 13 Whoever is liable to pay a charge according to this Ordinance shall provide the Swedish Chemicals Agency with the particulars needed to calculate the size of the charge.

The Swedish Chemicals Agency may issue regulations on the extent of the liability to provide information.

Section 14 The Swedish Chemicals Agency may issue whatever regulations needed for the enforcement of this Ordinance.

Section 15 If there are particular reasons for doing so, the Swedish Chemicals Agency may decide that charges according to this Ordinance are to be reduced or waived.

Section 16 Decisions concerning payment of charges on chemical products may be executed under the Debt Recovery Code.

Section 17 The Swedish Chemicals Agency may determine that its decisions under this Ordinance are to apply immediately even if appeals are lodged against them.

Section 18 Provisions on appeals are contained in Chapt. 19, Section 1 of the Environmental Code.

Transitional provisions

1. This Ordinance comes into force on 1 January 1999.
 2. By this Ordinance, the Charges on Chemical Products Ordinance (1989:216) is revoked. However, that Ordinance still applies with regard to charges relating to the period before 1 January 1999.
 3. Earlier provisions apply in cases of appeals of decisions made on charges before this Ordinance came into force.
 4. Provisions on continued application of regulations issued pursuant to an act being revoked by the Environmental Code are contained in Section 4 of the Implementation of the Environmental Code Act (1998:811).
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2005:31

1. This Ordinance comes into force on 10 March 2005.
 2. Older provisions apply to matters filed at the Swedish Chemicals Agency before 10 March 2005.
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2008:1408

1. This Ordinance comes into force on 2 February 2009.
2. Older provisions shall be applied to matters filed at the Swedish Chemicals Agency before 2 February 2009.