Pursuant to paragraph five of Article 5 and paragraph three of Article 8 of the Plant Protection Products Act (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 83/12 and [35/23](http://www.uradni-list.si/1/objava.jsp?sop=2023-01-1019) – Constitutional Court Decision), the Government of the Republic of Slovenia hereby issues the following

**DECREE**

on the implementation of EC and EU regulations on placing plant protection products on the market

Article 1

(Subject)

This Decree regulates competent authorities, obligations regarding the authorisation of and permits for plant protection products (hereinafter: PPPs), the labelling of PPPs and of seeds treated with PPPs, fees, supervision and penalty provisions for the implementation of:

* Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1), last amended by [Commission Regulation (EU) 2022/1438 of 31 August 2022 amending Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards specific criteria for the approval of active substances that are micro-organisms](https://eur-lex.europa.eu/legal-content/SL/AUTO/?uri=uriserv:OJ.L_.2022.227.01.0002.01.SLV&toc=OJ:L:2022:227:TOC) (OJ L 227, 1.9.2022, p. 2), (hereinafter: Regulation 1107/2009/EC),
* Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products (OJ L 155, 11.6.2011, p. 176), last amended by Commission Regulation (EU) No 519/2013 of 21 February 2013 adapting certain regulations and decisions in the fields of free movement of goods, freedom of movement for persons, right of establishment and freedom to provide services, company law, competition policy, agriculture, food safety, veterinary and phytosanitary policy, fisheries, transport policy, energy, taxation, statistics, social policy and employment, the environment, customs union, external relations, and foreign, security and defence policy, by reason of the accession of Croatia (OJ L 158, 10.6.2013, p. 74), (hereinafter: Regulation 547/2011/EU), and
* Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1), last amended by [Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures](https://eur-lex.europa.eu/legal-content/SL/AUTO/?uri=uriserv:OJ.L_.2022.129.01.0001.01.SLV&toc=OJ:L:2022:129:TOC) (OJ L 129, 3.5.2022, p. 1), (hereinafter: Regulation 1272/2008/EC).

Article 2

(Definitions)

(1) For the purposes of this Decree, the following definitions shall apply:

* application shall mean an application pursuant to Article 33, 40, 43, 45, 47, 48, 51 or 58 of Regulation 1107/2009/EC or an application pursuant to Article 52, 53 or 54 of Regulation 1107/2009/EC,
* the renewal of a PPP authorisation shall mean the renewal of a PPP authorisation in accordance with Article 43(1) to (5) of Regulation 1107/2009/EC,
* the extension of a PPP authorisation shall mean the extension of a PPP authorisation in accordance with Article 43(6) of Regulation 1107/2009/EC.

(2) For the purposes of PPP authorisation procedures, the following shall be deemed a PPP authorisation:

a) the authorisation of a new PPP referred to in Article 36 of Regulation 1107/2009/EC,

b) the authorisation of a PPP referred to in Article 41 of Regulation 1107/2009/EC,

c) the renewal or extension of a PPP authorisation referred to in Article 43 of Regulation 1107/2009/EC,

č) the withdrawal or amendment of a PPP authorisation referred to in Articles 44 and 45 of Regulation 1107/2009/EC,

d) the authorisation of a low-risk PPP referred to in Article 47 of Regulation 1107/2009/EC,

e) the authorisation of a PPP containing a genetically modified organism referred to in Article 48 of Regulation 1107/2009/EC, and

f) the extension of a PPP authorisation for minor uses referred to in Article 51 of Regulation 1107/2009/EC.

Article 3

(Competent authorities)

(1) Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection (hereinafter: AFSVSPP) shall be the authority responsible for implementing this Decree and the regulations referred to in Article 1 of this Decree.

(2) In the part concerning PPP authorisation, AFSVSPP shall decide on the authorisation of PPPs based on the assent of the Chemicals Office of the Republic of Slovenia (hereinafter: Chemicals Office), which shall be based on an assessment of the PPP with regard to human health and the environment in accordance with the regulations governing chemicals. The assent of the Chemicals Office shall not be necessary in authorisation procedures that do not require an assessment of PPPs with regard to human health and the environment or in procedures for amending an authorisation that do not affect the results of such assessment. If new circumstances that affect assessment results emerge in relation to a PPP for which an authorisation has already been granted, the Chemicals Office may withdraw the granted authorisation.

(3) AFSVSPP shall be the authority responsible for implementing the supervision referred to in this Decree and the controls referred to in the regulations referred to in Article 1 of this Decree and for submitting reports on controls to the European Commission under Article 68(1) of Regulation 1107/2009/EC.

(4) AFSVSPP shall be the coordinating national authority referred to in Article 75(2) of Regulation 1107/2009/EC.

Article 4

(Content of impurities)

The highest generic limit value for impurities in PPPs shall not exceed 1 g/kg (0.1% m/m), unless a lower concentration limit is provided for a particular substance in accordance with Regulation 1272/2008/EC.

Article 5

(Application and dossier for PPP authorisation)

(1) In addition to the information required for PPP authorisation under Regulation 1107/2009/EC, an application for the authorisation of a PPP shall also include:

* information on the applicant: personal name and address or company name and registered office address,
* the type of authorisation and the proposed use of the PPP in the Republic of Slovenia,
* information on the official representative with the registered office in the Republic of Slovenia or the person authorised to accept service of documents with the registered office in the Republic of Slovenia (personal name and address or company name and registered office address),
* information on the distributor with the registered office in the Republic of Slovenia (personal name and address or company name and registered office address) if the PPP will be marketed in the Republic of Slovenia; if the PPP will not be marketed in the Republic of Slovenia, the applicant shall submit a statement that the PPP concerned will not be marketed in the Republic of Slovenia.

(2) In an application referred to in the preceding paragraph, the information on the proposed use shall include at least the categories of users (professional or non-professional users), cultivated plants, including the corresponding code of the European and Mediterranean Plant Protection Organisation (hereinafter: EPPO code), or other intended use (e.g. storage facilities, silos, crops before storage), the place of use, pests or pathogens, including the corresponding EPPO code, the envisaged method of PPP application, the time of PPP use, which should be in compliance with the permitted use according to the scale for determining the development stages of cultivated plants (BBCH stage), the highest permitted number of PPP applications and the shortest time interval between two applications, in accordance with the tables of proposed PPP uses (hereinafter: GAP table) published on the state administration’s website. The doses of the PPP and the active substance shall also be indicated: the maximum and the minimum doses of the PPP and the active substance in one application and in one year or growth season, the maximum and the minimum quantity of water used in one application, the pre-harvest interval (the minimum time interval between the last application and harvest), and other information required for the use of the PPP.

(3) Applications for the authorisation of PPPs referred to in paragraph one of this Article shall be in the Slovenian language, except the information on the proposed use of the PPP in accordance with the GAP table and other documents enclosed with the application, which may be in Slovenian or English.

(4) Draft labels referred to in point 4 of Annex I to Regulation 547/2011/EU and the instructions for use, which shall be integral parts of dossiers, shall be in Slovenian.

(5) For the purposes of the implementation of Article 36(3) of Regulation 1107/2009/EC, AFSVSPP may, in order to determine additional measures to reduce risks to human or animal health or the environment in the use of a PPP in the Republic of Slovenia, require that the applicant include in the application for the authorisation of the PPP additional information concerning the efficacy of the PPP, safety in handling the PPP, the protection of surface and underground water, and the protection of aquatic organisms, birds, mammals and bees.

(6) More detailed instructions on the submission of information referred to in the preceding paragraph are published on AFSVSPP’s website.

(7) For the purposes of the implementation of Article 42(1)(c) of Regulation 1107/2009/EC, the applicant shall enclose with the application a complete dossier referred to in Article 33(3) of Regulation 1107/2009/EC.

(8) If safe use of a PPP cannot be ensured with additional measures for reducing the risks to human or animal health or the environment, the authorisation of this PPP or of a particular use thereof in the Republic of Slovenia shall not be granted and AFSVSPP shall inform the European Commission thereof.

(9) The application form template for the submission of information referred to in paragraphs one and two of this Article is published on the state administration’s website.

Article 6

(Decisions on PPP authorisation)

(1) In addition to the information referred to in Articles 31(1), (2) and (3) and Article 32 of Regulation 1107/2009/EC, a decision on the authorisation of a PPP shall also include:

* additional requirements concerning the placing on the market and use of the PPP if this is necessary to reduce the risks to human health and the environment,
* the approval of the label and the instructions for use,
* time intervals between consecutive treatments,
* re-entry interval (the required period of waiting before people or animals can re-enter a treated area),
* the size and material of the PPP’s packaging.

(2) For the purposes of the implementation of the second subparagraph of Article 31(2) of Regulation 1107/2009/EC, any holder of a PPP authorisation that amends the label approved by the decision on the PPP’s authorisation in the part related to the classification and labelling of the PPP in accordance with Regulation 1272/2008/EC shall immediately send a sample of the amended label to AFSVSPP.

(3) For the purposes of the implementation of the second subparagraph of Article 36(3) of Regulation 1107/2009/EC, AFSVSPP may reject an application for a particular use of a PPP or for the authorisation of a PPP if, based on the assessment of the risk to groundwater, the proposed use of the PPP is limited to every second, third, fourth year or longer intervals or if, due to specific environmental or agricultural conditions, the risk assessment shows that the PPP concerned poses an unacceptable risk to human or animal health or the environment.

Article 7

(PPP permits)

(1) An application for parallel trade in accordance with Article 52 of Regulation 1107/2009/EC, for emergency authorisation in accordance with Article 53 of Regulation 1107/2009/EC, or for a research and development permit in accordance with Article 54 of Regulation 1107/2009/EC shall be submitted on the form for the type of permit or authorisation concerned available on the state administration’s website.

(2) For the purposes of the implementation of Article 53(1) of Regulation 1107/2009/EC, any application for emergency authorisation referred to in the preceding paragraph shall be accompanied by a detailed statement of reasons for using the PPP.

(3) For the purposes of the implementation of Article 54 of Regulation 1107/2009/EC, any application for a research and development permit referred to in paragraph one of this Article shall be accompanied by:

* the safety data sheet for the PPP in accordance with the regulations governing registration, evaluation, authorisation and restriction of chemicals,
* a detailed plan and location of the trial in which the PPP will be used.

Article 8

(Provision of information)

In accordance with Article 57 of Regulation 1107/2009/EC, AFSVSPP shall publish on its website relevant data from the issued decisions on PPP authorisation, parallel trade permits and emergency authorisations referred to in the preceding Article.

Article 9

(Labelling of PPPs for the protection of bees)

(1) In accordance with point 4 of Annex I to Regulation 547/2011/EU, PPPs on the market shall bear a label and instructions for use in Slovenian.

(2) For the purposes of the implementation of Article 65(3) of Regulation 1107/2009/EC, PPP labels shall include a graphic symbol of a bee as set out in Annex 1, which is an integral part of this Decree. The symbol consists of a black bee on a white background with a red diamond-shaped border. The symbol shall cover at least one fifteenth of the label area and must not be smaller than 1 cm2. The icon shall be on the first page of the label.

Article 10

(Labelling of seeds treated with PPPs)

Seeds treated with PPPs shall bear a label with the data from the decision on the authorisation of the PPPs in accordance with Article 49(4) of Regulation 1107/2009/EC in Slovenian.

Article 11

(Indication of the expiration date of PPPs)

(1) For the purposes of the implementation of point 1(r) of Annex I to Regulation 547/2011/EU, the expiry date shall be indicated on the packaging of PPPs with an expiry date of less than two years in normal conditions of storage. The expiry date shall be stated as the year and the month when the PPP’s usage expires. The indicated expiry date shall be in accordance with the information on the stability of the PPP in storage, as submitted by the authorisation holder in the procedure for the authorisation of the PPP.

(2) If secondary packaging is used for packaging a PPP (e.g. a box), the expiry date and the formulation batch number of the PPP shall be indicated on both the primary and the secondary packaging.

(3) If the expiry date and the formulation batch number are imprinted in the packaging, they shall be in a colour distinguishable from the background and easily legible.

(4) A holder of expired PPPs on the market and in use shall dispose of such PPPs in accordance with the regulation governing waste.

(5) If the initially set expiry date of a PPP on shelves expires before the PPP is sold, the authorisation holder, agent, distributor or seller of the PPP may extend the expiry date for this PPP for no more than two years if they have relevant analytical data on active substance content acquired from an accredited laboratory. Analysis data indicating the PPP’s batch number and date of production may be used for all batches of this PPP produced in the same year. The extended expiry date shall be indicated on the PPP’s packaging with a self-adhesive label bearing the new date. The analysis data shall be available to the supervisory authorities at any time until the expiry date of the PPPs on the market. Analysis reports shall be available at points of sale of the PPP or in electronic form on the website of the person that ordered the analysis or shall be sent electronically or by post to the supervisory authorities at their request.

**Article 12**

**(Attachment of instructions for use)**

For the purposes of the implementation of point 2 of Annex I to Regulation 547/2011/EU, if there is not enough space on the packaging for the instructions for use of a PPP, the instructions shall be provided on a separate leaflet, which shall accompany the packaging at all times for as long as the PPP is on the market. The instructions leaflet can be included as a pull-out leaflet, wrapped and attached to the packaging or put in the box containing the PPP.

Article 13

(Fees and costs)

(1) For the purposes of the implementation of Article 74 of Regulation 1107/2009/EC, the applicant shall pay a fee to cover the costs incurred in the Republic of Slovenia in relation to the work and procedures conducted within the scope of Regulation 1107/2009/EC. The fees are set out in Annex 2, which is an integral part of this Decree.

(2) The fees under this Article shall constitute revenues of the budget of the Republic of Slovenia and shall be paid into the government revenues sub-account, in accordance with the regulation governing the sub-accounts and the manner of payment of compulsory charges and other government revenues.

(3) AFSVSPP shall inform the applicant of the type and amount of fees applying to their application and set the time limit for the payment thereof.

(4) If the applicant referred to in the preceding paragraph fails to pay the fee in the specified time limit, AFSVSPP shall request the applicant to pay the fee within 15 days of receiving the request.

(5) If the applicant fails to pay the fee within 15 days of receiving the request referred to in the preceding paragraph, AFSVSPP shall issue a decision on the staying of proceedings referred to in paragraph one of this Article.

(6) AFSVSPP shall refund the applicant any overpaid or erroneously paid fee.

(7) Notwithstanding the provision of paragraph one of this Article, the fee shall not be paid for the following applications, although an administrative charge shall be paid in accordance with the Act governing administrative charges:

* for the authorisation of a low-risk PPP referred to in Article 47 of Regulation 1107/2009/EC,
* for a permit for research in and the development of PPPs containing low-risk active substances referred to in Article 22 of Regulation 1107/2009/EC, or
* for the authorisation of PPPs containing active substances that are permitted in organic production, except the PPPs containing active substances that are candidates for substitution or the PPPs referred to in point 5 of Annex II to Regulation 1107/2009/EC.

(8) Notwithstanding the preceding paragraph, a fee shall also be paid for applications submitted under Article 33, 43 or 51 of Regulation 1107/2009/EC if the Republic of Slovenia is the Member State examining the application.

(9) AFSVSPP shall, in agreement with other Member States, cover the costs of coordination among the competent Member States related to the authorisation of PPPs under Article 75 of Regulation 1107/2009/EC.

Article 14

(Supervision)

(1) In addition to the authorisations under the general regulations on inspection, AFSVSPP’s inspectors responsible for PPPs may:

1. prohibit the placing on the market and use of PPPs and adjuvants that are not authorised or do not have an appropriate permit issued in accordance with Regulation 1107/2009/EC,
2. prohibit the placing on the market and use of PPPs and adjuvants that are not in compliance with the authorisation decision or the permit issued in accordance with Regulation 1107/2009/EC,
3. prohibit the placing on the market of PPPs and adjuvants packaged in such a way that they could be mistaken for food, drink or animal feed,
4. prohibit the placing on the market of PPPs and adjuvants that are not labelled, packaged or classified in accordance with Article 65(1) or (3) of Regulation 1107/2009/EC,
5. prohibit the use of a PPP if they find that it is not used in accordance with Article 55 of Regulation 1107/2009/EC,
6. inspect the keeping of records of the placing on the market and use of PPPs,
7. prohibit incorrect advertising of PPPs,
8. prohibit the placing on the market of expired PPPs,
9. prohibit the placing on the market and use of PPPs containing active substances, safeners, synergists or co-formulants that are not approved or are prohibited under Regulation 1107/2009/EC,
10. order the destruction of any PPP that, as regards its composition or production or active substances contained, is not in compliance with the authorisation decision or authorisation report or the permit or expert opinion on which the permit is based, at the expense of the legal or natural person responsible for the offence,
11. order the destruction of prohibited PPPs, at the expense of the legal or natural person responsible for the offence,
12. carry out other actions and impose other measures as required to implement Regulation 1107/2009/EC and this Decree.

(2) An inspector shall order the destruction referred to in points 10 and 11 of the preceding paragraph at the expense of the natural or legal person that is responsible for the offence and for the placing on the market in the Republic of Slovenia as a natural person or the authorisation holder with the registered office in the Republic of Slovenia or as the official representative with the registered office in the Republic of Slovenia, distributor with the registered office in the Republic of Slovenia, holder of the permit for parallel trade in the PPP or holder of emergency authorisation concerning plant protection.

Article 15

(Serious offences)

(1) Legal persons shall be fined from EUR 15,000 to EUR 32,000 for the offences of:

* placing on the market or using a PPP that is not authorised in accordance with Article 28 of Regulation 1107/2009/EC,
* failing to inform AFSVSPP of potential adverse or unacceptable effects in accordance with Article 56(1) of Regulation 1107/2009/EC.

(2) Sole traders or individuals who perform independent activities shall be fined from EUR 5,000 to EUR 15,000 for the offences referred to in the preceding paragraph.

(3) The responsible person of the legal person, sole trader or individual who performs independent activities shall also be fined from EUR 2,500 to EUR 5,000 for the offences referred to in paragraph one of this Article.

(4) An individual shall be fined from EUR 2,000 to EUR 3,000 for the offences referred to in paragraph one of this Article.

Article 16

(Other offences)

(1) Legal persons shall be fined from EUR 1,500 to EUR 5,000 for the offences under Regulation 1107/2009/EC of:

1. placing on the market a PPP containing active substances, safeners or synergists that are not approved or are prohibited in accordance with Article 4 of Regulation 1107/2009/EC,
2. placing on the market a PPP containing co-formulants that are not approved or are prohibited in accordance with Article 27 of Regulation 1107/2009/EC,
3. placing on the market a PPP that, as regards its composition and production and active substances contained, does not meet the conditions for authorisation referred to in Article 29(1) of Regulation 1107/2009/EC,
4. using a PPP contrary to the requirements of the decision on the authorisation of the PPP referred to in Article 31(2) or (3) of Regulation 1107/2009/EC,
5. placing on the market or using seeds treated with PPPs contrary to Article 49 of Regulation 1107/2009/EC,
6. placing on the market or using PPPs contrary to the parallel trade permit in accordance with Article 52 of Regulation 1107/2009/EC,
7. placing on the market or using PPPs contrary to the emergency authorisation in accordance with Article 53 of Regulation 1107/2009/EC,
8. placing on the market or using PPPs contrary to the research and development permit in accordance with Article 54 of Regulation 1107/2009/EC,
9. using PPPs contrary to Article 55 of Regulation 1107/2009/EC,
10. placing on the market or using adjuvants that are not authorised in accordance with Article 58 of Regulation 1107/2009/EC,
11. placing on the market a PPP that is packaged contrary to Article 64(1) of Regulation 1107/2009/EC,
12. placing on the market a PPP that is not labelled, packaged and classified in accordance with Article 65(1) or (3) of Regulation 1107/2009/EC,
13. advertising PPPs contrary to Article 66 of Regulation 1107/2009/EC,
14. failing to keep records of the placing on the market and use of PPPs in accordance with Article 67(1) of Regulation 1107/2009/EC,
15. failing to provide data on the volume of sales of PPPs in accordance with Article 67(3) of Regulation 1107/2009/EC.

(2) Legal persons shall be fined from EUR 1,500 to EUR 5,000 for the offences of:

1. placing on the market seeds treated with PPPs that are not labelled in accordance with Article 10 of this Decree,
2. placing on the market an expired PPP contrary to paragraph one or five of Article 11 of this Decree,
3. placing on the market a PPP in a packaging that is not labelled in accordance with paragraph two or three of Article 11 of this Decree,
4. failing to withdraw from the market an expired PPP in accordance with paragraph four of Article 11 of this Decree,
5. placing on the market a PPP that is not accompanied by instructions for use in accordance with Article 12 of this Decree.

(3) Sole traders or individuals who perform independent activities shall be fined from EUR 1,000 to EUR 2,500 for the offences referred to in paragraphs one and two of this Article.

(4) The responsible person of the legal person, sole trader or individual who performs independent activities shall also be fined from EUR 400 to EUR 1,000 for the offences referred to in paragraphs one and two of this Article.

(5) An individual shall be fined from EUR 300 to EUR 500 for the offences referred to in points 1, 2, 3, 4, 6 and 11 of paragraph one of this Article.

**Article 17**

**(Fines in expedited minor offence proceedings)**

A fine that is higher than the lowest fine prescribed by this Decree may be imposed in expedited proceedings, except for the offences referred to in point 15 of paragraph one and points 1, 2, 3, 4 and 5 of paragraph two of the preceding Article.

TRANSITIONAL AND FINAL PROVISIONS

**Article 18**

**(Initiated procedures)**

Any PPP authorisation procedures initiated before the entry into force of this Decree shall be concluded in accordance with the regulations applicable to date.

Article 19

(PPPs on the market)

Any PPPs on the market or in storage facilities at distributors on the day this Decree enters into force that meet the conditions of the Decree on the implementation of Regulations (EC) and (EU) on placing plant protection products on the market (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 5/15, 59/19 and 9/20) may stay on the market until 31 March 2024 or until their expiry date, whichever is earlier.

**Article 20**

**(End of validity)**

On the day this Decree enters into force, the Decree on the implementation of Regulations (EC) and (EU) on placing plant protection products on the market (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 5/15, 59/19 and 9/20) shall cease to be in force.

Article 21

(Entry into force)

This Decree shall enter into force on the fifteenth day following its publication in the Official Gazette of the Republic of Slovenia.

No 007-287/2022

Ljubljana, 21 September 2023

EVA 2022-2330-0057

Government of the Republic of Slovenia

Robert Golob

Prime Minister

**Annex 1**

Graphic symbol



**Annex 2**

**Fees**

I. Costs related to the inclusion or the renewal of inclusion of an active substance in the list of approved active substances if the Republic of Slovenia is the rapporteur Member State (if the Republic of Slovenia is a co-rapporteur Member State, the costs of the work performed shall be up to 30% of the relevant value)

|  |  |
| --- | --- |
| 1. Procedures related to the evaluation of active substances pursuant to Articles 7 to 27, 38 and 56 of Regulation 1107/2009/EC1 | EUR |
| Conduct of the procedure (meetings and additional communication with the applicant) | up to 6,000.00 |
| Dossier completeness check | 6,000.00 |
| Equivalence assessment within active substance evaluation | 8,000.00 |
| Assessment of physical and chemical properties and analytical methods | 14,863.00 |
| Assessment of toxicological and metabolism studies | 35,434.00 |
| Assessment of residues in or on food and feed | 17,934.00 |
| Assessment of behaviour in the environment | 23,512.00 |
| Assessment of ecotoxicological studies | 32,024.00 |
| Assessment of data on efficacy | 4,054.00 |
| Draft assessment report | 5,000.00 |
| TOTAL | 152,821.00 |
| Assessment of additional studies requested by EFSA in the procedure for evaluating an active substance | up to 3,000.00 |
| Assessment of confirmatory data | up to 8,000.00 |

|  |  |
| --- | --- |
| 2. Equivalence assessment procedures pursuant to Article 38 of Regulation 1107/2009/EC | EUR |
| Equivalence assessment (Tier I, Tier II) | up to 6,500.00 |

II. Costs related to a zonal PPP authorisation if the Republic of Slovenia is the Member State examining the application

|  |  |
| --- | --- |
| 1. Authorisation and extension and amendment of authorisation of a PPP with one active substance based on an application submitted under Articles 33, 43, 48 and 56 of Regulation 1107/2009/EC if the application is examined by the Republic of Slovenia2,3,4 | EUR |
| Conduct of the procedure (meetings and additional communication with the applicant) | up to 3,000.00 |
| Dossier completeness check | up to 4,200.00 |
| Assessment of physical and chemical properties and analytical methods | 2,500.00 |
| Assessment of toxicological and metabolism studies | 3,950.00 |
| Assessment of residues in or on food and feed | 3,292.00 |
| Assessment of behaviour in the environment | 3,048.00 |
| Assessment of ecotoxicological studies | 4,044.00 |
| Assessment of data on efficacy | 3,048.00 |
| Draft assessment report | 2,500.00 |
| Harmonisation of draft label with instructions for use | 360.00 |
| TOTAL | 29,942.00 |
| Assessment of each additional study | up to 300.00 |

|  |  |
| --- | --- |
| 2. Dossier compliance check against the requirements of Article 59 of Regulation 1107/2009/EC for the purposes of data protection | EUR |
| Dossier compliance check | up to 5,000.00 |
| Comparison of each additional study | 300.00 |

III. Costs related to the authorisation and the renewal of authorisation of a PPP where the Republic of Slovenia is the Member State concerned with regard to the mutual recognition of PPP authorisation and the amendment of PPP authorisation in the Republic of Slovenia (except for the procedures referred to in paragraph seven of Article 13 of this Decree, for which no fee is charged)

|  |  |
| --- | --- |
| 1. Authorisation and extension of authorisation where the Republic of Slovenia is the Member State concerned and the mutual recognition of a PPP authorisation based on an application submitted under Articles 33, 40 and 43 of Regulation 1107/2009/EC2,3 | EUR |
| Dossier completeness check | 375.00 |
| Assessment of physical and chemical properties and analytical methods | 437.50 |
| Assessment of toxicological and metabolism studies | 562.50 |
| Assessment of residues in or on food and feed | 437.50 |
| Assessment of behaviour in the environment | 652.50 |
| Assessment of ecotoxicological studies | 750.00 |
| Assessment of data on efficacy | 750.00 |
| Harmonisation of draft label with instructions for use | 375.00 |
| TOTAL | 4,250.00 |

|  |  |
| --- | --- |
| 2. Minor amendments to a PPP authorisation in accordance with Articles 33, 40 and 45 of Regulation 1107/2009/EC that do not require any additional assessment | EUR |
| Examination of application | up to 100.00 |

IV. Costs of the assessment of PPP comparability

|  |  |
| --- | --- |
| Costs of PPP comparability assessment where exemption from the submission of studies is invoked in accordance with Article 34 of Regulation 1107/2009/EC | EUR |
| Comparability assessment | up to 1,000.00 |

V. Costs of a comparative assessment of PPPs containing candidates for substitution

|  |  |
| --- | --- |
| Costs of comparative assessment of PPPs containing candidates for substitution in accordance with Article 50 of Regulation 1107/2009/EC3 | EUR |
| Comparative assessment | up to 3,000.00 |

VI. Costs related to the extension of a PPP authorisation for minor uses

|  |  |
| --- | --- |
| Extension of PPP authorisation for minor uses in accordance with Article 51 of Regulation 1107/2009/EC | EUR |
| Dossier completeness check | 100.00 |
| Assessment of toxicological and metabolism studies | 150.00 |
| Assessment of residues in or on food and feed | 250.00 |
| Assessment of behaviour in the environment | 100.00 |
| Assessment of ecotoxicological studies | 100.00 |
| Harmonisation of draft label with instructions for use3 | 100.00 |
| TOTAL | 800.00 |

VII. The costs related to PPP permits

|  |  |
| --- | --- |
| 1. Parallel trade permit in accordance with Article 52 of Regulation 1107/2009/EC | EUR |
| Examination of application and assessment of whether PPPs are identical | 200.00 |
| 2. Emergency authorisation in accordance with Article 53 of Regulation 1107/2009/EC | EUR |
| Review and examination of application | 875.00 |
| 3. Research and development permit in accordance with Article 54 of Regulation 1107/2009/EC | EUR |
| Examination of application | 100.00 |

VIII. Costs of determining limit values for PPP residues if based on the applicant’s application for an assessment of residues that is separate from the evaluation of active substances

|  |  |
| --- | --- |
| Determination of limit values of PPP residues if carried out in procedures not included in the procedure for the evaluation of active substances in accordance with Article 4 of Regulation 1107/2009/EC3 | EUR |
| Dossier completeness check | up to 700.00 |
| Assessment of residues for substances or uses not approved in the EU or assessment of residues for new uses | up to 16,012.00 |
| Proposal for residues of a particular product and consumer risk assessment | up to 1,250.00 |
| TOTAL | up to 17,962.00 |
| Assessment of confirmatory data | up to 8,000.00 |

1 The costs related to the renewal of an active substance inclusion in the list of approved active substances may vary, in accordance with the difference in the amount of work required, by no more than 30% of the basic price. The assessment of a larger number of representative products and more than three different uses shall be considered as a difference in the amount of work required. If a joint application is submitted by more than one applicant (task force), which includes one joint representative product, the costs shall be divided among all applicants, while the costs of equivalence assessment shall be charged for each active substance source to the holder of the source. If several applicants submit separate dossiers for the same substance, the costs of the full assessment of each dossier will be charged.

2 In the case of an authorisation of a PPP with more than one active substance, the costs may increase in proportion to the increase in the amount of work; however, the cost increase may not exceed 50% of the basic price for a PPP with two active substances or 75% of the basic price for a PPP with three or more active substances.

3 In the case of an authorisation of a PPP with five or more uses, the costs may increase in proportion to the increase in the amount of work; however, the cost increase may not exceed 50% of the basic price for a PPP with 5 to 10 uses or 75% of the basic price for a PPP with more than 10 uses.

4 The costs related to the authorisation or the extension or amendment of authorisation of a PPP may vary, in accordance with the difference in the amount of work required, by no more than 30% of the basic price.  
 The assessment of additional data required due to new or changed instructions and guidelines or other requirements for PPP assessment shall be considered as a difference in the amount of work required.