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/EC[1]	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 Slovenia[2,3,4]	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/EC[2,3]	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/EC[3]	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 use[3]	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/EC[3]	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.