Republic of Latvia

Cabinet
Regulation No. 509
Riga, 24 July 2012

Regulations Regarding the Placing on the Market of Plant Protection Products According to Regulation No 1107/2009

Issued pursuant to
Section 5, Clause 2
of the Plant Protection Law

I. General Provisions

1. This Regulation prescribes the procedures by which the State Plant Protection Service (hereinafter – Service) shall register plant protection products containing chemical and micro-organisms (hereinafter – plant protection product) and grant an authorisation for their placing on the market in accordance with 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 (hereinafter – Regulation No 1107/2009).

2. In granting the authorisation referred to in Article 28(1), Articles 30 and 40 of Regulation No 1107/2009 for the placing on the market and use of a plant protection product (hereinafter – authorisation), the Service shall concurrently register the plant protection product in the Register of Plant Protection Products (hereinafter – Register).

3. A plant protection product shall not be included in the Register if the authorisation:

3.1. in accordance with Article 52 of Regulation No 1107/2009 is granted for parallel trade of the plant protection product;

3.2. in accordance with Article 53 of Regulation No 1107/2009 is granted for use of the plant protection product in emergency situations in plant protection;

3.3. in accordance with Article 54 of Regulation No 1107/2009 is granted for research and development of the plant protection product.

II. Granting of an Authorisation and Inclusion of a Plant Protection Product in the Register

4. After receipt of the application referred to in Article 33 of Regulation No 1107/2009 and the necessary documentation the Service shall prepare and send the person an invoice for the preparation of an evaluation for inclusion of a plant protection product in the Register in accordance with the price list of the paid services provided by the Service.

5. If the plant protection product conforms to the requirements referred to in Article 29 of Regulation No 1107/2009, the Service shall, in accordance with Articles 36 and 37 of Regulation No 1107/2009, take a decision on granting of the authorisation and include the plant protection product in the Register.

6. If the plant protection product does not conform to the requirements referred to in Article 29 of Regulation No 1107/2009, the Service shall take a decision not to grant the authorisation and not to include the plant protection product in the Register.

7. In applying a procedure for the recognition of an authorisation issued by another country, the Service shall allow to place a plant protection product on the market and to include it in the Register in accordance with Article 41(1) of Regulation No 1107/2009.

8. In taking a decision on issue of an authorisation, the Service shall, in accordance with Article 31 of Regulation No 1107/2009, determine the requirements for the placing on the market and use of a plant protection product, as well as the information to be indicated on the labelling of the plant protection product.

9. Depending on the properties and the requirements for use of the plant protection product it shall be assigned a registration class.

10. Upon the request of a person the Service shall register the plant protection product in the third class of registration, if it has been packed in such packaging according to the content of which no more than 5000 square metres can be treated, using the minimum registered dosage of the plant protection product, and if it conforms to the criteria referred to in Paragraph 11 of this Regulation.

11. A plant protection product shall be registered in third class of registration if:

11.1. in accordance with the regulatory enactments regarding the procedures for the classification, labelling and packaging of chemical substances and chemical products it is not classified as:

11.1.1. toxic or very toxic (R23–R28);

11.1.2. carcinogen category 1, 2 or 3 (R40, R45, R49);

11.1.3. mutagen category 1, 2 or 3 (R46, R68);

11.1.4. toxic for reproductive system in category 1, 2 or 3 (R60, R61, R62, R63);

11.1.5. product which may cause serious damages to eyes (R41);

11.1.6. product which may cause harm to breast-fed babies (R64);

11.1.7. product which may cause serious harm to health by prolonged exposure (R48) or due to the use of which danger of harmful cumulative effects exists (R33);

11.2. in accordance with 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 and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 it is not classified as:

11.2.1. product of acute toxicity (if it enters the human body perorally) in category 1, 2 or 3 (H300 – fatal if swallowed; H301 – toxic if swallowed);

11.2.2. product of acute toxicity (if it enters the human body through skin) in category 1, 2 or 3 (H310 – fatal in contact with skin; H311 – toxic in contact with skin);

11.2.3. product of acute toxicity (in inhaling gas and dust or mist) in category 1, 2 or 3 (H330 – fatal if inhaled; H331 – toxic if inhaled);

11.2.4. product of acute toxicity (in inhaling vapour) in category 1 or 2 (H330 – fatal if inhaled; H331 – toxic if inhaled);

11.2.5. carcinogen category 1A, 1B and 2 (H350 – may cause cancer: indicate the type of exposure if it has been unequivocally proved that other types of exposure do not pose hazard; H351 – suspected of causing cancer: indicate the type of exposure if it has been unequivocally proved that other types of exposure do not pose hazard);

11.2.6. mutagen of category 1A, 1B and 2 (H340 – may cause genetic damages: indicate the type of exposure if it has been unequivocally proved that other types of exposure do not pose hazard; H341 – suspicion that it may cause genetic damages: indicate the type of exposure if it has been unequivocally proved that other types of exposure do not pose hazard);

11.2.7. toxic for reproductive system in category 1A, 1B and 2 (H360F – may negatively affect fertility; H361f – suspicion that it negatively affects fertility; H360D – may cause damage to the unborn child; H361d – suspicion that it may cause damage to the unborn child);

11.2.8. product which causes serious eye damages (H318);

11.2.9. product which may cause harm to breast fed children (H362);

11.2.10. product with toxic impact on target organs due to repeated exposure (STOT RE categories 1 and 2);

11.3. results of the risk calculations of the use of the plant protection product show that the danger to the persons who may come into contact with the plant protection product during and after the use thereof without using personal protective equipment do not exceed the admissible level of exposure, which has been approved by the European Commission for a specific active substance contained in the composition of the plant protection product in the review report in accordance with Annex II to Regulation No 1107/2009.

12. If in accordance with the regulatory enactments regarding the procedures for the classification, labelling and packaging of chemical substances and chemical products a plant protection product is classified as harmful – may cause lung damage if swallowed (R65) –, it shall be registered in the third class of registration if the packaging thereof is ensured with such design of opening, which cannot be opened by children.

13. If in accordance with the regulatory enactments regarding the procedures for the classification, labelling and packaging of chemical substances and chemical products a plant protection product is classified as harmful, extremely flammable or highly flammable, it shall be registered in the third class of registration if the packaging is labelled with a tactile warning symbol of hazard.

14. A plant protection product shall be registered in the first class of registration if it may cause increased hazard because of some specific properties or in case if mishandled or misused. Plant protection products, which in accordance with this Regulation are not to be registered in the first or third class of registration, shall be registered in the second class of registration.

15. The Service shall send a decision on registration of a plant protection product to the person within 10 days after taking thereof.

16. The inclusion of a plant protection product in the Register shall be attested by a registration certificate for the plant protection product issued by the Service (hereinafter – certificate).

17. The Service shall issue a certificate and make an entry in the Register after the person has paid the State fee and the Service has approved the conformity of the labelling text of the plant protection product with Article 1 of Commission Regulation 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.

18. The following information shall be indicated in the registration certificate:

18.1. the given name, surname or name of the holder of the registration certificate;
18.2. the name of the plant protection product;
18.3. the type of the preparation;
18.4. the registration number;
18.5. the preparatory form;
18.6. the registration class;
18.7. the volume or weight of the packaging for distribution in Latvia;
18.8. the name, content, degree of purity of the active substance contained in the composition of the plant protection product;
18.9. the decision on granting of an authorisation for the plant protection product (number);
18.10. the registration date;
18.11. the term of validity of the registration certificate;
18.12. the date of issue of the registration certificate.

III. Withdrawal or Amendment of an Authorisation

19. The Service shall, within a month after receipt of an application and such documents, which justify expansion of the scope of application, assess the conformity of a plant protection product with the conditions referred to in Article 51(2) of Regulation No 1107/2009. If the plant protection product conforms to the conditions referred to in Article 51(2) of Regulation No 1107/2009, the Service shall make changes in the Register and approve a draft labelling of the plant protection product with supplements submitted by the holder of registration.

20. If the holder of a registration certificate changes, the term of validity of the certificate shall remain unchanged.

21. In order to transfer a registration certificate to another person, the holder of the registration certificate shall submit an application to the Service and append documents with his or her signature and the signature of the subsequent owner of the certificate, indicating therein:
21.1. the trade name or names of the plant protection product included in the Register, the number of the registration certificate and the date of registration of the plant protection product;
21.2. the name and address of the present holder of the registration certificate and the name and address of the subsequent holder of the registration certificate;
21.3. the document that certifies the transference of the registration documentation of the plant protection product and the accessibility thereof for the subsequent holder of the certificate;
21.4. the date when the present holder of the registration certificate transfers all of the duties of the holder of the registration certificate to the subsequent holder of the certificate.

22. The Service shall, within a month after receipt of the documents referred to in Paragraph 21 of this Regulation, take a decision on making of changes in the registration certificate, notify the current and subsequent holder of the registration certificate thereof, issue a new registration certificate and make amendments to the Register.

IV. Granting of an Authorisation without Including the Plant Protection Product in the Register

23. The Service shall, within a month after receipt of an application and the documents referred to in Article 54(2) of Regulation No 1107/2009, evaluate the potential risk of a plant protection product to the health and environment and according to Article 54 of Regulation No 1107/2009 shall issue an authorisation for the use of the plant protection product for research and development purposes.

24. In order to receive an authorisation for parallel trade of a plant protection product, a person shall submit the information referred to in Article 52(4) of Regulation No 1107/2009 to the Service. The Service shall, within a month after receipt of this information, evaluate the identity of the plant protection product and take a decision on issue of an authorisation for parallel trade.

25. If a plant protection product is not identical within the meaning of Article 52(3) of Regulation No 1107/2009, the Service shall take a decision on refusal to issue an authorisation for parallel trade of the plant protection product. Upon a request of the person in such case a decision on granting of an authorisation shall be taken in accordance with Chapter II of this Regulation.

26. If deficiencies are detected in the application of a person for the receipt of the authorisation referred to in Paragraph 23 or 24 of this Regulation, the Service shall determine a deadline for the elimination thereof. If deficiencies are eliminated by the specified deadline, the Service shall take a decision on issue of the relevant authorisation. If deficiencies are not eliminated by the specified deadline, the Service shall take a decision on refusal to issue the authorisation.

27. The Service shall, within 10 days after taking of the decision, send the person a decision on issue of the authorisation referred to in Paragraphs 23 and 24 of this Regulation together with an invoice for the preparation of the evaluation.

28. If according to the evaluation a plant protection product intended for the use in trials or experiments for research and development purposes may have a harmful effect on human or animal health or unfavourable environmental impact, the Service shall determine restrictions for the performance of experiments or research in the authorisation in accordance with Article 54(1) of Regulation No 1107/2009.

29. In a decision on issue of an authorisation for the use of a plant protection product for research and development purposes the Service shall determine:

29.1. the term of validity of the authorisation;

29.2. the quantity permitted for distribution and use of the plant protection product;

29.3. the size of the area permitted for use;

29.4. the conditions for use with regard to the user and the plant protection product;

29.5. if necessary, the requirement regarding disposal of plants or plant products to be used in food and animal feed used in an experiment or research;

29.6. the person responsible for the use of the plant protection product.

30. The Service shall determine the size of the area permitted for use based on the request of the performer of the experiment or research and the results of an evaluation, however, it shall not exceed 20 hectares per year for trials in an open field or 2 hectares per year for trials in covered areas.

31. The Service shall determine the term of validity of the authorisation of not more than two years based on the request of the performer of the experiment or research and the results of the evaluation.

32. In order to extend the term of validity of an authorisation, the holder of the authorisation shall submit a request to the Service for an extension of the term of validity of the authorisation not later than two months before the end of the term of validity. The Service shall extend the term of validity of the authorisation in accordance with the request of the performer of the experiment or research, if the necessity to continue the experiment or research is substantiated.

V. Closing Provisions

33. Sub-paragraph 11.2 of this Regulation shall come into force on 1 June 2015.

34. Sub-paragraph 11.1, as well as Paragraphs 12 and 13 of this Regulation shall be in force until 1 June 2015.

Informative Reference to the European Union Directive

This Regulation contains legal norms arising from Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

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