

Requirements for Effectiveness Testing of Plant Protection Products and for Testing Entities, and Procedure for Application for Recognition and for Processing of Applications¹

Regulation No. 103 of the Minister of Agriculture of 4 November 2008

The Regulation is established on the basis of subsection 64 (4) of the Plant Protection Act.

§ 1. Requirements for effectiveness testing of plant protection products

- (1) The effectiveness testing of plant protection products shall be conducted in compliance with the principles of good testing practice.
- (2) The principles of good testing practice mean principles according to which acts are performed, testing is planned and reports are submitted in a testing entity.
- (3) The effectiveness testing of plant protection products shall comply with the requirements for effectiveness set out in Annex III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 230, 19.08.1991, p. 1–172).
- (4) Effectiveness testing shall be identifiable. In order to identify an effectiveness trial, it shall be provided with a unique reference number. Documents certifying acts and samples relating to effectiveness testing shall be provided with the specified reference number in order to ensure their traceability.

§ 2. Requirements for testing entities

- (1) According to subsection 64 (3) of the Plant Protection Act, a testing entity must have employees who have completed the required education and training and have the required technical knowledge and experience, equipment verified and calibrated pursuant to the Metrology Act, working premises and storage facilities, standard operating procedures, experimental fields and, depending on the field of testing, glasshouses, growth cabinets, storage rooms or warehouses (hereinafter testing facility) which enable organisation of effectiveness testing in compliance with the principles of good testing practice.
- (2) A person or an agency shall prepare the standard operating procedures which establish the appropriate operating procedures regarding the conduct of effectiveness testing or performance of acts and regarding documentation which is technically justified, including the procedure for the review of the operating procedures and for the establishment of amendments to the operating procedures.

- (3) The standard operating procedures shall include information on:
- 1) the person responsible for effectiveness testing;
 - 2) the equipment, including use, maintenance, cleaning and calibration of plant protection equipment or, if necessary, other activities relating to the equipment;
 - 3) the methods of effectiveness testing;
 - 4) the registration of meteorological data;
 - 5) the acceptance, identification, labelling, storage, weighting and disposal of tested plant protection products and reference plant protection products or, if necessary, other activities relating to tested plant protection products and reference plant protection products;
 - 6) the assessment methods;
 - 7) the marking of effectiveness trials and collection of information regarding testing, handling and archiving of information, use of a computer-based system or other relevant activities;
 - 8) the application of safety measures;
 - 9) the preparation of reporting regarding effectiveness testing.
- (4) A tested plant protection product is a plant protection product the effect of which is studied in order to assess the efficiency of the plant protection product and the effect of the plant protection product on crops upon control of harmful organisms.
- (5) A reference plant protection product is defined as an authorised plant protection product which has proved a sufficient performance in practice under the agricultural, plant health and environmental, including climatic, conditions in the area of proposed use.

§ 3. Application for recognition of testing entity

A person or an agency which wishes to conduct the effectiveness testing of a plant protection product shall, for a testing entity to be recognised, submit to the Plant Production Inspectorate a written application in compliance with the format specified in Annex 1 to the Regulation.

§ 4. Processing of applications

The Plant Production Inspectorate shall prepare an application and an assessment report concerning the results of an on-site inspection of a testing entity on the basis of which the Inspectorate shall make a decision to recognise or deny recognition of the testing entity pursuant

to the procedure and within the term provided for in subsection 64 (3²) of the Plant Protection Act.

§ 5. Decision to recognise testing entity and decision to deny recognition of testing entity and revocation of decision

(1) Pursuant to subsection 64 (3²) of the Plant Protection Act, the Plant Production Inspectorate shall make a decision to recognise if the testing entity complies with the requirements on the basis of the assessment results. A decision to recognise a testing entity shall be made separately for each field of effectiveness testing.

(2) A decision to recognise a testing entity and a decision to deny recognition of a testing entity shall, inter alia, set out:

1) the name and personal identification code or registry code of the person or agency regarding whose testing entity the decision is made;

2) the address of the person or agency regarding whose testing entity the decision is made;

3) the field of the effectiveness testing.

(3) According to subsection 64 (3³) of the Plant Protection Act, a person or an agency which wishes to continue effectiveness testing through a recognised testing entity shall apply for recognition of the testing entity not later than three months before the expiry of the term of recognition. For that purpose, the person or agency shall submit to the Plant Production Inspectorate an application specified in § 3, which shall be processed pursuant to the procedure established in § 4.

(4) The Plant Production Inspectorate shall revoke a decision to recognise a testing entity if, in the course of the inspection specified in 64 (3³) of the Plant Protection Act, it becomes evident that the testing entity and the organisation and conduct of effectiveness testing do not comply with the requirements.

(5) The list of recognised testing entities shall be published on the webpage of the Plant Production Inspectorate.

§ 6. Requirements for testing entity conducting effectiveness testing of plant protection products

(1) A person or an agency whose testing entity is recognised shall:

- 1) ensure the existence of employees who have completed the required education and training and have the required technical knowledge and experience;
 - 2) maintain a database regarding the education, training, technical knowledge and experience of employees in accordance with the requirements of the Personal Data Protection Act;
 - 3) determine the specific duties of each employee and ensure that the employee has completed the required education and training and has the technical knowledge and experience required for the performance of the assigned duties;
 - 4) ensure the availability of the standard operating procedures;
 - 5) ensure the existence of the appropriate equipment and technical means for the conduct of effectiveness testing;
 - 6) ensure the existence of an appropriate testing facility;
 - 7) ensure the compliance of the conducted effectiveness testing with the type, range, volume and intended purpose of the testing;
 - 8) prepare a detailed description of effectiveness testing and make it available to the employees;
 - 9) ensure compliance with the testing plan and scheme prepared regarding the effectiveness testing;
 - 10) indicate, in the detailed description of effectiveness testing, deviations from the standard operating procedures and take the deviations from the standard operating procedures into account in the results of the effectiveness testing;
 - 11) ensure the existence of the required working premises and storage facilities for plant protection products.
- (2) The equipment used in effectiveness testing shall be regularly inspected, maintained and cleaned, and calibrated and verified in accordance with the Metrology Act.
 - (3) By 15 June each year, a person or an agency shall submit to the Plant Production Inspectorate the relevant information which relates to effectiveness testing and is specified in subsection 64 (3⁵) of the Plant Protection Act and documents containing the information separately or as an aggregate in compliance with the format specified in Annex 2 to the Regulation.

§ 7. Maintaining records and storage of information

The Plant Production Inspectorate shall maintain records of applications, submitted information and documents and decisions of recognition or decisions to deny recognition and shall store the applications, information and documents submitted upon application for the recognition of testing entities for ten years.

§ 8. Repeal of Regulation

Regulation No. 54 of the Minister of Agriculture of 4 September 2000 "Designation of Research and Development Institution Authorised to Test Plant Protection Products" (RTL² 2000, 101, 1580) is repealed.

§ 9. Entry into force

Section 8 of this Regulation enters into force on 1 January 2009.

¹ Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 230, 19.08.1991, p. 1–172), amended by Directives 93/71/EEC (OJ L 221, 31.08.1993, p. 27–36), 94/37/EC (OJ L 194, 29.07.1994, p. 65–81), 94/79/EC (OJ L 354, 31.12.1994, p. 16–31), 95/35/EC (OJ L 172, 22.07.1995, p. 6–7), 95/36/EC (OJ L 172, 22.07.1995, p. 8–20), 96/12/EC (OJ L 65, 15.03.1996, p. 20–37), 96/46/EC (OJ L 214, 23.08.1996, p. 18–24), 96/68/EC (OJ L 277, 30.10.1996, p. 25–34), 97/57/EC (OJ L 265, 27.09.1997, p. 87–109), 2000/80/EC (OJ L 309, 9.12.2000, p. 14–23), 2001/21/EC (OJ L 69, 10.03.2001, p. 17–21), 2001/28/EC (OJ L 113, 24.04.2001, p. 5–7), 2001/36/EC (OJ L 164, 20.06.2001, p. 1–38), 2001/47/EC (OJ L 175, 28.06.2001, p. 21–23), 2001/49/EC (OJ L 176, 29.06.2001, p. 61–63), 2001/87/EC (OJ L 276, 19.10.2001, p. 17–20), 2001/99/EC (OJ L 304, 21.11.2001, p. 14–16), 2001/103/EC (OJ L 313, 30.11.2001, p. 37–39), 2002/18/EC (OJ L 55, 26.02.2002, p. 29–32), 2002/37/EC (OJ L 117, 4.05.2002, p. 10–12), 2002/48/EC (OJ L 148, 6.06.2002, p. 19–23), 2002/64/EC (OJ L 189, 18.07.2002, p. 27–32), 2002/81/EC (OJ L 276, 12.10.2002, p. 28–30), 2003/5/EC (OJ L 8, 14.01.2003, p. 7–9), 2003/23/EC (OJ L 81, 28.03.2003, p. 39–42), 2003/31/EC (OJ L 101, 23.04.2003, p. 3–9), 2003/39/EC (OJ L 124, 20.05.2003, p. 30–32), 2003/68/EC (OJ L 177, 16.07.2003, p. 12–16), 2003/70/EC (OJ L 184, 23.07.2003, p. 9–12), 2003/79/EC (OJ L 205, 14.08.2003, p. 16–18), 2003/81/EC (OJ L 224,

6.09.2003, p. 29–31), 2003/82/EC (OJ L 228, 12.09.2003, p. 11–28), 2003/84/EC (OJ L 247, 30.09.2003, p. 20–25), 2003/112/EC (OJ L 321, 6.12.2003, p. 32–35), 2003/119/EC (OJ L 325, 12.12.2003, p. 41–43), 2004/20/EC (OJ L 70, 9.03.2004, p. 32–34), 2004/30/EC (OJ L 77, 13.03.2004, p. 50–53), 2004/58/EC (OJ L 120, 24.04.2004, p. 26–29), 2004/60/EC (OJ L 120, 24.04.2004, p. 39–42), 2004/62/EC (OJ L 125, 28.04.2004, p. 38–40), 2004/66/EC (OJ L 168, 1.05.2004, p. 35–67), 2004/71/EC (OJ L 127, 29.04.2004, p. 104–106), 2004/99/EC (OJ L 309, 6.10.2004, p. 6–8), 2005/2/EC (OJ L 20, 22.01.2005, p. 15–18), 2005/3/EC (OJ L 20, 22.01.2005, p. 19–23), 2005/25/EC (OJ L 90, 8.04.2005, p. 1–34), 2005/34/EC (OJ L 125, 18.05.2005, p. 5–7), 2005/53/EC (OJ L 241, 17.09.2005, p. 51–56), 2005/54/EC (OJ L 244, 20.09.2005, p. 21–23), 2005/57/EC (OJ L 246, 22.09.2005, p. 14–16), 2005/58/EC (OJ L 246, 22.09.2005, p. 17–19), 2005/72/EC (OJ L 279, 22.10.2005, p. 63–69), 2006/5/EC (OJ L 12, 18.01.2006, p. 17–20), 2006/6/EC (OJ L 12, 18.01.2006, p. 21–23), 2006/10/EC (OJ L 25, 28.01.2006, p. 24–27), 2006/16/EC (OJ L 36, 8.02.2006, p. 37–39), 2006/19/EC (OJ L 44, 15.02.2006, p. 15–17), 2006/39/EC (OJ L 104, 13.04.2006, p. 30–35), 2006/41/EC (OJ L 187, 8.07.2006, p. 24–27), 2006/45/EC (OJ L 130, 18.05.2006, p. 27–28), 2006/64/EC (OJ L 206, 27.07.2006, p. 107–111), 2006/74/EC (OJ L 235, 30.08.2006, p. 17–22), 2006/75/EC (OJ L 248, 12.09.2006, p. 3–5), 2006/85/EC (OJ L 293, 24.10.2006, p. 3–5), 2006/104/EC (OJ L 363, 20.12.2006, p. 352–367), 2006/131/EC (OJ L 349, 12.12.2006, p. 17–21), 2006/132/EC (OJ L 349, 12.12.2006, p. 22–26), 2006/133/EC (OJ L 349, 12.12.2006, p. 27–31), 2006/134/EC (OJ L 349, 12.12.2006, p. 32–36), 2006/135/EC (OJ L 349, 12.12.2006, p. 37–41), 2006/136/EC (OJ L 349, 12.12.2006, p. 42–46), 2007/5/EC (OJ L 35, 8.02.2007, p. 11–17), 2007/6/EC (OJ L 43, 15.02.2007, p. 13–18), 2007/21/EC (OJ L 97, 12.04.2007, p. 42–46), 2007/25/EC (OJ L 106, 24.04.2007, p. 34–42), 2007/31/EC (OJ L 140, 1.06.2007, p. 44–46), 2007/50/EC (OJ L 202, 3.08.2007, p. 15–17), 2007/52/EC (OJ L 214, 17.08.2007, p. 3–8), 2007/76/EC (OJ L 337, 21.12.2007, p. 100–104), 2008/40/EC (OJ L 87, 29.3.2008, p. 5–8), 2008/41/EC (OJ L 89, 1.4.2008, p. 12–14), 2008/45/EC (OJ L 94, 5.04.2008, p. 21–23), 2008/66/EC (OJ L 171, 1.7.2008, p. 9–15), 2008/69/EC (OJ L 172, 2.7.2008, p. 9–14), 2008/70/EC (OJ L 185, 12.7.2008, p. 40–42) and Regulations (EC) No 806/2003 (OJ L 122, 16.05.2003, p. 1–35), (EC) No 2229/2004 (OJ L 379, 24.12.2004, p. 13–63) and (EC) No 396/2005 (OJ L 70, 16.03.2005, p. 1–16).

² RTL = *Riigi Teataja Lisa* = Appendix to the State Gazette

Annex 1 to Regulation No. 103 of the Minister of Agriculture of 4 November 2008

“Requirements for Effectiveness Testing of Plant Protection Products and for Testing Entities, and Procedure for Application for Recognition and for Processing of Applications¹”

Application for recognition of testing entity

1. Information concerning applicant

Name of person or agency:

Personal identification code or registry code:

Address and contact details:

Given name and surname of responsible person:

2. Field of effectiveness testing in which recognition of testing entity is applied for:

Field trial

Glasshouse trial

Growth cabinet trial

Storage room or warehouse trial

Trials on fruit and berry species

Forestry trial

3. Information on existence of equipment, employees, working premises, storage facilities and testing facilities required for recognition

existence of plant protection equipment

existence of seeding and harvesting machines

existence of employees who have completed required education and training and have required technical knowledge and experience

existence of standard operating procedures

existence of testing facility

existence of working premises and storage facilities

Date:

Signature:

Andres Oopkaup

Deputy Secretary General for Agricultural and Trade Policies in the capacity of Secretary
General

Annex 2 to Regulation No. 103 of the Minister of Agriculture of 4 November 2008

“Requirements for Effectiveness Testing of Plant Protection Products and for Testing Entities,
and Procedure for Application for Recognition and for Processing of Applications¹”

Aggregate regarding Effectiveness Testing of Plant Protection Products
in 200...

(name of person or agency)

Trial reference number

Field of testing

Testing facility

Tested plant protection product

Purpose of trial

Name and address of contracting entity

Area of trial plot and total testing area

Number of variants and repetitions

Crops used in trial

Person responsible for trial

Andres Oopkaup

Deputy Secretary General for Agricultural and Trade Policies in the capacity of Secretary
General