

Requirements for Authorisation of Plant Protection Products Pursuant to Simplified Procedure, and Substantial and Formal Requirements for Applications, and Procedure for Processing of Applications¹

Approved by Regulation No 82 of 6 July 2006 of the Minister of Agriculture (RTL² 2006, 55, 1004), entered into force 20.07.2006

Amended by the following Regulation (date, number, publication in the *Riigi Teataja*, date of entry into force):

1.07.2008 No 67 (RTL 2008, 57, 791) 13.07.2008 (implemented as of 1.07.2008)

The Regulation is established on the basis of subsection 72 (4) of the Plant Protection Act.

§ 1. Scope of application

This Regulation establishes the requirements for authorisation of plant protection products pursuant to a simplified procedure, and the substantial and formal requirements for applications, and the procedure for processing of applications.

§ 2. Requirements for authorisation of plant protection products pursuant to simplified procedure

(1) Plant protection products which conform to the requirements provided in subsection 72 (1) of the Plant Protection Act shall be authorised pursuant to a simplified procedure.

(2) A plant protection product authorised pursuant to a simplified procedure is identical to a plant protection product authorised in Estonia earlier if it is of the same quality, including the active ingredient, its content in the plant protection product and type of preparation, and of the same level of safety and effectiveness.

(RTL 2008, 57, 791 – entered into force 13.07.2008) – implemented as of 1.07.2008

§ 3. (Repealed – RTL 2008, 57, 791 – entered into force 13.07.2008) – implemented as of 1.07.2008

§ 4. Requirements for application for authorisation of plant protection products manufactured by same producer pursuant to simplified procedure

(1) A person wishing to be granted grant permission for authorisation for a plant protection product manufactured by the same producer pursuant to simplified procedure shall submit the

Plant Protection Inspectorate an application in the format set forth in the annex of this Regulation.

(2) The application specified in subsection (1) shall be accompanied by the label and manufacturer's notes of the plant protection product in its country of origin, the safety file of the plant protection product, the draft of the label of the plant protection product for marketing in Estonia and a detailed description of the composition of the plant protection product.

§ 5. (Repealed – RTL 2008, 57, 791 – entered into force 13.07.2008) – implemented as of 1.07.2008

§ 6. Requirements for processing of applications for authorisation of plant protection products manufactured by same producer

(1) The Plant Protection Inspectorate shall assess the conformity of an application and a plant protection product to the requirements during two months after receipt of the application.

(2) The Plant Protection Inspectorate shall assess the identity and conformity of a plant protection product manufactured by the same producer based on the information set forth in the application.

(3) The Plant Protection Inspectorate shall authorise a plant protection product manufactured by the same producer pursuant to a simplified procedure on the same terms and with the same area of use as the plant protection product authorised in Estonia earlier.

¹ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.08.1991, pp 1–172), amended by Directives 93/71/EC (OJ L 221, 31.08.1993, pp 27–36), 94/37/EC (OJ L 194, 29.07.1994, pp 65–81), 94/43/EC (OJ L 227, 01.09.1994, pp 31–55), 94/79/EC (OJ L 354, 31.12.1994, pp 16–31), 95/35/EC (OJ L 172, 22.07.1995, pp 6–7), 95/36/EC (OJ L 172, 22.07.1995, pp 8–20), 96/12/EC (OJ L 65, 15.03.1996, pp 20–37), 96/46/EC (OJ L 214, 23.08.1996, pp 18–24), 96/68/EC (OJ L 277, 30.10.1996, pp 25–34), 97/57/EC (OJ L 265, 27.09.1997, pp 87–109), 97/73/EC (OJ L 353, 24.12.1997, pp 26–28), 98/47/EC (OJ L 191, 07.07.1998, pp 50–52), 1999/1/EC (OJ L 21, 28.01.1999, pp 21–23), 1999/73/EC (OJ L 206, 05.08.1999, pp 16–18), 1999/80/EC (OJ L 210, 10.08.1999, pp 13–15), 2000/10/EC (OJ L 57, 02.03.2000, pp 28–30), 2000/49/EC (OJ L 197, 03.08.2000, pp 32–34), 2000/50/EC (OJ L 198, 04.08.2000, pp 39–40), 2000/66/EC (OJ L 276, 28.10.2000, pp 35–37), 2000/67/EC (OJ L 276, 28.10.2000, pp 38–40), 2000/68/EC (OJ L 276, 28.10.2000, pp 41–43), 2000/80/EC (OJ L 309, 09.12.2000, pp 14–23), 2001/21/EC (OJ L 069, 10.03.2001, pp 17–21), 2001/28/EC (OJ L 113, 10.03.2001, pp 5–7), 2001/36/EC (OJ L 164, 20.06.2001, pp 1–38), 2001/47/EC (OJ L 175, 28.06.2001, pp 21–23), 2001/49/EC (OJ L 176, 29.06.2001, pp 61–63), 2001/87/EC (OJ L 276, 19.10.2001, pp 17–20), 2001/99/EC (OJ L 304,

21.11.2001, pp 14–16), 2001/103/EC (OJ L 313, 30.11.2001, pp 37–39), 2002/18/EC (OJ L 055, 26.02.2002, pp 29–32), 2002/37/EC (OJ L 117, 04.05.2002, pp 10–12), 2002/48/EC (OJ L 148, 06.06.2002, pp 19–23), 2002/64/EC (OJ L 189, 18.07.2002, pp 27–32), 2002/81/EC (OJ L 276, 12.10.2002, pp 28–30), 2003/5/EC (OJ L 008, 14.01.2003, pp 7–9), 2003/23/EC (OJ L 081, 28.03.2003, pp 39–42), 2003/31/EC (OJ L 101, 23.04.2003, pp 3–9), 2003/39/EC (OJ L 124, 20.05.2003, pp 30–32), 2003/68/EC (OJ L 177, 16.07.2003, pp 12–16), 2003/70/EC (OJ L 184, 23.07.2003, pp 9–12), 2003/79/EC (OJ L 205, 14.08.2003, pp 16–18), 2003/81/EC (OJ L 224, 06.09.2003, pp 29–31), 2003/82/EC (OJ L 228, 12.09.2003, pp 11–28), 2003/84/EC (OJ L 247, 30.09.2003, pp 20–25), 2003/112/EC (OJ L 321, 06.12.2003, pp 32–35), 2003/119/EC (OJ L 325, 12.12.2003, pp 41–43), 2004/20/EC (OJ L 070, 09.03.2004, pp 32–34), 2004/30/EC (OJ L 077, 13.03.2004, pp 50–53), 2004/58/EC (OJ L 120, 24.04.2004, pp 26–28), 2004/60/EC (OJ L 120, 24.04.2004, pp 39–42), 2004/62/EC (OJ L 125, 28.04.2004, pp 38–40), 2004/66/EC (OJ L 168, 01.05.2004, pp 35–67), 2004/71/EC (OJ L 127, 29.04.2004, pp 104–106), 2004/99/EC (OJ L 309, 06.10.2004, pp 6–8), 2005/2/EC (OJ L 020, 22.01.2005, pp 15–18), 2005/3/EC (OJ L 020, 22.01.2005, pp 19–23), 2005/25/EC (OJ L 90, 08.04.2005, 1–34), 2005/34/EC (OJ L 125, 18.05.2005, pp 5–7), 2005/53/EC (OJ L 241, 17.09.2005, pp 51–56), 2005/54/EC (OJ L 244, 20.09.2005, pp 21–23), 2005/57/EC (OJ L 246, 22.09.2005, pp 14–16), 2005/58/EC (OJ L 246, 22.09.2005, pp 17–19), 2005/72/EC (OJ L 279, 22.10.2005, pp 63–69), 2006/5/EC (OJ L 12, 13.01.2006, pp 17–20), 2006/6/EC (OJ L 12, 13.01.2006, pp 21–23), 2006/10/EC (OJ L 25, 28.01.2006, pp 24–27), 2006/16/EC (OJ L 36, 08.02.2006, pp 37–39), 2006/19/EC (OJ L 44, 15.02.2006, pp 15–17), 2006/39/EC (OJ L 104, 13.04.2006, pp 30–35), 2006/41/EC (OJ L 187, 08.07.2006, pp 24–27), 2006/45/EC (OJ L 130, 18.05.2006, pp 27–28), 2006/64/EC (OJ L 206, 27.07.2006, pp 107–111), 2006/74/EC (OJ L 235, 30.08.2006, pp 17–22), 2006/75/EC (OJ L 248, 12.09.2006, pp 3–5), 2006/85/EC (OJ L 293, 24.10.2006, pp 3–5), 2006/104/EL (OJ L 363, 20.12.2006, pp 352–367), 2006/131/EL (OJ L 349, 12.12.2006, pp 17–21), 2006/132/EL (OJ L 349, 12.12.2006, pp 22–26), 2006/133/EL (OJ L 349, 12.12.2006, pp 27–31), 2006/134/EL (OJ L 349, 12.12.2006, pp 32–36), 2006/135/EL (OJ L 349, 12.12.2006, pp 37–41), 2006/136/EL (OJ L 349, 12.12.2006, pp 42–46), 2007/5/EL (OJ L 35, 8.02.2007, pp 11–17), 2007/6/EL (OJ L 43, 15.02.2007, 13–18), 2007/21/EL (OJ L 97, 12.04.2007, pp 42–46), 2007/25/EL (OJ L 106, 24.04.2007, pp 34–42), 2007/31/EL (OJ L 140, 1.06.2007, pp 44–46), 2007/50/EL (OJ L 202, 3.8.2007, pp 15–17), 2007/52/EL (OJ L 214, 17.8.2007, pp 3–8), 2007/76/EL (OJ L 337, 21.12.2007, pp 100–104), 2008/40/EL (OJ L 87, 29.3.2008, pp 5–8), 2008/41/EL (OJ L 89, 1.4.2008, pp 12–14), 2008/45/EL (OJ L 94, 05.04.2008, pp 21–23) and amended by Commission Decision 2005/303/EU (OJ L 97/38, 15.04.2005, pp 1–3) and amended by Council Regulation 806/2003 (OJ L 122, 16.05.2003, pp 1–35) and Commission Regulation 2229/2004 (OJ L 379, 24.12.2004, pp 1–61);

Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances (OJ L 033, 08.02.1979, pp 36–40), amended by Regulation of the European Parliament and of the Council (EC) No 850/2004 (OJ L 158, 30.04.2004, pp 7–49);

Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.08.1967, pp 1–98), amended by Directive of the European Parliament and of the Council 2006/121/EC (OJ L 396, 30.12.2006, pp 851–857);

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the

Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.07.1999, pp 1–68), amended by Directives 2001/60/EC (OJ L 226, 22.08.2001, pp 5–6), 2004/66/EL (OJ L 168, 1.05.2004, pp 35–67) and 2006/8/EL (OJ L 19, 24.01.2006, pp 12–19) and amended by Regulations of the European Parliament and of the Council (EC) No 1882/2003 (OJ L 284, 31.10.2003, pp 1–53) and (EC) No 1907/2006(OJ L 396, 30.12.2006, pp 1–850).

(RTL 2008, 57, 791 – entered into force 13.07.2008) – implemented as of 1.07.2008

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

Annex to Regulation No 82 of 6 July 2006 of the Minister of Agriculture "Requirements for Authorisation of Plant Protection Products Pursuant to Simplified Procedure, and Substantial and Formal Requirements for Applications, and Procedure for Processing of Applications¹"

Application for authorisation of plant protection products pursuant to simplified procedure

1. Name of applicant:
2. Address of residence or seat:
3. Telecommunications numbers:
4. Registry code or personal identification code:
5. The name of the country of origin from which the person wishes to bring the plant protection product in Estonia for placing it on the market.
6. Name of plant protection product in country of origin:
7. Manufacturer of plant protection product in its country of origin and address thereof:
8. Number of authorisation document for placing the plant protection product on market in its country of origin:
9. Content of active ingredient and type of preparation of the plant protection product for which authorisation pursuant to simplified procedure is applied:
10. Name of plant protection product authorised in Estonia earlier:
11. The name and address of the plant protection product authorised in Estonia earlier:

12. The number of the decision to authorise the plant protection product authorised in Estonia earlier:

Signature of applicant:

Date: