

Formal and Substantive Requirements for Applications Submitted for Inclusion of Active Substances in Annex I to Council Directive 91/414/EEC¹

Regulation No. 59 of the Minister of Agriculture of 1 June 2005

RTL², 10.06.05, 63, 912

Entered into force 15.06.05

This Regulation is established on the basis of subsections 60 (2) and 65 (2) of the Plant Protection Act (RT I 2004, 32, 226).

§1. Scope of application

This Regulation establishes the formal and substantive requirements for the applications submitted for inclusion of active substances in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 230, 19.08.1991, pp 1–172) and the applications for placing plant protection products on the market.

§2. Requirements for applications

(1) Applications submitted for inclusion of active substances in Annex I to Council Directive 91/414/EEC shall conform to the substantive and formal requirements provided in Annexes 2 and 3 to Council Directive 91/414/EEC.

(2) Applications submitted for placing plant protection products on the market shall conform to the substantive and formal requirements provided in Annexes 2 and 3 to Council Directive 91/414/EEC.

(3) The application specified in subsection (1) shall set out the name of the applicant, the address of the residence or seat thereof, telecommunication numbers, registry code or personal identification code, name of the active substance and area of application of the active substance.

(4) The application specified in subsection (2) shall set out the name of the applicant, the address of the residence or seat thereof, telecommunication numbers, registry code or personal

identification code, name(s) of the active substance(s) and area of application of the plant protection product.

(5) The information submitted concerning the active substance of a plant protection product in the applications specified in subsections (1) and (2) shall contain data based on which the possible danger directly or indirectly caused by the active substance to human life or the environment can be assessed, and a full and detailed description of conducted research together with research results and research methods or appropriate references.

(6) The information submitted concerning the characteristics of a plant protection product in the applications specified in subsections (1) and (2) shall contain data concerning the efficacy of the plant protection product as well as data based on which the possible danger which the plant protection product may cause to human life or the environment can be assessed, and a full and detailed description of conducted research together with research results and research methods or appropriate references

(7) The applications specified in subsections (1) and (2) shall be submitted to the Plant Production Inspectorate by electronic means and on paper. The requisite number of copies of those applications shall be set out in Annex 1 for existing active substances in plant protection products and in Annex 2 1 for new active substances in plant protection products.

§3. Entry into force of Regulation

This Regulation enters into force on 15 July 2005.

¹ Council Directive 91/414/EEC 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 39–41), 2004/62/EC (OJ L 125, 28.04.2004, pp 38–40), 2004/71/EC (OJ L 127, 29.04.2004, pp 104–106) 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).

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

Annex 1 to Regulation No. 59 of the
Minister of Agriculture of 1 June
2005 "Formal and Substantive
Requirements for Applications
Submitted for Inclusion of Active
Substances in Annex I to Council
Directive 91/414/EEC"

Requisite number of copies of applications submitted for the inclusion of active substances in Annex I to Council Directive 91/414/EEC and placing plant protection products on the market in the case of existing active substances

| | | |
|--|-------------|-------------|
| | Application | Application |
|--|-------------|-------------|

| | On electronic data medium | | Additional copy on paper | | On paper with a summary on an electronic data medium | | |
|--|---------------------------------------|------------------------|--------------------------|------------------------|--|-----------------------------------|------------------------|
| | Full set of data (CADDY) ² | Summary of application | Full set of data | Summary of application | Full set of data (on paper) | Summary of application (on paper) | Summary of application |
| Estonia is a rapporteur Member State of the EU | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Estonia is not a rapporteur Member State of the EU | 1 | | | 1 | | 1 | |

² *CADDY - Computer Aided Dossier and Data Supply* is an archiving and data processing program.

Annex 2 to Regulation No. 59 of the Minister of Agriculture of 1 June 2005 "Formal and Substantive Requirements for Applications Submitted for Inclusion of Active Substances in Annex I to Council Directive 91/414/EEC"

Requisite number of copies of applications submitted for the inclusion of active substances in Annex I to Council Directive 91/414/EEC and placing plant protection products on the market in the case of new active substances

| | Application | | | | Application | | |
|---|---------------------------|------------------------|--------------------------|------------------------|--|-----------------------------------|------------------------|
| | On electronic data medium | | Additional copy on paper | | On paper with a summary on an electronic data medium | | |
| | Full set of data (CADDY) | Summary of application | Full set of data | Summary of application | Full set of data (on paper) | Summary of application (on paper) | Summary of application |
| Estonia is a rapporteur Member State of the EU | 1 | 1 | 1 | | 1 | 1 | 1 |
| Estonia is not a rapporteur Member State of the EU | 1 | | | 1 | 1 | 1 | |
| Estonia is not a rapporteur Member State of the EU, and the application is not submitted for temporary placing of the plant protection product on the | 1 | | | 1 | 1 | | |

| | | | | | | | |
|--------|--|--|--|--|--|--|--|
| market | | | | | | | |
|--------|--|--|--|--|--|--|--|