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Micropropagation and laboratory requirements of propagating material¹

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Amended by the following acts

| Reception | Disclosure | Enforcement |
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| 27.12.2016 | RT I, 29.12.2016, 41 | 01.01.2017 |
| 08.06.2017 | RT I, 13.06.2017, 4 | 16.06.2017 |
| 20.03.2019 | RT I, 26.03.2019, 1 | 01.04.2019 |
| 13/05/2020 | RT I, 20.05.2020, 3 | 01.06.2020 |

The Regulation is established on the basis of § 64 (5) and § 65 (5) of the Plant Propagation and Variety Protection Act .

§ 1. Scope of regulation

The regulation establishes the requirements for the self-inspection system of the micropropagation of propagating material and the laboratory used for micropropagation, as well as the supplier engaged in the micropropagation of propagating material.

[RT I, 26.03.2019, 1 - enters into force. 01.04.2019]

§ 2. Requirements for micropropagation of propagating material

(1) Micropropagation of propagating material (hereinafter *micropropagation*) is the production of propagating material and seed potato plants (hereinafter *potato plants*) using the tissue culture method to quickly obtain a large amount of propagating material and potato plants.

[RT I, 26.03.2019, 1 - enters into force. 01.04.2019]

(2) Production by tissue culture method is the cultivation of organs, tissue sections, cells or cell parts isolated from a plant (hereinafter *mother plant*) used to obtain the initial propagating material (hereinafter *starting material*) in a test tube on sterile media. [RT I, 03.07.2015, 19 - entry into force 06.07.2015]

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(2) A mother plant is a plant that complies with the requirements set out in subsection 4 (3) from which starting material is taken for the propagation of new plants and which is marked accordingly.

[RT I, 03.07.2015, 19 - entry into force 06.07.2015]

(3) Micro-plants are propagating material and potato plants produced and grown and preserved by the tissue culture method.

(4) Micropropagated propagating material and potato plants are microplants that have been planted out of a test tube and adapted to external environmental conditions.

[RTL 2007, 45, 771 - entry into force. 04.06.2007]

§ 3. Requirements of the self-control system of a supplier engaged in microreproduction of reproduction material

[RT I, 26.03.2019, 1 - entered into force. 01.04.2019]

(1) To ensure the appropriateness of micropropagation, the supplier of propagating material determines the important critical points of micropropagation and the measures implemented in them, documents them and ensures the implementation of these measures (hereinafter *self-control system*).

[RT I, 26.03.2019, 1 - enters into force. 01.04.2019]

(2) A supplier engaged in microreproduction of reproductive material prepares a self-control plan, which describes the following important critical points of microreproduction and the measures to be implemented in order to ensure self-control:

[RT I, 26.03.2019, 1 - entered into force. 01.04.2019]

1) receiving and determining the quality of micropropagation source material and storing and preserving the source material;

[RT I, 03.07.2015, 19 - entered into force. 06.07.2015]

2) preparation and storage of media;

3) propagation of micropropagation source material and microplants using the tissue culture method (cutting, growing, storing, sampling, removing contaminated material);

4) ensuring the distinguishableness of batches of starting material and microplants and identification of different batches during micropropagation, packaging and transport;

5) following precautions to prevent the spread of plant pests;

6) packaging and transportation of microplants and micropropagated propagating material;

[RTL 2007, 45, 771 - entry into force. 04.06.2007]

7) organization of company activities;

8) monitoring and evaluation of critical points.

[RT I, 03.07.2015, 19 - entered into force. 06.07.2015]

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(2) For the purposes of the Regulation, plant pests of propagating and planting material are:

1) in the case of ornamental crops, quality-reducing plant pests specified in the Annex to Directive (EEC) 93/49;

2) in the case of the potato plant, potato leaf curl virus, potato virus A, M, S, X and Y, stem blight bacterium *Dickeya* Samson et al. spp., *Pectobacterium* spp. Waldee emendation. Hauben et al. spp. and *Candidatus* Liberibacter *solanacearum* , *Candidatus* Phytoplasma *solani* and potato stem virus;

3) in the case of vegetable crops, a quality-reducing plant pest specified in the Annex to Directive (EEC) 93/61;

4) in the case of fruit and berry culture, a quality-reducing plant pest specified in Annexes I and II of the European Commission's implementing directive (EU) 2014/98;

5) Implementing Regulation (EU) 2019/2072 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and of the Council in relation to protection measures against plant pests and repealing Commission Regulation (EC) No. 690/2008 and amending Commission Implementing Regulation (EU) 2018/ 2019 (OJ L 319, 10.12.2019, page 1–279), a dangerous plant pest mentioned in Annex II.

[RT I, 20.05.2020, 3 - enters into force. 01.06.2020]

(3) An employee responsible for the implementation and execution of the self-control system is appointed in the company.

(4) The supplier shall keep the self-control plan and the data documented on the basis of it within the term specified in § 77 subsection 4 of the Plant Propagation and Variety Protection Act.

[RT I, 29.12.2016, 41 - enters into force. 01.01.2017]

§ 4. Micropropagation source material requirements

(1) A plant, part of a plant or a microplant is used as the starting material for micropropagation. The microplant that is used as the starting material is produced in the proper laboratory of the person holding the micropropagation license of the plant species or in a laboratory under the supervision of the competent authority of another country.

(2) The source material is kept in a closed room or under sterile conditions until micropropagation. When handling the source material, its contact with other propagating material and produced micro-plants is excluded until it has been established that the source material is free from plant pests.

(3) The supplier determines that the source material is free from plant pests.

[RT I, 29.12.2016, 41 - enters into force. 01.01.2017]

(4) If a plant contaminated with a plant pest or suspected of contamination is discovered among the source material, this plant shall be eliminated and destroyed or, if possible, freed from the plant pest by heat treatment or meristem culture. After the source material has been cleared of a plant pest, the source material must be re-evaluated for the presence of that plant pest.

[RT I, 29.12.2016, 41 - enters into force. 01.01.2017]

§ 5. Treatment of micropropagation source material and microplants

(1) The source material is propagated using the tissue culture method in a laboratory designated for this purpose under sterile conditions.

(2) Only microplants may be kept in the room where microplants are grown and stored.

[RTL 2007, 45, 771 - entry into force. 04.06.2007]

§ 6. Adaptation of microplants to external environmental conditions

(1) Micro-plants are planted out of tissue culture and adapted to the conditions of the external environment in the open field, in a greenhouse or in a room with suitable conditions.

[RTL 2007, 45, 771 - entry into force. 04.06.2007]

(2) Microplants intended for the production of certifiable micropropagated propagating material and potato plants shall be adapted to the conditions of the external environment only in a greenhouse or room where access by plant pests, in particular aphids, is excluded and where plants belonging to another plant species or propagating material of the same species that has not been produced by the tissue culture method are not grown.

[RTL 2007, 45, 771 - entry into force 04.06.2007]

(3) In the adaptation of certifiable micropropagated propagating material and microplants intended for the production of potato plants to the conditions of the external environment:

[RTL 2007, 45, 771 - entered into force. 04.06.2007]

1) a new and pest-free growing substrate is used, which is not in direct contact with the ground;

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1) a growing substrate is used that is free from the plant pests listed in Annex III of the European Commission's implementing directive (EU) No. 2014/98 for the relevant plant family or plant species, which is the host for viruses damaging the plant family or plant species in question;

[RT I, 29.12.2016, 41 - enters into force. 01.01.2017]

2) plant platforms and reusable pots are cleaned and disinfected after each production period;

3) insect traps are used to detect the presence of plant pests in the room.

[RT I, 29.12.2016, 41 - enters into force. 01.01.2017]

(4) From the potato plants obtained by micropropagation of one potato clone, 0.5 percent of the plants are evaluated for potato leaf curl and potato X, S, M, A and Y virus. If a virus-contaminated plant is discovered, that plant will be removed and destroyed.
[RT I, 13.06.2017, 4 - enters into force. 16.06.2017]

§ 7. Requirements for varietal authenticity of micropropagated propagating material and potato plants

(1) Micropropagated propagating material and potato plants must meet the requirements set forth in § 65 subsection 2 of the Plant Propagation and Variety Protection Act. In order to assess the varietal authenticity of the micropropagated propagating material to be certified and the microplants intended for the production of potato plants, the supplier who produced these microplants plants twenty micropropagated plants in the open field for each horticultural variety and potato clone produced.

[RT I, 03.07.2015, 19 - entered into force. 06.07.2015]

(2) During the growing season, the supplier evaluates the varietal authenticity of the plants planted in open ground.

[RT I, 03.07.2015, 19 - entered into force. 06.07.2015]

§ 8. Requirements of the laboratory used for micropropagation

The laboratory used for micropropagation must have:

1) a room equipped with sterile conditions and the necessary equipment and tools for the propagation of the starting material for micropropagation;

[RTL 2007, 45, 771 - entered into force 04.06.2007]

2) a room equipped with adjustable temperature and light shelves for the cultivation and storage of microplants.

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Council Directive 2002/56/EC on the marketing of seed potatoes (OJ L 193, 20.07.2002, pp. 60–73), amended by Directives 2003/61/EC (OJ L 165, 03.07.2003, pp. 23–28), 2013/ 63/EU (OJ L 341, 18.12.2013, pp. 52–55) and 2020/177/EU (OJ L 41, 13.02.2020, pp. 1–77);

Council Directive 2008/90/EC on propagating material and marketing of fruit trees intended for fruit production (OJ L 267, 08.10.2008, pp. 8–22);

Commission Directive 93/49/EEC, which sets out the list of conditions to which ornamental plant propagating material and ornamental plants must comply in accordance with Council Directive 91/682/EEC (OJ L 250, 07.10.1993, pp. 9–18), amended by Directives 1999/67/ EC (OJ L 164, 30.06.1999, p 78), 2018/484/EU (OJ L 81, 23.03.2018, pp. 10–12) and 2020/177/EU (OJ L 41, 13.02.2020, pp. 1–77);

Commission Directive 93/61/EEC establishing a list of conditions to be met by vegetable propagating and planting material, other than seeds, pursuant to Council Directive 92/33/EEC (OJ L 250, 07.10.1993, pp. 101–110), amended by the Directive 2020/177/EU (OJ L 41, 13.02.2020, p. 1–77);

Commission Implementing Directive 2014/21/EU determining the minimum conditions and Union classes applicable to super elite seed potatoes (OJ L 38, 07.02.2014, pp. 39–41), amended by Directive 2020/177/EU (OJ L 41, 13.02.2020, p. 1–77);

Commission Implementing Directive 2014/98/EU implementing Council Directive 2008/90/EC with regard to the special requirements applicable to the families and species of fruit trees referred to in Annex I, the special requirements applicable to suppliers and detailed rules on official inspections (OJ L 298, 16.10.2014, p. 22–61), amended by Directive 2020/177/EU (OJ L 41, 13.02.2020, pp. 1–77).

[RT I, 20.05.2020, 3 - enters into force. 01.06.2020]