

Requirements for reference laboratories and requirements for content of application for grant of authorisation to operate as reference laboratory, list of documents to be annexed to application and procedure for processing applications¹

(20.12.2007 entered into force 01.01.08 - RTL² 2007, 101, 1684)

Regulation No 20 of the Minister of Agriculture of 13.03.2007

(RTL 2007, 24, 427)

entered into force 01.04.2007

Amended by the following Regulation:

20.12.2007 entered into force 01.01.2008 - RTL 2007, 101, 1684.

The Regulation is established pursuant to subsection 53 (7) of the Food Act and subsection 6 (8) of the Veterinary Activities Organisation Act.

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§ 1. Scope of application

This Regulation establishes the bio-safety requirements for national reference laboratories (hereinafter reference laboratory) provided by Article 33 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.04.2004, pp. 1–141) and the requirements for content of application for grant of authorisation to operate as a reference laboratory, the list of documents to be annexed to the application and the procedure for processing applications

(20.12.2007 entered into force 01.01.2008 - RTL 2007, 101, 1684)

§ 2. Requirements for content of application for grant of authorisation to operate as reference laboratory and list of documents to be annexed to application

(1) An applicant for authorisation to operate as a reference laboratory (hereinafter authorisation) shall submit a written application to the Minister of Agriculture setting out the following information:

1) the name, personal identification code or registry code and telecommunication numbers of the applicant and the representative thereof;

- 2) the address of the applicant;
 - 3) the scope of the applied authorisation and the list of used methods of analysis for the use of which the laboratory is accredited;
 - 4) the name and position of the person responsible for the organisation of the activities of the laboratory.
- (2) The following documents shall be annexed to an application:
- 1) copies of the accreditation certificate issued by the accreditation institution and its appendix;
 - 2) an action plan within the scope of the applied authorisation for compliance with the requirements provided for in Article 33.2 of Regulation (EC) No 882/2004 of the European Parliament and of the Council;
 - 3) in the case of application for grant of initial authorisation to operate as a reference laboratory, information regarding payment of the state fee shall be provided.

§ 2¹. Bio-safety requirements for reference laboratories

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- (1) Only laboratories complying with the bio-safety requirements established for reference laboratories in the relevant EU legislation for diagnosing an infectious animal disease may be authorised to operate as reference laboratories.
- (2) In order to diagnose foot-and-mouth disease a reference laboratory shall comply with the bio-safety requirements provided in Annex XV to Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, pp. 1–87).
- (3) In order to diagnose classical swine fever a reference laboratory shall comply with the bio-safety requirements provided in Commission Decision 2002/106/EC approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever (OJ L 39, 09.02.2002, pp. 71–88).
- (4) In order to diagnose African swine fever a reference laboratory shall comply with the bio-safety requirements provided in Commission Decision 2003/422/EC approving an African swine fever diagnostic manual (OJ L 143, 11.06.2003, pp. 35–49).

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§ 3. Procedure for processing applications for authorisation

- (1) Authorisation is granted or denied by a directive of the Minister of Agriculture within twenty days of the receipt of a written application of the laboratory.
- (2) Authorisation shall be granted for an unspecified term.
- (3) A copy of the directive of granting or denying authorisation shall be delivered to the applicant against a signature or sent by post within three working days after the date of issue of the directive.
- (4) In order to change the scope of authorisation a new authorisation shall be applied for pursuant to § 2.
- (5) A reference laboratory shall immediately notify the Minister of Agriculture in writing of any changes in the information submitted upon applying for grant of authorisation which may affect performance of the duties of the reference laboratory.

§ 4. Entry into force of Regulation

This Regulation enters into force on 1 April 2007.

¹Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, pp. 1–87), amended by Directive 2006/104/EC (OJ L 363, 20.12.2006, pp. 352–367)

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