



EXECUTIVE DIRECTORATE

DECISION OF THE EXECUTIVE DIRECTOR of the European Food Safety Authority concerning the electronic submission of applications for regulated products within the remit of the European Food Safety Authority during COVID-19 outbreak

THE EXECUTIVE DIRECTOR OF THE EUROPEAN FOOD SAFETY AUTHORITY, Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 178/2002 of 28 January 2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹, and in particular to Article 26(2) thereof, regarding the role of the Executive Director of the European Food Safety Authority²,

Whereas:

- 1. The Authority evaluates applications for regulated products which include substances used in feed and food (such as additives, enzymes, flavourings, nutrient sources), food contact materials and pesticides, GMOs, food manufacturing processes and processing aids, health claims;
- 2. The Authority receives applications (mandate and technical dossiers) for regulated products in different formats (on paper and/or in electronic format on a standard physical medium, (i.e. CD ROM, DVD, USB Key). Technical dossiers are submitted by applicants to the European Commission or to the Member States, who forward the technical dossiers and the mandate to EFSA. In some cases, technical dossiers are sent directly by the applicant to the Authority;
- 3. The Decision of the Executive Director of the European Food Safety Authority concerning the electronic submission of applications for regulated products within the remit of the European Food Safety Authority of 4 January 2017 (EFSA/ED/16487670/2016) authorised the submission of all technical dossiers of applications for regulated products by electronic means, the electronic copy of the technical dossier being also considered as the formal submission;
- 4. On 12 March 2020, the World Health Organisation declared the COVID-19 outbreak a global pandemic, urging all governmental actors to take action to prevent it from spreading further;
- 5. There have been reports of COVID-19 being able to survive on surfaces for a variable period of time;
- 6. For precautionary reasons, the Executive Director decided to adopt mandatory teleworking for all staff members, in order to limit its premises and staff exposure to COVID-19 pathogens;
- 7. The measures and restrictions adopted by several Member States of the European Union, combined with EFSA's decision to adopt mandatory teleworking for all staff mem-





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bers, following the COVID-19 outbreak of March 2020 risk hampering attempts by applicants and institutions of submitting efficiently to EFSA information or packages related to their applications;

HAS DECIDED AS FOLLOWS:

Article 1

Submission of applications by electronic means

- 1. With this Decision, by way of derogation to its Decision concerning the electronic submission of applications for regulated products within the remit of the European Food Safety Authority of 4 January 2017 (EFSA/ED/16487670/2016), the Executive Director authorises the submission of all technical dossiers of applications for regulated products to EFSA for scientific evaluation under applicable Union legal acts in electronic format via Internet-based software, hosted by the applicant or a third-party only. The chosen Internet-based software should be agreed with EFSA. The electronic copy of the technical dossier submitted in this way shall be considered as the formal submission.
- 2. This Decision shall apply to the submission of original technical dossiers, update of technical dossiers and responses to requests for missing or additional information during the life-cycle.
- 3. The submission may take place preferably via the Internet-based software chosen by the submitter of data or, only in case the previous option is not possible, by using the EFSA SharePoint site hosted by Microsoft.
- 4. The date of submission shall be meant to be the date in which the transfer of data is successfully completed, as stated by EFSA in its written acknowledgment of receipt sent to the sender.

Article 2

Entry into force and transitional measures

- 1. The present Decision shall enter into force and become applicable on the day of its signature.
- 2. The present Decision shall remain in force and applicable until further notice, when COVID-19 measures shall be proven not to be required anymore.





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3. For a period of two months from the entry into force of this Decision, EFSA shall accept all submissions under Article 1(1) as having been validly made insofar as complying with its Decision on the same matter of 4 January 2017.

Done at Parma on 30/03/2020

Bernhard Url Executive Director