

COMMISSION REGULATION (EC) No 1852/2001

of 20 September 2001

laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ⁽¹⁾, and in particular Article 4(5) and Article 10 thereof,

Whereas:

- (1) Experience has shown the need for detailed rules for the protection of the information provided by applicants to ensure the smooth functioning of the assessment of applications under Regulation (EC) No 258/97.
- (2) These rules should ensure the confidentiality of information relating to the manufacturing process where the disclosure of such information might harm the competitive position of the applicant in a disproportionate manner.
- (3) In order to improve transparency in the operation of the procedures established by Article 4 of Regulation (EC) No 258/97, certain information about products being assessed under that Article, and about the outcome of the assessment should be made available to the public. That information should be made available by the Commission on the Internet.
- (4) Such rules should be consistent with the new legislative framework laid down in Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ⁽²⁾.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

1. The Commission, the national authorities of the Member States and the food assessment bodies referred to in Article 4(3) of Regulation (EC) No 258/97 shall not divulge information identified as confidential pursuant to paragraph 3, except for information that must be made public if circumstances so require in order to protect human health.

2. The applicant may indicate the information submitted by him pursuant to Regulation (EC) No 258/97 relating to the manufacturing process that should be kept confidential because

its disclosure might harm his competitive position. Verifiable justification must be given in such cases.

3. The competent authority of the Member, which has received the application, shall determine, after consultation with the applicant, which information relating to the manufacturing process shall be kept confidential and shall inform the applicant, the competent food assessment body and the Commission of its decision.

4. The Commission shall ensure that the Member States are informed of any decision communicated to it pursuant to paragraph 3.

Article 2

1. When the initial assessment of the request is carried out pursuant to Article 4(1) of Regulation (EC) No 258/97, the Commission shall make the following information available to the public:

- (a) name and address of the applicant;
- (b) description allowing the identification of the food or food ingredient;
- (c) intended use of the food or food ingredient;
- (d) summary of the dossier, except for those parts for which the confidential character has been determined in accordance with Article 1(3);
- (e) date of receipt of a complete request.

2. The Commission shall make the initial assessment report available to the public, except for any information identified as confidential pursuant to Article 1(3), in the following way:

- (a) when there are no objections pursuant to Article 6(4) of Regulation (EC) No 258/97, the initial assessment report shall be made available to the public after the expiry of the period of 60 days referred to in that Article and after the time necessary for the information of the applicant;
- (b) when, pursuant to Article 7 of Regulation (EC) No 258/97, an authorisation decision is required, the initial assessment report shall wherever possible be made available to the public at the same time the opinion of the Scientific Committee for Food is given or, if no such opinion is required, at the time that the decision is published in the *Official Journal of the European Communities*.

Article 3

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ OJ L 106, 17.4.2001, p. 1.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 September 2001.

For the Commission
David BYRNE
Member of the Commission
