

COMMISSION IMPLEMENTING DECISION

of 29 November 2013

authorising the placing on the market of rooster comb extract as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council*(notified under document C(2013) 8319)***(Only the Spanish text is authentic)**

(2013/705/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 7 thereof,

Whereas:

- (1) On 8 February 2011 the company Bioiberica S.A. made a request to the competent authorities of the United Kingdom to place rooster comb extract on the market as a novel food ingredient.
- (2) On 25 October 2011 the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that rooster comb extract for use in certain foods at the levels proposed by the applicant meets the criteria set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 10 November 2011 the Commission forwarded the initial assessment report to the other Member States.
- (4) Reasoned objections were raised within the 60 day period laid down in the second subparagraph of Article 6(4) of Regulation (EC) No 258/97. In particular, questions concerning the specifications and possible allergenicity of the product were raised.
- (5) On 22 May 2012 the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for rooster comb extract as food ingredient in accordance with Regulation (EC) No 258/97.

- (6) On 31 May 2013 the Authority adopted a Scientific Opinion on the rooster comb extract⁽²⁾, concluding that it is safe under the proposed uses and use levels.
- (7) The Scientific Opinion gives sufficient grounds to establish that rooster comb extract in the proposed uses and use levels complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Rooster comb extract as defined and specified in Annex I may be placed on the market as a novel food ingredient for the uses defined and at the maximum levels established in Annex II.

Article 2

The designation of rooster comb extract, authorised by this Decision on the labelling of the foodstuffs containing it shall be 'rooster comb extract' or 'cockereel comb extract'.

Article 3

This Decision is addressed to Bioiberica S.A., Plaça Francesc Macià, 7. 8B, 08029 Barcelona Spain.

Done at Brussels, 29 November 2013.

For the Commission

Tonio BORG

Member of the Commission⁽¹⁾ OJ L 43, 14.2.1997, p. 1.⁽²⁾ EFSA Journal 2013; 11(6):3260.

ANNEX I

SPECIFICATION OF ROOSTER COMB EXTRACT

Definition

Rooster comb extract is obtained from *Gallus gallus* by enzymatic hydrolysis of rooster comb and by subsequent filtration, concentration and precipitation steps. The principal constituents of rooster comb extract are the glycosaminoglycans hyaluronic acid, chondroitin sulphate A and dermatan sulphate (chondroitin sulphate B).

Hyaluronic acid	60-80 %
Chondroitin sulphate A	Not more than 5 %
Dermatan sulphate (chondroitin sulphate B)	Not more than 25 %

Description

White or almost white hygroscopic powder.

Identification

pH	5,0-8,5
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Purity

Chlorides	Not more than 1 %
Nitrogen	Not more than 8 %
Loss on drying (105 °C for 6 hours)	Not more than 10 %
Mercury	Not more than 0,1 mg/kg
Arsenic	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Chromium	Not more than 10 mg/kg
Lead	Not more than 0,5 mg/kg

Microbiological criteria

Total viable aerobic count	Not more than 10 ² cfu/g
<i>Escherichia coli</i>	Absent in 1 g
<i>Salmonella</i> spp.	Absent in 1 g
<i>Staphylococcus aureus</i>	Absent in 1 g
<i>Pseudomonas aeruginosa</i>	Absent in 1 g

ANNEX II

Authorised uses of rooster comb extract

Food category	Maximum use level (mg/100 g or mg/100 ml)
Milk-based drinks	40
Milk based fermented drinks	80
Yoghurt-type products	65
<i>Fromage frais</i>	110