COMMISSION IMPLEMENTING DECISION (EU) 2017/810

of 10 May 2017

on a derogation from mutual recognition of the authorisation of a biocidal product containing boric acid by France in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2017) 2935)

(Only the French text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 37(2)(b) thereof,

Whereas:

(1) The company Rütgers Organics GmbH ('the applicant') submitted a complete application to France for mutual recognition of an authorisation granted by Germany in respect of a wood preservative containing the active substance boric acid ('the product'). Germany authorised the product for the preventive treatment against wood rotting fungi, insects and subterranean and dry-wood termites by professional users.

(2) Boric acid is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]) as toxic for reproduction category 1B and therefore meets the exclusion criterion referred to in Article 5(1)(c) of Regulation (EU) No 528/2012. In accordance with the third subparagraph of Article 5(2) of that Regulation, the use of a biocidal product containing boric acid shall be restricted to Member States in which at least one of the conditions set out in that paragraph is met.

(3) France considered that none of the conditions of Article 5(2) of Regulation (EU) No 528/2012 were satisfied and communicated to the applicant, pursuant to Article 37(2) of that Regulation, its proposal to refuse to grant the authorisation in France. The justification of such refusal is the protection of health and life of humans, particularly of vulnerable groups, as referred to in Article 37(1)(c) of that Regulation.

(4) The applicant disagreed with the proposed refusal and considered that that measure is not sufficiently justified on the grounds laid down in Article 37(1) of Regulation (EU) No 528/2012. As a result, on 6 October 2016 France informed the Commission in accordance with the second subparagraph of Article 37(2) of that Regulation.

(5) From the arguments put forward by France, it follows that the risk associated with the use by professional users of the product, while acceptable according to the relevant exposure assessment models, is not negligible; other wood preservatives containing active substances not meeting the exclusion criteria referred to in Article 5(1) of Regulation (EU) No 528/2012 are available on the French market for the intended uses in the product, and that the product was so far not available on the French market. Thus, France considers the product as not essential to control any serious danger to human health, animal health or the environment and that not authorising the product in France would not have any disproportionate negative impact on the French society.

(6) None of the conditions of Article 5(2) of Regulation (EU) No 528/2012 are satisfied. The purpose of that Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment, in particular of vulnerable groups. Professional users are subject to high exposure to biocidal products over the long term and meet the definition of 'vulnerable groups' pursuant to Article 3(1)(ad) of Regulation (EU) No 528/2012. The Commission therefore considers that the proposed derogation from mutual recognition fulfils the condition referred to in Article 37(1)(c) of that Regulation.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

1. The derogation from mutual recognition proposed by France for the product referred to in paragraph 2 is justified on the grounds of the protection of health and life of humans, particularly of vulnerable groups, as referred to in Article 37(1)(c) of Regulation (EU) No 528/2012.

2. Paragraph 1 applies to the product identified by the following case number, as provided for by the Register for Biocidal Products:

BC-QC011565-51.

Article 2

This Decision is addressed to the Republic of France.

Done at Brussels, 10 May 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission