COMMISSION IMPLEMENTING DECISION (EU) 2018/1297

of 25 September 2018

on a derogation from mutual recognition of the authorisation of biocidal products containing creosote 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(2018) 5412)

(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 companies Bilbaina de Alquitranes, SA, Koppers International BV and Rain Carbon BVBA ('the applicants') submitted complete applications to France for mutual recognition of three authorisations granted by Sweden in respect of three biocidal product families of wood preservatives containing the active substance creosote ('the products'). Sweden authorised the products for the treatment of poles for overhead electricity and telecommunication ('transmission poles') and railway sleepers by professional users.

(2) Creosote is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]) as carcinogen category 1B. Creosote also meets the criteria for being a persistent, bioaccumulative and toxic substance (PBT substance), or a very persistent and very bioaccumulative substance (vPvB substances) according to Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]). Therefore, it meets the exclusion criteria set out in points (a) and (e) of Article 5(1) of Regulation (EU) No 528/2012. In accordance with the third subparagraph of Article 5(2) of Regulation (EU) No 528/2012, the use of biocidal products containing creosote is to 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 concerning the treatment of transmission poles in its territory and that refusal of authorisation for this use was justified on grounds of the protection of the environment and of the health and life of humans, as referred to in points (a) and (c) of Article 37(1) of Regulation (EU) No 528/2012, respectively. Therefore, pursuant to Article 37(2) of that Regulation, France informed the applicants about its intention to adjust the terms and conditions of the authorisations to be granted in France by not authorising the products for the treatment of transmission poles ('the restricted use').

(4) Two of the applicants disagreed with the proposed adjustment and one of them did not reply within 60 days of that communication. As a result, on 22 November 2017, France informed the Commission in accordance with the second subparagraph of Article 37(2) of Regulation (EU) No 528/2012.

(5) From the arguments put forward by France, it follows that the risk to humans or the environment from the exposure to creosote associated with the restricted use of the products cannot be considered negligible. France also pointed out that 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 restricted use. Thus, not authorising the restricted use would not have any disproportionate negative impact on the French society. According to France, the restricted use is not essential to control any serious danger to human health, animal health or the environment.

([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).

([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(6) Therefore, none of the conditions of Article 5(2) of Regulation (EU) No 528/2012 are satisfied for the restricted use in France. With a view to achieving a high level of protection of human health, animal health and the environment, Regulation (EU) No 528/2012 lays down that the authorisation of biocidal products containing active substances with the worst hazard profiles shall be restricted to specific situations. Moreover, pursuant to the second subparagraph of Article 37(1) of that Regulation, Member States may, in particular, propose on the grounds referred to in the first subparagraph of that Article to refuse to grant an authorisation or to adjust the terms and conditions of the authorisations to be granted for biocidal products containing an active substance to which Article 5(2) or Article 10(1) of that Regulation applies. Creosote meets several of the exclusion criteria referred to in Article 5(1) of that Regulation both in terms of hazardous properties for the environment and for human health.

(7) The Commission therefore considers that the derogation from mutual recognition proposed by France is justified on the grounds referred to in points (a) and (c) of Article 37(1) of that Regulation.

(8) 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 biocidal product families referred to in paragraph 2 is justified on the grounds of the protection of the environment and of the health and life of humans as referred to in points (a) and (c) of Article 37(1) of Regulation (EU) No 528/2012, in conjunction with the second subparagraph of Article 37(1) of Regulation (EU) No 528/2012.

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

BC-WK024516-27;

BC-DQ024492-36;

BC-EU013041-45.

Article 2

This Decision is addressed to the French Republic.

Done at Brussels, 25 September 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission