

COMMISSION IMPLEMENTING DECISION**of 29 October 2014****rejecting the refusal of the authorisation of a biocidal product notified by Germany in accordance with Directive 98/8/EC of the European Parliament and of the Council***(notified under document C(2014) 7915)***(Text with EEA relevance)**

(2014/758/EU)

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 36(3) thereof,

Whereas:

- (1) Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ contained the list of active substances approved at Union level for inclusion in biocidal products. Commission Directives 2008/78/EC ⁽³⁾, 2008/79/EC ⁽⁴⁾ and 2008/86/EC ⁽⁵⁾ added the active substances propiconazole, IPBC and tebuconazole, respectively, for use in products belonging to product-type 8, wood preservatives, as defined in Annex V to Directive 98/8/EC. By virtue of Article 86 of Regulation (EU) No 528/2012, these substances are therefore approved active substances included in the list referred to in Article 9(2) of that Regulation.
- (2) In accordance with Article 8 of Directive 98/8/EC, the company Arch Timber Protection Ltd submitted on 2 April 2010 an application to The United Kingdom for authorisation of a wood preservative biocidal product containing propiconazole, IPBC and tebuconazole ('the contested product'). The United Kingdom authorised the contested product on 7 June 2012 for industrial use and temporary protection of freshly sawn/felled wood and unseasoned timber only, also indicating that wood treated with this product can be used for Use Classes 2 and 3 as described in the Technical Notes for Guidance on Product Evaluation ⁽⁶⁾. The product consists of two packs to be mixed and diluted at industrial premises depending on site-specific application conditions by dipping or enclosed deluge. Ten Member States have subsequently authorised the contested product through mutual recognition.
- (3) Arch Timber Protection Ltd ('the applicant') submitted on 16 July 2012 a complete application to Germany for mutual recognition of the authorisation of the contested product granted by the United Kingdom.
- (4) Germany notified the Commission, the other Member States and the applicant on 19 August 2013 of its proposal to refuse the authorisation in accordance with Article 4(4) of Directive 98/8/EC. Germany considered that the contested product does not meet the requirements of Article 5(1) of Directive 98/8/EC with regard to the environment.
- (5) According to Germany, the authorisation did not reflect well that the product was intended for temporary wood protection and the product was not appropriately assessed by the United Kingdom in terms of environmental risks. The assessment performed by Germany concluded in an unacceptable risk for the environment at day 30 following the application of the product ('time 1'), which also raised concerns regarding the potential use of wood treated with the contested product under Use Classes 2 and 3 conditions.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽³⁾ Commission Directive 2008/78/EC of 25 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include propiconazole as an active substance in Annex I thereto (OJ L 198, 26.7.2008, p. 44).

⁽⁴⁾ Commission Directive 2008/79/EC of 28 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include IPBC as an active substance in Annex I thereto (OJ L 200, 29.7.2008, p. 12).

⁽⁵⁾ Commission Directive 2008/86/EC of 5 September 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include tebuconazole as an active substance in Annex I thereto (OJ L 239, 6.9.2008, p. 9).

⁽⁶⁾ Available on the website http://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg-product-evaluation_en.pdf

- (6) Germany also considered that, since the ratio of the active substances and non-active substances in the working solutions of the product is variable, the product does not meet the definition of biocidal products in Article 2(a) of Directive 98/8/EC and should have been authorised as a frame formulation as defined by Article 2(j) of Directive 98/8/EC.
- (7) The Commission invited other Member States and the applicant to submit comments to the notification in writing within 90 days in accordance with Article 27(1) of Directive 98/8/EC. Comments were submitted within that deadline by Germany, The United Kingdom and the applicant. The notification was also discussed on 24 September 2013 in the meeting of the coordination group established under Article 35 of Regulation (EU) No 528/2012.
- (8) With regard to the risks for the environment, from those discussions and comments it follows that the evaluation carried out by the United Kingdom, in the absence of an agreed model for temporary wood protection, followed the best guidance available at the time ⁽¹⁾, which is based on models for treated wood to be placed on the market under Use Classes 2 and 3 conditions. The assessment was also based on a worst-case assumption of a complete release of the active substances at time 1.
- (9) It also follows that the evaluation performed by the United Kingdom following those models is compatible with current guidance ⁽²⁾. Where a risk is identified at time 1 as a result of a worst-case assumption, safe use of treated wood under Use Classes 2 and 3 conditions can be assumed when the risk for the environment at the end of the service life is considered acceptable.
- (10) The Commission also notes that cases where an unacceptable risk is identified at time 1 are currently under discussion at Union level in order to establish a harmonised approach. Against this background the Commission considers that, until such an approach is formally adopted, the conclusions of the assessment of the contested product by the United Kingdom should be considered as valid until the renewal of the product authorisation.
- (11) With regard to the identity of the product, from those discussions and comments it follows that the contested product, in the form in which it is supplied to the industrial users, has specific fixed concentrations of the active and non-active substances. The Commission considers that the fact that industrial users can prepare different solutions of the product at the work place, which are process dependant, cannot be interpreted in a way as if the authorisation holder was placing on the market a group of different biocidal products as referred to in Article 2(j) of Directive 98/8/EC.
- (12) In the light of those arguments, the Commission supports the conclusions of the evaluation carried out by the United Kingdom and the other Member States having approved the product through mutual recognition, considering that the contested product meets the definition in Article 2(a) of Directive 98/8/EC and fulfils the requirements set by Article 5(1) of that Directive with regard to the environment. The Commission therefore considers that the request by Germany to refuse the authorisation cannot be justified on the grounds put forward.
- (13) Finally, on the basis of the discussions held, it appears necessary to explicitly mention in the product authorisation that the use of the product is for temporary wood protection and to ensure, as a condition for the authorisation, that specific instructions for use of the product are provided to industrial users taking into consideration the characteristics of the industrial sites where the product is to be used.
- (14) Regulation (EU) No 528/2012 applies to the contested product in accordance with the provisions of Article 92(2) of that Regulation. Since the legal basis for this Decision is Article 36(3) of that Regulation, this decision should be addressed to all Member States by virtue of Article 36(4) of that Regulation.
- (15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ See OECD Emission Scenario Documents (EDS) for Wood Preservatives: Part 1 — 4 (2003), available on the website <http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents>

⁽²⁾ Report of leaching workshop (Arona, Italy, 13-14 June 2005), available on the website http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/ESD/ESD_PT/PT_08/PT_8_Leaching_Workshop_2005.pdf/at_download/file

HAS ADOPTED THIS DECISION:

Article 1

This Decision applies to products identified by the following application reference number in the Reference Member State, as provided for by the Register for Biocidal Products:

2010/2509/5687/UK/AA/6745

Article 2

The proposal by Germany to refuse the authorisation granted by the United Kingdom on 7 June 2012 of the products referred to in Article 1, is rejected.

Article 3

The intended use described in the product authorisation shall be amended as follows:

‘For temporary wood protection use against wood staining fungi and surface moulds on freshly sawn/felled wood and unseasoned timber only. Wood treated with this product can be used for Use Classes 2 and 3 (i.e. timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting).’.

Article 4

The following condition for authorisation is imposed to the products referred to in Article 1:

‘As a condition of the authorisation, the authorisation holder must ensure that detailed instructions for use of the product, taking into account the characteristics of the industrial site where the product is to be used, are provided to users at the site of application.’.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 29 October 2014.

For the Commission
Janez POTOČNIK
Member of the Commission