Official Journal
of the European Union

EN
L series

2024/2420

16.9.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/2420

of 13 September 2024

on a derogation from mutual recognition of an authorisation for the biocidal product 'URAGAN D2', containing hydrogen cyanide, by Hungary in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2024) 6413)

(Only the Hungarian 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 Lučební závody Draslovka a.s. Kolín ('the applicant') submitted an application to Hungary, on 29 March 2018, for mutual recognition of an authorisation granted by Czechia in respect of the biocidal product URAGAN D2, containing the active substance hydrogen cyanide ('the product'). The application was registered under case number BC-JN038446-27 in the Register for Biocidal Products. Czechia had authorised the product for professional use for fumigation in specific area types against wood boring beetles (product-type 8), rats (product-type 14) and beetles, cockroaches and moths (product-type 18).

(2) The product is a mixture of approximately 98 % of hydrogen cyanide and stabilising additives. Hydrogen cyanide is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]) as follows: Acute Tox. Category 1, hazard codes H300, H310 and H330 (fatal if swallowed, in contact with skin or if inhaled) and STOT RE 1, hazard code H372 (causes damage to the thyroid through prolonged and repeated exposure).

(3) After having assessed the application, the Hungarian competent authority concluded that not all of the conditions set in the product assessment report and in the summary of biocidal product characteristics of the product could be fulfilled in Hungary. As indicated in the product assessment report, operators performing the fumigation have to be equipped with a first-aid box containing, among other, an antidote. In Hungary, however, the antidotes listed in that report were not available to users of the product. The fact that the antidote would not be available to administer immediately to potential victims of poisoning in the place where the fumigation is carried out could result in a severe impact to the health of the potential victims of poisoning or their death.

(4) On 9 October 2018, the Hungarian competent authority communicated to the applicant its intention to refuse to grant the product authorisation, on grounds of the protection of health and life of humans in accordance with Article 37(1), point (c), of Regulation (EU) No 528/2012, as the availability of the requested antidote could not be ensured in Hungary. In its reply of 11 October 2018, the applicant communicated its disagreement with the intention of the Hungarian competent authority and presented a solution concerning the supply of an antidote together with the product, to be administered by a doctor at the site of fumigation. The Hungarian competent authority liaised with Hungary's National Institute of Pharmacy and Nutrition ('the Institute') to investigate the proposed solution and then informed the applicant on 16 October 2018 about technical and legal obstacles to that solution.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

(5) On 6 November 2018, the Hungarian competent authority informed the applicant that, unless an agreement was reached with it by 7 December 2018, it would inform the Commission, in accordance with Article 37(2), second subparagraph, of Regulation (EU) No 528/2012, that Hungary was unable to reach an agreement with the applicant. Following the applicant's reply of 7 December 2018 and since at that time it was not yet clear whether an antidote was potentially available in Hungary, the Hungarian competent authority decided to postpone sending the information to the Commission and continue discussing with the Institute the possibilities for the applicant to make an antidote available in Hungary.

(6) On 9 August 2019, the Hungarian competent authority informed the applicant that for the import of antidotes in Hungary, a specific procedure has to be initiated at the Institute by the potential importer of the antidotes. It also requested the applicant to submit, by 20 December 2019, proof of the availability of all antidotes mentioned in the product assessment report or, if the applicant could not meet that deadline, an explanation of the reasons for not meeting the deadline.

(7) On 20 August 2019, on request of the applicant, the Czech competent authority clarified that not all antidotes listed in the product assessment report have to be available and that the availability of any of the antidotes listed in the product assessment report sufficed to fulfil the requirements set for granting the authorisation. This clarification was acknowledged by the Hungarian competent authority.

(8) On 18 December 2019, the applicant informed the Hungarian competent authority that all its efforts to make any of the antidotes available in Hungary failed. Given that no immediate follow-up communication of the Hungarian competent authority with the applicant ensued, as the COVID-19 pandemic hit, the applicant requested an update on the status of the procedure on 18 June 2020. No reply was provided by the Hungarian competent authority. However, according to the information provided by the Hungarian competent authority, by that date the applicant had still not managed to fulfil in Hungary all of the conditions set in the product assessment report.

(9) The Hungarian competent authority contacted again the Institute to further investigate whether any of the antidotes listed in the product assessment report could be available at the site of fumigation. The Institute clarified that only two of those antidotes could be imported to Hungary, and only with individual import requests. The Institute further clarified that neither of those antidotes could be available at the site of fumigation, as they could only be stored in hospital pharmacies.

(10) On 3 July 2023, the Hungarian competent authority communicated to the applicant that the use of the product poses unacceptable risks for the users in Hungary and set a 60-day deadline for the applicant to provide any new information that could ensure a safe use of the product or to withdraw the application for authorisation, if it changed its intention regarding the mutual recognition of the authorisation in Hungary.

(11) The applicant's response of 21 July 2023 did not address the requests of the Hungarian competent authority.

(12) The Hungarian competent authority contacted again the applicant on 9 October 2023 and asked it to indicate its intention regarding the mutual recognition application, either by providing a reasonable schedule to ensure the availability of an antidote at the sites of fumigation in Hungary, or by withdrawing the application. Neither of the requested actions were taken by the applicant within the deadline indicated by the Hungarian competent authority. Therefore, on 25 October 2023, the Hungarian competent authority informed the Commission of the continuing disagreement, in accordance with Article 37(2), second subparagraph, of Regulation (EU) No 528/2012.

(13) From the justification put forward by the Hungarian competent authority, it follows that some risks resulting from the chemical and physical properties of the active substance in the product cannot be managed in a satisfactory way in Hungary. Those risks are related to the lack of available effective means to provide an immediate treatment in case of accidental poisoning during the product application. In fact, antidotes for hydrogen cyanide, with which the operators should be equipped when performing the fumigation operation, are not available in Hungary. Moreover, even if they had been available in Hungary, such antidotes could only be stored in hospital pharmacies and could not be available to administer immediately to potential victims of poisoning in the place where the fumigation is carried out. Therefore, an accidental exposure of operators to the product might result in a severe impact to the health of the potential victims of poisoning or their death.

(14) In addition, in examining the proportionality of the proposed derogation, the Commission notes that other fumigation products, containing other active substances than hydrogen cyanide (such as aluminium phosphide releasing phosphine), are currently authorised for use on the Hungarian market. For none of those products the summary of the biocidal product characteristics requires that the operators be equipped with antidotes.

(15) Having analysed the justification put forward by the Hungarian competent authority, the Commission considers that, due to the hazardous properties of the active substance hydrogen cyanide and the difficulties in managing health risks related to the use of the product in Hungary, the derogation from mutual recognition proposed by the Hungarian competent authority, namely the intended refusal to grant an authorisation, is justified on the grounds of protection of health and life of humans, in accordance with Article 37(1), point (c), of Regulation (EU) No 528/2012.

(16) 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 Hungary, namely the refusal to grant an authorisation for the biocidal product referred to in paragraph 2, is justified on the grounds of protection of the health and life of humans, as referred to Article 37(1), point (c), of Regulation (EU) No 528/2012.

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

BC-JN038446-27.

Article 2

This Decision is addressed to Hungary.

Done at Brussels, 13 September 2024.

For the Commission
Stella KYRIAKIDES
Member of the Commission