Commission Implementing Decision (EU) 2019/1958 of 25 November 2019 on a derogation from mutual recognition of an authorisation for a biocidal product containing hydrogen cyanide by Poland in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2019) 8346) (Only the Polish text is authentic)

COMMISSION IMPLEMENTING DECISION (EU) 2019/1958

of 25 November 2019

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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 Poland for mutual recognition of an authorisation granted by the Czech Republic in respect of a biocidal product containing the active substance hydrogen cyanide ('the product'). The Czech Republic authorised the product for professional use for fumigation in specific area types against wood boring beetles (product-type 8), against rats (product-type 14) and against beetles, cockroaches and moths (product-type 18).

The product is a mixture of approximately 98% of hydrogen cyanide and stabilising additives and is supplied completely soaked into a porous material in 1,5 kg gas-tight steel cans or as liquid in 27,5 kg stainless steel pressurised cylinders. 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).

(2) Taking into account all the information included in the product assessment report and the summary of the biocidal product characteristics, especially the classification of the product and the risk for human health, the Polish competent authority expressed serious concerns in a letter to the applicant on 13 September 2017 with respect to the protection of health of Polish citizens if the product were to be placed on the Polish market.

(3) In response to that letter the applicant proposed a meeting with the Polish competent authority to discuss the concerns expressed, which took place on 22 September 2017, and sent a letter containing its views on the arguments raised by the Polish competent authority on 29 September 2017. Following the discussion with the applicant, the Polish competent authority consulted the Polish authorities responsible for public health, for public security and for the enforcement of Regulation (EU) No 528/2012, to have their views on the placing on the market of the product. All the consulted authorities expressed serious concerns with respect to the placing of the product on the Polish market. On 21 June 2018, the Polish competent authority informed the applicant of its intention to propose to refuse to grant the product authorisation, on grounds of the protection of health and life of humans as referred to in point (c) of Article 37(1) of Regulation (EU) No 528/2012. The Polish competent authority invited the applicant to withdraw the application for mutual recognition of the product in Poland.

(4) In its response of 20 July 2018 the applicant communicated its disagreement with the points raised by the Polish competent authority and made known its intention not to withdraw the application. As a result, on 23 October 2018, Poland informed the Commission of the continuing disagreement in accordance with the second subparagraph of Article 37(2).

(5) From the justification put forward by the Polish 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 Poland. 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

(6) According to the summary of the biocidal product characteristics of the product, operators have to be equipped with a first-aid box containing, among other things, an antidote. The Polish competent authority pointed out that this condition cannot be fulfilled in Poland. In accordance with the Polish law, antidotes for hydrogen cyanide cannot be distributed or stored by entities other than pharmacies or hospital pharmacies. It would therefore not be possible for an authorisation holder to supply the antidote together with the biocidal product. Moreover, ambulances are not equipped with the antidotes. As ensuring an immediate administration of antidotes to possible victims of poisoning in the place where the fumigation takes place is impossible, according to the Polish competent authority, the poisoning would result in death of the victims or a severe health impact.

(7) Other fumigation products, containing other active substances than hydrogen cyanide (e.g. aluminium phosphide releasing phosphine, magnesium phosphide releasing phosphine) are currently authorised for use on the Polish market. For none of those products the summary of the biocidal product characteristics requires that the operators be equipped with antidotes.

(8) Having analysed the justification put forward by the Polish competent authority and the views expressed by the applicant in its letter of 20 July 2018, the Commission considers that, due to the hazardous properties of the active substance and the difficulties in managing health risks related to the use of the product in Poland, the derogation from