COMMISSION IMPLEMENTING DECISION (EU) 2022/323

of 22 February 2022

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Sojet in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2022) 973)

(Text with EEA relevance)

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) On 8 April 2020, the company Sharda Cropchem España S.L. ('the applicant') submitted an application to France for the mutual recognition in sequence in accordance with Article 33 of Regulation (EU) No 528/2012, of a national authorisation of the biocidal product Sojet ('the biocidal product') already granted in Germany. The biocidal product is an insecticide of product-type 18 to be used by professionals for indoor application in industrial or commercial premises, households or private areas, public areas and animal housings for the control of flies. The biocidal product is dispersed in water and applied on cardboard sheets by brushing and contains as active substances imidacloprid and cis-Tricos-9-ene.

(2) On 6 October 2020, pursuant to Article 35(2) of Regulation (EU) No 528/2012, France referred objections to the coordination group, indicating that the conditions of the authorisation set by Germany do not ensure that the biocidal product meets the requirement laid down in Article 19(1), point (b)(iii), of that Regulation. France considers that in order to ensure the safe handling of the biocidal product, wearing of personal protective equipment, consisting of protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and single-use coverall of at least type-6 EN 13034, is required. According to France, the application of technical and organisational measures in accordance with Council Directive 98/24/EC ([2]), as set out in the authorisation granted by Germany, as a possible replacement for wearing personal protective equipment does not ensure an adequate protection if those measures are not specified and evaluated in the assessment of the biocidal product.

(3) Germany considers that Directive 98/24/EC establishes the order of preference of different risk mitigation measures for protection of workers and prioritises the application of technical and organisational measures over wearing personal protection equipment for the use of the biocidal product. According to Germany, pursuant to that Directive the employer is to decide which technical and organisational measures are to be applied, and as there is a broad range of such measures, it is not feasible to describe and evaluate the measures in the authorisation of the biocidal product.

(4) As no agreement was reached by the coordination group, on 3 March 2021 Germany referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. It thereby provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and the applicant.

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

([2]) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

(5) Article 2(3), points (b) and (c), of Regulation (EU) No 528/2012 provides that that Regulation is to be without prejudice to Council Directive 89/391/EEC ([3]) and Directive 98/24/EC.

(6) Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 indicates as one of the criterion for granting an authorisation that the biocidal product has no unacceptable effects itself, or as a result of its residues, on the health of humans.

(7) Point 9 of Annex VI to Regulation (EU) No 528/2012 states that the application of the common principles laid down in that Annex for the evaluation of dossiers for biocidal products referred to in Article 19(1), point (b), of that Regulation, when taken together with the other conditions set out in its Article 19, is to lead to the competent authorities or the Commission deciding whether or not a biocidal product can be authorised. Such authorisation may include restrictions on the use of the biocidal product or other conditions.

(8) Point 18(d) of Annex VI to Regulation (EU) No 528/2012 states that the risk assessment conducted for the product is to determine the measures necessary to protect humans, animals and the environment, both during the proposed normal use of the biocidal product and in a realistic worst-case situation.

(9) Point 56(2) of Annex VI to Regulation (EU) No 528/2012 indicates that in establishing compliance with the criteria set out in Article 19(1), point (b), one of the conclusions to which the evaluating body is to make, is that subject to specific conditions/restrictions the biocidal product can comply with the criteria.

(10) Point 62 of Annex VI to Regulation (EU) No 528/2012 states that the evaluating body is, where appropriate, to conclude that the criterion under Article 19(1), point (b)(iii), of that Regulation can only be complied with by application of prevention and protection measures including the design of work processes, engineering controls, use of adequate equipment and materials, application of collective protection measures and, where exposure cannot be prevented by other means, application of individual protection measures including the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles, in order to reduce exposure for professional operators.

(11) However, point 62 of Annex VI to Regulation (EU) No 528/2012 does not provide that the assessment leading to the conclusion that the criterion under Article 19(1), point (b)(iii), of that Regulation can only be complied with by application of prevention and protection measures is to be done in accordance with Directive 98/24/EC. It also does not explicitly provide that that Directive would not apply. Therefore, it should not be inferred from those provisions that Directive 98/24/EC does not apply. In addition, the relevant obligations under Directive 98/24/EC are imposed on employers, not on the authorities of Member States.

(12) Article 4 of Directive 98/24/EC provides that for the assessment of any risk to the safety and health of workers arising from the presence of chemical agents, employers are to obtain additional information needed from the supplier or from other readily available sources and that where appropriate, that information is to comprise the specific assessment concerning the risk to users established on the basis of Union legislation on chemical agents.

(13) Article 6 of Directive 98/24/EC lays down prioritisation of the measures to be taken by the employer for the protection of workers from the risks related to chemical agents at work. Priority is to be given to replacement of the hazardous substance and when this is not possible, the risk from a hazardous chemical agent to the safety and health of workers at work needs to be reduced to a minimum by application of protection and prevention measures. If it is not possible to prevent exposure to the hazardous substance by other means, protection of the workers is to be ensured by applying individual protection measures including personal protective equipment.

([3]) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

(14) Taking into account the method of application of the biocidal product and the available information from the evaluating body, no such technical or organisational measures have been identified in the application for authorisation of the biocidal product, nor during the evaluation of that application.

(15) The Commission therefore considers that the biocidal product meets the criterion laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, provided that the following condition regarding its use is included in the authorisation and on the label of the biocidal product: 'The wearing of protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and single-use protective coverall of at least type-6 EN 13034 or equivalent is required for the handling of the product. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work'.

(16) However, if the applicant for authorisation or the authorising authority identify effective technical or organisational measures leading to an equivalent or higher level of exposure reduction, those measures should replace the wearing of personal protective equipment and should be specified in the authorisation and on the label of the biocidal product.

(17) On 23 November 2021, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant provided comments which the Commission, subsequently, took into account.

(18) 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

The biocidal product identified by the case number BC-RW058475-96 in the Register for Biocidal Products meets the condition laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 provided that the following condition regarding its use is included in the authorisation and on the label of the biocidal product: 'The wearing of protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and single use protective coverall of at least type-6 EN 13034 or equivalent is required for the handling of the product. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.'

However, where the applicant for authorisation or the authorising authority identify technical or organisational measures that achieve a level of exposure reduction equivalent to or higher than the reduction achieved by wearing the protective equipment referred to in the first paragraph, those measures shall be used instead of that personal protective equipment and shall be specified in the authorisation and on the label of the biocidal products. In that case the obligation to include the condition regarding the use of the biocidal product laid down in the first paragraph shall not apply.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 22 February 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission