EUROPEAN
COMMISSION

Brussels, 20.1.2023
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COMMISSION OPINION

of 20.1.2023

on the application of the principle of mutual recognition and the requirements of Regulation (EU) 2019/515 regarding fertilisers (AD | 220603102954 | F | 10960 - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) based on Article 8 of Regulation (EU) 2019/515 on the mutual recognition of goods

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on the application of the principle of mutual recognition and the requirements of Regulation (EU) 2019/515 regarding fertilisers (AD | 220603102954 | F | 10960 - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) based on Article 8 of Regulation (EU) 2019/515 on the mutual recognition of goods

Having regard to Article 8 of Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008[1] (hereafter: Regulation),

Having regard the request to the Commission for an opinion by SOLVIT Centre Luxemburg on 26 September 2022,

The Commission issues the following opinion:

1. FACTS AND PROCEDURE

The company , (hereafter: economic operator) submitted to the *Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* (hereafter: Agency) an application for marketing authorisation in France of the fertiliser which is lawfully marketed in Belgium. It is a liquid solution based on *Bacillus mojavensis*, strain MVY-007.

On 12 April 2022, the Agency sent the conclusions of its first assessment to the applicant economic operator. By decision of the Agency of 5 May 2022, the application of the economic operator for marketing authorisation in France was refused by virtue of Article L.255-7 of the French Rural and Maritime Fishing Code. According to this national technical rule, the authorisation for marketing of a fertiliser shall be granted following an assessment which reveals the absence of harmful effect on human and animal health and the environment.

The marketing authorisation in France of the fertiliser was refused on four grounds. Firstly, on the basis of the available information it is not possible to sufficiently identify the strain of the microorganism composing the product and there is no certainty that it was registered in a recognised international collection, with the result that it is impossible to qualify the product and check its conformity.

Secondly, according to the decision, from the information provided by the economic operator, the Agency could not assess the capacity of *Bacillus mojavensis* to produce toxic metabolites, therefore a risk for consumers and the environment cannot be excluded.

Thirdly, as *Bacillus mojavensis* is an endophytic bacterium, consumers' exposure to this microorganism cannot be excluded.

Finally, the results of the analysis relating to *Staphylococcus* (< 100 g) do not ensure the respect of the requirements of the decree of 1 April 2020, which defines the maximum content of fertilisers, in particular in *Staphylococcus aureus* or *coagulase* to + (< 10 g).

[1] *OJ L 91, 29.3.2019, p. 1.*

The decision concludes that, in view of the available information, a risk for human or animal health and the environment cannot be excluded, therefore the marketing authorisation of the product in France is refused.

On 5 May 2022 the decision was sent the economic operator and on 3 June 2022 notified to the Information and Communication System for Market Surveillance (ICSMS).

The company [redacted] and authorised distributor of the fertiliser, complained to the SOLVIT Centre Luxemburg, which on 26 September 2022 requested the opinion of the European Commission according to Article 8 of the Regulation. The Commission received additional information and documents on 5 October 2022. Therefore, the deadline of 45 working days provided in Article 8(4) of the Regulation for issuing the opinion started on 6 October 2022.

2. THE APPLICATION OF THE PRINCIPLE OF MUTUAL RECOGNITION AND OF THE REGULATION

The compulsory elements of an administrative decision

Article 5(10) of Regulation (EU) 2019/515 prescribes that the administrative decisions should set out the reasons for the decision in a manner that is sufficiently detailed and reasoned to facilitate an assessment of its compatibility with the principle of mutual recognition and with the requirements of the Regulation.

Paragraph 11 of Article 5 enumerates among the elements that an administrative decision should include:

(a) the national technical rule on which the administrative decision is based;

(b) the legitimate public interest grounds justifying the application of the national technical rule on which the administrative decision is based;

(c) the technical or scientific evidence that the competent authority of the Member State of destination considered, including, where applicable, any relevant changes in the state of the art that have occurred since the national technical rule came into force;

(d) a summary of the arguments put forward by the economic operator concerned that are relevant for the assessment, if any;

(e) the evidence demonstrating that the administrative decision is appropriate for the purpose of achieving the objective pursued and that the administrative decision does not go beyond what is necessary in order to attain that objective.

The administrative decision at issue does not seem to comply with points (c) and (e).

First, the decision does not mention in a sufficient way the technical or scientific evidence the Agency considered. Therefore, it appears it does not comply with Article 5(10) and Article 5(11) (c) of the Regulation.

The decision of the Agency at issue essentially refers to the impossibility, due to the absence of necessary information, to characterise the product, check its conformity and evaluate its capacity to produce toxic metabolites, and to the fact that, therefore, a risk for human and animal health, the environment or the consumer cannot be excluded.

The decision does not provide a full reasoning based on technical or scientific elements and demonstrating that the product at stake presents a risk for public health or the environment.

The third ground for refusal is that it cannot be excluded a risk of exposure of the consumer to an endophyte bacterium as *Bacillus mojavensis*. This element is not sufficient to conclude to the existence of a risk for human health.

The fourth ground for refusal is that the content of the fertiliser in *Staphylococcus* is higher than the limit set in the national technical rule. The decision does not mention the technical or scientific evidence on the basis of which the national technical rule set the maximum authorised content in France.

Second, the decision at issue does not contain sufficient evidence demonstrating that it is appropriate and does not go beyond what is necessary, therefore it does not comply with Article 5(10) and Article 5(11) (e) of the Regulation.

The decision should contain elements showing compliance with the principle of proportionality. In this regard, it should be recalled that the proportionality analysis should be done on a case-by-case basis (Recitals 27 and 28, Article 5(1) of Regulation (EU) 2019/515). It should among others be assessed whether the protection of the public interest objective can be achieved by a measure that is less restrictive from the perspective of the free movement of goods. However, such an assessment is missing in the decision at stake.

In addition, the decision at issue mentions that it is not attested that the strain of the microorganism is registered in a recognised international collection. However, the decision does not contain evidence on the proportionality of such a requirement.

3. CONCLUSION

Having regard to the above, and based on the information available, the Commission considers that the administrative decision is not compatible with the requirements of Regulation (EU) 2019/515, and in particular with the requirements laid down in Article 5 of that Regulation.

The Commission invites the French authorities to take the necessary measures to ensure the proper application of the principle of mutual recognition and Regulation (EU) 2019/515, having regard to the concerns identified in this opinion.

Done at Brussels, 20.1.2023

For the Commission
Thierry Breton
Member of the Commission

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COMMISSION OPINION

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on the application of the principle of mutual recognition and the requirements of Regulation (EU) 2019/515 regarding fertilisers (AD | 220603102949 | F | 10960 - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) based on Article 8 of Regulation (EU) 2019/515 on the mutual recognition of goods

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on the application of the principle of mutual recognition and the requirements of Regulation (EU) 2019/515 regarding fertilisers (AD | 220603102949 | F | 10960 - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) based on Article 8 of Regulation (EU) 2019/515 on the mutual recognition of goods

Having regard to Article 8 of Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008[1] (hereafter: Regulation),

Having regard the request to the Commission for an opinion by SOLVIT Centre Luxemburg on 26 September 2022,

The Commission issues the following opinion:

1. FACTS AND PROCEDURE

The company [redacted] (hereafter: economic operator) submitted to the *Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* (hereafter: Agency) an application for marketing authorisation in France of the fertiliser [redacted] which is lawfully marketed in Belgium. It is a liquid solution based on *Bacillus mojavensis*, strain MVY-007, *Bacillus amyloliquefaciens*, strain MVY-008, *Bacillus megaterium*, strain MVY-001, and *Trichoderma harzianum*, strain MVY-021.

On 12 April 2022, the Agency sent the conclusions of its first assessment to the applicant economic operator. By decision of the Agency of 5 May 2022, the application of the economic operator for marketing authorisation in France was refused by virtue of Article L.255-7 of the French Rural and Maritime Fishing Code. According to this national technical rule, the authorisation for marketing of a fertiliser shall be granted following an assessment which reveals the absence of harmful effect on human and animal health and the environment.

The marketing authorisation in France of the fertiliser [redacted] was refused on four grounds. Firstly, on the basis of the available information it is not possible to sufficiently identify the strains of the microorganisms composing the product and there is no certainty that they were registered in a recognised international collection, with the result that it is impossible to qualify the product and check its conformity.

Secondly, according to the decision, from the information provided by the economic operator, the Agency could not assess the capacity of *Bacillus mojavensis*, *Bacillus amyloliquefaciens*, *Bacillus megaterium* and *Trichoderma harzianum* to produce toxic metabolites, therefore a risk for consumers and the environment cannot be excluded.

Thirdly, as *Bacillus mojavensis* is an endophytic bacterium, consumers' exposure to this microorganism cannot be excluded.

[1] *OJ L 91, 29.3.2019, p. 1.*

Finally, the results of the analysis relating to *Staphylococcus* (< 100 g) provided by the economic operator do not ensure the respect of the requirements of the decree of 1 April 2020, which defines the maximum content of fertilisers, in particular in *Staphylococcus aureus* or *coagulase* to + (< 10 g).

The decision concludes that, in view of the available information, a risk for human or animal health and the environment cannot be excluded, therefore the marketing authorisation of the product in France is refused.

On 5 May 2022 the decision was sent the economic operator and on 3 June 2022 notified to the Information and Communication System for Market Surveillance (ICSMS).

The company and authorised distributor of the fertiliser, complained to the SOLVIT Centre Luxemburg, which on 26 September 2022 requested the opinion of the European Commission according to Article 8 of the Regulation. The Commission received additional information and documents on 5 October 2022. Therefore, the deadline of 45 working days provided in Article 8(4) of the Regulation for issuing the opinion started on 6 October 2022.

2. THE APPLICATION OF THE PRINCIPLE OF MUTUAL RECOGNITION AND OF THE REGULATION

The compulsory elements of an administrative decision

Article 5(10) of Regulation (EU) 2019/515 prescribes that the administrative decisions should set out the reasons for the decision in a manner that is sufficiently detailed and reasoned to facilitate an assessment of its compatibility with the principle of mutual recognition and with the requirements of the Regulation.

Paragraph 11 of Article 5 enumerates among the elements that an administrative decision should include:

(a) the national technical rule on which the administrative decision is based;

(b) the legitimate public interest grounds justifying the application of the national technical rule on which the administrative decision is based;

(c) the technical or scientific evidence that the competent authority of the Member State of destination considered, including, where applicable, any relevant changes in the state of the art that have occurred since the national technical rule came into force;

(d) a summary of the arguments put forward by the economic operator concerned that are relevant for the assessment, if any;

(e) the evidence demonstrating that the administrative decision is appropriate for the purpose of achieving the objective pursued and that the administrative decision does not go beyond what is necessary in order to attain that objective.

The administrative decision at issue does not seem to comply with points (c) and (e).

First, the decision does not mention in a sufficient way the technical or scientific evidence the Agency considered. Therefore, it appears it does not comply with Article 5(10) and Article 5(11) (c) of the Regulation.

The decision of the Agency at issue essentially refers to the impossibility, due to the absence of necessary information, to characterise the product, check its conformity and evaluate its capacity to produce toxic metabolites, and to the fact that, therefore, a risk for human and animal health, the environment or the consumer cannot be excluded.

The decision does not provide a full reasoning based on technical or scientific elements and demonstrating that the product at stake presents a risk for public health or the environment.

The third ground for refusal is that it cannot be excluded a risk of exposure of the consumer to an endophyte bacterium as *Bacillus mojavensis*. This element is not sufficient to conclude to the existence of a risk for human health.

The fourth ground for refusal is that the content of the fertiliser in *Staphylococcus* is higher than the limit set in the national technical rule. The decision does not mention the technical or scientific evidence on the basis of which the national technical rule set the maximum authorised content in France.

Second, the decision at issue does not contain sufficient evidence demonstrating that it is appropriate and does not go beyond what is necessary, therefore it does not comply with Article 5(10) and Article 5(11) (e) of the Regulation.

The decision should contain elements showing compliance with the principle of proportionality. In this regard, it should be recalled that the proportionality analysis should be done on a case-by-case basis (Recitals 27 and 28, Article 5(1) of Regulation (EU) 2019/515). It should among others be assessed whether the protection of the public interest objective can be achieved by a measure that is less restrictive from the perspective of the free movement of goods. However, such an assessment is missing in the decision at stake.

In addition, the decision at issue mentions that it is not attested that the strain of the microorganism is registered in a recognised international collection. However, the decision does not contain evidence on the proportionality of such a requirement.

3. CONCLUSION

Having regard to the above, and based on the information available, the Commission considers that the administrative decision is not compatible with the requirements of Regulation (EU) 2019/515, and in particular with the requirements laid down in Article 5 of that Regulation.

The Commission invites the French authorities to take the necessary measures to ensure the proper application of the principle of mutual recognition and Regulation (EU) 2019/515, having regard to the concerns identified in this opinion.

Done at Brussels, 20.1.2023

For the Commission
Thierry Breton
Member of the Commission

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Having regard to Article 8 of Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008[1] (hereafter: Regulation),

Having regard the request to the Commission for an opinion by SOLVIT Centre Luxemburg on 26 September 2022,

The Commission issues the following opinion:

1. FACTS AND PROCEDURE

The company [redacted] (hereafter: economic operator), submitted to the *Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* (hereafter: Agency) an application for marketing authorisation in France of the fertiliser [redacted] which is lawfully marketed in Belgium[2]. It is a liquid solution based on *Paenibacillus polymyxa*, strain MVY-024.

On 12 April 2022, the Agency sent the conclusions of its first assessment to the applicant economic operator. By decision of the Agency of 5 May 2022, the application of the economic operator for marketing authorisation in France by mutual recognition of the fertiliser was refused by virtue of Article L.255-7 of the French Rural and Maritime Fishing Code. According to this national technical rule, the authorisation for marketing of a fertiliser shall be granted following an assessment which reveals the absence of harmful effect on human and animal health and the environment.

The marketing authorisation in France of the fertiliser [redacted] was refused on the grounds that, firstly, the available information does not permit the sufficient identification of the strain of the microorganism composing the product and there is no certainty that it was registered in an recognised international collection, with the result that it is impossible to qualify the product and check its conformity.

Secondly, according to the decision at issue, from the information provided by the economic operator, the Agency cannot evaluate the capacity of *Paenibacillus polymyxa* to produce toxic metabolites, therefore a risk for consumers and the environment cannot be excluded.

The decision concludes that in view of the available information a risk for human or animal health and the environment cannot be excluded, therefore the marketing authorisation of the product in France is refused.

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1 *OJ L 91, 29.3.2019, p. 1.*

2 It is also lawfully marketed in Lithuania, Denmark, Norway, Italy, Bulgaria and Luxemburg (in the three last Member States the product is exempt from marketing authorisation).

On 5 May 2022 the decision was sent to the economic operator and on 3 June 2022 notified to the Information and Communication System for Market Surveillance (ICSMS).

The company [redacted] and distributor of the fertiliser in the EU, complained to the SOLVIT Centre Luxemburg, which on 26 September requested the opinion of the European Commission according to Article 8 of the Regulation. The complete file with all the necessary documents was submitted on 5 October 2022. Therefore, the deadline of 45 working days provided in Article 8(4) of the Regulation for issuing the opinion started on 6 October 2022.

2. THE APPLICATION OF THE PRINCIPLE OF MUTUAL RECOGNITION AND OF THE REGULATION

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(a) the national technical rule on which the administrative decision is based;

(b) the legitimate public interest grounds justifying the application of the national technical rule on which the administrative decision is based;

(c) the technical or scientific evidence that the competent authority of the Member State of destination considered, including, where applicable, any relevant changes in the state of the art that have occurred since the national technical rule came into force;

(d) a summary of the arguments put forward by the economic operator concerned that are relevant for the assessment, if any;

(e) the evidence demonstrating that the administrative decision is appropriate for the purpose of achieving the objective pursued and that the administrative decision does not go beyond what is necessary in order to attain that objective.

The administrative decision at issue does not seem to comply with points (c) and (e).

First, the decision does not mention in a sufficient way the technical or scientific evidence the Agency considered. Therefore, it appears it does not comply with Article 5(10) and Article 5(11) (c) of the Regulation.

The decision of the Agency at issue essentially refers to the impossibility, due to the absence of necessary information, to characterise the product, check its conformity and evaluate its capacity to produce toxic metabolites, and to the fact that, therefore, a risk for human and animal health, the environment or the consumer cannot be excluded.

The decision does not provide a full reasoning based on technical or scientific elements and demonstrating that the product at stake presents a risk for public health or the environment.

Second, the decision at issue does not contain sufficient evidence demonstrating that it is appropriate and does not go beyond what is necessary, therefore it does not comply with Article 5(10) and Article 5(11) (e) of the Regulation.

The decision should contain elements showing compliance with the principle of proportionality. In this regard, it should be recalled that the proportionality analysis should be

done on a case-by-case basis (Recitals 27 and 28, Article 5(1) of Regulation (EU) 2019/515). It should among others be assessed whether the protection of the public interest objective can be achieved by a measure that is less restrictive from the perspective of the free movement of goods. However, such an assessment is missing in the decision at stake.

In addition, the decision at issue mentions that it is not attested that the strain of the microorganism is registered in a recognised international collection. However, the decision does not contain evidence on the proportionality of such a requirement.

3. CONCLUSION

Having regard to the above, and based on the information available, the Commission considers that the administrative decision is not compatible with the requirements of Regulation (EU) 2019/515, and in particular with the requirements laid down in Article 5 of that Regulation.

The Commission invites the French authorities to take the necessary measures to ensure the proper application of the principle of mutual recognition and Regulation (EU) 2019/515, having regard to the concerns identified in this opinion.

Done at Brussels, 20.1.2023

For the Commission
Thierry Breton
Member of the Commission