

通报

以下通报根据 TBT 协定第 10.6 条分发

1.	通报成员: 欧盟
2.	负责机构: 欧盟委员会
3.	通报依据的条款: [X] 2.9.2,[] 2.10.1,[] 5.6.2,[] 5.7.1 通报依据的条款其他:
4.	覆盖的产品: 联苯肼酯 (杀虫剂活性物质); 农药和其他农用化学品 (ICS 65.100)

	ICS: 65.100 HS: 3808
5.	<p>通报标题: 根据欧洲议会和理事会关于将植物保护产品投放市场的 (EC) 第 1107/2009 号法规更新活性物质联苯胺酸盐批准的委员会实施法规草案, 并修订 (EU) 第 540/2011 号委员会实施法规附件</p> <p>页数: 5,4 使用语言: 英语 链接网址:</p>
6.	<p>内容简述: 该委员会实施法规草案规定, 根据 (EC) 第 1107/2009 号法规的规定, 活性物质双歧化酶的批准延期。然而, 有必要包括某些条件和限制, 即限制在永久性温室中对非食用作物使用含有双歧杆菌的植物保护产品, 并要求提供进一步的确认信息。将根据本法案中规定的条件和限制, 对现有的含双芬酸的授权植物保护产品进行审查。</p> <p>这些条件和限制基于欧盟 (EC) 第 1107/2009 号法规对该物质作为农药活性物质的首次评估。该物质是过去根据指令 91/414/EEC 批准的。</p> <p>该决定仅涉及该物质的上市。在批准受到限制以及产品库存的所有宽限期到期后, 可能会对最大残留限量采取单独的法律行动, 并将根据 SPS 程序在适当的时候发出单独的通报。</p>
7.	<p>目的和理由: 为了根据 (EC) 第 1107/2009 号法规批准活性物质 (关于将植物保护产品投放市场), 必须证明该物质对人类健康、动物健康或环境无害。本法规第 4 条 (以及附件 II 中的详细说明) 列出了认证所需满足的标准。在对双歧化酶进行评估和同行评审期间, 发现了一些无法最终确定的问题和领域。欧洲食品安全局 (EFSA) 的结论对此进行了详细说明。这意味着, 只有在永久性温室中的非食用作物中使用双歧化酶时, 其才符合 (EC) 第 1107/2009 号法规中概述的批准标准。对非食用作物的使用限制将排除消费者的饮食接触, 这是必需的, 因为消费者风险评估无法最终确定。由于通过长期接触双歧化酶被确定为鸟类</p>

	<p>的高风险，（EC）第 1107/2009 号法规第 3 条规定的温室使用限制将确保鸟类不会接触双歧化酶。根据（EC）第 1107/2009 号法规第 43 条的规定，在授权续期后，现有授权将需要修改或撤销；保护人类健康或安全；保护动植物生命或健康；保护环境</p>
	<p>相关文件：</p> <p>2009 年 10 月 21 日欧洲议会和理事会关于将植物保护产品投放市场并废除理事会指令 79/117/EEC 和 91/414/EEC 的（EC）第 1107/2009 号法规：</p> <p>http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&qid=1437730988988&from=EN</p> <p>8. 欧盟委员会 2011 年 5 月 25 日（EU）第 540/2011 号实施法规欧洲议会和理事会关于批准活性物质清单的（EC）第 1107/2009 号实施法规（OJ L 153，2011 年 6 月 11 日，第 1-186 页）</p> <p>http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&uri=CELEX:32011R0540</p> <p>《2017 年双歧化酶活性物质 EFSA 期刊》农药风险评估同行评审结论；第 15（1）卷：第 4693 页。EFSA 更新了活性物质 BiZe AZATE EFSA 期刊 2021 的农药风险评估同行评审；第 19（8）卷：第 6818 页，网址：www.efsa.europa.eu</p>
9.	<p>拟批准日期：2022 年第二季度</p> <p>拟生效日期：在《欧盟官方公报》发表 20 天后</p>
10.	<p>意见反馈截至日期：自通报之日起 60 天</p>
11.	<p>文本可从以下机构得到：</p> <p>欧洲委员会</p>

EU-TBT 查询点

传真: + (32)2 299 80 43

电子邮件: grow-eu-tbt@ec.europa.eu

文本可在欧盟- tbt 网站上查阅: <http://ec.europa.eu/growth/tools-databases/tbt/en/>

https://members.wto.org/crnattachments/2022/TBT/EEC/22_0730_00_e.pdf

https://members.wto.org/crnattachments/2022/TBT/EEC/22_0730_01_e.pdf

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<p>1. Notifying Member: <u>EUROPEAN UNION</u></p> <p>If applicable, name of local government involved (Article 3.2 and 7.2):</p>
<p>2. Agency responsible: European Commission</p> <p>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</p> <p>European Commission, EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu</p>

Website: <http://ec.europa.eu/growth/tools-databases/tbt/en/>

3. **Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:**

4. **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Bifenazate (pesticide active substance); Pesticides and other agrochemicals (ICS 65.100)

5. **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Regulation renewing the approval of the active substance bifenazate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (5 page(s), in English; 4 page(s), in English)

6. **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance bifenazate is renewed in accordance with Regulation (EC) No 1107/2009. It is however, necessary to include certain conditions and restrictions, i.e. to restrict the use of plant protection products containing bifenazate to non-edible crops in permanent greenhouses and to require further confirmatory information.

Existing authorised plant protection products containing bifenazate will be reviewed in accordance with the conditions and restrictions set in this act. The conditions and restrictions are based on the first evaluation of the substance for use as a pesticide active substance in the EU under Regulation (EC) No 1107/2009. The substance was formerly approved under Directive 91/414/EEC.

This decision only concerns the placing on the market of this substance. Following restriction of the approval and the consequent expiry of all grace periods for stocks of products, separate legal action may be taken on Maximum Residue Levels and a separate notification will be made in accordance with SPS procedures in due time.

7. Objective and rationale, including the nature of urgent problems where applicable: In order for an active substance to be approved in accordance with Regulation (EC) No 1107/2009 (concerning the placing of plant protection products on the market), it must be demonstrated that the substance is not harmful to human health, animal health or the environment. Criteria are listed in Article 4 of the Regulation (and also detailed in Annex II thereto) which must be met to enable approval. During the evaluation and peer-review of bifentazate, a number of concerns and areas that could not be finalised were identified. These are detailed in the conclusion of the European Food Safety Authority (EFSA). This means that bifentazate meets the approval criteria as outlined in Regulation (EC) No 1107/2009 only if its use is restricted to non-edible crops in permanent greenhouses. The restriction to use on non-edible crops will exclude dietary exposure of consumers and is required since the consumer risk assessment could not be finalised. As a high risk was identified to birds via long term exposure to bifentazate, a restriction to use in greenhouses as defined in Article 3 of Regulation (EC) No 1107/2009 will ensure that birds are not exposed to bifentazate. Existing authorisations will need to be amended or withdrawn following renewal of authorisation in accordance with Article 43 of Regulation (EC) No 1107/2009.; Protection of human health or safety; Protection of animal or plant life or health; Protection of the environment

8. Relevant documents: Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&qid=1437730988988&from=EN>

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (*OJ L 153, 11.6.2011, p. 1–186*)

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&uri=CELEX:32011R0540>

Conclusion on the peer review of the pesticide risk assessment of the active substance bifentazate EFSA Journal 2017;15(1):4693. EFSA Updated peer review of the pesticide risk assessment of the active substance bifentazate EFSA Journal 2021;19(8):6818 Available online: www.efsa.europa.eu

9. Proposed date of adoption: 2nd quarter 2022.

Proposed date of entry into force: 20 days following publication in the Official Journal of the EU

10. **Final date for comments:** 60 days from notification

11. **Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

European Commission,
EU-TBT Enquiry Point,
Fax: + (32) 2 299 80 43,
E-mail: grow-eu-tbt@ec.europa.eu

The text is available on the EU-TBT Website : <http://ec.europa.eu/growth/tools-databases/tbt/en/>

https://members.wto.org/crnattachments/2022/TBT/EEC/22_0730_00_e.pdf

https://members.wto.org/crnattachments/2022/TBT/EEC/22_0730_01_e.pdf