



16 October 2015

(15-5429)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	<b>Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved:</b>
2.	<b>Agency responsible:</b> European Commission, Health and Food Safety Directorate-General
3.	<b>Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):</b> Feed additives included in HS code 2309
4.	<b>Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5.	<b>Title of the notified document:</b> Commission Implementing Regulation (EU) 2015/1399 of 17 August 2015 concerning the denial of authorisation of the preparation of <i>Bacillus toyonensis</i> (NCIMB 14858 <sup>1</sup> ) (formerly <i>Bacillus cereus</i> var. <i>toyoi</i> NCIMB 40112/CNCM I-1012) as a feed additive for cattle for fattening, rabbits for fattening, chickens for fattening, piglets (weaned), pigs for fattening, sows for reproduction and calves for rearing and the revocation of the authorisations of the preparation of <i>Bacillus cereus</i> var. <i>toyoi</i> (NCIMB 40112/CNCM I-1012) as a feed additive for turkeys for fattening and rabbit breeding does, amending Regulations (EC) No 256/2002, (EC) No 1453/2004, (EC) No 255/2005 and (EC) No 1200/2005 and repealing Regulations (EC) No 166/2008, (EC) No 378/2009 and Implementing Regulation (EU) No 288/2013 (Text with EEA relevance) <b>Language(s):</b> English, French and Spanish <b>Number of pages:</b> 4 <a href="http://members.wto.org/crnattachments/2015/SPS/EEC/15_4124_00_e.pdf">http://members.wto.org/crnattachments/2015/SPS/EEC/15_4124_00_e.pdf</a> <a href="http://members.wto.org/crnattachments/2015/SPS/EEC/15_4124_00_f.pdf">http://members.wto.org/crnattachments/2015/SPS/EEC/15_4124_00_f.pdf</a> <a href="http://members.wto.org/crnattachments/2015/SPS/EEC/15_4124_00_s.pdf">http://members.wto.org/crnattachments/2015/SPS/EEC/15_4124_00_s.pdf</a>
6.	<b>Description of content:</b> The regulatory measure denies the authorisation of commercialisation of the preparation <i>Bacillus toyonensis</i> (NCIMB 14858 <sup>1</sup> ) as a feed additive for use for cattle for fattening, rabbits for fattening, chickens for fattening, piglets (weaned), pigs for fattening, sows for reproduction and calves for rearing. This is a definitive measure, following a suspension of the authorisation issued in 2013 (Regulation (EC) 288/2013 of 25 March 2013).  The feed additive <i>Bacillus cereus</i> var. <i>toyoi</i> (NCIMB 40112/CNCM I-1012) ("Toyocerin®") was re-evaluated by the European Food Safety Authority (EFSA) under Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Official Journal of the EU L 268, 18.10.2003, p. 29).  On 16 October 2012, EFSA adopted an opinion raising safety concerns about the use of Toyocerin® as feed additive. On that basis, supplementary data were submitted by the applicant for authorisation concerning essentially the taxonomic classification of the micro-organism, the issue of the transferability of the antibiotic resistance and the issue of the functionality of the enterotoxin genes present in the genome of the micro-organism.

<p>After assessment of those supplementary data, EFSA adopted an opinion on 1 July 2014 which confirmed the safety concerns as regards antibiotic susceptibility and toxigenic potential of the additive.</p> <p>Consequently, the regulatory conditions for authorisation of the feed additive Toyocerin® were no longer met as regards the absence of adverse effects on human and animal health. Therefore the authorisation had to be denied.</p> <p>Since existing stocks of the preparation of <i>Bacillus cereus</i> var. <i>toyoi</i> (NCIMB 40112/CNCM I-1012), of premixtures containing that preparation and of feed materials and compound feed produced from that preparation were already to be withdrawn from the market according to Article 7 of Implementing Regulation (EU) No 288/2013, no transitional measures were provided for.</p>
<p><b>7. Objective and rationale:</b> <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.</p>
<p><b>8. Is there a relevant international standard? If so, identify the standard:</b></p> <p><input checked="" type="checkbox"/> <b>Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text)</b> Code of practice on Good Animal Feeding CAC/RCP 54-2004, Guidelines on the Application of Risk Assessment for Feed CAC/GL 80-2013</p> <p><input type="checkbox"/> <b>World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number)</b></p> <p><input type="checkbox"/> <b>International Plant Protection Convention (e.g. ISPM number)</b></p> <p><input type="checkbox"/> <b>None</b></p> <p><b>Does this proposed regulation conform to the relevant international standard?</b></p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b></p>
<p><b>9. Other relevant documents and language(s) in which these are available:</b></p> <ul style="list-style-type: none"> <li>- Commission Implementing Regulation (EU) No 288/2013 of 25 March 2013 concerning the suspension of the authorisation of the preparation of <i>Bacillus cereus</i> var. <i>toyoi</i> (NCIMB 40112/CNCM I-1012) as provided for by Regulations (EC) No 256/2002, (EC) No 1453/2004, (EC) No 255/2005, (EC) No 1200/2005, (EC) No 166/2008 and (EC) No 378/2009 (Text with EEA relevance)</li> <li>- EFSA Scientific Opinion on Toyocerin® (<i>Bacillus cereus</i>) as a feed additive for sows, piglets, pigs for fattening, cattle for fattening, calves for rearing, chickens for fattening and rabbits for fattening: <a href="http://www.efsa.europa.eu/en/efsajournal/pub/2924">http://www.efsa.europa.eu/en/efsajournal/pub/2924</a></li> <li>- EFSA Scientific Opinion on the safety and efficacy of Toyocerin® (<i>Bacillus toyonensis</i>) as a feed additive for chickens for fattening, weaned piglets, pigs for fattening, sows for reproduction, cattle for fattening and calves for rearing and for rabbits for fattening: <a href="http://www.efsa.europa.eu/en/efsajournal/pub/3766">http://www.efsa.europa.eu/en/efsajournal/pub/3766</a></li> </ul>
<p><b>10. Proposed date of adoption (dd/mm/yy):</b> 17 August 2015</p> <p><b>Proposed date of publication (dd/mm/yy):</b> 18 August 2015</p>
<p><b>11. Proposed date of entry into force:</b> <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 7 September 2015</p> <p><input type="checkbox"/> Trade facilitating measure</p>

**12. Final date for comments: [ ] Sixty days from the date of circulation of the notification and/or (dd/mm/yy):** Not applicable

**Agency or authority designated to handle comments: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

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**13. Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

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