Commission Implementing Regulation (EU) 2017/377 of 3 March 2017 concerning the non-approval of the active substance Pseudozyma flocculosa strain ATCC 64874 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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/377

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 13(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC[(2)] is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For *Pseudozyma flocculosa* strain ATCC 64874 the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2002/305/EC[(3)].

(2) In accordance with Article 6(2) of Directive 91/414/EEC the Netherlands (hereinafter 'the rapporteur Member State') received on 6 March 2001 an application from Maasmond-Westland for the inclusion of the active substance *Pseudozyma flocculosa* strain ATCC 64874 in Annex I to Directive 91/414/EEC. Decision 2002/305/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 11 March 2004.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/377. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) Artechno SA took over the responsibility of Maasmond-Westland on 4 June 2012 and in accordance with Article 11(6) of Commission Regulation (EU) No 188/2011[(4)] additional information was requested from the applicant.

(5) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance *Pseudozyma flocculosa* strain ATCC 64874[(5)] on 22 September 2015. The Authority identified several data gaps. In particular, it was not possible to conclude on the risk assessment for human health and aquatic organisms deriving from the use of *Pseudozyma flocculosa* strain ATCC 64874.

(6) Consequently, it was not possible to conclude on the basis of the information available that *Pseudozyma flocculosa* strain ATCC 64874 met the criteria for inclusion in Annex I to Directive 91/414/EEC.

(7) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with Article 9 of Regulation (EU) No 188/2011, the Commission invited the applicant to submit comments on the draft review report. The applicant submitted its comments, which have been carefully examined.

(8) However, despite the arguments put forward by the applicant, the concerns referred to in recital 5 could not be eliminated. Consequently, it has not been demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing *Pseudozyma flocculosa* strain ATCC 64874 satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(9) *Pseudozyma flocculosa* strain ATCC 64874 should therefore not be approved pursuant to Article 13(2) of Regulation (EC) No 1107/2009.

(10) In accordance with Article 8(1)(b) of Directive 91/414/EEC, Member States were given the possibility to grant provisional authorisations, for plant protection products containing *Pseudozyma flocculosa* strain ATCC 64874 for an initial period of three years.

(11) Existing authorisations should consequently be withdrawn.

(12) Member States should be provided with time to withdraw authorisations for plant protection products containing *Pseudozyma flocculosa* strain ATCC 64874.

(13) For plant protection products containing *Pseudozyma flocculosa* strain ATCC 64874, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 24 June 2018.

(14) This Regulation does not prejudice the submission of a further application for *Pseudozyma flocculosa* strain ATCC 64874 in accordance with Article 7 of Regulation (EC) No 1107/2009.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,