EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11867/2017
(POOL/E3/2017/11867/11867-EN.doc)
[…](2017) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving PHMB (1415; 4.7) as an existing active substance for use in biocidal products of product-types 1, 5 and 6

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving PHMB (1415; 4.7) as an existing active substance for use in biocidal products of product-types 1, 5 and 6

(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 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014[2] establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes PHMB (1415; 4.7) (EC No: n.a., CAS No: 32289-58-0 and 1802181-67-4).

(2) PHMB (1415; 4.7) has been evaluated for use in products of product-type 1, human hygiene, 5, drinking water, and 6, preservatives for products during storage, as described in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 13 December 2016.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 4 October 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products used for product-types 1, 5 and 6 containing PHMB (1415; 4.7) may not be expected to satisfy the requirements laid down in Article 19(1)(b) of Regulation (EU) No 528/2012. For those product-types, the scenarios evaluated in the human health and environmental risk assessments identified unacceptable risks.

(6) It is therefore not appropriate to approve PHMB (1415; 4.7) for use in biocidal products of product-types 1, 5 and 6.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

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

[2] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

PHMB (1415; 4.7) (EC No: n.a., CAS No: 32289-58-0 and 1802181-67-4) is not approved as an active substance for use in biocidal products of product-types 1, 5 and 6.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER