



EUROPEAN
COMMISSION

Brussels, **XXX**
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[...](2018) **XXX** draft

COMMISSION IMPLEMENTING DECISION (EU) .../...

of **XXX**

**pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament
and of the Council on Wolbachia trans-infected mosquitos used for vector control
purposes**

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING DECISION (EU) .../...

of **XXX**

pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on *Wolbachia* trans-infected mosquitoes used for vector control purposes

(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 products¹, and in particular Article 3(3) thereof,

Whereas:

- (1) On 28 September 2017, France requested the Commission to decide whether bacteria of the species *Wolbachia endobacterium* ("the bacteria") or any preparation containing the bacteria injected into non-infected mosquitoes, and mosquitoes infected with the bacteria ("the trans-infected mosquitoes") used in the context of vector control strategies are biocidal products within the meaning of Article 3(1)(a) of Regulation (EU) No 528/2012 or treated articles within the meaning of Article 3(1)(l) of that Regulation or neither.
- (2) According to the information provided by France, these intracellular bacteria are transmitted vertically and naturally present in arthropods. The infection of mosquitoes by the bacteria reduces the ability of some mosquitoes to transmit certain pathogenic viruses and parasites by interfering with those pathogens within the mosquitoes, and promotes the reproduction of infected females mosquitoes and the spread of the bacteria in the mosquitoes' population. Therefore, vector control campaigns are based on the release of trans-infected mosquitoes within a population of mosquitoes in order to reduce their ability to transmit certain pathogens to humans.
- (3) According to the information provided by France, not all species of mosquitoes or individuals within one species are naturally infected with the bacteria, or with a strain of the bacteria that is exploitable for the vector control purposes. Therefore, non-natural infections have to be carried out under laboratory conditions in order to create trans-infected mosquitoes with a suitable strain of the bacteria. That can be achieved by different infection techniques, including the inoculation of the bacteria into adult female mosquitoes or into the cytoplasm of mosquitoes' eggs.
- (4) For the purpose of the provisions in Article 3(3) of Regulation (EU) No 528/2012, it is therefore relevant to assess separately the status of the bacteria or any preparation containing the bacteria inoculated into non-infected mosquitoes and the status of the trans-infected mosquitoes, irrespectively of the infection technique used.

¹ OJ L 167, 27.6.2012, p. 1.

- (5) The bacteria are micro-organisms within the meaning of Article 3(1)(b) of Regulation (EU) No 528/2012
- (6) The non-infected mosquitoes are harmful organisms within the meaning of Article 3(1)(g) of Regulation (EU) No 528/2012, since they may have an unwanted presence or a detrimental effect on humans or animals.
- (7) The bacteria has an action on or against non-infected mosquitoes and therefore should be considered an active substance within the meaning of Article 3(1)(c) of Regulation (EU) No 528/2012.
- (8) Product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to Regulation (EU) No 528/2012, includes products used for the control of arthropods, by means other than repulsion or attraction. Since the bacteria are inoculated into the non-infected mosquitoes with the intention to exert a controlling effect on mosquitoes' populations, such use falls under the description of product-type 18.
- (9) The bacteria or the preparation containing the bacteria is exerting a controlling effect on the non-infected mosquitoes by other means than mere physical or mechanical action.
- (10) For the purposes of Article 3(1)(a) of Regulation (EU) No 528/2012, the bacteria or the preparation containing the bacteria should be considered a substance or a mixture, respectively, consisting of or containing an active substance. As a consequence, the bacteria or any preparation containing the bacteria, as it is supplied to the user carrying out the inoculation into non-infected mosquitoes, is a biocidal product within the meaning of the first indent of Article 3(1)(a) of Regulation (EU) No 528/2012 and falls within product-type 18.
- (11) Trans-infected mosquitoes are not micro-organisms within the meaning of Article 3(1)(b) of Regulation (EU) No 528/2012.
- (12) Trans-infected mosquitoes are not a substance or a mixture within the meaning of points 1 and 2 of Article 3, respectively, of Regulation (EC) No 1907/2006. Therefore, pursuant to points (a) and (b) of Article 3(2) of Regulation (EU) No 528/2012, they are neither a substance nor a mixture for the purposes of that Regulation.
- (13) As a consequence, trans-infected mosquitoes are not an active substance within the meaning of Article 3(1)(c) of Regulation (EU) No 528/2012. Therefore, trans-infected mosquitoes cannot be a biocidal product within the meaning of the first indent of Article 3(1)(a) of that Regulation.
- (14) Trans-infected mosquitoes are not articles within the meaning of Article 3(3) of Regulation (EC) No 1907/2006. Therefore, pursuant to Article 3(2)(c) of Regulation (EU) No 528/2012, they are not considered articles for the purposes of that Regulation. Consequently, the trans-infected mosquitoes cannot be considered treated articles within the meaning of Article 3(1)(l) of Regulation (EU) No 528/2012.
- (15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The bacteria of the species *Wolbachia endobacterium* or any preparation containing those bacteria used for the purpose of inoculating those bacteria into non-infected mosquitoes with the objective of creating trans-infected mosquitoes for vector control shall be considered a biocidal product within the meaning of Article 3(1)(a) of Regulation (EU) No 528/2012.

Experimentally trans-infected mosquitoes, irrespectively of the infection technique used, shall be considered neither a biocidal product nor a treated article within the meaning of points (a) and (l) of Article 3(1), respectively, of Regulation (EU) No 528/2012.

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*