Commission Implementing Decision (EU) 2018/1623 of 29 October 2018 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on mosquitoes non-naturally infected with Wolbachia used for vector control purposes (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2018/1623

of 29 October 2018

pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on mosquitoes non-naturally infected with *Wolbachia* 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 products[(1)], and in particular Article 3(3) thereof,

Whereas:

(1) On 28 September 2017, France requested the Commission to decide whether bacteria of the genus *Wolbachia* ('the bacteria') or any preparation containing the bacteria to be inoculated into mosquitoes, and mosquitoes non-naturally infected with the bacteria ('the non-naturally infected mosquitoes') used for vector control purposes 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, maternally inherited and naturally present in around 40 % of arthropods. The infection of mosquitoes by the bacteria may reduce 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 mosquito population. Furthermore, since male mosquitoes infected with the bacteria are incompatible with local females, the introduction of those infected males in the target population reduces its potential for reproduction. Therefore, vector control campaigns are based on the release of non-naturally infected mosquitoes within a population of mosquitoes in order to control the population size and/or 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 non-naturally 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 to be inoculated into mosquitoes and the status of the non-naturally infected mosquitoes, irrespectively of the infection technique used.

(5) The bacteria are micro-organisms within the meaning of Article 3(1)(b) of Regulation (EU) No 528/2012

(6) 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 indirect action on the mosquitoes population, either by controlling its size or by reducing its ability to transmit certain pathogens, and should therefore 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 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 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 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) Non-naturally infected mosquitoes are not micro-organisms within the meaning of Article 3(1)(b) of Regulation (EU) No 528/2012.

(12) Non-naturally 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 of the European Parliament and of the Council[(2)]. 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, non-naturally infected mosquitoes are not an active substance within the meaning of Article 3(1)(c) of Regulation (EU) No 528/2012. Therefore, non-naturally infected mosquitoes cannot be a biocidal product within the meaning of the first indent of Article 3(1)(a) of that Regulation.

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

Non-naturally 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, 29 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

(**1**) OJ L 167, 27.6.2012, p. 1.

(**2**) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2018/1623.