

## Simplified procedure and PPE for oak processionary caterpillar

### Initial E-consultation

Ctgb 22 June 2020

Dear Colleagues,

The Ctgb would like to consult MSCAs regarding an issue with a product to control oak processionary caterpillars. A company would like to apply for the authorisation of a biocidal product which claims to protect humans and domesticated animals from nuisance by the venomous setae (hairs) of the caterpillars, which can cause skin irritation and/or asthma. As the product is based on an active substance included in Annex I, the company wishes to apply for a simplified authorization in accordance with article 25 of the BPR. The product is intended to be used by non-professional and professional users.

However, approaching oaks for control of oak processionary caterpillars is not safe without suitable protective clothing, because of presence of hairs of the pest organism in the air surrounding oaks. The hairs are easily carried in the air by wind or vibrations of passing traffic.

Usually, the directions for use in the SPC are meant to protect a user from risks coming from the use of a biocidal product and not from the environment where a biocidal product is used. E.g warnings to protect oneself against risk of infection in hospitals are not included in an SPC of a disinfectant. Similarly, an SPC does not include a warning to protect oneself from the sun when working with a biocidal product outdoors. Only in exceptional cases, an MSCA could consider to issue a warning for risks not coming from the biocidal product itself.

In this particular case, the Ctgb is of the opinion that it is appropriate to warn the users against the risks of coming into contact with the caterpillars' hairs. Therefore, Ctgb proposes to add the following instruction in the instructions for use section of the SPC: *make sure you do not come into contact with setae of caterpillars by wearing suitable protective clothing*. Furthermore, the Ctgb proposes to authorize the product *for professional users only* to ensure correct use of the protective clothing.

Our question: Do you agree that this biocidal product can be considered eligible for an application for authorization under a simplified authorization procedure, taking into account that it has to meet the criteria of article 25 of the BPR, including 25(e): *the handling of the biocidal product and its intended use do not require personal protective equipment*.

The reasoning of the Ctgb is that in this particular case the wearing of suitable protective clothing is inherent to being in the environment of this specific pest organism. It is not triggered by handling of the biocidal product, e.g. the control of another pest organism with this product would not require protective clothing.

Earlier, the Ctgb has initiated a HelpEx question on this subject, however, no clear conclusion could be drawn. This e-consultation is launched to find a harmonized way forward.

Please let us know your opinion:

- 1) Yes, a product to control oak processionary caterpillars can be eligible for an application under the simplified procedure. The wearing of suitable protective clothing is inherent to being in the environment of this particular pest organism and is not triggered by handling of the biocidal product.
- 2) No, a product to control oak processionary caterpillars is by definition not eligible for an application under the simplified procedure as users are advised to wear protective clothing, which does not match with the criterion of article 25(e).

## **Background**

NL requested fellow MSCA's 22 June 2020 to discuss the topic of "Simplified procedure and PPE for oak processionary caterpillar" regarding an issue with a product to control oak processionary caterpillars. The e-consultation was issued by ECHA on 23 June 2020.

The main question was: Do you agree that this biocidal product can be considered eligible for an application for authorization under a simplified authorization procedure, taking into account that it has to meet the criteria of article 25 of the BPR, including 25(e): the handling of the biocidal product and its intended use do not require personal protective equipment.

## **Response MSCA's**

In July 2020, four MSCA's responded to the NL questions in writing. Three member states consider that a product against oak processionary caterpillars can be eligible for an application under the simplified procedure (option 1).

One member state considered that as the need for PPE is not a result from the risk assessment, an RMM that prescribes PPE should not be included in the SPC at all.

## **Conclusions**

All member states that responded in writing considered that a product against oak processionary caterpillars can be eligible for an application under the simplified procedure because the wearing of suitable protective clothing is inherent to being in the environment of this particular pest organism and is not triggered by handling of the biocidal product.

One member state considers that the prescription of protective clothing to protect against the caterpillars' hairs should not be included in the SPC because this RMM is not triggered by the risk assessment should not be included in the SPC. This is an interesting remark which may be further discussed either in the frame of this on-going e-consultation, or in the frame of a separate one.

The e-consultation was further discussed in the Coordination Group (meeting CG-43).

### **Outcome of the e-consultation (agreed in CG-43, 29 September 2020)**

A product against oak processionary caterpillars can be eligible for an application under the simplified procedure because the wearing of suitable protective clothing is inherent to being in the environment of this particular pest organism and is not triggered by handling of the biocidal product.

Whether and where in the SPC an RMM prescribing protective clothing can be included, while it is not triggered by the risk assessment of the product, should be discussed in the frame of a separate e-consultation.