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Risk assessment of *Macrolophus pygmaeus* as biological control product

Opinion of the Panel on Plant Production Products of the Norwegian Scientific Committee for Food Safety

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Norwegian Scientific Committee for Food Safety (VKM)
Po 4404 Nydalen
N – 0403 Oslo
Norway

Phone: +47 21 62 28 00
Email: vkm@vkm.no

www.vkm.no
www.english.vkm.no

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Risk assessment of *Macrolophus pygmaeus* as biological control product

Authors preparing the draft opinion

Torsten Källqvist (chair), May-Guri Sæthre

Assessed and approved

The opinion has been assessed and approved by Panel on Plant Protection Products of VKM. Members of the panel are:

Torsten Källqvist (chair), Katrine Borgå, Hubert Dirven, Ole Martin Eklo, Merete Grung, Jan Ludvig Lyche, Marit Låg, Asbjørn M Nilsen, Line Emilie Sverdrup

(Panel members in alphabetical order after chair of the panel)

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Summary

Several commercial products, i.e. Macrolophus-System, Macrolophus-N-System and Macro-line c, containing mirids as the active organism(s) belonging to the genus *Macrolophus* (Insecta: Hemiptera: Heteroptera: Miridae), are registered in Norway. The area of application of these agents are for control of whiteflies in ornamentals, vegetables, spices, fruits and berries cultivated in greenhouses, tunnels and open fields. The current approval of these products was given in 2008. The active organism was at the time identified as *Macrolophus caliginosus* (syn. *M. melanotoma*), but recent clarification of the taxonomy has revealed that the correct identity is *Macrolophus pygmaeus*. The name has been changed accordingly in EPPO's List of Biological Control Agents widely used in the EPPO region.

The Norwegian Food Safety Authority (NFSA) has received applications to maintain the registration for the products with the revised species name *Macrolophus pygmaeus*. NFSA has requested VKM's Panel for plant protection products for their opinion on the consequences of the new knowledge with respect to the active species in the products, as well as an assessment of risks to human health and the environment.

Macrolophus caliginosus does not occur naturally in Norway, and a previous environmental risk assessment concluded that *M. caliginosus* represented a low environmental risk, due to a very low probability that this species could establish in Norway. *Macrolophus pygmaeus* on the other hand, is already established in Norway. VKM considers that dispersal/migration of *M. pygmaeus* into the surrounding environment when used for biological control in greenhouses, tunnels and open fields is very likely, and that such escapes (animals) are likely to become established in the environment. However, since the species is already present in Norway, VKM considers the probability for significant non-target environmental effects from commercial use and distribution of *M. pygmaeus* to be low.

Regarding possible human health effects, VKM recognises that the species of *Macrolophus* previously available in commercial products in Norway and Europe has probably always been *M. pygmaeus* and, consequently, experience and documentation referring to commercial use of *M. caliginosus* should be considered valid for *M. pygmaeus*.

The opinion of VKM is that the previous misidentification of the active species of *Macrolophus* does not have any implication on the health hazard of the products, as was concluded in 2007. Consequently VKM considers that the specified use of *M. pygmaeus* will involve a minimal health risk for users.

Key words: VKM, risk assessment, Norwegian Scientific Committee for Food Safety, *Macrolophus pygmaeus*, *M. caliginosus*, *M. melanotoma*, Macrolophus-System, Macrolophus-N-System, Macro-line c, pesticide, biological control product

Sammendrag på norsk

Flere kommersielle produkter, som *Macrolophus*-System, *Macrolophus*-N-System og *Macroline c* er godkjent i Norge og inneholder en rovtege av slekten *Macrolophus*. Bruksområdet for disse midlene er mot mellus i prydplanter, grønnsaker, krydder, frukt og bær dyrket i veksthus, tunneler og på åpne jorder. Den nåværende godkjenning av disse produktene ble gitt i 2008. Den aktive organismen var på den tiden identifisert som *Macrolophus caliginosus* (synonymt med *M. melanotoma*), men nyere avklaring av taksonomi har avdekket at riktig identitet er *Macrolophus pygmaeus*. Navnet er også endret i EPPO List of Biological Control Agents, liste over organismer som er i utstrakt bruk i flere EPPO-land.

Mattilsynet har mottatt søknader om å beholde godkjenningen for preparatene, men med artsnavn endret til *M. pygmaeus*. Mattilsynet har bedt VKMs Faggruppe for plantevernmidler om å vurdere konsekvenser av den nye kunnskapen om identiteten til rovtegen, samt å gjøre en vurdering av miljø-risiko og risiko for menneskers helse.

Macrolophus caliginosus forekommer ikke naturlig i Norge, og en tidligere miljørisikovurdering konkluderte med at *M. caliginosus* representerte liten miljørisiko, siden det vurderes som usannsynlig at arten vil kunne etablere seg i Norge. *Macrolophus pygmaeus* derimot, er allerede etablert i Norge. VKM anser spredning/migrasjon av *M. pygmaeus* til det omkringliggende miljø som sannsynlig når middelet brukes til biologisk kontroll i veksthus, tunneler og åpen åker, og at det er sannsynlig at de også vil kunne etablere seg i miljøet. Imidlertid, siden *M. pygmaeus* allerede er tilstede i Norge, anser VKM risiko for vesentlige ikke-target miljøeffekter som følge av spredning av *M. pygmaeus* å være lav.

Når det gjelder mulige helseeffekter, erkjenner VKM at den arten av *Macrolophus* som tidligere var tilgjengelig i kommersielle produkter i Norge og Europa sannsynligvis alltid har vært *M. pygmaeus*. Som følge av dette mener VKM at den erfaring og dokumentasjon som gjelder kommersiell bruk av *M. caliginosus* også vil være gyldig for *M. pygmaeus*.

VKM's konklusjon er derfor at den tidligere feil-identifisering av *Macrolophus* ikke har noen betydning for vurdering av mulig helserisiko, og at den angitte bruk av *M. pygmaeus* vil innebære en minimal helserisiko for brukerne.

Abbreviations and/or glossary

Abbreviations

EPPO European Plant Protection Organisation

IBCA Insect Biological Control Agent

Background as provided by the Norwegian Food Safety Authority

Due to the recent clarification of the taxonomy of *Macrolophus spp.*, The Norwegian Food Safety Authority has received applications for maintained approval of biological control agents under the revised species name *Macrolophus pygmaeus*. The background for the application is the realization that the active species in the products is in fact *M. pygmaeus* and not *M. caliginosus*.

In order to consider the change of name of the species used in products approved for use in Norway, the Norwegian Food Safety Authority asked the importers to provide documentation pertaining to the environmental and human health hazards of *M. pygmaeus*. The applicants responded that all documentation on *M. caliginosus* also applies to *M. pygmaeus*. Additional documents describing the background for changing the species name are included in the available documentation. Insight in this documentation can be obtained from the Norwegian Food Safety Authority, National Centre of Plants and Vegetable Foods.

Terms of reference as provided by the Norwegian Food Safety Authority

Macrolophus pygmaeus is the active organism in several biological control products against whiteflies for use in ornamental plants, vegetables and herbs in greenhouses and plastic tunnels, indoor plantings, as well as fruit and berries in greenhouses, plastic tunnels and open field.

In this regard, The Norwegian Food Safety Authority would like an assessment of the following:

- Prevalence, especially if the organism is found naturally in Norway.
- The potential of the organism for establishment and spread under Norwegian conditions specified for use in greenhouses and open field.
- Any ambiguities regarding the taxonomy which hampers risk assessment.
- An assessment of the product and the organism with regard to possible health risk.

Assessment

1 Introduction

The genus *Macrolophus* are insects belonging to the family Miridae in the group Heteroptera, order Hemiptera. They are omnivorous predators e.g. on whiteflies, different species of aphids, thrips and spider mites. *Macrolophus* has been marketed as a biological control agent since the 1990-ies under the name of *M. caliginosus* or *M. melanotoma* (synonymes).

Macrolophus pygmaeus and *M. caliginosus* (= *melanotoma*) are closely related species, which both occur in the Mediterranean region. *M. pygmaeus* appears to have also a more northerly distribution, and has been reported in England, Finland and Scandinavia. The two species are difficult to distinguish morphologically. However, as a result of recent taxonomic clarification it has been concluded that the species used in commercial *Macrolophus* Insect Biological Control Agent (IBCA) products is in fact *M. pygmaeus* (Klapwijk, 2011). EPPO corrected in 2009 the name of the species to *M. pygmaeus* in the list of established biological control agents which are recognized by the EPPO Panel on Safe Use of Biological Control to have been widely used in several EPPO countries (EPPO, 2014).

Macrolophus pygmaeus and *M. caliginosus* are sympatric species in the Mediterranean region. In earlier literature, it has been stated that the two species are associated with a number of different host plants and it has been concluded that they have different host plant preferences; *M. pygmaeus* is associated with tomatoes while *M. caliginosus* prefers *Dittrichia viscosa*. However, more recent studies by Cascales et al. (2006) and Castane et al. (2013), largely agrees with earlier publications with respect to host plant preferences of the two species regarding the above mentioned host plants, but they also raise the question whether the two species coexist on crops or non-crop host plants in all or some parts of their geographical distribution area, and whether *C. melanotoma* is restricted to *D. viscosa* only (Castane et al., 2013; Martinez-Cascales et al., 2006). The conclusion of both Martinez-Cascales et al. and Castane et al. is therefore that host plants of the two species still remain largely unknown, due to the taxonomic difficulties in separating the two species. This is of course of importance for predicting establishment of IBCA in natural ecosystems in Norway.

1.1 Status in Norway

Biological control agents based on *M. caliginosus* have been approved in Norway for use against greenhouse whitefly and silver leaf whitefly on ornamentals, vegetables, spices, fruits and berries cultivated in greenhouses, tunnels and open fields. The current approval expires in 2017.

- Product names:** Macrolophus-System, Macrolophus-N-System, Macro-line c, Macrolophus-System Mellusrovtege, Macrolophus Mellusrovtege, Mirical Mellusrovtege, Mirical, Macrolophus caliginosus
- Species name:** *Macrolophus pygmaeus*. Predatory mirid (Family: Miridae; Order: Hemiptera)
- Target pests:** Greenhouse whitefly and silver leaf whitefly
- Area for use:** Ornamental plants, vegetables, spice plants, fruit and berries cultivated in greenhouses, tunnels and open field.

2 Hazard identification and characterisation

2.1 Occurrence and distribution in Norway

In contrast to *M. caliginosus*, *M. pygmaeus* is established in Norway. According to Artsdatabanken (<http://www.artsdatabanken.no/>), observations date back to 1925. Thus, *M. pygmaeus* was established in Norway before *Macrolophus* was introduced as a biological control agent. The distribution seems to be confined to southern Norway.

2.2 Potential for establishment and dispersal

Studies in Spain have shown that *M. pygmaes* used in tomato crops disperses readily into areas with abundant, complex vegetation, and that it is able to colonise tomato fields again from such habitats (Gabarra et al., 2004). *M. pygmaeus* can utilize a wide variety of prey and can survive on many plants including *Solanum nigrum*, which grows sporadically in Southern Norway (EPA, 2014). It is therefore likely that commercial strains of *M. pygmaeus*, released for pest control, will disperse to the neighboring ecosystems and interbreed with wild populations also in Norway. Dispersal is more likely to occur from tunnels and open fields compared to greenhouses.

Since *M. pygmaeus* is endemic in Norway, establishment in the environment from IBCA products will not be an issue unless the population used in the products has properties that differ from the local populations. Whether such differences include e.g. prey preference, interference with the local fauna cannot be totally excluded. However, Bale (2011) as cited in EPA (2014) reported no significant non-target effects from the use of *M. pygmaeus* in the UK, where this species also occurs naturally. Furthermore, no such effects have been reported after use of *Macrolophus* IBCA products in Norway.

2.3 Taxonomic challenges

The Palearctic species of the genus *Macrolophus* (Insecta: Hemiptera: Heteroptera: Miridae) constitute a monophyletic group of eight species. Two of these species, *Macrolophus melanotoma* (Costa) (which is considered a synonym to *Macrolophus caliginosus* (Wagner)) and *Macrolophus pygmaeus* (Rambur) are of economic importance as predators on crop pests in Europe.

Species of *Macrolophus* are difficult to differentiate morphologically, and criteria to identify *M. melanotoma* (= *M. caliginosus*) from *M. pygmaeus* were only recently established by combining genetic and morphological characteristics (Castane et al., 2013; Martinez-Cascales et al., 2006), although Castane et al. (2013) opposed to Martinez-Cascales et al. (2006),

could not identify a single morphological character that was reliable in separating the two species. Castane et al. (2013) therefore proposed a linear discriminant function that combines the length of the second antennal segment with the relative sizes of eyes and the head as a mean to classify the two species. They also designed two pairs of specific primers that allowed species identification by performing a simple PCR assay.

The taxonomical studies by Martinez-Cascales et al. (2006) and Castane et al. (2013) included specimens from local populations as well as from commercial strains, and the latter were all identified as *M. pygmaeus*. Likewise, in UK, *Macrolophus* from three commercial suppliers and a residual nursery population dating from the mid-1990s were all identified as *M. pygmaeus* using molecular techniques (HDC, 2013). Thus, it appears that the commercial IBACs used in Europe have always been *M. pygmaeus*, although previously marketed as *M. caliginosus*.

Sanchez et al. (2012), who studied genetic diversity in populations of *M. pygmaeus* from different localities in the Palearctic region found that this species showed a moderate to high degree of population differentiation among the three main geographic areas of distribution, with the highest degree of divergence found between eastern (Turkey and Greece) and western populations (Italy, France, England, Iberia, and the Canary Islands).

2.4 Health hazards

VKM has performed an assessment of human health risks among users of Biological Control Agents based on *M. caliginosus* (VKM, 2007). The available documentation was mainly on insects in general and it was concluded that:

VKM is not aware of any studies that indicate that the use of the mired *M. caliginosus* as an IBCA in greenhouses or tunnels may have human health implications. VKM concluded that the specified use of *M. caliginosus* will involve a minimal health risk (VKM, 2007).

As pointed out by Klapwijk (2011), the species of *Macrolophus* that has been used commercially as an IBCA has probably always been *M. pygmaeus* and, consequently, all experience and documentation referring to the use of *M. caliginosus* should be considered valid for *M. pygmaeus*. The name of the active species has been changed accordingly in the List of Biological Control Agents widely used in the EPPO region, issued by the EPPO Panel on Safe Use of Biological Control (EPPO, 2014).

3 Conclusions (with answers to the terms of reference)

3.1 Distribution

Macrolophus pygmaeus occurs naturally in the southern part of Norway. The establishment of the species occurred long before the introduction of *Macrolophus* as a biological control agent.

3.2 Distribution and establishment

Dispersal and migration of *Macrolophus* from use as a biological control product in greenhouses, tunnels and open fields to the surrounding environment is likely. In habitats suitable for *M. pygmaeus*, there is also a potential for animals dispersed in the environment to establish and possibly interbreed with the local population. VKM considers the probability for significant non-target environmental effects from distribution of *M. pygmaeus* to be low.

3.3 Taxonomic challenges

There is convincing evidence that the species used in the biological control products Macrolophus-System, Macrolophus-N-System, Macro-line c, Macrolophus-System Mellusrovtege, Macrolophus Mellusrovtege, Mirical Mellusrovtege, Mirical, Macrolophus caliginosus is *Macrolophus pygmaeus*, and not *M. caliginosus* as previously assumed. This has implications on the potential environmental hazard since *M. pygmaeus* occurs naturally in Norway, while *M. caliginosus* does not. In a risk assessment of *M. caliginosus* by Frode Ødegård at NINA (Norwegian Institute for Nature Research) (2001), it was concluded that *M. caliginosus* represented a low environmental risk, because of very low probability that this species could establish in Norway. This conclusion is no longer valid since the active organism is *M. pygmaeus* (See above).

3.4 Health hazards

The opinion of VKM is that the previous misidentification of the active species of *Macrolophus* does not have any implication on the health hazard of the products as previously assessed (VKM, 2007). Consequently VKM considers the specified use of *M. pygmaeus* will involve a minimal health risk for users.

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