

**Guidance to Member States and industry on the data requirements for naturally occurring substances used as attractants / repellents**

**This document was endorsed at the 18<sup>th</sup> meeting of representatives of Member States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (29-30 March 2005).**

**Disclaimer: This document attempts to provide guidance to Member States and industry on the data requirements for naturally occurring substances used as attractants / repellents. It does not intend to produce legally binding effects, nor does it pre-empt the outcome of discussions between participants and Rapporteur Member States regarding data requirements or the verification of completeness of submitted dossiers.**

## 1. Introduction

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For Product Type (PT) 19<sup>1</sup> industry suggested that some of the active substances would fall in a category that is a priori 'low risk' and therefore the data requirements could be significantly reduced. A special effort was undertaken for the four pheromones notified for PT19 via Regulation (EC) No 1896/2000 and the Biocides Technical Meeting arrived at defining conditions for waiving actual testing for certain end-points. The outcome is published on the web page of the European Chemicals Bureau (ECB) at <http://ecb.jrc.it/biocides> .

Based on these discussions regarding the 4 pheromones the Member States and COM attempted to derive a general proposal for reduced data requirements for PT 19 substances.

However, the substances notified for PT 19 do not appear to have common (eco)toxicological characteristics that would allow for general data waiving for the product type, and the general use/exposure pattern within PT 19 is not so well defined that this in itself would lead to a general reduction in the data requirements.

The ECB then tried to derive the data requirements for a subgroup of PT 19, the naturally occurring substances used as attractants / repellents and the outcome is described here.

## 2. Comparison of the Data Requirements for naturally occurring substances used as attractants / repellents with the data requirements for pheromones.

All pheromones belong to the product type 19. Several naturally occurring substances used as attractants / repellents are also notified under this product type. As the data requirements analysis is more advanced for the pheromones, the possibilities for re-using the ideas applied to generate the pheromones data requirements were examined in order to understand if these ideas would be applicable to the product type in general.

Pheromones have a (narrow) concentration range within which they are effective, whereas the naturally occurring substances used as attractants / repellents are also effective at high concentrations. Thus, low potential risk, due to known low exposure, can not be assumed in general for naturally occurring substances used as attractants / repellents. These may, in addition, be applied directly to skin, e.g. as mosquito repellent. In table 1 below the main differences between pheromones and naturally occurring substances are indicated.

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<sup>1</sup> *Product-type 19: Repellents and attractants*

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

**Table 1. Differences between naturally occurring substances and pheromones**

<b>Arguments according to Document</b>	<b>Pheromones to Guidance</b>	<b>Applicable to naturally occurring substances</b>	<b>Comment</b>
Pheromones have an intra-species specific effect		no	Naturally occurring substances have a much broader target group, not necessarily species specific
Probably comparable to naturally efficacious concentrations		not necessarily	There is probably a minimum effective concentration that could e.g. attract pollinating insects, but in contrast to pheromones the ‘naturally occurring substances’ work also at higher concentrations
Application rate is typically low		not necessarily	See above
Low toxicity		no	No data is available that corroborates this as a general statement. Naturally occurring substances are also notified under other product types as disinfectants and insecticides (E.g. pyrethrins and azadirachtins are toxic chemicals).
Indoor use		no	‘naturally occurring substances’ are likely to be used indoor as well as outdoor, indicating a greater need for environmental toxicity data
Dispersion in air main mode of action		no	e.g. some can be applied to skin
Negligible exposure		no	Background exposure could vary widely e.g. a lavender field versus in house
Enclosed dispensers		no	Method of application could vary widely

The possibilities for developing a general guidance document on naturally occurring substances used as attractants / repellents are, as illustrated by the table above, somewhat limited. In contrast to the pheromones there appears no general arguments for naturally occurring substances used as attractants / repellents, e.g. in terms of low exposure, to justify reduced human toxicology data sets or reduced environmental toxicology data sets. For the naturally occurring substances used as attractants / repellents, the main issue could potentially be the fact that naturally occurring substances used as attractants / repellents are in general mixtures, which could in itself require more specific guidance on how to deal with. This is, however, not specific to the naturally occurring substances used as attractants / repellents and more related to test methods.

### **3. Conclusions**

The exposure profile for the substances in PT 19 is not a priori 'well-defined' and does include scenarios like direct application to skin and both out-door and in-door applications limiting the possibilities for non-submission of data. Furthermore, the substances notified for PT 19 do not appear to have common (eco)toxicological characteristics that would allow for general data waiving for the product type.

Thus it appears most relevant to define the data requirements for naturally occurring substances used as attractants / repellents on substance level, i.e. substance by substance, as general commonalities with regard to exposure and hazardous properties for these substances within PT 19 are not evident. Obviously, the general principles for non-submission of data, as outlined in chapter 1 of the TNsG on Data Requirements continue to apply. The experience in analysing the data requirements for the pheromones showed that the exposure pattern might be a key argument in reducing the data requirements.