EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E - Safety of the food chain
E3 - Chemicals, contaminants, pesticides

SANCO/5272/2009 rev. 3
28 October 2010[1]

Guidance Document on the assessment of new substances falling into the group of Straight Chain Lepidopteran Pheromones (SCLPs) included in Annex I of Council Directive 91/414/EEC

This document has been conceived as a working document of the Commission Services, which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Annex II, III and VI of Council Directive 91/414/EEC, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

[1] The SCFCAH took note of the Guidance revision 1 on 3 July 2009, the new amended revision 3 has been agreed upon by the SCFCAH on 28 October 2010

Content

1. Introduction and Legal Basis

This document intends to establish an harmonised simplified procedure for assessing new substances falling into the group of straight chain lepidopteran pheromones (SCLPs).
Pheromones are a category of semiochemicals produced by individuals of a species that modify the behaviour of other individuals within the same species having consequently a target intraspecific effect.

It is important to underline that within the scope of Directive 91/414/EEC, the need of the assessment of a pheromone as active substance of a plant protection product, as well as the need of authorisation of a product as a plant protection product depends on the intended use of the substance: A pheromone is considered as active substance of a plant protection product, if the pheromone aims to protect the plant. This is the case when the pheromone is used for sexual confusion or in the case of mass trapping.
However, pheromones are not considered as active substances of plant protection products, when they are used to only monitor the population cycle of the insects. Such traps used for monitoring purposes may contain the same substances assessed within the framework of Dir. 91/414, but in this case neither the product has to be considered as plant protection product, nor has the pheromone to be considered as active substance in the sense of 91/414.
Also the case of a pheromone added to attract insects which in the end are killed by an insecticide is another situation. Then the pheromone can be considered as adjuvant in a sort of formulation, where the active substance is the insecticide and therefore in this case the pheromone itself is considered out of the scope of the Directive.

With regard to SCLPs, it is a group of pheromones naturally produced by insects in the order Lepidoptera, consisting of unbranched aliphatics having a chain of nine to eighteen carbons, containing up to three double bonds, and ending in an alcohol, acetate or aldehyde functional group. This structural definition encompasses the majority of known pheromones produced by insects in the order Lepidoptera, which includes butterflies and moths (OECD/ENV/JM/MONO/(2001) 12). It has to be

emphasized, that it was decided within the OECD to adhere to this definition of SCLPs. Any semiochemical not fitting the definition cannot be regarded as SCLP.

Commission Regulation (EC) No 2229/2004 on the 4th stage of the review programme of existing active substances included several substances falling into SCLPs group. The rapporteur member state (RMS) for pheromones was Austria. Austria finalised a draft assessment report on the SCLPs group in 2008.
On the basis of the results of the evaluation performed by the RMS and in compliance with the criteria of Annex VI of Commission Regulation 1095/2007, the SCLPs group was included in Annex I of Council Directive 91/414/EEC by Commission Directive 2008/127/EC. The inclusion concerned the group with listed specific substances evaluated and reference to the Review Report (SANCO/2633/2008) where specifications were given for each substance or blend of substances evaluated.

2. Background/Justification

This document is based on the OECD Monograph 12 (OECD/ENV/JM/MONO/(2001) 12), on comments received by Member States and EFSA. It takes into account the specific properties of SCLPs with respect to conventional chemicals: in particular their target-specificity, their mode of action as they act modifying the behaviour of the target species and not directly killing, the fact they naturally occur and their application at low rates often at levels naturally occurring, their high volatility and rapid dissipation in the environment. In addition, many end use products are formulated in passive dispensers (hollow fibres, tapes) that present little direct exposure to humans and non-target organisms. All these factors minimise the risk of adverse effects from the use of SCLPs.

The OECD Guidance document (*OECD/ENV/JM/MONO/(2001) 12)*
The OECD Working Group on Pesticides (WGP) has developed a guidance for specific registration requirements for pheromones and other semiochemicals to facilitate the development, registration and use of pheromones and other semiochemicals. The harmonisation of these requirements was considered critical for

research, and for encouraging the development and use of pheromones and other semiochemicals in Integrated Pest Management (IPM) techniques. Austria as Rapporteur Member State (RMS) of the SCLPs for the Directive 91/414 EU review program, has been invited by the OECD Biopesticide Steering Group to the “OECD Workshop on the Regulation of Biopesticides: Registration and Communication Issues”, which took place on April 17-18 2008 at the US EPA in Arlington, Virginia, USA. Austria was asked to give a presentation on the outcome of the SCLPs evaluation and to provide suggestions for a revision/update of this guidance document. Currently a draft of the updated version is under discussion with the involvement of OECD and all OECD Member States.

Based on the OECD Guidance (OECD/ENV/JM/MONO/(2001) 12), on the SCLPs DAR conclusions and taking into account the REBECA Proposal on Improved regulatory procedures for botanicals and semiochemicals and list of knowledge gaps (Project n.o SSPE-CT-2005-022709 delivered December 2007), the SCLPs were included as group in Annex I of Directive 91/414/EEC.

3. Conclusions

On the basis of the information provided in the previous chapters and considering the existence of a broad scientific consensus on the OECD MONO 12, a simplified procedure should be laid down to permit new substances falling into the SCLPs group to be promptly evaluated and when appropriate to be confirmed with respect to their individual inclusion.

The inclusion of the SCLPs as a group allows to add new substances falling into this same group in a separate list after they have been evaluated. This list has to be maintained updated in the Review Report (SANCO/2633/2008) and shall be amended by taking note in the Standing Committee on the Food Chain and Animal Health.

The applicant asks for a national authorisation of a plant protection product at Member State level. In case the formulation contains (a) new substance(s) falling into the group of SCLPs, the MS will then assess the properties of the new substance(s) - if falling into the SCLPs group - according to this guidance document with respect to

the definition and the conclusion on the reference dossier on SCLPs respecting the provisions of Directive 91/414/EEC, and will write an evaluation report.

4. Definitions

Reference SCLPs DAR and reference SCLPs dossier

A DAR (Draft Assessment Report) has been prepared by the RMS for the SCLPs group. This DAR is defined as the reference SCLPs DAR. Therefore the reference SCLPs DAR contains several substances falling into the SCLPs group supported by a task force dossier which represents the reference dossier for the SCLPs group for inclusion into Annex I.

New SCLPs substances

A new substance falling into the SCLPs group already included in annex I of directive 91/414/EEC is subject to this simplified procedure, if it can be demonstrated that this new substance complies with the definition and the properties of the SCLPs group as defined by OECD 12 (OECD/ENV/JM/MONO/(2001) 12).

5. Evaluation of new substance / procedure

- The plant protection product containing the new substance(s) will be applied for at Member State level by the applicant within the scope of a national authorisation.
- The MS will request the applicant for the complete Dossier (Annex II). In ecotoxicology, for some sections it may be more feasible to cover Annex II data requirements with formulation data (Annex III).
- For each new substance falling into the SCLPs group an evaluation report shall be elaborated by the MS receiving the application in the form of the attached Appendix I and II.
- If the new substance(s) do(es) not comply with the definition and the properties of the SCLPs group as defined by OECD 12 (OECD/ENV/JM/MONO/(2001) 12), the normal EU procedure for a new active substance has to be followed.

5.1. Data requirements

For these applications for new substances falling into the SCLPs group, in principle a complete Dossier (Annex II) fulfilling the requirements of OECD 12 (OECD/ENV/JM/MONO/(2001) 12) should be submitted at Member State level as well as to the RMS. However, for many data requirements reference could be made to the existing reference DAR taking into account when necessary data protection provisions. Notifiers are reminded that data requirements can be addressed not only by studies, but also by relevant literature and/or scientific justifications.

Each data point for the active substance has to be addressed by data or by a justification. However, it is not necessary to submit specific information for many data points in line with OECD Monograph 12. Most of the data required are relevant for all SCLPs and have already been assessed by the RMS.

Based on published and/or own data, the applicant shall explain why the new substance should be considered as falling into the SCLPs group. Specific data have to be submitted for data points concerning the identity and properties of the substance itself as well as to demonstrate that it falls into the SCLPs group.

The following specific information has to be provided for the active substance (according to Annex II data requirements, in line with OECD Monograph 12):

- Identity of the active substance (Annex IIA Point 1)
- Physical and chemical properties of the active substance (Annex IIA Point 2)
- Further information on the active substance (function, mode of action, handling) (Annex IIA Point 3)
- Analytical methods and validation (Annex IIA Point 4)
- Mammalian toxicology (Annex IIA Point 5)
- Residues (Annex IIA Point 6)
- Ecotoxicology/Fate (Annex IIA Point 7 and Point 8).

Furthermore, data on application, field of use, application rate and other information on use conditions and exposure which allow bridging of the risk assessment of SCLP already included in Annex I to the new SCLP may be requested.

5.2 Data Protection

Unpublished data submitted for the inclusion of a new substance in Annex I are in principle protected for a certain period. This means that all notifiers applying for national authorisation of a plant protection product containing an active substance which was included in Annex I should either prove legal access to all protected data that were necessary for the Annex I inclusion, or provide equivalent own data. This refers only to data still under data protection (i.e., not to published literature). For submitted studies, for which the notifier claims data protection, the standard EU rules for data protection apply. Likewise, notifiers of products containing a new substance have to provide own data or legal access to the protected parts of an already submitted dossier (the reference dossier).

5.3 Evaluation process

The MS receiving the application shall carry out a risk assessment and compare the outcome with the risk of the already included SCLPs group. The MS will inform COM and the MSs with a report of its assessment in the format of the appendix I and II.

5.4 Decision making

- If the assessment of the new substance concludes that it is comparable to the already listed SCLPs, the new substance can, after noting by the Standing Committee, be added to the Review Report which is publicly available. Thus, all Member States are adequately informed and involved in the decision.
- If the assessment of the new substance concludes that it is not falling into the SCLPs group, the Standing Committee has to take note of the report. The consequence of such a conclusion is that the notifier has to follow the normal EU procedure for inclusion as new active substance in Annex I.

5.5. Reporting

An evaluation report should be prepared in the format of Appendix I and II.

6. References

OECD - ENVIRONMENT DIRECTORATE JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND

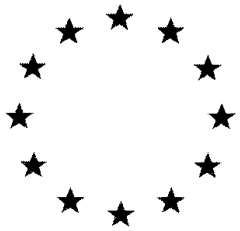
BIOTECHNOLOGY Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control OECD MONO 12

REBECA proposal on improved regulatory procedures for botanicals and semiochemicals and list of knowledge gaps (REBECA Project SSPE- CT- 2005-022709 final report 31 December 2007)

DGENV Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC (May 2005).

Guidance document on the preparation of dossiers and draft assessment reports for substances covered in the fourth stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC (SANCO/10393/2004).

European Commission



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Author(s)	Annex point/ reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Owner

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Author(s)	Annex point/ reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Owner

C. FURTHER INFORMATION ON THE ACTIVE SUBSTANCE (ANNEX IIA 3)

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E. TOXICOLOGY (ANNEX IIA 5)

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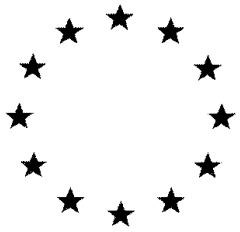
Author(s)	Annex point/ reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Owner

APPENDIX II Confidential report of a new substance falling into the SCLPs group

European Commission



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-MAXIMUM CONTENT OF ALL COMPONENTS EXCEEDING 1G/KG (0.1%W/W)

A.4 MATERIAL ACCOUNTABILITY (ANALYTICAL PROFILE OF BATCHES) AND METHODOLOGY (INCLUDING SPECTRAL CONFIRMATION OF IDENTITY) (ANNEX IIA 1.11)

SECTION B: ANALYTICAL METHODS AND VALIDATION (ANNEX IIA 4)

B.1 METHODS FOR THE ANALYSIS OF PURE ACTIVE INGREDIENT IN THE ACTIVE INGREDIENT AS MANUFACTURED (ANNEX IIA 4.2.1)

B.2 METHODS FOR THE DETERMINATION OF SIGNIFICANT AND/OR RELEVANT IMPURITIES AND ADDITIVES (E.G. STABILISER) IN THE ACTIVE INGREDIENT AS MANUFACTURED (ANNEX IIA 4.2.3-4)

[5] OECD data point

B.3 SUBMISSION OF ANALYTICAL STANDARDS (SAMPLES) (ANNEX IIA 4.1)

REFERENCES RELIED ON

A. IDENTITY OF THE ACTIVE SUBSTANCE (ANNEX IIA 1)

Author(s)	Annex point/ reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Owner

B. ANALYTICAL METHODS AND VALIDATION (ANNEX IIA 4)

Author(s)	Annex point/ reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Owner