

## REPORT OF PESTICIDE PEER REVIEW TC 105

PYRETHRINS – AIR IV

Rapporteur Member State: IT

### 1. Identity, Physical and Chemical properties

Date: 22 May 2023

List of participants:

Status	Name of institution/attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Germany	Federal Office of Consumer Protection and Food Safety – (DE)
National Experts nominated by RMS Italy	ICPS – (IT)
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) – (NL)
National Experts nominated by MS Sweden	Swedish Chemicals Agency – (SE)
Observer	Swedish Chemicals Agency – (SE)

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



**Discussion points/Outcome**

**1. Identity, Physical and Chemical properties**

Please note that information part of this report may have been masked by EFSA in accordance with Article 63 of [Regulation \(EC\) No 1107/2009](#) as well as [EFSA’s Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation \(EC\) No 1107/2009](#), or [EFSA’s Practical Arrangements concerning transparency and confidentiality](#) as a consequence of confidentiality requests submitted by the applicant on application dossiers for pesticides active substances or Maximum Residue Levels, respectively. Please note that information disclosed in this report is without prejudice to pre-existing intellectual property rights and data exclusivity clauses set out in Union law, and particularly in Article 62 of Regulation (EC) No 1107/2009.

Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
<p><b>Expert Consultation 1.1</b></p> <p>MSs experts to discuss:</p> <ol style="list-style-type: none"> <li>1. If based on SANCO/11470/2012–rev. 8 a common reference specification is applicable for all <b>three</b> sources (MGK, BRA, KPCI) or individual reference specifications should be proposed for each manufacturing source.</li> <li>2. The statistical basis to be applied for the content proposed in the technical specification e.g. ‘mean-3SD’ or “mean - 5 SD”.</li> <li>3. The components to be included in the reference specification(s) e.g. min. total pyrethrins; individual content in pyrethrins; content in Pyrethrins I and II; ratio between Pyrethrins I and II.</li> </ol>	<p>All Member State experts, except the RMS expert, agreed and concluded on the approach to be followed to derive the proposed reference specifications for the renewal.</p> <p>It was agreed that the RMS proposal on the reference specification(s), including the reasoning behind it, should be reported in the revised RAR Vol.4. In addition, RMS agreed to report in the RAR the proposed reference specifications following the approach agreed by the rest MS experts.</p> <p>The following <b>open points</b> were identified:</p> <ol style="list-style-type: none"> <li>1. RMS to include in the amended RAR the revised specifications based on the approach concluded during the meeting among the MS experts (i.e., a common reference specification is not applicable to all sources, and individual reference specifications should be proposed for each source).</li> <li>2. RMS to include in the amended RAR the RMS proposal for the reference specification(s) including the reasoning behind it, and to clearly report that the RMS does not agree with the approach proposed during the expert meeting from the rest MS experts.</li> <li>3. EFSA to report in its conclusion the divergent views from RMS and MSs experts on the proposed reference specification(s).</li> </ol>



## REPORT OF PESTICIDE PEER REVIEW TC 74

HYDROLYSED PROTEINS – AIR IV

Rapporteur Member State: ES

### 1. Identity, Physical and Chemical properties

Date: 27 April 2022

List of participants:

Institute	Member States Country code
National Institute for Agricultural and food research and technology (INIA)	ES
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## Discussion points/Outcome

### 1. Identity, Physical and Chemical properties

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
<p><b>Experts' consultation 1.1</b></p> <p>To discuss the expression of purity of the active substance and the basis of technical specifications for equivalence assessment (markers).</p>	<p>RMS and experts agreed to specify the hydrolysed protein purity for each manufactured technical concentrate based on the organic nitrogen excluding inorganic nitrogen and nitrogen from urea. The reasoning is that if ureic and inorganic nitrogen are considered in purity calculation this would lead to an over estimation of the hydrolysed proteins content. RMS and experts agreed to specify urea content separately, when it is appropriated.</p> <p>Experts and RMS discussed the proposed specifications for each manufacturing source of the active substance separately.</p> <p>Experts and RMS concluded on the proposed specifications for the BIOIBERICA source (see open point 4 at experts' consultation 1.1) and agreed and concluded that specifications of SICIT source cannot be proposed as no 5-batch data were provided (See also the data gap at experts' consultation 1.3).</p> <p>Experts and RMS agreed on the proposed specifications for the PHYTOPHYL (see also the open points 1 at experts' consultation 1.1) and PROALAN S.A. sources (see also the open points 2 and 3 at experts' consultation 1.1), however, the finalisation of these specification and if relevant impurities are present would be concluded based on their toxicological assessment.</p> <p><b>Open point 1:</b> RMS to amend the proposed RMS specifications as reported on PHYTOPHYL Vol. 4 Table C.1.2.1-2 and the composition of the representative formulation (Table C.1.3.2-1: Composition of ENTOMELA 50SL/ENT50) based on the agreement.</p>



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Hydrolysed proteins

Subject	Conclusions Pesticide Peer Review Meeting
	<p><b>Open point 2:</b> RMS to delete the proposed specifications on amino acids from Table C.1.2.3-2 Analytical profile of 5-batch analysis of Hydrolysed proteins from PROALAN (amino acids content).</p> <p><b>Open point 3:</b> RMS to amend the proposed RMS specifications as reported on Vol. 4 PROALAN S.A., Table C.1.2.3-1 Analytical profile of 5-batch analysis of Hydrolysed proteins from PROALAN, p. 19 based on the agreement.</p> <p><b>Open point 4:</b> RMS to amend the proposed specifications as reported on Vol. 4 BIOIBERICA, Table C.1.2.3-4, p. 25, based on the agreement.</p>
<p><b>Experts' consultation 1.2</b></p> <p>To discuss the name of the active substance. RMS proposal is to consider a general common name "Hydrolysed proteins" and different variants taking into account the origin of the active substance (e.g. beet molasses-urea hydrolysate or collagen protein hydrolysate or animal tissues hydrolysate).</p>	<p>RMS and experts concluded and agreed on proposed common name of hydrolysed proteins and the following specific naming based on the origin of hydrolysed proteins and manufacturing process.</p> <ol style="list-style-type: none"> <li>1. Urea enriched beet molasses, hydrolysed</li> <li>2. Collagen protein hydrolysate</li> <li>3. Animal tissues hydrolysate excluding ruminants hides and skins</li> </ol> <p>The specific names 'Collagen protein hydrolysate' and 'Animal tissues hydrolysate excluding ruminants hides and skins', are according to the Review report SANCO/2615/08 – rev. 4. The specific name 'Beet molasses urea hydrolysate', as reported in the Review report SANCO/2615/08 – rev. 4, is proposed to be amended to 'Urea enriched beet molasses, hydrolysed', as according to the submitted 5-batch data the amended specific name better reflects the manufactured technical concentrate of hydrolysed proteins produced by beet molasses.</p> <p><b>Open point:</b> RMS to amend in the RAR Vol. 1 (Point 1.3 Identity of the active substance) and RAR_Vol. 3 B1_CA the common name and specific naming for this active substance based on the agreement.</p>
<p><b>Experts' consultation 1.3</b></p> <p>Following the submission and evaluation of the outstanding 5-batch data (see confidential RTs for Bioiberica, Phytophyl and Sicit), an expert consultation to be organized to discuss the expression of purity of the active substance, the basis of technical</p>	<p>Experts agreed not to propose to set a common reference specification but three separate reference specifications - one for each group of hydrolysed proteins (See also Experts' consultation point 1.2). This was based on the fact that different manufacturing processes are used (including different starting (raw) materials) which leads to different impurities to be present in the technical concentrate (TK), and the minimum purity of each TK differs significantly.</p> <p><b>Data gap:</b> Applicant SICIT to provide 5-batch data on the manufactured TK.</p> <p><b>Open point:</b> RMS to report in Vol.4 of SICIT p. 17 on RMS conclusion that RMS and experts disagree on the calculation of TK specifications</p>



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Hydrolysed proteins

Subject	Conclusions Pesticide Peer Review Meeting
specifications (markers) and if hydrolysed proteins from different origin can be considered as different variants with different specifications.	based on 5-batch data from formulation. Agreed that a data gap should be set for SICIT for 5-batch data on TK.