FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: CHR/H/PENDIF 599.5 SC

Product name(s): Cevino Trio 599.5 SC/ Trivino 599.5 SC

Chemical active substance(s):

Penoxsulam, 37.5 g/L
Diflufenican, 250 g/L

Flufenacet, 312 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: October 2020

MS Finalisation date: 24/08/2022

Version history

When	What
February 2022	Dossier sent for evaluation
April 2022	zRMS evaluation of dRR
August 2022	Final version prepared by zRMS after Commenting period

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zRMS comments:
The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for authorization of CHR/H/PENDIF 599.5 SC SC (Cevino Tri 599.5 SC, Trivino 599.5 SC) containing penoxsulam, diflufenican and flufenacet in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part A and C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to CHR/H/PENDIF 599.5 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/I/ADEL 280 SC have been made using endpoints agreed in the EU review of penoxsulam, diflufenican and flufenacet.

This document describes the specific conditions of use and labelling required for the registration of (Cevino Trio 599.5 SC, Trivino 599.5 SC), product code CHR/H/PENDIF 599.5 SC.

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013

In addition to the submission of studies as listed in section(s) B1-B10, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	Poland: CHR/H/PENDIF 599.5 SC Cevino Trio 599.5 SC/Trivino 599.5 SC	

0.1.3 Regulatory history of the active(s)

0.1.3.1 Penoxsulam

Table 0.1-2: Summary of regulatory history of CAS No: 219714-96-2

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION DIRECTIVE 2010/25/EU of 18 March 2010
RMS	IT

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/08/2010
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.07/2023
Date of final Commission (re-registration) deadline (Step 2)	31.07/2023
Current expiration of approval	31.07/2023
Low risk substance or Candidate for Substitution?	-

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the protection of aquatic organisms;
- the dietary exposure of consumers to residues of the metabolite BSCTA in succeeding rotational crops
- the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
-

The SANCO report for penoxsulam (SANCO/11082/09 – final 22 January 2010) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 31.08.2009

Table 0.1-3: Information on minimum purity of penoxsulam

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
980 g/kg	~~For the purity of active substance, please refer to PART C- confidantial information~~ 981 g/kg

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.3.2 Diflufenican

Table 0.1-4: Summary of regulatory history of CAS No: 83164-33-4

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION DIRECTIVE 2008/66/EC of 30 June 2008
RMS	CZ
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/12/2022

Status	
Date of final Commission (re-registration) deadline (Step 2)	31/12/2022
Current expiration of approval	31/12/2022
Low risk substance or Candidate for Substitution?	

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- the protection of aquatic organisms. Risk mitigation measures such as buffer zones should be applied, where appropriate.
- the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones should be applied, where appropriate.
-

The SANCO report for diflufenican (SANCO/3782/08 – rev. 1 14 March 2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 31.08.2009

Table 0.1-5: **Information on minimum purity of diflufenican**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report**
970 g/kg	~~For the purity of active substance, please refer to PART C- confidantial information~~ Source 1 – 975 g/kg Source 2 – 985 g/kg Source 3 – 980 g/kg Source 4 – 975 g/kg

0.1.3.1 Flufenacet

Table 0.1-6: Summary of regulatory history of CAS No: 142459-58-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2003/84/EC of 25 September 2003
RMS	PL
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2004
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/10/2020
Date of final Commission (re-registration) deadline (Step 2)	31/10/2020

Status	
Current expiration of approval	31/10/2020
Low risk substance or Candidate for Substitution?	CfS

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- should pay particular attention to the protection of algae and aquatic plants.
- should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.
- should pay particular attention to the protection of operators.

Risk mitigation measures must be applied, where appropriate.

The SANCO report for Flufenacet 7469/VI/98-Final 3 July 2003 is considered to provide the relevant information on the evaluation or a reference to where such information can be found. There is no EFSA peer review at the moment of application

Table 0.1-7: Information on minimum purity of Flufenacet

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report**
950 g/kg	~~For the purity of active substance, please refer to PART C- confidantial information~~ Equivalence report available: Y (available on CIRCA) RMS:UK (CRD) Source 1 – 980 g/kg Source 2 – 980 g/kg Source 3 – 985 g/kg Source 4 – 975 g/kg

0.1.4 Regulatory history of the product

Not authorized yet.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
The two-year storage stability study is ongoing and has to be provided for evaluation when available.

Section 3. Efficacy
The evaluation of the application of Cevino Trio 599,5 SC/Trivino 599,5 SC resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical Methods
The analytical method used for analysing the active substance in the PPP is accepted.

Section 6. Mammalian Toxicology
Based on data of the active substances and co-formulants formulation the CHR/H/PENDIF 599.5 SC requires the classification as Acute Tox. 4, H302; Skin Sens. 1, H317 and STOT RE 2, H373. The results of exposure estimations and the product classification indicate that the product CHR/H/PENDIF 599.5 SC is safe for operator (with appropriate PPE), worker (wearing work wear), as well as for bystander and resident (both adult and child).

Section 7. Metabolism and Residues

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.

Section 8. Environmental Fate
In accordance with proposed pattern use, an exposure assessment for the formulation CHR/H/PENDIF 599.5 SC was submitted. The safe use is acceptable if product is used every other year.
The mitigation measures were proposed, and final decision will be made in ecotoxicological section.

Section 9. Ecotoxicology
In accordance with proposed pattern use, risk assessment to non-target organisms for the formulation of CHR/H/PENDIF 599.5 SC was sufficient.
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of CHR/H/PENDIF 599.5 SC as herbicide in winter cereals poses an acceptable risk to non-target organisms in application rate 0.4 L/ha.

Section 10. Assessment of the relevance of metabolites in groundwater
Penoxsulam. Based on PECgw assessment all relevant metabolites with concentration higher than trigger value of 0.1 µg/L were considered.
Flufenacet. The only metabolite FOE-sulfonic acid has to be considered. The PECgw value for this metabolite was above the trigger value of 10 µg/L for winter cereals in Jokioinen scenario and was not taken into account as this scenario is not relevant for Central Zone.
Diflufenican. The PECgw values for metabolites of active substance were below the trigger value of 0.1 µg/L.
Groundwater metabolite BSTCA reaches levels above 0.75 µg/L when applied every year. STEP 5: Refined risk assessment could not be completed. Risk mitigation measures: application every other year (see Section 10).

Uses to be considered safe on the basis of EU methodology:
1
The safe use is acceptable if product is used every other year.

Uses to be considered non-safe on the basis of EU methodology:
none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

Effects on aquatic organisms and non-target arthropods need to be confirmed.

Particular precautions to reduce the environmental concentrations resulting from CHR/H/PENDIF 599.5 SC applications are required for:

- groundwater protection

- aquatic organisms
- non-target terrestrial plants

Appendix 1 ALL intended uses

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Winter triticale (TTLWI),	F	*Apera spica -venti*; dicotyledonous weeds	Spray, medium sprayer	autumn BBCH 11-25	a)1 b)1	n/a	a) 0.4 l/ha b) 0.4 l/ha	a) 0.2398 kg a.s./ha (0.1248 FLU + 0.1 D + 0.015 P) b) 0.2398 kg a.s./ha (0.1248 FLU + 0.1 D + 0.015 P)	200-~~400~~ 300	n/a		**The safe use is acceptable if product is used every other year.**