FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: CHR/H/FETEC-PART B 110 EC

Product name(s): Fenoxinn Max 110 EC, Herbos Max 110 EC

Chemical active substance:

Fenoxaprop-P-ethyl, 110 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: February 2023

MS Finalisation date: 23/09/2024

Version history

When	What
05/2023	Dossier sent for evaluation
11/2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period
September 2024	Evaluator's update in the context of the proposed TMs

Table of Contents

0 Product background, regulatory context and GAP information 4

0.1 Introduction 4
0.1.1 Reason for application 4
0.1.2 Details of zRMS(s) and concerned MS 4
0.1.3 Regulatory history of the active(s) 4
0.1.3.1 Fenoxaprop-P-ethyl 4
0.2 zRMS conclusion 5

Appendix 1 ALL intended uses 7

Evaluator 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/FETEC-PART B 110 EC (Fenoxinn Max 110 EC/Herbos max 110 EC) containing fenoxaprop-P-ethyl 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/FETEC-PART B 110 EC where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/H/FETEC-PART B 110 EC have been made using endpoints agreed in the EU review of dicamba

This document describes the specific conditions of use and labelling required for the registration of Fenoxinn Max 110 EC/Herbos max 110 EC, product code CHR/H/FETEC-PART B 110 EC.

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) B0-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)**
Northern zone	-	-
Central zone	CHR/H/FETEC-PART B 110 EC Fenoxinn Max 110 EC/Herbos Max 110 EC	-
Southern zone	-	-
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Fenoxaprop-P-ethyl

Table 0.1-2: Summary of regulatory history of CAS No: 71283-80-2

Status	
Approved in EU	Y
Original Inclusion Directive	COMMISSION IMPLEMENTING

Status	
or Commission Implementing Regulation	REGULATION (EU) No 540/2011 of 25 May 2011
RMS	Austria
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
Date of final Commission (re-registration) deadline (Step 2)	31.12.2022
Current expiration of approval	31.12.2023
Low risk substance or Candidate for Substitution?	N/A

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 operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;
- the protection of non target plants;
- the presence of the safener mefenpyr-diethyl in formulated products as regards operator, worker and bystander exposure;
- the persistence of the substance and of some of its degradation products in colder zones and areas where anaerobic conditions may occur .

The SANCO report for fenoxaprop-P-ethyl (SANCO/3777/08 – rev. 1 14 December 2007) provides the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 29 November 2007

Table 0.1-3: Information on minimum purity of fenoxaprop-P-ethyl

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 *, ** **
920 mg/kg	Please refer to Part C

* 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.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information

The two years storage stability study is on-going (January 2024). It has to be assessed in the post registration at national level, but there is Shelf life test after 12 months under normal conditions at 20±2°C.

Section 3. Efficacy

The evaluation of the application of Fenoxinn Max 110 EC/Herbos Max 110 EC resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical methods

The analytical methods have been accepted.

Section 6. Mammalian Toxicology
Classification of the product: Asp. Tox. 1 (H304), Skin Irrit. 2 (H315), Skin Sens. 1 (H317), Eye Dam. 1 (H318), STOT RE 2 (H373).

Operator: Taking into account the results of exposure estimations and the classification of the product CHR/H/FETEC-PART B 110 EC, the use of protective gloves, face/eye protection and work wear during mixing/loading and protective gloves and work wear during application is necessary.

Worker: Taking into account the results of exposure estimation for the formulation, the use of CHR/H/FETEC-PART B 110 EC causes no unacceptable exposure risk when the product is used as intended with risk mitigation measures as work wear covering arms, legs and body for the worker. The protective gloves are recommended during field inspection

Bystander/resident: The use of CHR/H/FETEC-PART B 110 EC causes no unacceptable exposure risk for an bystander and resident (child and adult).

Section 7. Metabolism and Residues
The data available for the subject of the present authorisation request can be considered sufficient for risk assessment of the proposed solo uses of "CHR/H/ FETEC – PART B 110 EC" in cereals. The products indicated as mixing partners of the proposed Tank Mix, must be applied only according to their currently valid GAPs and consistently with the intended FENOXINN MAX 110 EC GAP (the PPPs indicated in the label and in the Appendix 1 GAP are differed).

~~The intended TMs must be removed from the submitted GAP table (see B7 for details) because the present application does not include a formal approval request for the uses in cereals of 2-actives mixes, and also no such residue data were submitted. Therefore, for these uses there are no tool within the present dossier to evaluate them consistently with the regular authorization procedure. However, the proposed mixes as "untested" TMs still are acceptable within the proposed label. This is common practice, the instructions for use often state such mixes recommendations (in Poland also). It should be considered also that for TMs Member States will need to consider if the submitted information is sufficient to support the claims made in their Member State, based on their knowledge of the active substances, the situations of use and national experience/conventions with labelling.~~

Section 8. Environmental Fate
In accordance with proposed pattern use, an exposure assessment for the Fenoxinn Max 110 EC/Herbos Max 110 EC formulation was submitted.

Section 9. Ecotoxicology
Based on the risk assessment provided ecotoxicology section it can be concluded that the proposed use of CHR/H/FETEC-PART B 110 EC as a herbicide on: winter and spring wheat, winter triticale, winter and spring barley poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Based on risk assessment to aquatic organisms no mitigation measure is needed.

Section 10. Assessment of the relevance of metabolites in groundwater
The maximum PECgw values for metabolites fenoxaprop-P and chlorobenzoxazolone are below the trigger value of 0.1 µg/L.

Uses to be considered safe on the basis of EU methodology:

1-6

Uses to be considered non-safe on the basis of EU methodology:

Appendix 1 ALL intended uses

GAP rev. , date: 2021-01-13

PPP product name:		Formulation type:	EC [a, b]
product code:	CHR/H/FETEC-PART B 110 EC		
Active substance 1:	Fenoxaprop-P-ethyl	Conc. of as 1:	110 g/l [c]
Active substance 2:	-	Conc. of as 2:	- [c]
Active substance 3:	-	Conc. of as 3:	- [c]
Safener:	Cloquintocet-mexyl	Conc. of safener:	55 g/l [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐

Verified by MS: ~~no~~yes

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use-No. [e]	**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: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**	ZRMs Conclu-sion
					Method / Kind	Timing / Growth stage of crop & season	Max. num-ber a) per use b) per crop/ season	Min. inter-val between applications (days)	kg or L prod-uct / 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		e.g. g saf-ener/syn-ergist per ha [f]	

Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW)	F	monocotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.7 l/ha b) 0.7 l/ha	a) 0.077 kg a.s./ha b) 0.077 kg a.s./ha	200-~~400~~ 300	n/a		
2	PL	Spring wheat (TRZAS), Spring barley (HORVS)	F	monocotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.7 l/ha b) 0.7 l/ha	a) 0.077 kg a.s./ha b) 0.077 kg a.s./ha	200-~~400~~ 300	n/a		
~~3~~	~~PL~~	~~Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW)~~	~~F~~	~~monocotyledonous and dicotyledonous weeds~~	~~Spray, medium sprayer~~	~~spring BBCH 20-31~~	~~a)1 b)1~~	~~n/a~~	~~a) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG / Draco 50 SG /Toraya 50 SG b) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG / Draco 50 SG /Toraya 50 SG~~	~~a) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG / Draco 50 SG /Toraya 50 SG b) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG / Draco 50 SG /Toraya 50 SG~~	~~200-400~~	~~n/a~~		~~The products indicated as components of the proposed Tank Mix, must be applied only according to their currently valid GAPs and consistently with the intended FENOXINN MAX 110 EC GAP.~~

4	PL	Spring wheat (TRZAS), Spring barley (HORVS)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG / Draco 50 SG /Toraya 50 SG b) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG / Draco 50 SG /Toraya 50 SG	a) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG / Draco 50 SG /Toraya 50 SG b) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG / Draco 50 SG /Toraya 50 SG	200-400	n/a		The products indicated as components of the proposed Tank Mix, must be applied only according to their currently valid GAPs and consistently with the intended FENOXINN MAX 110 EC GAP.
5	PL	Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	a) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	200-400	n/a		The products indicated as components of the proposed Tank Mix, must be applied only according to their currently valid GAPs and consistently with the intended FENOXINN MAX 110 EC GAP.

6	PL	Spring wheat (TRZAS), Spring barley (HORVS)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	a) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	200-400	n/a		The products indicated as components of the proposed Tank Mix, must be applied only according to their currently valid GAPs and consistently with the intended FENOXINN MAX 110 EC GAP.
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
7														
8														
Minor uses according to Article 51 (zonal uses)														
9														
10														
Minor uses according to Article 51 (interzonal uses)														
11														
12														

Uses 3-6 were removed after the Applicant request.