

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: CHR/H/FETEC 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: 10/09/2024**

## Version history

When	What
05/2023	Dossier sent for evaluation
11/2023	zRMS evaluation of dRR
March 2024	Version prepared by zRMS after Commenting period
July 2024	Final version prepared by zRMS after Commenting period
September 2024	zRMS update

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## **PART A**

### **RISK MANAGEMENT**

#### **1 Details of the application**

This document describes the acceptable use conditions required for zonal registration of CHR/H/FETEC-PART B 110 EC (Fenoxinn Max 110 EC/Herbos Max 110 EC) containing fenoxprop-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 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 fenoxaprop-P-ethyl.

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.

##### **1.1 Application background**

This application was finalized by Innvigo Sp. z o.o. Innvigo Sp. z o.o. is a company located at Aleje Jerozolimskie 178, 02-486, Warsaw, Poland, and registered in the Polish National Court Registry of entrepreneurs (KRS), with the number 0000540684.

The application is for the approval of CHR/H/FETEC-PART B 110 EC an emulsifiable concentration type formulation (EC) containing 110 g/L fenoxaprop-P-ethyl as an active substance and 55 g/L cloquintocet-mexyl as a safener for use as a herbicide for controls a broad-spectrum of dicot and monocots weeds in wheat, triticale and barley.

It is applied by spray at BBCH 20-31 (details GAP table B0 Section).

To obtain authorisation the product CHR/H/FETEC-PART B 110 EC must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed endpoints.

This application was submitted in order to allow the first authorisation of this product in Poland, in accordance with the above.

##### **1.2 Letters of Access**

Letters of access are being submitted, however data included in these documents are confidential.

For details please refer to Part C.

##### **1.3 Justification for submission of tests and studies**

In accordance with Art. 33 (3), the submitted studies and presented in Appendix 4, are relevant and necessary to obtain the first authorisation the product CHR/H/FETEC-PART B 110 EC in Poland and other countries.

##### **1.4 Data protection claims**

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

#### **2 Details of the authorization decision**

## 2.1 Product identity

Product code	CHR/H/FETEC-PART B 110 EC
Product name in MS	Fenoxinn Max 110 EC, Herbos Max 110 EC
Authorization number	N/A
Function	herbicide
Applicant	Innvigo Sp. z o.o.
Active substance(s) (incl. content)	Fenoxaprop-P-ethyl, 110 g/L
Formulation type	EC
Packaging	<p>275 ml HDPE/PA bottle  323 ml HDPE/PA bottle  500 ml HDPE/PA bottle  550 ml HDPE/PA bottle  574 ml HDPE/PA bottle  1000 ml HDPE/PA bottle  1100 ml HDPE/PA bottle  5000 ml HDPE/PA bottle  5000 ml HDPE/PA cannister  5500 ml HDPE/PA bottle  5850 ml HDPE/PA container  10000 ml HDPE/PA container</p> <p>Comment: The packaging material HDPE/PA was tested during the accelerated storage stability studies. The packaging material was found to be stable. Extrapolation of the data conducted with HDPE/PA packaging material to HDPE/F or HDPE/EvOH is possible according to SANCO/10473/2003 –rev.5 21.10.2021 when provided that stability is demonstrated in an accelerated test (seepage data). We propose consent to expand it to include HDPE/EvOH and HDPE/F packaging that seepage data will be provided.</p> <p>312 ml HDPE/F bottle  318 ml HDPE/F bottle  570 ml HDPE/F bottle  575 ml HDPE/F bottle  580 ml HDPE/F bottle  585 ml HDPE/F bottle  1150 ml HDPE/F bottle  1160 ml HDPE/F bottle  1170 ml HDPE/F bottle  1185 ml HDPE/F bottle  1200 ml HDPE/F bottle  5880 ml HDPE/F cannister  5950 ml HDPE/F bottle  5950 ml HDPE/F cannister  10000 ml HDPE/F cannister</p> <p>250 ml HDPE/EvOH bottle  310 ml HDPE/EvOH bottle  500 ml HDPE/EvOH bottle  579 ml HDPE/EvOH bottle  1000 ml HDPE/EvOH bottle  1200 ml HDPE/EvOH bottle  5000 ml HDPE/EvOH container  5650 ml HDPE/EvOH cannister</p>

	10000 ml HDPE/EvOH container 20000 ml HDPE/EvOH container
Coformulants of concern for national authorizations	N/A
Restrictions related to identity	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

## 2.2 Conclusion

Section B7: The evaluation of the application for **Fenoxinn Max 110 EC** resulted in the decision to grant the authorization. All solo uses applied for were authorised.

## 2.3 Substances of concern for national monitoring

This point is not relevant for authorisation of CHR/H/FETEC-PART B 110 EC

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Flam. Liq. 3 (H226), Asp. Tox. 1 (H304), Skin Irrit. 2 (H315), Skin Sens. 1 (H317), Eye Dam. 1 (H318), STOT RE 2 (H373), Aquatic Acute 1 (H400), Aquatic Chronic 2 (H411)
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS02, GHS05, GHS07, GHS08, GHS09
Signal word:	Danger
Hazard statement(s):	H226 – Flammable liquid and vapour. H304 – May be fatal if swallowed and enters airways. H315 – Causes skin irritation. H317 – May cause an allergic skin reaction. H318 – Causes serious eye damage. H373 – May cause damage to organs (kidneys) through prolonged or repeated exposure. H410 – Very toxic to aquatic life with long lasting effects.*
Precautionary statement(s):	<b><u>WARNING SECTION OF THE LABEL (first page):</u></b> P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P260 – Do not breathe spray. P301 +310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P331: Do NOT induce vomiting. P280 – Wear protective gloves, eye protection/face protection. P302 + P352 – IF ON SKIN: Wash with plenty of water P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  <b><u>Other sections of the label:</u></b> P264 – Wash face, hands and contaminated skin thoroughly after handling. P362: Take off contaminated clothing and wash before reuse. P363: Wash contaminated clothing before reuse.

	<p>P272: Contaminated work clothing should not be allowed out of the workplace.  P405: Store locked up.  P391: Collect spillage.  P501: Dispose of contents/container to ...</p> <p>And P280 as follows:  Operator:  “Wear protective gloves, eye/face protection and work wear during mixing/loading, and protective gloves and work wear during application.”  <i>„Stosować rękawice ochronne, ochronę oczu/twarzy oraz odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu.”</i>  Worker:  “Wear protective gloves and work wear (long trousers, long-sleeve shirt) during inspection.”  <i>„Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem) podczas wchodzenia na teren poddany opryskowi”.</i></p> <p><u>Section First Aid:</u>  P301 +310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.  P331: Do NOT induce vomiting.  P302 + P352 – IF ON SKIN: Wash with plenty of water.  P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER or doctor/physician.</p>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Hazardous ingredients that must be listed on the label: Cloquintocet-mexyl; Hydrocarbons, C10-C13, aromatics,<1% naphthalene; Benzenesulfonic acid, C10-13-(linear)alkyl derivs., calcium salt

Special rule for labelling of plant protection product (PPP):

EUH401	To avoid risks to man and the environment, comply with the instructions for use.
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\* Since the whole formulation is classified as Aquatic Acute 1, H400 and Aquatic Chronic 2, H411, the labelling statement has been unified according to the Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 (See Table 4.1, page 552 of Guidance).

**See Part C for justifications of the toxicological classification and labelling proposals.**

## 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	Cereals - To protect aquatic organisms respect 1 m non-spray buffer zone to surface water bodies.

## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

	N/A
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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
	Exposure: Protective clothing during mixing/loading and gloves during mixing/loading and application. Classification: protective gloves, eye/face protection during mixing/loading.
Worker protection:	
	Based on exposure estimation: Work wear – arms, body and legs covered. Recommendation: protective gloves and work wear when inspecting treated area.
Integrated pest management (IPM)/sustainable use:	
N/A	The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
N/A	N/A
Other specific restrictions	
N/A	N/A

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
N/A	

### 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
N/A	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.	use number from GAP table in 2.6
Environmental protection:		Relevant for use no.
N/A	N/A	N/A

## 2.6 Intended uses (only NATIONAL GAP)

PPP product name: Fenoxinn Max 110 EC/Herbos Max 110 EC  
product code: CHR/H/FETEC-PART B 110 EC  
Active substance 1: Fenoxaprop-P-ethyl  
Active substance 2: -  
Active substance 3: -  
Safener: Cloquintocet-mexyl  
Synergist: -  
Applicant: Innvigo Sp. z o.o.  
Zone(s): Central <sup>(d)</sup>

GAP rev. , date: 2021-01-13  
Formulation type: EC <sup>(a, b)</sup>  
Conc. of as 1: 110 g/l <sup>(c)</sup>  
Conc. of as 2: - <sup>(c)</sup>  
Conc. of as 3: - <sup>(c)</sup>  
Conc. of safener: 55 g/l <sup>(c)</sup>  
Conc. of synergist: - <sup>(c)</sup>  
Professional use: ☒  
Non professional use: ☐

Verified by MS: yes

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use- No. <sup>(e)</sup>	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:  e.g. g safen- er/synergist per ha <sup>(f)</sup>	ZRMs Conclusion
					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			

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	200-300	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	200-300	n/a		

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
(c) g/kg or g/l

(d) Select relevant  
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

1 Numeration necessary to allow references  
2 Use official codes/nomenclatures of EU Member States  
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  
8 The maximum number of application possible under practical conditions of use must be provided.  
9 Minimum interval (in days) between applications of the same product  
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".  
13 PHI - minimum pre-harvest interval  
14 Remarks may include: Extent of use/economic importance/restrictions

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by CMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

### **3 Background of authorization decision and risk management**

#### **3.1 Physical and chemical properties (Part B, Section 2)**

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of yellow, with a intensive characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of 58.55°C. It has auto-ignition temperature of 470°C. In aqueous solution, it has a pH value around 5.35 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 1 years at ambient temperature when stored in HDPE/PA. Its technical characteristics are acceptable for a EC formulation. The intended concentration of use is 0.125% to 0.35%.

#### **3.2 Efficacy (Part B, Section 3)**

The Applicant has submitted data collected from 15 efficacy field trials (8 in winter wheat, 7 in spring barley) carried out in 2020 and 2021 in the North-East EPPO zone within the Central registration zone to evaluate the efficacy of applied:

- solo to the control monocotyledonous weeds/ grass weeds in winter and spring cereals at the proposed label rate:

0.7 L/ha – postemergence application once a season, which are corresponding to 77 g a.s./ha (fenoxaprop-P-etylu),

- in a mixture to the control dicotyledonous and monocotyledonous weeds in winter and spring cereals at the proposed label rate:

0.5 L/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG – postemergence application once a season, which are corresponding to 55 g a.s./ha (fenoxaprop-P-etylu),

0.5 L/ha + 0.4 L/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC – postemergence application once a season, which are corresponding to 55 g a.s./ha (fenoxaprop-P-etylu).

Trials were conducted in different regions in the North-East EPPO zone in Poland where winter wheat and spring barley are grown commercially. The herbicide CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B was applied once per season at the following rates:

0.7 L/ha, which are corresponding to 77 g a.s./ha (fenoxaprop-P-etylu),

0.5 L/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG, which are corresponding to 55 g a.s./ha (fenoxaprop-P-etylu),

0.5 L/ha + 0.4 L/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC, which are corresponding to 55 g a.s./ha (fenoxaprop-P-etylu).

The reference product was not applied.

Tested herbicide was applied at the growth stage in:

BBCH 25-32 in winter wheat,

BBCH 21-31 in spring barley.

#### **3.3 Efficacy data**

The submitted efficacy data (reports from 15 field trials) and additional information fulfill requirements and conditions determined in the following EPPO guidelines:

- PP 1/135 (4) Phytotoxicity assessment

- PP 1/152 (3) Design and analysis of efficacy evaluation trials

- PP 1/181 (3) Conduct and reporting of efficacy evaluation trials including good experimental practice

They were carried out on the field in the conditions of natural agrofag infestation. The efficacy trials were concluded according to the EPPO standards:

- PP 1/93 (3) Weeds in cereals

The studies fulfill also requirements of the Commission Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products.

The formulation of CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B in winter wheat, spring wheat, winter triticale, winter barley and spring barley is EC – Emulsifiable Concentrate and it comprises active substance 110 g/L fenoxaprop-P-etylu. The applicant submitted 15 reports in total showing the results in research into product efficacy carried out in 2020 and 2021 in winter wheat, spring wheat, winter triticale, winter barley and spring barley.

The obtained data in performed trials show that CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B provides benefits against the most important weeds in winter wheat, spring wheat, winter triticale, winter barley and spring barley as shown in the tables below.

The following table describes the effectiveness of weeds:

S (Susceptible)	> 85% (within each trial the average must be higher than 85%)
MS (Moderately Susceptible)	70 – 85%
MT (Moderately Tolerant )	60 – 70%
T (Tolerant)	< 60%

#### **Efficacy in winter wheat**

- at the dose rate 0,7 l/ha CHR/H/FET 110 EC Part B applied solo, the target weed species were categorized as:

- susceptible (S): ALOMY  
- tolerant (T): PAPRH, STEME, VIOAR, CENCY, ANTAR, CAPBP

The effectiveness of the product against APESV has depended on its growth stage. APESV has been moderately susceptible (73,0%) at BBCH 23-39 (2-4 weeks after application) and susceptible (93,1%) 6-10 weeks after application (at BBCH 50-69). In the case of the application of Fenoxin Max 110 EC against APESV, the weed was susceptible 6-10 weeks after the application of the product, when APESV was already in the late stages of vegetation (at the panicle stage and beyond, closer to the natural end of its vegetation). In these circumstances, it is not entirely possible to determine whether APESV dieback was due to the herbicide applied or whether it was at the same time a result of the end of APESV vegetation. However, it remains most plausible that the product was moderately effective against APESV 2-4 weeks after application, which leads to the classification APESV as a medium susceptible weed. It should be mentioned that the product was applied at developmental stages of APESV - BBCH 21-28, other than those commonly recommended (2 to 8 leaves). This information should be clearly incorporated in the label.

- in application of 0,5 L/ha of CHR/H/FETEC 110 EC Part B +25 g/ha Tristar 50 SG/Toraya 50 SG/Triben Super 50 SG/Draco 50 SG, the target weed species were categorized as:

- susceptible (S): STEME  
- moderately susceptible (MS): ALOMY, PAPRH, APESV, CENCY, ANTAR, CAPBP  
- moderately tolerant (MT): VIOAR

- in application of 0,5 L/ha of CHR/H/FETEC 110 EC Part B + 0,4 L/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC, the target weed species were categorized as:

- susceptible (S): STEME  
- moderately susceptible (MS): ALOMY, APESV  
- moderately tolerant: CAPBP  
- tolerant (T): PAPRH, VIOAR, CENCY, ANTAR

#### **Efficacy in spring barley**

- at the dose rate 0,7 l/ha CHR/H/FET 110 EC Part B applied solo, the target weed species were categorized as:

- susceptible (S): AVEFA, ECHCG

- tolerant (T): CENCY, POLCO, VIOAR, CHEAL, GALAP, MATIN, STEME

- in application of 0,5 L/ha of CHR/H/FETEC 110 EC Part B +25 g/ha **Tristar 50 SG**/Toraya 50 SG/Triben Super 50 SG/Draco 50 SG, the target weed species were categorized as:

- susceptible (S): ECHCG, STEME

- moderately susceptible (MS): AVEFA, CENCY, POLCO, CHEAL, GALAP, MATIN

- moderately tolerant (MT): VIOAR

- in application of 0,5 L/ha of CHR/H/FETEC 110 EC Part B + 0,4 L/ha **Galaper 200 EC**/ Fluroherb 200 EC/ Herbistar 200 EC, the target weed species were categorized as:

- susceptible (S): ECHCG, GALAP, STEME

- moderately susceptible (MS): AVEFA, POLCO, MATIN

- moderately tolerant (MT): CENCY

- tolerant (T): VIOAR, CHEAL

Data from winter wheat can be extrapolated on winter barley and winter triticale, while data from spring barley can be extrapolated on spring wheat.

Herbicide CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B have demonstrated good crop tolerance to winter wheat, spring wheat, winter triticale, winter barley and spring barley. Therefore concluded that CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B is safe usage at proposed rate and this support the label claim for the use in winter wheat, spring wheat, winter triticale, winter barley and spring barley.

Undesirable effects are not expected on succeeding crops, adjacent crop, part of plants used for propagating purposes and beneficial organisms.

According to the above, the plant protection product CHR/H/FETEC 110 EC Part B can be approved to the market and use in Poland according to proposed range of use – GAP.

Due to the fact that the spectrum of weeds controlled by CHR/H/FET 110 EC Part A (first formulation - before processing) and CHR/H/FETEC 110 EC Part B (new formulation - after processing/new ingredients) containing fenoxaprop-P-etylu in the cultivation of winter wheat and spring barley is the same like in the cultivation of winter barley, winter triticale and spring wheat. Therefore it can be assumed that the effectiveness of the new formulation CHR/H/FETEC 110 EC Part B will be comparable to the to the first formulation. Based on the submitted new data ( efficacy and selectivity reports) the follow-ing regulation on the label is proposed:

Based on submitted data the following regulation on the label is proposed:

Poland

winter wheat, spring wheat, winter triticale, winter barley and spring barley:

Recommended dose at:

0.7 L/ha – postemergence application once a season, which are corresponding to 77 g a.s./ha (fenoxaprop-P-etylu),

0.5 L/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG – postemergence application once a season, which are corresponding to 55 g a.s./ha (fenoxaprop-P-etylu),

0.5 L/ha + 0.4 L/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC – postemergence application once a season, which are corresponding to 55 g a.s./ha (fenoxaprop-P-etylu).

The product CHR/H/FETEC 110 EC Part B should be use once per season in winter wheat, spring wheat, winter triticale, winter barley and spring barley at spring postemergence. To avoid resistance, products contain active substance with the same group shouldn't be used year after year on the same field.

CHR/H/FETEC 110 EC Part B is to be applied in spring:  
BBCH 20-31 in winter wheat, spring wheat, winter triticale, winter barley and spring barley.

Recommended volume of water 200-300 L/ha  
Recommended medium droplet spraying

Use of CHR/H/FETEC 110 EC Part B according to the proposed GAP does not represent a hazard to rotational crops and does not justify a specific labelling. CHR/H/FETEC 110 EC Part B is not persistent in soil nor is it taken up by succeeding crops.

### **3.3.1 Information on the occurrence or possible occurrence of the development of resistance**

#### **3.3.1 Mode of action**

CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B is a herbicide containing active substance fenoxaprop-P-ethyl 110 g/L. Fenoxaprop-P-ethyl belongs to the Aryloxyphenoxy-propionate ("fop") chemical family. According to HRAC, fenoxaprop-P-ethyl is a Group 1 – inhibition of acetyl CoA carboxylase (legacy A). Fenoxaprop-P-ethyl, once in the plant, is quickly converted into the free D+ acid fenoxaprop-P, which inhibits the biosynthesis of fatty acids. The further formation of cell membranes in the growing points of the weed plants is inhibited eventually causing the plant death. In addition this inhibition of fatty acid biosynthesis causes further changes within the weed plant, such as an increase in soluble sugars and free amino acids in the stem tissues of the grass weed plants and also a reduction in the chlorophyll content as a consequence of the reduction of thylakoid membranes. Based on the comparison of the in vitro efficacy of Fenoxaprop-P-ethyl compared to its free acid it could be shown that the free acid showed the main herbicidal activity. However, due to the significantly reduced uptake of the free acid in vivo and better uptake together with the fast hydrolysis in the plant, Fenoxaprop-P-ethyl is used for the application.

#### **3.3.2 Mechanism of resistance**

CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B is a herbicide containing active substance fenoxaprop-P-ethyl 110 g/L. Fenoxaprop-P-ethyl belongs to the Aryloxyphenoxy-propionate ("fop") chemical family. According to HRAC, fenoxaprop-P-ethyl is a Group 1 – inhibition of acetyl CoA carboxylase (legacy A). According HRAC Resistance of weed biotypes to herbicides is a consequence of naturally occurring mutations and evolutionary processes. Individuals within a species that are best adapted and not susceptible to a particular practice, such as application of a specific herbicide, are selected for and will increase in the population. Mitigating or slowing the evolution of herbicide resistance relies on reducing selection pressure for resistance through application of a diversity of weed management practices. There are two general categories of resistance mechanisms, target-site resistance and non-target-site resistance. Target-site resistance inhibits herbicide action by: a change in structure of the target protein that decreases herbicide binding to its usual site of action; an increase in target protein expression; or an increase in copies of the gene containing the target site. Non-target-site resistance includes decreased translocation of an herbicide to its site of action, increased metabolic detoxification of an herbicide, and sequestration or immobilization of an herbicide in a part of the plant so it cannot reach its site of action. According to EPPO PP 1/213 (4) Resistance risk analysis weeds usually only produce one generation per year and development of resistance is usually a relatively slow process. It is difficult to class any weed species as inherently more or less likely to develop resistance to a particular herbicide.

#### **3.3.3 Evidence of resistance**

CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B is a herbicide containing active substance fenoxaprop-P-ethyl 110 g/L. Fenoxaprop-P-ethyl belongs to the Aryloxyphenoxy-propionate ("fop") chemical family. According to HRAC, fenoxaprop-P-ethyl is a Group 1 – inhibition of acetyl CoA carboxylase (legacy A). This group of herbicides is quite well known and has been applied commercially for decades.

According to Ian Heap's website (<http://www.weedscience.org>):

Table 1. Herbicide resistance cases to fenoxaprop-P-ethyl

Year	Species	Country	Actives	Situations
1982	<i>Alopecurus myosuroides</i>	United Kingdom	clodinafop-propargyl, diclofop-methyl, fluazifop-butyl, quizalofop-ethyl, fenoxaprop-ethyl, sethoxydim, clethodim, cycloxydim, pinoxaden	Cereals, Wheat, Canola
1983	<i>Alopecurus myosuroides</i>	Germany	fenoxaprop-ethyl, isoproturon, chlorotoluron	Wheat, Sugar beets
1986	<i>Avena fatua</i>	South Africa	clodinafop-propargyl, diclofop-methyl, fluazifop-butyl, fenoxaprop-ethyl, sethoxydim, tralkoxydim, sulfosulfuron, imazamox, iodosulfuron-methyl-Na	Wheat
1990	<i>Avena fatua</i>	Canada	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, sethoxydim, clethodim, tralkoxydim	Spring Barley, Cropland, Wheat, Canola
1990	<i>Avena fatua</i>	Canada	fenoxaprop-ethyl, sethoxydim	Spring Barley, Wheat, Canola
1990	<i>Avena fatua</i>	United States	diclofop-methyl, fenoxaprop-ethyl	Wheat
1991	<i>Avena fatua</i>	Australia	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, clethodim	Spring Barley, Lentils, Wheat, Lupins, Canola, Chickpea, Faba beans
1991	<i>Avena fatua</i>	Canada	diclofop-methyl, quizalofop-ethyl, fenoxaprop-ethyl, tralkoxydim	Wheat, Canola
1991	<i>Setaria viridis</i>	Canada	diclofop-methyl, fenoxaprop-ethyl, sethoxydim, tralkoxydim	Spring Barley, Cropland, Wheat, Canola
1991	<i>Sorghum halepense</i>	United States	fluazifop-butyl, quizalofop-ethyl, fenoxaprop-ethyl	Cotton, Cropland
1991	<i>Avena fatua</i>	United States	diclofop-methyl, fenoxaprop-ethyl	Cereals, Wheat
1991	<i>Avena fatua</i>	United States	diclofop-methyl, quizalofop-ethyl, fenoxaprop-ethyl, sethoxydim, pinoxaden	Wheat
1992	<i>Setaria viridis</i>	Canada	diclofop-methyl, fenoxaprop-ethyl, sethoxydim, tralkoxydim, ethalfluralin, trifluralin	Spring Barley, Wheat, Canola, Flax
1992	<i>Avena fatua</i>	United States	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl	Cereals, Wheat
1993	<i>Alopecurus myosuroides</i>	France	haloxyfop-methyl, clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, sethoxydim, cycloxydim	Wheat
1993	<i>Phalaris minor</i>	Israel	fenoxaprop-ethyl	Wheat



1 9 9 3	<i>Avena sterilis</i>	United Kingdom	fluazifop-butyl, fenoxaprop-ethyl, tralkoxydim, imazamethabenz-methyl, flamprop-methyl, iodosulfuron-methyl-Na, mesosulfuron-methyl	Cereals, Wheat
1 9 9 4	<i>Avena fatua</i>	Canada	fenoxaprop-ethyl, imazamethabenz-methyl, rimsulfuron, flamprop-methyl	Spring Barley, Cropland, Wheat, Canola
1 9 9 4	<i>Echinochloa colona</i>	Costa Rica	fenoxaprop-ethyl	Rice
1 9 9 4	<i>Avena fatua</i>	United Kingdom	fluazifop-butyl, fenoxaprop-ethyl, tralkoxydim, imazamethabenz-methyl, flamprop-m, mesosulfuron-methyl, pinoxaden, pyroxsulam	Cereals, Wheat, Canola
1 9 9 4	<i>Setaria faberi</i>	United States	fluazifop-butyl, quizalofop-ethyl, fenoxaprop-ethyl, sethoxydim, clethodim	Soybean
1 9 9 5	<i>Lolium perenne ssp. multiflorum</i>	United States	diclofop-methyl, fenoxaprop-ethyl, chlorsulfuron	Wheat
1 9 9 6	<i>Avena fatua</i>	Belgium	clodinafop-propargyl, fenoxaprop-ethyl	Winter wheat
1 9 9 6	<i>Alopecurus myosuroides</i>	Belgium	clodinafop-propargyl, fenoxaprop-ethyl	Winter wheat
1 9 9 6	<i>Alopecurus myosuroides</i>	Belgium	clodinafop-propargyl, propaquizafop, fenoxaprop-ethyl, flupyrsulfuron-methyl-Na, atrazine, chlorotoluron, pendimethalin	Winter wheat
1 9 9 6	<i>Setaria viridis</i>	Canada	diclofop-methyl, fenoxaprop-ethyl, sethoxydim	Wheat
1 9 9 6	<i>Setaria viridis</i>	Canada	fenoxaprop-ethyl, sethoxydim	Spring Barley, Cropland, Wheat, Canola
1 9 9 6	<i>Setaria viridis</i>	Canada	fenoxaprop-ethyl, trifluralin	Spring Barley, Wheat, Canola, Peas
1 9 9 6	<i>Avena fatua</i>	Canada	fenoxaprop-ethyl, imazamethabenz-methyl, tri-allate	Spring Barley, Lentils, Wheat, Canola
1 9 9 6	<i>Avena sterilis ssp. ludoviciana</i>	France	fenoxaprop-ethyl	Wheat
1 9 9 6	<i>Avena fatua</i>	France	fenoxaprop-ethyl	Wheat
1 9 9 6	<i>Phalaris paradoxa</i>	Mexico	clodinafop-propargyl, fenoxaprop-ethyl, tralkoxydim, pinoxaden	Wheat
1 9 9 6	<i>Phalaris minor</i>	Mexico	clodinafop-propargyl, fluazifop-butyl, fenoxaprop-ethyl, sethoxydim, tralkoxydim, pinoxaden	Wheat
1 9 9 6	<i>Alopecurus myosuroides</i>	Netherlands	clodinafop-propargyl, fenoxaprop-ethyl, isoproturon, chlorotoluron	Winter wheat
1	<i>Digitaria ischaemum</i>	Uni-	fenoxaprop-ethyl	Turf

9 9 6		ted States		
1 9 9 7	<i>Phalaris paradoxa</i>	Au- stralia	fenoxaprop-ethyl, sethoxydim	Wheat, Winter pulses
1 9 9 7	<i>Urochloa plantaginea</i> (= <i>Brachiaria plantagi- nea</i> )	Brazil	haloxyfop-methyl, diclofop-methyl, fluazifop-butyl, propaquizafop, quizalo- fop-ethyl, fenoxaprop-ethyl, sethoxydim, butoxydim	Soybean
1 9 9 7	<i>Avena fatua</i>	Ca- nada	fenoxaprop-ethyl, imazamethabenz-methyl, tri-allate, flamprop-methyl	Wheat
1 9 9 7	<i>Avena sterilis</i>	Tur- key	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, tralkoxydim	Wheat
1 9 9 8	<i>Avena fatua</i>	Ca- nada	fenoxaprop-ethyl, imazamethabenz-methyl, tri-allate	Cereals, Wheat, Canola, Peas
1 9 9 8	<i>Echinochloa colona</i>	Costa Rica	fenoxaprop-ethyl, azimsulfuron, propanil	Rice
1 9 9 8	<i>Snowdenia polystachya</i>	Ethio- pia	fenoxaprop-ethyl	Wheat
1 9 9 8	<i>Avena fatua</i>	Mexi- co	clodinafop-propargyl, diclofop-methyl, fluazifop-butyl, fenoxaprop-ethyl, sethoxydim, tralkoxydim, cycloxydim	Wheat
1 9 9 8	<i>Echinochloa phyllopo- gon</i> (= <i>E. oryzicola</i> )	Uni- ted States	fenoxaprop-ethyl	Rice
1 9 9 9	<i>Sorghum bicolor ssp. drummondii</i> (= <i>Sorghum sudanese</i> )	Bo- livia	haloxyfop-methyl, fluazifop-butyl, quizalofop-ethyl, fenoxaprop-ethyl	Soybean
1 9 9 9	<i>Alopecurus myosuroides</i>	Net- her- lands	clodinafop-propargyl, fenoxaprop-ethyl, cycloxydim, penoxsulam	Winter wheat
1 9 9 9	<i>Phalaris minor</i>	South Afri- ca	haloxyfop-methyl, clodinafop-propargyl, diclofop-methyl, propaquizafop, quizalofop-ethyl, fenoxaprop-ethyl, sulfosulfuron, iodosulfuron-methyl-Na, mesosulfuron-methyl	Pastures, Wheat
1 9 9 9	<i>Setaria viridis</i> var. <i>major</i> (= var. <i>robusta-alba</i> , var. <i>robustapurpurea</i> )	Uni- ted States	fluazifop-butyl, fenoxaprop-ethyl	Soybean
1 9 9 9	<i>Setaria viridis</i> var. <i>major</i> (= var. <i>robusta-alba</i> , var. <i>robustapurpurea</i> )	Uni- ted States	fluazifop-butyl, fenoxaprop-ethyl, sethoxydim	Soybean
2 0 0 0	<i>Ischaemum rugosum</i>	Co- lom- bia	fenoxaprop-ethyl	Rice
2 0 0 0	<i>Echinochloa colona</i>	Nica- ragua	fenoxaprop-ethyl	Rice
2 0 0 0	<i>Echinochloa crus-galli</i> var. <i>crus-galli</i>	Uni- ted States	cyhalofop-butyl, fenoxaprop-ethyl, thiobencarb/benthiocarb, molinate	Rice
2 0 0 0	<i>Echinochloa phyllopo- gon</i> (= <i>E. oryzicola</i> )	Uni- ted	cyhalofop-butyl, fenoxaprop-ethyl, thiobencarb/benthiocarb, molinate	Rice

0		States		
0				
2				
0	<i>Alopecurus myosuroides</i>	Denmark	fenoxaprop-ethyl	Winter wheat
0				
1				
2	<i>Alopecurus myosuroides</i>	Denmark	clodinafop-propargyl, fenoxaprop-ethyl, cycloxydim, flupyr-sulfuron-methyl-Na, pendimethalin, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Winter wheat
0				
1	<i>Echinochloa crus-galli var. crus-galli</i>	Thailand	cyhalofop-butyl, quizalofop-ethyl, fenoxaprop-ethyl	Rice
2				
0	<i>Phalaris minor</i>	United States	fluazifop-butyl, fenoxaprop-ethyl, sethoxydim, clethodim	Onions
0				
1				
2	<i>Digitaria ciliaris</i>	Brazil	haloxyfop-methyl, cyhalofop-butyl, fluazifop-butyl, propaquizafop, fenoxaprop-ethyl, sethoxydim	Soybean
0				
0	<i>Leptochloa chinensis</i>	Thailand	quizalofop-ethyl, fenoxaprop-ethyl, profoxydim	Rice
2				
0	<i>Avena fatua</i>	United States	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, tralkoxydim	Cropland, Wheat, Sugar beets
0				
2	<i>Eleusine indica</i>	Brazil	cyhalofop-butyl, fenoxaprop-ethyl, sethoxydim	Soybean
0				
0	<i>Alopecurus myosuroides</i>	France	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, sethoxydim, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
3				
2	<i>Alopecurus myosuroides</i>	Germany	fluazifop-butyl, fenoxaprop-ethyl, clethodim, cycloxydim	Winter wheat, Sugar beets
0				
0	<i>Phalaris minor</i>	Iran	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, tralkoxydim, pinoxaden	Winter wheat
4				
2	<i>Phalaris paradoxa</i>	Israel	haloxyfop-methyl, clodinafop-propargyl, diclofop-methyl, fluazifop-butyl, fenoxaprop-ethyl, clethodim, tralkoxydim, cycloxydim	Wheat, Peas
0				
0	<i>Ischaemum rugosum</i>	Venezuela	fenoxaprop-ethyl, imazethapyr, imazapyr, pyribenzoxim, bispyribac-sodium, propanil, profoxydim	Rice
4				
2	<i>Setaria viridis</i>	United States	diclofop-methyl, fluazifop-butyl, fenoxaprop-ethyl, sethoxydim, pinoxaden	Spring Barley, Wheat, Canola, Peas
0				
0	<i>Echinochloa colona</i>	Bolivia	haloxyfop-methyl, cyhalofop-butyl, fluazifop-butyl, fenoxaprop-ethyl	Rice, Soybean
6				
2	<i>Phalaris minor</i>	India	clodinafop-propargyl, fenoxaprop-ethyl, sulfosulfuron, isoproturon, mesosulfuron-methyl, pinoxaden, pyroxsulam	Wheat
0				
0	<i>Avena sterilis ssp. ludoviciana</i>	Iran	haloxyfop-methyl, clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, sethoxydim, tralkoxydim, pinoxaden	Winter wheat, Canola
6				
2	<i>Avena sterilis</i>	Israel	clodinafop-propargyl, fenoxaprop-ethyl, cycloxydim	Wheat
0				

6				
2006	<i>Echinochloa phyllopogon</i> (= <i>E. oryzicola</i> )	South Korea	cyhalofop-butyl, fenoxaprop-ethyl, pyribenzoxim, pyriminobac-methyl, bispyribac-sodium, azimsulfuron, bensulfuron-methyl, pyrazosulfuron-ethyl, imazosulfuron, halosulfuron-methyl, metamifop	Rice
2007	<i>Alopecurus japonicus</i>	China	haloxyfop-methyl, clodinafop-propargyl, fenoxaprop-ethyl, pinoxaden	Winter wheat, Canola
2007	<i>Alopecurus myosuroides</i>	Germany	fenoxaprop-ethyl, isoproturon, chlorotoluron, flufenacet, mesosulfuron-methyl, pinoxaden	Wheat
2008	<i>Echinochloa crus-galli</i> var. <i>crus-galli</i>	South Korea	cyhalofop-butyl, fenoxaprop-ethyl, pyribenzoxim, pyriminobac-methyl, bispyribac-sodium, azimsulfuron, bensulfuron-methyl, pyrazosulfuron-ethyl, imazosulfuron, halosulfuron-methyl, metamifop, flucetosulfuron	Rice
2009	<i>Lolium persicum</i>	Canada	fenoxaprop-ethyl, tralkoxydim, pinoxaden	Spring Barley, Wheat
2009	<i>Echinochloa crus-galli</i> var. <i>crus-galli</i>	Egypt	fenoxaprop-ethyl	Rice
2009	<i>Apera spica-venti</i>	Germany	fenoxaprop-ethyl, sulfosulfuron, isoproturon, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden, pyroxsulam	Spring Barley, Winter wheat
2009	<i>Alopecurus myosuroides</i>	Germany	fenoxaprop-ethyl, cycloxydim, flupyrsulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Cereals
2009	<i>Avena fatua</i>	Germany	fenoxaprop-ethyl, cycloxydim, flupyrsulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Sugar beets
2009	<i>Avena sterilis</i>	Greece	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl, tralkoxydim, pinoxaden	Wheat
2009	<i>Alopecurus myosuroides</i>	Italy	clodinafop-propargyl, fenoxaprop-ethyl, pinoxaden	Durum wheat
2009	<i>Leptochloa panicoides</i>	United States	cyhalofop-butyl, fenoxaprop-ethyl	Rice
2009	<i>Avena fatua</i>	United States	fenoxaprop-ethyl	Cereals
2010	<i>Avena fatua</i>	Argentina	clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl	Spring Barley, Wheat
2010	<i>Beckmannia syzigachne</i>	China	fenoxaprop-ethyl	Winter wheat
2010	<i>Sclerochloa kengiana</i>	China	clodinafop-propargyl, fenoxaprop-ethyl	Winter wheat
2010	<i>Echinochloa crus-galli</i> var. <i>crus-galli</i>	China	quizalofop-ethyl, fenoxaprop-ethyl	Rice, Soybean
2010	<i>Alopecurus aequalis</i>	China	clodinafop-propargyl, fenoxaprop-ethyl	Wheat

2 0 1 0	<i>Apera spica-venti</i>	Poland	fenoxaprop-ethyl, pinoxaden	Winter wheat
2 0 1 1	<i>Digitaria sanguinalis</i>	Canada	fluazifop-butyl, quizalofop-ethyl, fenoxaprop-ethyl, sethoxydim, clethodim	Carrots, Onions
2 0 1 1	<i>Apera spica-venti</i>	Poland	fenoxaprop-ethyl, sulfosulfuron, chlorsulfuron, sulfometuron-methyl, pinoxaden	Winter wheat
2 0 1 1	<i>Alopecurus myosuroides</i>	Poland	fenoxaprop-ethyl, pinoxaden	Winter wheat
2 0 1 1	<i>Avena fatua</i>	Poland	fenoxaprop-ethyl, pinoxaden	Spring Barley, Spring wheat
2 0 1 1	<i>Avena fatua</i>	Poland	fenoxaprop-ethyl, metsulfuron-methyl, sulfometuron-methyl, iodosulfuron-methyl-Na, pinoxaden, propoxycarbazone-Na	Spring Barley, Spring wheat
2 0 1 1	<i>Alopecurus myosuroides</i>	Sweden	clodinafop-propargyl, fenoxaprop-ethyl, cycloxydim	Winter wheat
2 0 1 1	<i>Alopecurus myosuroides</i>	Sweden	fenoxaprop-ethyl, flupyr-sulfuron-methyl-Na, prosulfocarb, pyroxsulam	Wheat
2 0 1 1	<i>Avena fatua</i>	Turkey	diclofop-methyl, fenoxaprop-ethyl, tralkoxydim	Wheat
2 0 1 1	<i>Echinochloa crus-galli</i> var. <i>crus-galli</i>	United States	fenoxaprop-ethyl, imazethapyr, propanil, quinclorac (MOA in monocots), imazamox	Rice
2 0 1 2	<i>Avena fatua</i>	Canada	fenoxaprop-ethyl, tralkoxydim	Wheat, Winter barley
2 0 1 2	<i>Avena fatua</i>	Germany	clodinafop-propargyl, fenoxaprop-ethyl, pinoxaden	Sugar beets
2 0 1 2	<i>Alopecurus myosuroides</i>	Poland	fenoxaprop-ethyl, sulfometuron-methyl, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Winter wheat
2 0 1 2	<i>Leptochloa chinensis</i>	South Korea	cyhalofop-butyl, fenoxaprop-ethyl, metamifop	Rice
2 0 1 2	<i>Avena fatua</i>	United States	fenoxaprop-ethyl, mesosulfuron-methyl	Wheat
2 0 1 4	<i>Polypogon fugax</i>	China	clodinafop-propargyl, fluazifop-butyl, quizalofop-ethyl, fenoxaprop-ethyl, sethoxydim, clethodim, pinoxaden	Wheat, Canola
2 0 1 4	<i>Alopecurus aequalis</i>	China	quizalofop-ethyl, fenoxaprop-ethyl, nicosulfuron, flucarbazone-Na, mesosulfuron-methyl, penoxsulam, pinoxaden	Wheat
2 0 1 4	<i>Alopecurus japonicus</i>	China	fenoxaprop-ethyl, pyribenzoxim, sulfosulfuron, nicosulfuron, mesosulfuron-methyl, pyroxsulam	Wheat
2	<i>Phalaris brachystachys</i>	Iran	haloxyfop-methyl, clodinafop-propargyl, diclofop-methyl, fenoxaprop-ethyl	Winter wheat

0 1 4				
2 0 1 4	<i>Avena fatua</i>	New Zealand	haloxyfop-methyl, fenoxaprop-ethyl	Wheat, Clover
2 0 1 4	<i>Alopecurus myosuroides</i>	Sweden	fenoxaprop-ethyl, cycloxydim, flupyr-sulfuron-methyl-Na, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Spring wheat, Winter wheat, Winter barley
2 0 1 5	<i>Avena fatua</i>	Canada	quizalofop-ethyl, fenoxaprop-ethyl, imazamethabenz-methyl, imazapyr, sulfentrazone, tri-allate, pyroxsulfone	Spring wheat
2 0 1 5	<i>Phalaris minor</i>	Pakistan	fenoxaprop-ethyl	Wheat
2 0 1 5	<i>Phalaris brachystachys</i>	Syria	clodinafop-propargyl, fenoxaprop-ethyl	Wheat, Potatoes, Faba beans
2 0 1 5	<i>Phalaris paradoxa</i>	Syria	clodinafop-propargyl, fenoxaprop-ethyl	Wheat, Potatoes, Faba beans
2 0 1 5	<i>Avena fatua</i>	Syria	clodinafop-propargyl, fenoxaprop-ethyl	Wheat, Potatoes, Faba beans
2 0 1 6	<i>Digitaria insularis</i>	Brazil	haloxyfop-methyl, fenoxaprop-ethyl	Soybean
2 0 1 6	<i>Apera spica-venti</i>	Denmark	fenoxaprop-ethyl, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Wheat
2 0 1 6	<i>Lolium perenne ssp. multiflorum</i>	United States	cyhalofop-butyl, fluazifop-butyl, fenoxaprop-ethyl, sethoxydim, clethodim, paraquat, glyphosate, imazamox, mesosulfuron-methyl	Alfalfa, Orchards
2 0 1 7	<i>Eleusine indica</i>	Brazil	haloxyfop-methyl, fenoxaprop-ethyl, glyphosate	Corn (maize), Cotton, Soybean, Beans
2 0 1 7	<i>Sorghum halepense</i>	Serbia	haloxyfop-methyl, fluazifop-butyl, propaquizafop, quizalofop-ethyl, fenoxaprop-ethyl	Soybean
2 0 2 0	<i>Digitaria insularis</i>	Brazil	haloxyfop-methyl, fenoxaprop-ethyl, glyphosate	Soybean

### 3.3.4 Cross-resistance

According to <https://hracglobal.com/files/Herbicide-Cross-Resistance-and-Multiple-Resistance-in-Plants.pdf>

Cross resistance is defined as the expression of a genetically-endowed mechanism conferring the ability to withstand herbicides from different chemical classes. There are two broad cross resistance categories; target site cross resistance and non-target site cross resistance.

Target site cross resistance occurs when a change at the biochemical site of action of one herbicide also confers resistance to herbicides from a different chemical class that inhibit the same site of action in the plant. Target site cross resistance does not necessarily result in resistance to all herbicide classes with a similar mode of action or indeed all herbicides within a given herbicide class.

Non target site cross resistance is defined as cross resistance to dissimilar herbicide classes conferred by a

mechanism(s) other than resistant enzyme target sites. Until recently documented for *L. rigidum* and *A. myosuroides*, non-target site cross resistance was largely unknown in herbicide-resistant weeds but is well known in the insecticide resistance literature (Brattsten et al., 1986; Georgiou, 1986).

Cross resistance occurs mainly in the group of ALS inhibitors, acetyl-CoA carboxylase (ACCase)-inhibitors and photosystem two (PS2)-inhibitors.

Target site cross resistance to ACCase inhibiting herbicides

During the 1970s and 1980s, two chemically dissimilar herbicide groups, the aryloxyphenoxypropionic acid (APP) and cyclohexanedione (CHD) herbicides, which target the plastid enzyme ACCase, were commercially developed and widely adopted. These herbicides are lethal to many Gramineae but are harmless to dicot species and have therefore become widely employed for grass weed control. Following widespread usage of ACCase-inhibiting herbicides, resistance to these modern generation graminicides has become extensive in *L. rigidum* in Australia and is developing rapidly in the closely related *L. multiflorum* in Oregon, in wild oats (*Avena* spp.) in Australia and N. America, and in other species (for a review of resistance to ACCase herbicides see Devine and Shimabukuro, 1994). In *L. rigidum* in Australia, and *L. multiflorum* in North America, many ACCase target site-based resistant biotypes have appeared (Stanger and Appleby, 1989; Holtum and Powles, 1991; Gronwald et al., 1992; Tardif and Powles, 1993). In *L. rigidum*, selection either with an APP herbicide (Holtum and Powles, 1991), or a CHD herbicide (Tardif et al., 1993), has led to target site cross resistance to both the APP and HD herbicides, however in both cases, the level of resistance to APPs is greater than that to CHDs (Table 4). It is evident from the data collated in Table 4 that different resistant *L. rigidum* biotypes possessing resistant ACCase exhibit different patterns of resistance at the whole plant level and in ACCase assays (Tardif and Powles, 1993). Many, but not all, *L. rigidum* biotypes exhibit target site cross resistance across the APP and CHD herbicide chemistries. In contrast, a biotype of *L. multiflorum* selected with diclofop-methyl and with an ACCase resistant to APP herbicides shows no target site cross resistance to the CHD herbicides (Gronwald et al., 1992). Two biotypes of *A. myosuroides* (Mason and Otmoor) have been documented as highly resistant to the APP herbicides as a result of resistant ACCase (Hall, Moss and Powles, unpublished). The ACCase from these biotypes is also resistant to CHD herbicides. Resistance to APP herbicides in several biotypes of the wild oat species *Avena fatua* and *Avena sterilis* is also endowed by resistant forms of the ACCase enzyme. In these cases, there are varying degrees of target site cross resistance to the CHD herbicides, ranging from none to moderate (Maneechote et al., 1994; Maneechote, Preston and Powles, unpublished). These levels of target site cross resistance to the CHD herbicides at the whole plant level correlate with the level of resistance displayed by ACCase from these biotypes (Maneechote, Preston and Powles, unpublished). From the foregoing it is clear that target site-based resistance to ACCase herbicides does not always lead to cross resistance to other herbicides with the same site of action. This is the expected result where herbicides from different chemical classes bind to overlapping, but not identical sites on the target enzyme (see also (a) above and (c) below). This is likely, although not yet established at the molecular level, for APP and CHD herbicides interacting with ACCase. The patterns of resistance of ACCase to herbicides can be strikingly different even among resistant biotypes of the same species as can be seen from Table 4. For example, among biotypes of *L. rigidum*, resistance to haloxyfop can range from moderate to high, and resistance to sethoxydim can range from nonexistent to moderate. Therefore, we suggest the differences in target site cross resistance are the result of selection for different mutations of the ACCase gene in different resistant populations. Evidence exists from maize cell lines that different alleles at the same locus encode different resistant forms of ACCase with different levels of target site cross resistance (Marshall et al., 1992). There remains a wealth of valuable information to be obtained from these various ACCase mutants. While the ACCase gene has recently been sequenced from a number of plant species (Roessler and Ohlrogge, 1993; Ashton et al., 1994; Ellborough et al., 1994; Shorrosh et al., 1994) there is, as yet, no specific knowledge of herbicide binding site(s) within the CCase enzyme.

The various different herbicide resistant ACCase mutants (Table 4) will be very useful in elucidating herbicide binding and the specific mutations which endow resistance while retaining enzyme functionality. A second site of action has been proposed for APP and CHD herbicides. These herbicides cause a rapid depolarization of plant cell membrane potentials by allowing the influx of protons (Lucas et al., 1984; Shimabukuro, 1990). The maintenance of an electrogenic potential is vital to survival of the cells, however, the importance of the herbicide-induced depolarization of the membrane potential as a herbicidal mode of action has been questioned (DiTomaso et al., 1991). Also, the relevance of the herbicide-induced depolarization of the membrane potential to the field performance of these herbicides is entirely unknown. Cells from root tips and coleoptiles of some biotypes of *L. rigidum* resistant to APP and CHD herbicides are able to re-establish the membrane potential following removal of herbicide from the bathing solution (Häusler et al., 1991; Holtum et al., 1991; Shimabukuro and Hoffer, 1992). This ability to repolarize the membrane potential following removal of the herbicide is not observed with susceptible biotypes. Similar results have been obtained with a herbicide-resistant biotype of *Avena fatua* (Devine et al., 1993), however, in other resistant biotypes of *A. fatua* and *A. sterilis* repolarization of the membrane potential does not occur following removal of the herbicide (Maneechote et al., 1994; Maneechote, Preston and Powles, unpublished). Repolarization of the membrane potential occurred in resistant *L. rigidum* biotypes irrespective of the possession or absence of a resistant ACCase. Repolarization is pH dependent even in susceptible biotypes (DiTomaso, 1993; Holtum et al., 1994; Maneechote, Preston and Powles, unpublished). The biotypes of *L. rigidum* which show repolarization of the membrane potential following removal of the herbicide also displayed a reduced ability to acidify the external solution bathing roots or coleoptiles (Häusler et al., 1991; DiTomaso, 1993). DiTomaso (1993) claimed a direct connection between the differential abilities of the resistant *L. rigidum* biotypes to acidify the external medium and the repolarization of the membrane potential following removal of the herbicide. In contrast to the above, the biotype of *A. fatua* displaying the membrane repolarization phenomenon acidifies the external medium at the same rate as the susceptible biotype (Devine et al., 1993). There is still a myriad of unsolved questions regarding the repolarization of the membrane potential and its role, if any, in resistance to APP and CHD herbicides (see Holtum et al., 1994). What is clear is that there may be a fundamental difference in membrane properties of some resistant biotypes of *L. rigidum* compared to the susceptible biotypes (Häusler et al., 1991). What relevance this has to herbicide resistance is unclear.

#### Non target site cross resistance to ACCase inhibiting herbicides

Over the past decade in Australia, the ACCaseinhibiting herbicide diclofop-methyl has been annually applied to millions of hectares of cereal crop to control *L. rigidum* and wild *Avena* species. Since the first reports of *L. rigidum* resistant to diclofop-methyl (Heap and Knight, 1982; 1986; 1990), at least two thousand field populations have developed resistance. Similarly, in laboratory experiments, (Matthews and Powles, unpublished) resistance to diclofop-methyl was selected in as little as three generations from an initially susceptible population following application of diclofop-methyl at agriculturally-relevant rates. Many of the *L. rigidum* biotypes selected with and resistant to diclofop-methyl do not contain a resistant ACCase (Matthews et al., 1990; Holtum et al., 1991). Extensive studies have been conducted with one such biotype (SLR31) to identify the basis of non target site resistance. This biotype exhibits a modest increase in the rate of diclofop-methyl metabolism (Holtum et al., 1991). The rate of metabolism of diclofop-acid, the herbicidally-active form, occurs at about 1.5 times the rate observed in a susceptible biotype. An increase in the rate of metabolism of this order should provide, at least, lowlevel resistance to diclofop-methyl – however, the overall contribution that metabolism makes to diclofop-methyl resistance in SLR31 is difficult to assess. A considerable proportion of the diclofop acid, about 20 percent in SLR31 and 30 percent in susceptible biotypes, remains un-metabolized even 192 h after treatment (Holtum et al., 1991). The location of this remaining herbicide is not known, however, we speculate that it has been sequestered away from the metabolizing enzymes, and the active site (Holtum et al., 1991; Holtum et al.,



1994). Not all of the metabolism products of diclofop-methyl in *L. rigidum* have been identified, however, glucose conjugates of both arylhydroxy diclofop and diclofop acid have been observed (Shimabukuro and Hoffer, 1991; Preston, unpublished). SLR31 produced more glucose conjugates of arylhydroxy diclofop than did the susceptible biotype (Preston, unpublished), suggesting the involvement of a Cyt P450 in the enhanced metabolism of diclofop in this biotype. Despite these observations, in pot experiments the level of diclofop-methyl resistance in SLR31 is not altered by the addition of the cytochrome P450 inhibitors 1-aminobenzotriazole (ABT), piperonyl butoxide (PBO), or tetracyclis (Tardif, Preston and Powles, unpublished). Differences in diclofop metabolism between SLR31 and susceptible biotypes do not appear to be due to secondary differences between herbicide affected and unaffected plants as other *L. rigidum* biotypes (SLR3 and WLR96) with ACCase enzyme-based resistance to diclofop, show no increase in diclofop metabolism (Tardif et al., 1993; Tardif, Preston, Holtum and Powles, unpublished). In addition, this biotype also displays a membrane recovery response whose relationship to resistance is uncertain (Häusler et al., 1991; Shimabukuro and Hoffer, 1992). Studies to identify the precise nature of non target site cross resistance in this biotype are continuing in our laboratory. A number of biotypes of *A. myosuroides* exhibit varying levels of resistance to diclofop-methyl and fenoxaprop-ethyl (Moss, 1992). Two biotypes, Peldon A1 and Lincs. E1, from the U.K. have been examined and are resistant to the APP herbicides diclofopmethyl and fenoxaprop-ethyl, and the CHD herbicide tralkoxydim (Moss, 1990; Hall, Moss and Powles, unpublished). Both resistant biotypes show enhanced metabolism of diclofop-methyl and fenoxaprop-ethyl. Rates of diclofop acid detoxification in the resistant biotypes (Peldon A1 and Lincs. E1) are 1.6 times faster than in the susceptible biotype (Hall, Moss and Powles, unpublished). Similarly, the rate of metabolism of fenoxaprop acid is about two times faster in these two resistant biotypes compared to the susceptible (Hall, Moss and Powles, unpublished). These biotypes also show increased metabolism of the substituted urea herbicides chlorotoluron and isoproturon (Kemp and Caseley, 1987; Kemp et al., 1990). It appears likely that enhanced metabolism is the common mechanism of herbicide resistance operating in the Peldon A1 biotype (Kemp et al., 1990).

### 3.3.5 Sensitivity data

Applicant didn't conduct separately trials for sensitivity data, this data was evaluated in efficacy trials. The 15 field trials use were established in order to determine the sensitivity of weeds in winter wheat and spring barley. The CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B was tested in postemergence application in winter wheat and spring barley for the control of mono and dicot weeds. Detailed studies on the weeds sensitivity are submitted and summarised in 3.2 Efficacy data (KCP 6.2).

### 3.3.6 Use pattern

Herbicide CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B have demonstrated good crop tolerance to winter wheat, spring wheat, winter triticale, winter barley and spring barley. Therefore concluded that CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B is safe usage at proposed rate and this support the label claim for the use in winter wheat, spring wheat, winter triticale, winter barley and spring barley.

Undesirable effects are not expected on succeeding crops, adjacent crop, part of plants used for propagating purposes and beneficial organisms.

According to the above, the plant protection product CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B can be approved to the market and use in Poland according to proposed range of use – GAP.

Based on submitted data the following regulation on the label is proposed:

Poland

winter wheat, spring wheat, winter triticale, winter barley and spring barley:

Recommended dose at:

0.7 L/ha – postemergence application once a season in winter wheat, spring wheat, winter triticale, winter barley and spring barley, which are corresponding to 77 g a.s./ha (fenoxaprop-P-etylu),

0.5 L/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG – postemergence application once a season in winter wheat, spring wheat, winter triticale, winter barley and spring barley, which are corresponding to 55 g a.s./ha (fenoxaprop-P-etylu),

0.5 L/ha + 0.4 L/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC – postemergence application once a season in winter wheat, spring wheat, winter triticale, winter barley and spring barley, which are corresponding to 55 g a.s./ha (fenoxaprop-P-etylu).

The product CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B should be use once per season in winter wheat, spring wheat, winter triticale, winter barley and spring barley at spring postemergence. To avoid resistance, products contain active substance with the same group shouldn't be used year after year on the same field.

CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B is to be applied in spring:  
BBCH 20-31 in winter wheat, winter triticale, winter barley, spring barley, spring wheat

Recommended volume of water 200-300 L/ha

Recommended medium droplet spraying

Use of CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B according to the proposed GAP does not represent a hazard to rotational crops and does not justify a specific labelling. CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B is not persistent in soil nor is it taken up by succeeding crops.

### **3.3.7 Resistance risk assessment of unrestricted usepattern**

Not applicable

### **3.3.8 Test methods**

Not applicable

### **3.3.9 Acceptability of the resistance risk**

CHR/H/FET 110 EC Part A and CHR/H/FETEC 110 EC Part B is a herbicide containing active substance fenoxaprop-P-etylu 110 g/L. Fenoxaprop-P-etylu belongs to the Aryloxyphenoxy-propionate ("fop") chemical family. According to HRAC, fenoxaprop-P-etylu is a Group 1 – inhi-bition of acetyl CoA carboxylase (legacy A). According HRAC Resistance of weed biotypes to herbicides is a consequence of naturally occur-ring mutations and evolutionary processes. Individ-uals within a species that are best adapted and not susceptible to a particular practice, such as appli-cation of a specific herbicide, are select-ed for and will increase in the population. Mitigating or slowing the evolution of herbicide resistance relies on reducing selection pressure for resistance through application of a diversity of weed manage-ment practices. Accrod-ing to EPPO PP 1/213 (4) Resistance risk analysis weeds usually only produce one generation per year and development of resistance is usually a relatively slow process. It is difficult to class any weed species as inherently more or less likely to develop resistance to a particular herbicide.

In conclusion, in the applicant's opinion, this level of weeds resistance risk should be considered to be acceptable.

### **3.3.10 Management strategy**

Accroding to *Herbicide Resistance Action Committee (HRAC)* (<https://hracglobal.com/prevention-management/best-management-practices>)

Integrated Weed Management (IWM) refers to using chemical, cultural, mechanical and biological methods, in an integrated fashion, to control weeds. It does not rely excessively on any one method. When used in a integrated approach, the following tools help reduce selection pressure and survival of resistant weeds.

- Chemical - Applying herbicides to a crop.
- Mechanical - Includes measures such as hand-weeding using cultivation or ploughing to control emerged plants and bury non-germinated seed. It also includes harvest weed seed destruction such as stubble burning and cutting for hay or silage to prevent the weeds from setting seed.
- Cultural - Includes altering the crop planting date, row spacing and harvest timing to disrupt the weed cycle. It also includes planting crops that can out-compete weeds, buying certified seed that's free of weeds and using a diverse crop rotation. Growers should also sanitize farm equipment when moving between fields.
- Biological - Includes introducing insects and pathogens that control target weed species and introducing post-harvest grazing of growing weeds.

Using a diversified crop rotation allows farmers to use these different weed techniques. Avoid successive crops that use herbicides with the same mechanism of action to control the same weed species in the same field.

Guidelines for the sustainable use of herbicide site of action groups:

- Use mixtures or sequential treatments of herbicides having different sites of action. Each herbicide in the mixture should target the same weed species.
- Consider all chemical control options before planting, in-crop and after harvest.
- Avoid continued use of the same herbicides, or herbicides with the same site of action in the same field, unless integrated with other weed control practices.
- Limit the number of applications of a single herbicide or herbicides with the same site of action in a single growing season.
- Herbicide mixtures and herbicide rotations alone are not enough to prevent resistance. They must be used in a diversified plan than also incorporates mechanical, cultural and biological practices.

Growers should also do the following:

- Follow label use instructions, such as application rates, timing and equipment recommendations.
- Know the weeds in their fields and nearby non-crop areas and tailor their weed control program to weed densities and economic thresholds.
- Monitor herbicide results and be aware of any trends or changes in weed populations.
- Maintain detailed field records to confirm cropping and herbicide history.

### **3.3.11 Implementation of the management strategy**

The herbicide label provides all the necessary information for preventing weed resistance to herbicides.

### **3.3.12 Monitoring, reporting and reaction to changes in performance**

According to <https://hracglobal.com/files/Monitoring-and-Mitigation-of-Herbicide-Resistance.pdf>

Managing the risk of herbicide resistance (HR) is an area of strategic importance for leading herbicide technology providers and is the focus of the Global Herbicide Resistance Action Committee (HRAC), an organization comprised of 8 major companies working as a part of Crop Life International. Early detection of HR, understanding the scope of HR in a defined area, and potential mitigation of resistance through efforts to limit its spread are important aspects of managing the risk of HR. Monitoring for HR populations has been employed by public and private weed scientists for both early detection and defining the scope of resistance. The primary methods used to monitor for resistance include:

- 1) field surveys where seed from putative resistant plants are collected and tested in a controlled environment using bioassay procedures,
- 2) market research surveys of farmers and weed management experts, and
- 3) tracking farmer performance inquiries with appropriate follow up field evaluation and testing.

The most common monitoring method is the use of field surveys designed to either qualitatively (i.e., determine whether the level of resistance is high, medium, or low) or quantitatively (i.e., determine the area infested with HR populations) define existing HR. The primary method to detect resistance in new species and in new geographies is to track farmer performance inquiries. Once resistance is detected, steps may be taken to mitigate its impact. A critical aspect to mitigation is the implementation of best management practices (BMPs) which is facilitated by effective education and training programs. Education efforts can be enhanced with information obtained from monitoring studies and early detection of resistant populations using appropriate monitoring methods can improve the outcome of mitigation efforts.

### **3.3.2 Adverse effects on treated crops**

The 10 trials selectivity (winter wheat 3 trials, spring barley 3 trials, winter barley 2 trials, spring wheat 2 trials) and 15 efficacy trials (with phytotoxicity assessment) have been carried out in 2020 and in 2021 in Poland on a wide range of commercially grown varieties.

#### **Winter wheat**

The 3 selectivity and 8 efficacy trials in winter wheat were carried out in Poland in 2020 and 2021 on a wide range of commercially grown varieties. There were not observed any phytotoxicity symptoms on tested product in trials.

#### **Spring wheat**

The 2 selectivity trials in spring wheat were carried out in Poland in 2021 on a wide range of commercially grown varieties. There were not observed any phytotoxicity symptoms on tested product in trials.

#### **Winter barley**

The 2 selectivity trials in winter barley were carried out in Poland in 2021 on a wide range of commercially grown varieties. There were not observed any phyto-toxicity symptoms on tested product in trials.

#### **Spring barley**

The 3 selectivity and 7 efficacy trials in spring barley were carried out in Poland in 2020 and 2021 on a wide range of commercially grown varieties. There were not observed any phytotoxicity symptoms on tested product in trials.

Data were submitted to support the evaluation for the authorization of CHR/H/FETEC 110 EC Part B - the new formulation after changing ingredients in the former formulation CHR/H/FET 110 EC Part A. The evaluator has taken under consideration rules concerning requirements for bridging trials (the product applied solo).

Selectivity of the product solo and in mixtures was not tested on winter triticale. In according to PP 1/307(2) "Efficacy considerations and data generation when making changes to the chemical composition or formulation type of plant protection products", testing of selectivity on closely related crops may not be necessary. Winter triticale is closely related with winter wheat therefore this exception can be applicable in this case. Nevertheless it is proposed to submit 2 bridging trials post-authorised in order to assess the selectivity of the product used solo in winter triticale.

Generally CHR/H/FET 110 EC Part A solo and in mixtures gave more of transient phyto toxicity symptoms than CHR/H/FETEC 110 EC Part B solo and in mixtures. CHR/H/FETEC 110 EC Part B applied solo gave some slight phytotoxicity symptoms only on spring barley, which was tested from early phase BBCH 23. What is more there was not observed any negative relationship between phytotoxicity and yield in concerned crops. It might concluded that crop safety of CHR/H/FETEC 110 EC Part B application (solo)

in winter wheat, winter barley, winter triticale, spring wheat and spring barley can be claimed as proposed in the GAP table (BBCH 20-31).

What is more, for CHR/H/FET 110 EC Part A applied in mixtures with other authorized products additional selectivity data should be submitted. Because CHR/H/FET 110 EC Part A in mixtures gave transient phytotoxicity symptoms, it is proposed to submit the following selectivity data post-authorised in order to confirm selectivity of use mixtures: winter wheat - 1 for each mixture, spring wheat – 2 for each mixture, winter barley – 2 for each mixture, spring barley 1 for each mixture, triticale – 4 for each mixture.

Details will be provided in the dRR Part B Section 3 KCP 6.4 point 3.4.

### 3.3.3 Observations on other undesirable or unintended side-effects

Details will be provided in the dRR Part B Section 3 KCP 6.5 point 3.5.

## 3.4 Methods of analysis (Part B, Section 5)

Analytical methods for determination of fenoxaprop-P-ethyl impurities and relevance of CIPAC methods in CHR/H/FETEC-PART B 110 EC were not evaluated as part of the EU reviews of fenoxaprop-P-ethyl. Therefore all relevant data are provided and are considered adequate.

### 3.4.1 Analytical method for the formulation

An overview on the acceptable methods and possible data gaps for analysis of fenoxaprop-P-ethyl in plant protection product is provided as follows:

The method for determination of active substances in CHR/H/FETEC-PART B 110 EC preparation is specific. The validation parameters for linearity, instrument precision, repeatability and accuracy are within the acceptance range. The determined average content of active substance and safener in CHR/H/FETEC-PART B 110 EC is respectively:

**Fenoxaprop-P-ethyl:** 108.81 g/L  $\pm$  6%

**Cloquintocet-mexyl:** 55.86 g/L  $\pm$  10%

### 3.4.2 Analytical methods for residues

All analytical methods are active substance data and were provided in the EU review of fenoxaprop-P-ethyl and were considered adequate.

## 3.5 Mammalian toxicology (Part B, Section 6)

Type of test, species, model system (Guideline)	Result	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral (calculation method – alternative method)	> 2000 mg/kg bw	None	Žero, K. (2022)
LD <sub>50</sub> dermal (calculation method – alternative method)	> 2000 mg/kg bw	None	Žero, K. (2022)
LC <sub>50</sub> inhalation (calculation method – alternative method)	> 20 mg/L air	None	Žero, K. (2022)
Skin irritation (calculation method – alternative method)	Irritant	<b>Skin Irrit. 2, H315</b>	Žero, K. (2022)
Eye irritation (calculation method – alternative method)	Corrosive	<b>Eye Dam. 1, H318</b>	Žero, K. (2022)
Skin sensitisation (calculation method – alternative method)	Sensitising	<b>Skin Sens. 1, H317</b>	Žero, K. (2022)

alternative method)			
Supplementary studies for combinations of plant protection products	No data – not required		
Aspiration Toxicity (calculation method – alternative method)	Classified	<b>Asp. Tox. 1, H304</b>	Žero, K. (2022)
Specific target organ toxicity - repeated exposure (calculation method – alternative method)	Classified	<b>STOT RE 2, H373</b>	Žero, K. (2022)

### 3.5.1 Acute toxicity

Acute toxicity studies for CHR/H/FETEC-PART B 110 EC were not evaluated as part of the EU review of fenoxaprop-P-ethyl. Therefore, all relevant data were provided and are considered adequate.

### 3.5.2 Operator exposure

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.

Thus, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

*„Stosować rękawice ochronne, ochronę oczu/twarzy oraz odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu.”*

“Wear protective gloves, eye/face protection and work wear during mixing/loading, and protective gloves and work wear during application.”

### 3.5.3 Worker exposure

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 sensitization potential of CHR/H/FETEC 110 EC is expected when using undiluted product. However, bearing in minds the risk for the most sensitive individuals and no dose-effect relationship in case of sensitization, the protective gloves and work wear is recommended for the worker during field inspection.

Thus, following sentence regarding the use of PPE is recommended by the evaluator to be placed in the section of precautions for the workers:

*„Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem) podczas wchodzenia na teren poddany opryskowi”.*

“Wear protective gloves and work wear (long trousers, long-sleeve shirt) during inspection.”

### 3.5.4 Bystander and resident exposure

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

## 3.6 Residues and consumer exposure (Part B, Section 7)

**ZRMs:** 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 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, for example due to advice which has been given or based on the operator's own experience. 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.

### 3.6.1 Residues

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.1 mg/kg for fenoxaprop-P-ethyl as laid down in Reg. (EU) 149/2008 is not expected.

The chronic and the short-term intakes of fenoxaprop-P-ethyl residues are unlikely to present a public health concern.

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

### 3.6.2 Consumer exposure

TMDI (% ADI) according to EFSA PRIMo	8 % (based on IT toddler)
IENTI (% ARfD) according to EFSA PRIMo*	1 % (based on wheat for children)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

The proposed used of fenoxaprop-P-ethyl in the formulation CHR/H/FETEC-PART B 110 EC do not pose unacceptable acute and chronic risks for the consumer.

## 3.7 Environmental fate and behaviour (Part B, Section 8)

No new studies are presented; all data were reviewed in the EU review of fenoxaprop-P-ethyl. Appropriate endpoints from the EU review were used to calculate PECs for CHR/H/FETEC-PART B 110 EC, fenoxaprop-P-ethyl, and metabolites in soil, surface water, ground water and air for the intended use patterns.

### 3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

The PEC<sub>soil</sub> of fenoxaprop-P-ethyl and its relevant metabolites in soil have been assessed with the DT<sub>50</sub> values established in the EU review. Based on the recommended use rate of one application of 77 g/ha fenoxaprop-P-ethyl.

### 3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

According to PEC<sub>gw</sub> modelling with FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 a groundwater contamination of the active substance fenoxaprop-P-ethyl at a concentration of  $\geq 0.1 \mu\text{g/L}$  is not expected in use on cereals. For the metabolites in groundwater concentration of  $\geq 0.1 \mu\text{g/L}$  can be excluded. The risk assessment for metabolites was performed in B-10 section and concluded that there is no risk to consumer.

Toxicological assessment:

The metabolites of Fenoxaprop-P-ethyl contained in the product CHR/H/FETEC-PART B 110 EC are predicted to occur in groundwater at concentrations below  $0.1 \mu\text{g/L}$ . Thus the assessment of the relevance of this metabolite according to the stepwise procedure (acc. to SANCO/221/2000 –rev.10) is not required.

### 3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

The PEC surface water of fenoxaprop-P-ethyl and metabolites in surface water (PEC<sub>sw</sub> and PEC<sub>sed</sub>) have been assessed with the FOCUS SW and the DT<sub>50</sub> water/sediment values established in the EU review. Based on the maximum recommended use rate of one application of 77 g fenoxaprop-P-ethyl per

hectare. The maximum PEC values for surface water and sediment have been calculated according to FOCUS Steps 1-3 for the parent and FOCUS 1-2 for the metabolites.

The results for PEC surface water for the active substance and its metabolites were used for the ecotoxicological risk assessment.

### **3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)**

Not relevant.

## **3.8 Ecotoxicology (Part B, Section 9)**

### **3.8.1 Effects on terrestrial vertebrates**

CHR/H/FETEC-PART B 110 EC no pose any unacceptable risk to birds and mammals.

### **3.8.2 Effects on aquatic species**

CHR/H/FETEC-PART B 110 EC no pose any unacceptable risk to aquatic species.

### **3.8.3 Effects on bees**

CHR/H/FETEC-PART B 110 EC no pose any unacceptable risk to bees.

### **3.8.4 Effects on other arthropod species other than bees**

CHR/H/FETEC-PART B 110 EC no pose any unacceptable risk to arthropods other than bees.

### **3.8.5 Effects on soil organisms**

CHR/H/FETEC-PART B 110 EC no pose any unacceptable risk to soil organisms.

### **3.8.6 Effects on non-target terrestrial plants**

CHR/H/FETEC-PART B 110 EC no pose any unacceptable risk to non-target terrestrial plants.

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

Not relevant.

## **3.9 Relevance of metabolites (Part B, Section 10)**

The metabolites of fenoxaprop-P-ethyl are predicted to occur in groundwater at concentrations lower than 0.1 µg/L (see PART B Section 8 of CHR/H/FETEC-PART B 110 EC) Assessment of the relevance of these metabolites is not required.

## **4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

Not relevant.

## **5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

Noticed data gaps are:

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.

## **Appendix 1 Copy of the product authorization**



## Appendix 2 Copy of the product label

### Uwagi do etykiet:

Fizykochemia – brak uwag do etykiet.

Toksykologia – brak uwag do etykiet.

Pozostałości – brak zgody na stosowanie w mieszaninach zbiornikowych.

Los i zachowanie w środowisku – usunięto zwrot P273.

Ekotoksykologia – dodano zwroty P391, P501.

Skuteczność działania – zmieniono treść etykiet w zakresie „Działanie na chwasty”.

Załącznik do zezwolenia MRiRW nr R - / z dnia . . . r.

Posiadacz zezwolenia:

INNVIGO Sp. z o.o., Al. Jerozolimskie 178, 02-486 Warszawa, xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:  
(...)

## FENOXINN MAX 110 EC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych


Zawartość substancji czynnej:

fenoksaprop-P-etylu (związek z grupy arylofenoksykwasów) - 110 g/l (10.7 %)

Inne substancje niebezpieczne:

kłokwintocet meksylowy; węglowodory, C10-C13, aromatyczne, <1% naftalenu; kwas benzenosulfonowy, pochodne C10-13-(liniowe)alkilowe, sól wapniowa

Zezwolenie MRiRW nr R - / z dnia . . . r.

	
<b>Niebezpieczeństwo</b>	
H226	Łatwopalna ciecz i opary.
H304	Połknięcie i dostanie się przez drogi oddechowe może grozić śmiercią.
H315	Działa drażniąco na skórę.
H317	Może powodować reakcję alergiczną skóry.
H318	Powoduje poważne uszkodzenie oczu.
H373	Może powodować uszkodzenie narządów poprzez długotrwałe lub narażenie powtarzane.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

P210	Przechowywać z dala od źródeł ciepła, gorących powierzchni, źródeł iskrzenia, otwartego ognia i innych źródeł zapłonu. Nie palić.
P260	Nie wdychać rozpylonej cieczy.
P264	Dokładnie umyć ręce po użyciu.
P272	Zanieczyszczonej odzieży ochronnej nie wynosić poza miejsce pracy.
P280	Stosować rękawice ochronne, odzież ochronną, ochronę oczu oraz ochronę twarzy.
P301+P310	W PRZYPADKU POŁKNIECIA: natychmiast skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem.
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P314	W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza.
P391	Zebrać wyciek.
P501	Zawartość, pojemnik usuwać do firm posiadających odpowiednie uprawnienia.

## OPIS DZIAŁANIA

Herbicyd selektywny o działaniu układowym, stosowany nalistnie w formie koncentratu do sporządzania emulsji wodnej (EC).

Zgodnie z klasyfikacją HRAC substancja czynna fenoksaprop-P-etylu zaliczana jest do grupy A 1.

## DZIAŁANIE NA CHWASTY

Środek zawiera substancję czynną zaliczaną do inhibitorów funkcjonowania enzymu – karboksylazy acetylokoenzymu A (ACCaza), a tym samym blokuje syntezę lipidów.

Środek pobierany jest przez zielone części roślin, a następnie przemieszczany do miejsc oddziaływania, to jest do stożków wzrostu pędów i korzeni. Po upływie 2-3 dni od wykonania zabiegu, wzrost chwastów ulega zahamowaniu. Efekty działania środka widoczne są po upływie 2-4 tygodni od zastosowania w zależności od warunków atmosferycznych. Pełną skuteczność zwalczania chwastów obserwuje się w okresie 6-10 tygodni od zabiegu. Działanie środka widoczne jest po upływie 2-4 tygodni od zastosowania w zależności od warunków atmosferycznych.

Środek niszczy najskuteczniej chwasty jednoliścienne od fazy dwóch liści do końca fazy krzewienia. Miotła zbożowa jest najlepiej zwalczana w fazie od 2 do 8 liści. Środek był badany w innych niż powszechnie zalecanych (to jest od 2 do 8 liści) fazach rozwojowych miotły zbożowej, t.j. od początku fazy krzewienia do widocznych 8 rozkrzewień. Środek aplikowany pojedynczo jest nieskuteczny na chwasty dwuliścienne.

a) Stosowanie środka pojedynczo

Pszenica ozima, jęczmień ozimy, pszenżyto ozime

<b>Chwasty wrażliwe:</b>	miotła zbożowa od fazy kłoszenia do fazy kwitnienia (skuteczność 6-10 tygodni po aplikacji), wyczyniec polny
<b>Chwasty średniowrażliwe</b>	miotła zbożowa od fazy krzewienia do fazy strzelania w źdźbło (skuteczność 2-4 tygodni po aplikacji)

Najskuteczniejsze zwalczanie miotły zbożowej następuje po 6-10 tygodniach po aplikacji produktu.

Pszenica jara, jęczmień jary

<b>Chwasty wrażliwe:</b>	chwastnica jednostronna, owies głuchy
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b) Stosowanie w mieszkankach zbiornikowych z:

• Tristar 50 SG/Toraya 50 SG/Triben Super 50 SG/Draco 50 SG

Pszenica ozima, jęczmień ozimy, pszenżyto ozime

<b>Chwasty wrażliwe:</b>	gwiazdnica pospolita
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<b>Chwasty średniowrażliwe:</b>	wieczyniec polny, mak polny, miotła zbożowa, chaber bławatek, rumian polny, tasznik pospolity
<b>Chwasty średnioodporne:</b>	fiolatek polny

Pszenica jara, jęczmień jary

<b>Chwasty wrażliwe:</b>	ehwastnica jednostronna, gwiazdnica pospolita
<b>Chwasty średniowrażliwe:</b>	owies głuchy, chaber bławatek, rdestówka powojowata, komosa biała, przytulia czepna, maruna bezwonna
<b>Chwasty średnioodporne:</b>	fiolatek polny

- Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC

Pszenica ozima, jęczmień ozimy, pszenżyto ozime

<b>Chwasty wrażliwe:</b>	gwiazdnica pospolita
<b>Chwasty średniowrażliwe:</b>	wieczyniec polny, miotła zbożowa
<b>Chwasty średnioodporne:</b>	tasznik pospolity

Pszenica jara, jęczmień jary

<b>Chwasty wrażliwe:</b>	ehwastnica jednostronna, przytulia czepna, gwiazdnica pospolita
<b>Chwasty średniowrażliwe:</b>	owies głuchy, rdestówka powojowata, maruna bezwonna
<b>Chwasty średnioodporne:</b>	ehaber bławatek

Pszenica ozima, jęczmień ozimy, pszenżyto ozime

<b>Chwasty wrażliwe:</b>	bodiszek drobny, gwiazdnica pospolita, jasnota różowa, maruna bezwonna, mak polny, niezapominajka polna, przytulia czepna, tasznik pospolity, wieczyniec polny
<b>Chwasty średniowrażliwe:</b>	ehaber bławatek, fiolatek polny, jasnota purpurowa, przetaicznik perski
<b>Chwasty średnioodporne:</b>	miotła zbożowa, przetaicznik polny

Pszenica jara, jęczmień jary

<b>Chwasty wrażliwe:</b>	ehaber bławatek, ehwastnica jednostronna, gwiazdnica pospolita, jasnota różowa, komosa biała, maruna bezwonna, owies głuchy, przytulia czepna, rdestówka powojowata (rdest powojowaty), rdest szczytliwy (rdest kolankowy), żółtlica drobnokwiatowa
<b>Chwasty średniowrażliwe:</b>	fiolatek polny, przetaicznik perski

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

**Pszenica ozima, pszenica jara, jęczmień ozimy, jęczmień jary, pszenżyto ozime.**

Termin stosowania: oprysk wykonać na wiosnę, od początku krzewienia do fazy 1 kolanka zbóż (BBCH 20-31).

a) Stosowanie pojedynczo

Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,7 l/ha.

Liczba zabiegów: 1.

Lub

b) Stosowanie w mieszkach zbiornikowych

~~W celu rozszerzenia spectrum zwalczanych chwastów o chwasty dwuliścienne środek FENOXINN MAX 110 EC stosować w mieszaniu ze środkami: Tristar 50 SG/Toraya 50 SG/Triben Super 50 SG/Draco 50 SG i Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC~~

~~Maksymalna /zalecana dawka środka dla jednorazowego zastosowania:~~

~~FENOXINN MAX 110 EC – 0,5 l/ha~~

~~+ Tristar 50 SG/Toraya 50 SG/Triben Super 50 SG/Draco 50 SG – 25 g/ha~~

~~+ Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC – 0,40 l/ha.~~

~~Liczba zabiegów: 1.~~

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

### NASTĘPSTWO ROŚLIN

Środek rozkłada się w ciągu okresu wegetacji, nie stwarzając zagrożenia dla roślin uprawianych następco. W przypadku konieczności wcześniejszej likwidacji plantacji, na której stosowano środek FENOXINN MAX 110 EC (np. w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki) po wykonaniu uprawy przedsięwziętej, można uprawiać na tym polu wszystkie rośliny.

W przypadku łącznego zastosowania środka FENOXINN MAX 110 EC ze środkami Tristar 50 SG (Triben Super 50 SG, Toraya 50 SG, Draco 50 SG) i Galaper 200 EC (Fluroherb 200 EC, Herbistar 200 EC) koniecznym jest przestrzeganie zaleceń dotyczących następstwa roślin zawartych w etykietach ww. środków ochrony roślin lub też dobór i uprawę roślin następnych należy skonsultować z posiadaczem zezwolenia.

#### Uwaga:

- Istotnym elementem działania herbicydów jest temperatura, środek Fenoxinn Max 110 EC należy stosować w zakresie temperatur: min. 10°C, optymalna 15-22°C, max. 28°C panujących w okresie 3-4 dni przed i po zabiegu, bez przymrozków w nocy.

- preparat Fenoxinn Max 110 EC nie wykazuje działania wobec biotypów odpornych na inhibitory karboksylazy aceto-CoA (ACCazy)."

### ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy

1. Długotrwała susza zmniejsza skuteczność działania środka, w takich warunkach zabieg należy przeprowadzać w późniejszym z zalecanych terminów.
2. Środka nie stosować:
  - na rośliny chore, uszkodzone przez szkodniki,
  - w okresie występowania przymrozków,
  - w temperaturze powyżej 28°C i wilgotności względnej powietrza poniżej 30%.
3. Podczas stosowania środka nie dopuścić do:
  - znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
  - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
4. Strategia zarządzania odpornością.

Uproszczenie uprawowe, uprawy w monokulturze, stosowanie dawek obniżonych oraz stosowanie po sobie herbicydów o tym samym mechanizmie działania mogą prowadzić do wyselekcjonowania chwastów odpornych. Aby zminimalizować ryzyko wystąpienia i rozwoju odporności chwastów, herbicydy powinny być stosowane zgodnie z Dobrą Praktyką Rolniczą:

- postępuj zgodnie z zaleceniami zawartymi w etykiecie środka ochrony roślin – stosuj środek w zalecanej dawce w terminie zapewniającym najlepsze zwalczanie chwastów,

- dostosuj zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używaj różnych metod kontroli zachwaszczenia w tym rotację upraw, itp.,
- stosuj rotacje herbicydów o różnym mechanizmie działania,
- informuj posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji skontaktuj się z doradcą lub z producentem środka ochrony roślin.

5. Środek, w ochronie jęczmienia jarego może powodować przemijające objawy fitotoksyczności bez wpływu na plonowanie rośliny uprawnej.

### **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Środek przed użyciem dokładnie wymieszać. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka wprowadzić (z włączonym mieszałem) do zbiornika przez rozwadniacz górnowlewowy lub bocznikowy do opryskiwacza napełnionego częściowo wodą, dokładnie wymieszać, a następnie uzupełnić wodą do potrzebnej objętości i ponownie dokładnie wymieszać. Opróżnione opakowanie przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

W przypadku stosowania środka w mieszaninach z innymi środkami przestrzegać ściśle zaleceń i przeciwwskazań dotyczących sporządzania cieczy użytkowej tych środków.

W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

### **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

### **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Nie wprowadzać do oczu, na skórę lub na odzież.

Unikać wdychania rozpylonej cieczy.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu wyschnięcia cieczy użytkowej na powierzchni roślin.

Stosować rękawice ochronne i odzież roboczą podczas inspekcji.

### **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg. Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

W przypadku stosowania w mieszance zbiornikowej należy uwzględnić i przestrzegać również ograniczeń zawartych w etykietach pozostałych środków ochrony roślin wchodzących w skład takiej mieszanki.

### **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych. Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W przypadku kontaktu ze skórą: Umyć dużą ilością wody z mydłem.

W przypadku połknięcia: Natychmiast skontaktować się z ośrodkiem zatruc lub z lekarzem.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

Załącznik do zezwolenia MRiRW nr R - / z dnia . . . r.

Posiadacz zezwolenia:

INNVIKO Sp. z o.o., Al. Jerozolimskie 178, 02-486 Warszawa, xx

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

(...)

## HERBOS MAX 110 EC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych


Zawartość substancji czynnej:

fenoksaprop-P-etylu (związek z grupy arylofenoksykwasów) - 110 g/l (10.7 %)

Inne substancje niebezpieczne:

kłokwintocet meksylowy; węglowodory, C10-C13, aromatyczne, <1% naftalenu; kwas benzenosulfonowy, pochodne C10-13-(liniowe)alkilowe, sól wapniowa

Zezwolenie MRiRW nr R - / z dnia . . . r.

	
<b>Niebezpieczeństwo</b>	
H226	Łatwopalna ciecz i opary.
H304	Połknięcie i dostanie się przez drogi oddechowe może grozić śmiercią.
H315	Działa drażniąco na skórę.
H317	Może powodować reakcję alergiczną skóry.
H318	Powoduje poważne uszkodzenie oczu.
H373	Może powodować uszkodzenie narządów poprzez długotrwałe lub narażenie powtarzane.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P210	Przechowywać z dala od źródeł ciepła, gorących powierzchni, źródeł iskrzenia, otwartego ognia i innych źródeł zapłonu. Nie palić.
P260	Nie wdychać rozpylonej cieczy.
P264	Dokładnie umyć ręce po użyciu.
P272	Zanieczyszczoną odzież ochronną nie wyciągać poza miejsce pracy.
P280	Stosować rękawice ochronne, odzież ochronną, ochronę oczu oraz ochronę twarzy.
P301+P310	W PRZYPADKU POŁKNIECIA: natychmiast skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem.
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez

P314	kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P391	W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza.
P501	Zebrać wyciek. Zawartość, pojemnik usuwać do firm posiadających odpowiednie uprawnienia.

## OPIS DZIAŁANIA

Herbicyd selektywny o działaniu układowym, stosowany nalistnie w formie koncentratu do sporządzania emulsji wodnej (EC).

Zgodnie z klasyfikacją HRAC substancja czynna fenoksaprop-P-etylu zaliczana jest do grupy A 1.

## DZIAŁANIE NA CHWASTY

Środek zawiera substancję czynną zaliczaną do inhibitorów funkcjonowania enzymu – karboksylazy acetylokoenzymu A (ACCaza), a tym samym blokuje syntezę lipidów.

Środek pobierany jest przez zielone części roślin, a następnie przemieszczany do miejsc oddziaływania, to jest do stożków wzrostu pędów i korzeni. Po upływie 2-3 dni od wykonania zabiegu, wzrost chwastów ulega zahamowaniu. Efekty działania środka widoczne są po upływie 2-4 tygodni od zastosowania w zależności od warunków atmosferycznych. Pełną skuteczność zwalczania chwastów obserwuje się w okresie 6-10 tygodni od zabiegu. Działanie środka widoczne jest po upływie 2-4 tygodni od zastosowania w zależności od warunków atmosferycznych.

Środek niszczy najskuteczniej chwasty jednoliścienne od fazy dwóch liści do końca fazy krzewienia. Miotła zbożowa jest najlepiej zwalczana w fazie od 2 do 8 liści. Środek był badany w innych niż powszechnie zalecanych (to jest od 2 do 8 liści) fazach rozwojowych miotły zbożowej, t.j. od początku fazy krzewienia do widocznych 8 rozkrzewień. Środek aplikowany pojedynczo jest nieskuteczny na chwasty dwuliścienne.

### c) Stosowanie środka pojedynczo

Pszenica ozima, jęczmień ozimy, pszenżyto ozime

<b>Chwasty wrażliwe:</b>	miotła zbożowa od fazy kłoszenia do fazy kwitnienia (skuteczność 6-10 tygodni po aplikacji); wyczyniec polny
<b>Chwasty średniowrażliwe</b>	miotła zbożowa od fazy krzewienia do fazy strzelania w źdźbło (skuteczność 2-4 tygodni po aplikacji)

Najskuteczniejsze zwalczanie miotły zbożowej następuje po 6-10 tygodniach po aplikacji produktu.

Pszenica jara, jęczmień jary

<b>Chwasty wrażliwe:</b>	chwastnica jednostronna, owies głuchy
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### d) Stosowanie w mieszankach zbiornikowych z:

- Tristar 50 SG/Toraya 50 SG/Triben Super 50 SG/Draeo 50 SG

Pszenica ozima, jęczmień ozimy, pszenżyto ozime

<b>Chwasty wrażliwe:</b>	gwiazdnica pospolita
<b>Chwasty średniowrażliwe:</b>	wyczyniec polny, mak polny, miotła zbożowa, chaber bławatek, rumian polny, tasznik pospolity
<b>Chwasty średnioodporne:</b>	fiolek polny

Pszenica jara, jęczmień jary

<b>Chwasty wrażliwe:</b>	chwastnica jednostronna, gwiazdnica pospolita
<b>Chwasty średniowrażliwe:</b>	owies głuchy, chaber bławatek, rdestówka powojowata, komosa biała,



	przytulia czepna, maruna bezwonna
<b>Chwasty średnioporne:</b>	fiolatek polny

• Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC

Pszenica ozima, jęczmień ozimy, pszenżyto ozime

<b>Chwasty wrażliwe:</b>	gwiazdnica pospolita
<b>Chwasty średniowrażliwe:</b>	wyczyniec polny, miotła zbożowa
<b>Chwasty średnioporne:</b>	tasznik pospolity

Pszenica jara, jęczmień jary

<b>Chwasty wrażliwe:</b>	ehwastnica jednostronna, przytulia czepna, gwiazdnica pospolita
<b>Chwasty średniowrażliwe:</b>	owies głuchy, rdestówka powojowata, maruna bezwonna
<b>Chwasty średnioporne:</b>	ehaber bławatek

Pszenica ozima, jęczmień ozimy, pszenżyto ozime

<b>Chwasty wrażliwe:</b>	bodziszek drobny, gwiazdnica pospolita, jasnota różowa, maruna bezwonna, mak polny, niezapominajka polna, przytulia czepna, tasznik pospolity, wyczyniec polny
<b>Chwasty średniowrażliwe:</b>	ehaber bławatek, fiolatek polny, jasnota purpurowa, przetaecznik perski
<b>Chwasty średnioporne:</b>	miotła zbożowa, przetaecznik polny

Pszenica jara, jęczmień jary

<b>Chwasty wrażliwe:</b>	ehaber bławatek, ehwastnica jednostronna, gwiazdnica pospolita, jasnota różowa, komosa biała, maruna bezwonna, owies głuchy, przytulia czepna, rdestówka powojowata (rdest powojowaty), rdest szczytlistny (rdest kolankowy), żółtlica drobnokwiatowa
<b>Chwasty średniowrażliwe:</b>	fiolatek polny, przetaecznik perski

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

**Pszenica ozima, pszenica jara, jęczmień ozimy, jęczmień jary, pszenżyto ozime.**

Termin stosowania: oprysk wykonać na wiosnę, od początku krzewienia do fazy 1 kolanka zbóż (BBCH 20-31).

c) Stosowanie pojedynczo

Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 0,7 l/ha.

Liczba zabiegów: 1.

**Lub**

d) Stosowanie w mieszkach zbiornikowych

W celu rozszerzenia spectrum zwalczanych chwastów o chwasty dwuliścienne środek FENOXINN MAX 110 EC stosować w mieszaninie ze środkami: Tristar 50 SG/Toraya 50 SG/Triben Super 50 SG/Draco 50 SG i Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC

Maksymalna/zalecana dawka środka dla jednorazowego zastosowania:

FENOXINN MAX 110 EC – 0,5 l/ha

+ Tristar 50 SG/Toraya 50 SG/Triben Super 50 SG/Draco 50 SG – 25 g/ha

+ Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC – 0,40 l/ha.

**Liczba zabiegów: 1.**

**Zalecana ilość wody: 200-300 l/ha.**

**Zalecane opryskiwanie: średniokropliste.**

**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.**

### **NASTĘPSTWO ROŚLIN**

Środek rozkłada się w ciągu okresu wegetacji, nie stwarzając zagrożenia dla roślin uprawianych następnie. W przypadku konieczności wcześniejszej likwidacji plantacji, na której stosowano środek FENOXINN MAX 110 EC (np. w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki) po wykonaniu uprawy przedsięwziętej, można uprawiać na tym polu wszystkie rośliny.

W przypadku łącznego zastosowania środka FENOXINN MAX 110 EC ze środkami Tristar 50 SG (Triben Super 50 SG, Toraya 50 SG, Draco 50 SG) i Galaper 200 EC (Fluroherb 200 EC, Herbistar 200 EC) koniecznym jest przestrzeganie zaleceń dotyczących następstwa roślin zawartych w etykietach ww. środków ochrony roślin lub też dobór i uprawę roślin następczych należy skonsultować z posiadaczem zezwolenia.

#### **Uwaga:**

- Istotnym elementem działania herbicydów jest temperatura, środek Fenoxinn Max 110 EC należy stosować w zakresie temperatur: min. 10<sup>0</sup>C, optymalna 15-22<sup>0</sup> C, max. 28<sup>0</sup> C panujących w okresie 3-4 dni przed i po zabiegu, bez przymrozków w nocy.

- preparat Fenoxinn Max 110 EC nie wykazuje działania wobec biotypów odpornych na inhibitory karboksylazy aceto-CoA (ACCazy)."

### **ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA**

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy

1. Długotrwała susza zmniejsza skuteczność działania środka, w takich warunkach zabieg należy przeprowadzać w późniejszym z zalecanych terminów.
2. Środka nie stosować:
  - na rośliny chore, uszkodzone przez szkodniki,
  - w okresie występowania przymrozków,
  - w temperaturze powyżej 28°C i wilgotności względnej powietrza poniżej 30%.
3. Podczas stosowania środka nie dopuścić do:
  - znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
  - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
4. Strategia zarządzania odpornością.  
Uproszczenie uprawowe, uprawy w monokulturze, stosowanie dawek obniżonych oraz stosowanie po sobie herbicydów o tym samym mechanizmie działania mogą prowadzić do wyselekcjonowania chwastów odpornych. Aby zminimalizować ryzyko wystąpienia i rozwoju odporności chwastów, herbicydy powinny być stosowane zgodnie z Dobrą Praktyką Rolniczą:
  - postępuj zgodnie z zaleceniami zawartymi w etykiecie środka ochrony roślin – stosuj środek w zalecanej dawce w terminie zapewniającym najlepsze zwalczanie chwastów,
  - dostosuj zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
  - używaj różnych metod kontroli zachwaszczenia w tym rotację upraw, itp.,
  - stosuj rotacje herbicydów o różnym mechanizmie działania,
  - informuj posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
  - w celu uzyskania szczegółowych informacji skontaktuj się z doradcą lub z producentem środka ochrony roślin.

5. Środek, w ochronie jęczmienia jarego może powodować przemijające objawy fitotoksyczności bez wpływu na plonowanie rośliny uprawnej.

### **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Środek przed użyciem dokładnie wymieszać. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka wprowadzić (z włączonym mieszadłem) do zbiornika przez rozwadniacz górnolewowy lub boczniowy do opryskiwacza napełnionego częściowo wodą, dokładnie wymieszać, a następnie uzupełnić wodą do potrzebnej objętości i ponownie dokładnie wymieszać. Opróżnione opakowanie przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

W przypadku stosowania środka w mieszaninach z innymi środkami przestrzegać ściśle zaleceń i przeciwwskazań dotyczących sporządzania cieczy użytkowej tych środków.

W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

### **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

### **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Nie wprowadzać do oczu, na skórę lub na odzież.

Unikać wdychania rozpylonej cieczy.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu wyschnięcia cieczy użytkowej na powierzchni roślin.

Stosować rękawice ochronne i odzież roboczą podczas inspekcji.

### **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg. Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

W przypadku stosowania w mieszance zbiornikowej należy uwzględnić i przestrzegać również ograniczeń zawartych w etykietach pozostałych środków ochrony roślin wchodzących w skład takiej mieszanki.

## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

## **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W przypadku kontaktu ze skórą: Umyć dużą ilością wody z mydłem.

W przypadku połknięcia: Natychmiast skontaktować się z ośrodkiem zatruc lub z lekarzem.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

## **Appendix 3 Letter of Access**

## **Appendix 4 Lists of data considered for national authorization**

### **List of data submitted by the applicant and relied on**

Please refer to the reference list.

### **List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

Please refer to the reference list.