REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information
Concise summary

Product name: **KINVARA**

Chemical active substance(s):

MCPA, 233 g/L
Fluroxypyr, 50 g/L
Clopyralid, 28 g/L

Central Zone

CORE ASSESSMENT

Applicant: XXXX

Submission date: 31/01/2024

Evaluation date: October 2024

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Version history

When	What
31/01/2024	Initial version submitted by the applicant for art. 43
October 2024	Version evaluated by ZRMS
February 2026	ZRMS correction following Applicant’s comment

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

This is the version of dRR from January 2024, submitted by applicant XXXX, in the framework of Article 43 of Regulation (EC) 1107/2009. The applicant´s text is commented by zRMS and the comments and conclusions are placed in commenting boxes shaded in grey at the end of each chapter. Amendments in the text are highlighted in yellow.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

This report concerns the renewal of authorization on the application of herbicide Kinvara, containing three chemical active substances: MCPA (233 g/L), fluroxypyr (50 g/L), and clopyralid (28 g/L) for weeds control in the Central zone, under article 43 of Regulation (EC) 1107/2009. This product is intended for foliar application for annual and perennial broadleaf weed control in cereal crops (wheat, barley, oats, rye, triticale), established grassland, and new grassland. Registration in established grassland applies only to such countries as AT, IE, BE, CZ, and DE, and in new grassland applies only to DE.

Registration renewal for Kinvara covers the same uses as the currently applicable label. No changes in the GAP and dose rates have been made for this renewal, compared to the currently approved GAP. The applicant did not submit any additional data on efficacy and selectivity, the yield, and its quality, and only presented new information on resistance, which is very important for the practice, as it may delay or prevent the development of resistance to the active substances contained in the composition of the herbicide. The renewal of registration in terms of efficacy is based on the data assessed during the previous registration. The renewal of registration also applies to Poland.

Weed resistance for all active substances included in Kinvara has been identified; 45 weed species show resistance to HRAC group 4. The overall risk of resistance to these active substances can be regarded as low to moderate. The resistance risk for established grassland is low, while for cereals it is moderate. The risk management strategy for Kinvara is needed.

The proposed label claim: the use of Kinvara in one foliar application in wheat, barley, oats, rye, and triticale, at the rates of 2-3 L/ha in RO, CZ, HU, PL, and 3 L/ha in AT, NI, IE, and DE, in established grassland at the rate of 2.5 ~~3~~ L/ha in AT, IE, CZ, DE and 2.25 L/ha or 2.5 L/ha in BE and 2.25-2.5 L/ga in new grasslands in BE. The maximum rates for established grasslands, and for new grasslands have been set by ecotoxicology at a maximum of 2.5 l/ha. The efficacy of these rates is still considered acceptable. The application time at the growth stage is BBCH 24-39 in cereals, from March to September in established grasslands, and from March to the end of September in new grasslands, with a water volume of 200–400 L/ha. The aim of Kinvara application is the control of annual and perennial broadleaf weeds.

The applicant presented lists of weeds resistant to all active substances (MCPA, clopyralid, and fluroxypyr), and stated that cross-resistance to herbicides with other modes of action is also possible. To reduce the risk of resistance to the active substances contained in the Kinvara herbicide, the resistance management strategy should be introduced into the label of this product. The weed management strategy should follow Good Agricultural Practices and Good Plant Protection Practices (EPPO Standard 2/1 (2)). Kinvara should be used in alternation with herbicides comprising different modes of action to avoid the build-up of resistant biotypes and cross-resistance. It should be used as recommended on the label, do not use reduced doses. Kinvara should be used a maximum once a year on the same field.

Conclusion. The product label should have a clear statement regarding resistance risk and the management strategy. The modified risk and the resistance management strategy allow to manage the risk to the acceptable level.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (*)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I** (**)	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (***)	**zRMS Conclusion** (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	AT, NI, IE, BE, RO, CZ, DE, HU, PL	Wheat, Barley, Oats, Rye, Triticale DE – Spring and Winter Wheat, Barley, Oats, Rye, Triticale	F	Annual and perennial broadleaf weeds DE - annual broadleaf weeds	Foliar spray	BBCH 24-39	a) 1 b) 1	N/A	a) 3 b) 3	a) 0.699 MCPA, 0.150 Flur, 0.084 CLP b) 0.699 MCPA, 0.150 Flur, 0.084 CLP	200-400	N/A	BBCH 25-39 (AT) BE- 3L/ha RO- 2-3L/ha CZ -2-3L/ha HU – 2-3L/ha PL – 2-3L/ha	A
2	AT, IE, BE, CZ, DE	Established Grassland	F	Annual and perennial broadleaf weeds	Foliar spray	March- Sept	a) 1 b) 1	N/A	~~a) 3~~ ~~b) 3~~ a) 2.5 b) 2.5	a) 0.583 MCPA, 0.125 Flur, 0.070 CLP b) 0.583 MCPA, 0.125 Flur, 0.070 CLP	200-400	PHI 7d	IE (1st March-31st Aug) BE – 2.25 or 2.5L/ha DE-broad leaf dock only	A
3	BE	New grassland	F	Annual and perennial broadleaf weeds	Foliar spray	March – End Sept	a) 1 b) 1	N/A	~~a) 3~~ ~~b) 3~~ c) 2.5 d) 2.5	a) 0.583 MCPA, 0.125 Flur, 0.070 CLP b) 0.583 MCPA, 0.125 Flur, 0.070 CLP	200-400		BE – 2.25/2.5L/ha	A

* 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
*** To be completed with the relevant footnote

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

3.2 Efficacy data (KCP 6)

Introduction

KINVARA is an herbicide with a ME formulation containing 233g/l of MCPA, 50g/l of fluroxypyr and 28g/l of clopyralid for the control of broadleaved weeds in cereals.

This document reviews the efficacy data for the renewal under Article 43 of Regulation (EC) No. 1107/2009 of the product KINVARA containing 233g/l of MCPA, 50g/l of fluroxypyr and 28g/l of clopyralid. The 3 active substances were first included into Annex I of Directive 91/414 Regulation (EU) No 540/2011 for MCPA, Regulation (EU) No 736/2011 for fluroxypyr and Regulation (EU) No 540/2011 for clopyralid. Clopyralid approval has been renewed in accordance with Regulation (EC) No. 1107/2009 (Regulation (EU) 2021/1191 of 19/07/2021). The date of entry into force of the renewal of clopyralid is 01/10/2021.

The overall objective of this dRR is to provide information in support of the renewal of KINVARA as an herbicide for the control of broadleaved weeds in cereals and grassland.

No changes in the GAP and in dose rates have been made for this renewal, in comparison to the GAP currently approved. Subtil GAP changes resulting in rate reduction within the existing registered range of rates or resulting in a reduction of a dose rate of 10% or less do not require the submission of new Biology data. According to SANCO/2010/13170 rev. 14, 7 Oct. 2016, if no changes in the GAP have been made, no new efficacy data have to be submitted and only resistance has to be considered for Article 43 re-registrations.

Applications of KINVARA are made to wheat, barley, rye, triticale, oats, grassland (less than 1 year old and more than 1 year old).

Description of active substances

KINVARA consists of a mixture of three active substances, MCPA discovered in 1941 and introduced in 1955, clopyralid introduced in 1977 and fluroxypyr in 1983. These compounds are now established as a key part of weed control programmes across the world.

Mode of action

MCPA, fluroxypyr and clopyralid are each, a selective, synthetic auxin herbicide, predominantly taken up by leaves and rapidly translocated to other parts of the plant. Symptoms include characteristic auxin-type effects, such as leaf curling (Tomlin 2003). It controls a range of economically important broadleaved weeds, particularly *Galium aparine* (Cleavers), *Matricaria sp., Cyanus segetum, Polygonum sp., Rumex obtusifolius* (Bitter dock) and *Cirsium arvense* (Creeping thistle). It is currently the mainstay of Cleavers control in the spring in cereals and plays a very valuable part in weed control programmes across Europe.

Table 3.2-1: Details of the active substances

Active substance	MCPA	Fluroxypyr	Clopyralid
Concentration	233 g/L	50 g/L	28 g/L
Chemical group	Synthetic auxin		
Mode of action	Selective, systemic with translocation		
Absorbed by	predominantly by leaves	predominantly by leaves	By leaves and roots
Biological action	Post-emergence herbicide		
Targets	Annual and perennial broadleaved weeds		
Persistence	Non-persistent		

Description of the plant protection product

KINVARA is an agricultural herbicide for the control of annual and perennial weeds in cereals, and grassland. It consists of a mixture of three active substances, MCPA discovered in 1941 and introduced in 1955, clopyralid introduced in 1977 and fluroxypyr in 1983. Use rates vary depending on the crop and weed situation. These compounds are now established as a key part of weed control programmes across the world.

The product is currently registered as an herbicide for the control of broadleaved weeds in several countries of the Central zone, as shown in Table 3.2-2.

Table 3.2-2: Simplified table of currently registered uses and requested uses for KINVARA

Member State	Registered brand name	Authorization number	Uses		Currently registered rate(s)	Requested rate
			Crop(s)	Target(s)		
Austria	KINVARA	4168-0	Wheat, Barley, Rye, Triticale, Oats	Boradleaved weeds	3.0 L/ha	3.0 L/ha
			Established Grassland (> 1year)	Boradleaved weeds	3.0 L/ha	3.0 L/ha
Belgium	KINVARA	30980-B	Wheat, Barley, Rye, Triticale, Oats	Boradleaved weeds	3.0 L/ha	3.0 L/ha
Czech Republic	KINVARA	5310-0	Wheat, Barley, Rye, Triticale, Oats	Boradleaved weeds	2.0-3.0 L/ha	2.0-3.0 L/ha
			Established Grassland (> 1year)	Boradleaved weeds	3.0 L/ha	3.0 L/ha
Germany	KINVARA	4168-0	Wheat, Barley, Rye, Triticale, Oats	Boradleaved weeds	3.0 L/ha	3.0 L/ha
			Established Grassland (> 1year)	Boradleaved weeds*	3.0 L/ha	3.0 L/ha
Hungary	KINVARA	6300/19632-1/2019	Wheat, Barley, Rye, Triticale, Oats	Boradleaved weeds	2.0-3.0 L/ha	2.0-3.0 L/ha
Ireland	KINVARA	05381	Wheat, Barley, Rye, Triticale, Oats	Boradleaved weeds	3.0 L/ha	3.0 L/ha
			Established Grassland (> 1year)	Boradleaved weeds	3.0 L/ha	3.0 L/ha
Northern Ireland	KINVARA	18436	Wheat, Barley, Rye, Triticale, Oats	Boradleaved weeds	3.0 L/ha	3.0 L/ha
Poland	KINVARA	R-231/2019	Wheat, Barley, Rye, Triticale, Oats	Boradleaved weeds	2.0-3.0 L/ha	2.0-3.0 L/ha
Romania	KINVARA	560PC/20.11.2019	Wheat, Barley, Rye, Triticale, Oats	Boradleaved weeds	2.0-3.0 L/ha	2.0-3.0 L/ha

*Requested only on broad leaf dock

Compliance with the Uniform Principles

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

Information on trials submitted (3.1 Efficacy data)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.2.1 Preliminary tests (KCP 6.1)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.2.2 Minimum effective dose tests (KCP 6.2)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.2.3 Efficacy tests (KCP 6.2)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

Comments of zRMS:	**Efficacy** This report concerns the renewal of authorization on the application of herbicide Kinvara, containing three chemical active substances: MCPA (233 g/L), fluroxypyr (50 g/L), and clopyralid (28 g/L) for weeds control in the Central zone, under article 43 of Regulation (EC) 1107/2009. This product is intended for foliar application for annual and perennial broadleaf weed control in cereal crops (wheat, barley, oats, rye, triticale), established grassland, and new grassland. Registration in established grassland applies to such countries as AT, IE, BE, CZ, and DE, and in new grassland applies only to DE. Registration renewal for Kinvara covers the same uses as the currently applicable label. No changes in the GAP and dose rates have been made for this renewal, compared to the currently approved GAP. The applicant did not submit any additional data on efficacy and selectivity, the yield, and its quality, and only presented new information on resistance, which is very important for the practice, as it may delay or prevent the development of resistance to the active substances contained in the composition of the herbicide. The renewal of registration in terms of efficacy is based on the data assessed during the previous registration. The renewal of registration also applies to Poland. **The proposed label claim**: the use of Kinvara in one foliar application in wheat, barley, oats, rye, and triticale, at the rates of 2-3 L/ha in RO, CZ, HU, PL, and 3 L/ha in AT, NI, IE, and DE, in established grassland at the rate of 2.5 ~~3~~ L/ha in AT, IE, CZ, DE and 2.25 L/ha or 2.5 L/ha in BE and 2.25-2.5 L/ga in new grasslands in BE. The maximum rates for established grasslands, and for new grasslands have been set by ecotoxicology at a maximum of 2.5 l/ha. The efficacy of these rates is still considered acceptable. The application time at the growth stage is BBCH 24-39 in cereals, from March to September in established grasslands, and from March to the end of September in new grasslands, with a water volume of 200–400 L/ha. The aim of Kinvara application is the control of annual and perennial broadleaf weeds.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

When herbicides with the same mode of action are used repeatedly over several years in the same field, selection of resistant biotypes can take place. These can propagate and may become dominating. A weed species is considered resistant to an herbicide if it survives to a correctly applied treatment at the recommended dose and timing. Development of resistance in a weed species can be avoided or delayed by alternating (or tank mixing) with suitable products having a different mode of action. A strategy for preventing and managing resistance should be adopted.

Mode of action

KINVARA is an agricultural herbicide for the control of annual and perennial weeds in cereals. It consists of a mixture of three active substances, MCPA discovered in 1941 and introduced in 1955, clopyralid introduced in 1977 and fluroxypyr in 1983. The three actives have similar modes of action, mimicking the activity of auxin - indole-3-acetic acid (IAA), but slightly different spectra of activity, thus the mixture gives a broader range of weed control than any of the actives used individually.

All three actives are in the Herbicide Resistance Action Committee (HRAC) herbicide Group HRAC 4 (HRAC legacy Group O), which consists of synthetic auxins that act as indoleacetic acid (IAA), and includes molecules such as dicamba, 2,4-D, triclopyr and quinmerac. The three compounds are from two different chemical groups, MCPA is a phenoxy-carboxylic acid, while fluroxypyr and clopyralid are pyridine carboxilic acids.

The effects of auxinic herbicides on growth and anatomy of susceptible plant species are similar to those caused by IAA. With increased dosage, cupping and stunting of the leaves are observed. Terminal leaf growth ceases. Tissue proliferation along the stem may take place first at the stem tip, then at the nodes, and finally along the length of the entire stem. Meanwhile, epinasty, bending and splitting of the stem and leaves, occur. The roots become thickened and stunted. Adventitious root initials develop which crush the phloem and cortex, eventually resulting in rupturing of the epidermis of stem tissues. The plant soon dies.[1]

The precise details of how auxins, both IAA and herbicidal analogues work, has still not been fully elucidated. Studies to determine the mode of action of synthetic auxins and mechanism of resistance in a number of weeds have been summarised by Mithila *et al* (2011)[2] and indicate that different herbicidal chemicals may affect different parts of the auxin perception and signalling pathway. There may also be a range of different resistance mechanisms which may differentially affect different herbicides. Members of the synthetic auxin group are therefore not necessarily cross resistant.

The soil DT50 of all three actives is in the range DT50 of 3-55 days. Clopyralid potentially has a DT50 of up to 14 months but is readily leached in most cases resulting in observed DT50s in soil of 1-2 months. This means that weeds are exposed to sub-lethal doses of the compounds for a limited period, thereby reducing the potential for the generation of resistant biotypes.

Mechanism of resistance

The mechanism of resistance in the few cases observed remains currently uncertain but there is evidence that there may be a range of different mechanisms.

Evidence of resistance

Although the synthetic auxin herbicides were introduced over 50 years ago and have seen heavy long-term usage, relatively few resistant weed populations have evolved. There are currently 85 biotypes of 43 species reported to be resistant to herbicides of this mode of action. Of these, synthetic-auxin-resistant *Galium aparine*, *Papaver rhoeas, Sinapis arvensis, Stellaria media*, are the most relevant ones to European agriculture. Among these cases only few are reported for the 3 active substances of KINVARA (and mostly outside of Europe) as listed in Table 3.3-1 for MCPA, in Table 3.3-2 for fluroxypyr and in
Source: Heap, I. The International Survey of Herbicide Resistant Weeds. September 07, 2023. Available on *www.weedscience.org*
Table 3.3-3 for clopyralid.

[1] T. J. Sterling & J. C. Hall (1997) Natural Auxins and the Auxinic Herbicides, In, Herbicide Activity: Toxicology, Biochemistry and Molecular Biology, R. Michael Roe, James D. Burton, Ronald J. Kuhr (Eds).

[2] J. Mithila, J. Christopher Hall, William G. Johnson, Kevin B. Kelley, & Dean E. Riechers (2011) Evolution of Resistance to Auxinic Herbicides: Historical Perspectives, Mechanisms of Resistance, and Implications for Broadleaf Weed Management in Agronomic Crops. *Weed Science* 59(4) 445-457.

Table 3.3-1: Weeds species resistant to MCPA

Species	Country	Year	Crop	Cross resistance with
Amaranthus powelli	Canada	2019	Soybean	Group HRAC 2 (HRAC legacy Group B)
Carduus pycnocephalus	New Zealand	1997	Pastures	-
Cirsium arvense	Hungary	1985	Pastures	-
	Sweden	1979	Cropland	-
Descurainia sophia	China	2011	Winter wheat	-
Galeopsis tetrahit	Canada	1998	Cereals, Cropland, Spring Barley, Wheat	-
Galium aparine	Iran	2016	Wheat	-
		2017	Wheat	Group HRAC 2 (HRAC legacy Group B)
Lactuca serriola	USA	2007	Cereals	-
Papaver rhoeas	France	2016	Cereals	Group HRAC 2 (HRAC legacy Group B)
Ranunculus acris	New Zealand	1988	Pastures	-
		2010	Pastures	Group HRAC 2 (HRAC legacy Group B)
Raphanus raphanistrum	Australia	2006	Cereals	Group HRAC 2 (HRAC legacy Group B) Group HRAC 12 (HRAC legacy Group F1)
		2010	Fallow	Group HRAC 2 (HRAC legacy Group B) Group HRAC 12 (HRAC legacy Group F1) Group HRAC 9 (HRAC legacy Group G)
Sinapis arvensis	Canada	1990	Cropland, Spring Barley, and Wheat	-
Sisymbrium orientale	Australia	2005	Cereals	Group HRAC 2 (HRAC legacy Group B)
Stellaria media	China	2010	Winter wheat	-

Source: Heap, I. The International Survey of Herbicide Resistant Weeds. September 07, 2023. Available on www.weedscience.org

Table 3.3-2: Weeds species resistant to fluroxypyr

Species	Country	Year	Crop	Cross resistance with
Galium aparine	China	2014	Wheat	-
Galeopsis tetrahit	Canada	1998	Cereals, Cropland, Spring Barley, Wheat	-
Kochia scoparia	USA	1994	Cropland and wheat	-
	USA	2013	Maize and sorghum	Group HRAC 9 (HRAC legacy Group G)
	Canada	2015	Spring wheat	Group HRAC 2 (HRAC legacy Group B)
Stellaria media	China	2010	Winter wheat	-

Source: Heap, I. The International Survey of Herbicide Resistant Weeds. September 07, 2023. Available on www.weedscience.org

Table 3.3-3: Weeds species resistant to clopyralid

Species	Country	Year	Crop	Cross resistance with
Centaurea stoebe ssp. micranthos	Canada	2013	Rangeland	-
Chenopodium album	New Zealand	2005	Maize	-
Soliva sessilis	New Zealand	1999	Golf courses, and Turf	-

Source: Heap, I. The International Survey of Herbicide Resistant Weeds. September 07, 2023. Available on www.weedscience.org

Cross resistance

Cross-resistance to herbicides with other modes of action (mostly with Group HRAC 2 (HRAC legacy Group B) = ALS inhibitors) has been observed in 6 biotypes resistant to MCPA and in 2 biotypes resistant to fluroxypyr (See previous Tables).
It also appears that there may be differences in the site of action or uptake mechanisms of different synthetic auxin herbicides so that resistance to one compound in the class does not result in cross-resistance to all the others.

Sensitivity data

All three actives have been used commercially in Europe for many years. It is therefore no longer possible to conduct true baseline sensitivity testing. A modified version of this sensitivity testing, in which performance in field trials is recorded and monitored, is possible. The trials data presented in the previous submission of KINVARA represent a suitable baseline, from which variations in control levels can be measured.

Inherent Product Risk

Most broadleaved weeds are regarded as being of minimal risk, with regard to the development of resistant biotypes (PSD Efficacy Guideline 606, May 2008).

KINVARA is intended for use as a post-emergence herbicide to control broadleaved weeds in cereals and grassland.
In cereals, the primary target is *Galium aparine* in the spring, typically in sequence with an autumn-applied herbicide product. In China this weed has evolved resistance to fluroxypyr, but no resistance to synthetic auxins has ever been reported in Europe.

In Canada resistance has been observed in *Galeopsis tetrahit* a common weed in spring cereals. In Europe spring cropping of cereals is usually undertaken in rotation with other crops, including oilseed rape, potatoes, winter cereals and sugar beet (e.g. Finch et al. 2002). In broadleaved crops it is not possible to use synthetic auxin herbicides; the use of different modes of action over the course of the rotation, coupled with the use of cultivations, probably explains the absence of any herbicide-resistant *G. tetrahit* in Europe.

The herbicide is also active against *Stellaria media* and *Papaver rhoeas*. Several herbicide-resistant biotypes of *S. media* exist, including one in the UK which is resistant to HRAC Group 4 (HRAC legacy Group O) herbicides (mecoprop). Testing in 1986-87 indicated that there was no cross-resistance to the synthetic auxin herbicides fluroxypyr, dicamba or benazolin in these biotypes (Lutman and Snow, 1987). It has also been reported that the mecoprop resistant variants show less vigorous vegetative growth and take longer to flower and produce mature seeds and that there is therefore a fitness penalty to the resistance[3].
Resistance in poppy, *P. rhoeas,* to synthetic auxins has not been found in Northern Europe but has been found in Spain, Italy and Southern France. Largely this is to 2,4 D but not to the 3 active ingredients in KINVARA.

In grassland, the primary target is *Rumex spp.,* and currently no biotype of Rumex species resistant to auxinic herbicides has ever been reported.

Overall, it is therefore reasonable to conclude that the inherent risk of the development of resistance in any of the target species is low.

Agronomic Risk Analysis

It is possible that the use of this product in a repeated fashion on the same fields, without any rotation of crops or the use of any mixtures or sequences with herbicides with different modes of action could

[3] Barnwell P and Cobb A H (1989)Physiological studies of mecoprop-resistance in chickweed (*Stellaria media*) *Weed Research* 29, 135-140.

generate resistant biotypes of *G. tetrahit* or *S. media*. Although the risk of this is extremely low, this use pattern is therefore not proposed by the applicant.

It is suggested that the 'Directions for use' section of the label for KINVARA should bear the wording, 'Strains of weeds resistant to herbicides may develop, in which case reduced levels of control may be seen. It is recommended that KINVARA is used as part of a cropping programme which includes the use of herbicides with different modes of action. Do not rely on one herbicide mode of action in the same field over several years' (WRAG 2003).

This text supports the use pattern recommended by the applicant, which would allow the benefits of the product to be available to growers while managing the risk of resistance developing. This use pattern has been used successfully in the case of atrazine in the United States (Ritter and Menberre, 1997), where the use of mixtures of herbicides of different modes of action has allowed.

The resistance management strategy proposed by the applicant is the use of the product as part of a crop production programme that follows the principles of Good Agricultural Practice. This would include the use of crop rotation, and the use of herbicides of differing modes of action, either in combination or in sequence with KINVARA. This is outlined in the label text detailed above.

The resistance management strategy proposed by the applicant will be implemented using the label text proposed above. In addition, staff giving advice on this product will be instructed to give information on the recommended use pattern to growers and other customers.

The applicant will take a pro-active approach to dealing with any product performance issues. This will include the intervention of agents of the applicant or its distribution partners to establish the exact circumstances of any product failure, and the collection of information on previous herbicide use and crop rotation. If product performance is still in question, seed from 'resistant' plants will be collected and tested under controlled conditions for response to the synthetic auxins, in comparison to a biotype of known susceptibility to the chemistry. If resistance is confirmed, weed control recommendations specific for that situation will be developed in co-operation with the grower.

The inherent risk is low and the use pattern does not contain any parameters that particularly favour the development of weed resistance against KINVARA. The target species are regarded as of low potential for the generation of resistant biotypes. The product gives effective control of many broadleaved weed species and may be used alone or in sequence with other herbicides of different modes of action. The agronomic risk for resistance development in cereals and grassland is therefore considered low.

Conclusion on the risk of the possible occurrence of the development of resistance or cross-resistance

The risk for the development of resistance of target species were analysed following EPPO guideline PP1/213(1).

The risk of the development of resistance to KINVARA is real, but low. Resistance to synthetic auxin herbicides is relatively uncommon. Resistance when it occurs may result in a fitness penalty. If the resistance management strategy outlined above is followed, this risk would be reduced further to the point where growers could be confident that the use of KINVARA was sustainable for the long term.

The use pattern proposed by the applicant is low risk, and the product itself has a low risk of the development of resistance. The overall risk is therefore considered to be low, and no specific resistance management strategy is required.

No modifiers are required.

Comments of zRMS:	<u>**Resistance risk**</u> Kinvara is a herbicide mixture of three active substances MCPA, clopyralid, and fluroxypyr, intended for control of annual and perennial weeds in cereals, established, and new grasslands. These active substances are selective, synthetic auxins, and have similar modes of action (HRAC group 4), but slightly different spectra of activity, thus

	the mixture gives a broader range of weed control than any of the actives used individually. The actives are from different chemical groups, MCPA is a phenoxy-carboxylic acid, while fluroxypyr and clopyralid are pyridine carboxylic acids. The applicant presented lists of weeds resistant to all active substances (MCPA, clopyralid, and fluroxypyr), and stated that cross-resistance to herbicides with other modes of action is also possible. Currently, resistance cases for all three active substances in Kinvara have been identified; 89 biotypes across 45 weed species show resistance to HRAC group 4. The weed species controlled by Kinvara, such as *Capsella bursa-pastoris*, *Centaurea cyanus*, *Chenopodium album*, *Matricaria* spp., and *Stellaria media*, have already developed resistance to one or more modes of herbicide action, indicating a high inherent risk of resistance for these species. In contrast, no resistance has been observed in target species like Rumex spp., which are especially found in grasslands, suggesting a low inherent resistance risk for these plants. The overall risk of resistance to the active substances in Kinvara can be regarded as low to moderate. Therefore, it can be concluded that the overall resistance risk for grassland is low, while for cereals it is moderate. When considering crop rotation, particularly with cereals followed by grassland in subsequent years, the risk of resistance may increase. Thus, it is advisable to grow a different crop before establishing grassland. To reduce the risk of resistance to the active substances contained in the Kinvara herbicide, the resistance management strategy should be introduced into the label of this product. The weed management strategy should follow Good Agricultural Practices and Good Plant Protection Practices (EPPO Standard 2/1 (2)). Kinvara should be used in alternation with herbicides comprising different modes of action to avoid the build-up of resistant biotypes and cross-resistance. It should be used as recommended on the label, do not use reduced doses. Kinvara should be used a maximum once a year on the same field. For the use of Kinvara, the key to resistance management is to reduce selection pressure by using a combination of the following techniques: crop rotation, cultural techniques (non-chemical control methods), and herbicide rotation. The risk management strategy to reduce the risk of resistance development to MCPA, clopyralid, and fluroxypyr should based on Good Agricultural Practices (GAP) and recommendations of HRAC to apply the label recommended rate, the proper application time relative to risk for resistance development, the use of herbicides with different mode of actions, checking the effects of weeds control to ensure adequate efficacy is achieved, and also the use the non-chemical methods of prevention and protection against weeds, including cultural and agronomic methods depending on the soil and climatic conditions. **Conclusion**. The product label should have a clear statement regarding resistance risk and the management strategy. The modified risk and the resistance management strategy allow to manage the risk to the acceptable level.

3.4 Adverse effects on treated crops (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.4.4 Effects on transformation processes (KCP 6.4.4)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

Comments of zRMS:	Concerning point 3.4, zRMS agrees with an applicant.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

Comments of zRMS:	Concerning point 3.5, zRMS agrees with an applicant.

3.6 Other/special studies

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

3.7 List of test facilities including the corresponding certificates

No new data are submitted as this is not considered necessary as no changes in the GAP and in dose rates have been made for this renewal in comparison to the GAP currently approved (see the introductory statement).

Comments of zRMS:	oncerning point 3.6 and 3.7, zRMS agrees with an applicant.

Appendix 1 Lists of data considered in support of the evaluation

No data is submitted for Part B Section 3 of the Core Assessment.