

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: **102000025743**

Product name(s): **Foramsulfuron + Thiencarbazone-methyl
OD 80 (50+30 g/L)**

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Re-Authorisation)

Applicant: **Bayer Crop Science Division**

Submission date: **31/08/2020**

MS Finalisation date: **19/05/2021** ; **12/2021**



M-687150-01-1

Version history

When	What
31/08/2020	Original Bayer CropScience document (Regulation 1107/2009 - Art. 43) Foramsulfuron
May 2021	ZRMs evaluated dRR submitted by Applicant
December 2021	ZRMs corrected dRR according to comments received.

OECD Statement on Confidentiality

The summaries and evaluations contained in this monograph or review report may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this Monograph or review report unless they have received the data on which the summaries and evaluation are based, either:

- From the owner of the data; or
- From a second party that has obtained permission from the owner of the data for this purpose or, alternatively, the applicant has received permission from the data owner that the summaries and evaluation contained in this Monograph or review report may be used in lieu of the data; or
- Following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation;

unless the period of protection of the proprietary data concerned has expired.

Applicants wishing to avail of information in this Monograph or review report should seek advice from the regulatory authority to which application is made concerning the requirements in their country.

Table of Contents

3	Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)	5
3.1	Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6).....	6
3.2	Efficacy data (KCP 6)	11
3.2.1	Preliminary tests (KCP 6.1)	29
3.2.2	Minimum effective dose tests (KCP 6.2).....	29
3.2.3	Efficacy tests (KCP 6.2)	30
3.3	Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)	30
3.4	Adverse effects on treated crops (KCP 6.4).....	40
3.4.1	Phytotoxicity to host crop (KCP 6.4.1).....	40
3.4.2	Effect on the yield of treated plants or plant product (KCP 6.4.2)	41
3.4.3	Effects on the quality of plants or plant products (KCP 6.4.3).....	41
3.4.4	Effects on transformation processes (KCP 6.4.4).....	41
3.4.5	Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)	41
3.5	Observations on other undesirable or unintended side-effects (KCP 6.5)...	42
3.5.1	Impact on succeeding crops (KCP 6.5.1).....	42
3.5.2	Impact on other plants including adjacent crops (KCP 6.5.2)	42
3.5.3	Effects on beneficial and other non-target organisms (KCP 6.5.3)	42
3.6	Other/special studies	42
3.7	List of test facilities including the corresponding certificates	43
Appendix 1	Lists of data considered in support of the evaluation	44

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

This document is a summary of the data submitted to support the re-registration of the plant protection product **Foramsulfuron+Thiencarbazon-methyl OD 80 (50+30 g/L)** which is proposed to be commonly named as **FSN+TCM OD 80** to ease the reading on this dossier. **FSN+TCM OD 80** is a formulation that is submitted for re-registration under Article 43 and for which no new biological data are deemed required as there is no GAP change compared to the current registered uses.

Appendix 1 of this document contains the list of references included for support of the evaluation.

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

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	The commenting boxes are filled-in by the zRMS. They are usually placed at the end of each chapter. Commenting boxes should be understandable alone and refer very precisely to the text commented. The main advantage of their use is to distinguish easily between the applicant and the zRMS text.
-------------------	---

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

Abstract

zRMS provided main conclusions on each use. Overall summaries are not necessary here, cause they were provided at the end of each chapter of the dRR.

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	Crop and/or situation (crop destination / purpose of crop)	F, G, I	Pests / group of pests controlled (*) (additionally: developmental stages)	Application				Application rate			PHI (days)	Remarks	zRMS Conclusion (efficacy)
					Appl. method / kind	Appl. timing / growth stage of crop & season	Appl. max number a) per use b) per crop / season	Min interval between applications (days)	Appl. rate (L or kg PPP/ha) a) max per appl. b) max total per crop / season	Appl. rate (g AS/ha) a) max per appl. b) max total per crop / season	Water (L/ha) min-max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
22	POL	Sugar beet (BEAVA)	F	AETCY, ECHCG, VIOAR, STEME, LAMPU, MAT-IN, CHEAL, GALAP, POLCO, POLAV, POLPE, BRSNN, VERPE, THLAR, POAAN, VERAR	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	100-300	as per growth stage		Acceptable
23	AUT	Sugar beet (BEAVA) only ALS tolerant varieties	F	GGGAN, BBBAN 3ANDIT, 3ANMNT	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by eCMS Acceptable
24	BEL	Sugar beet (BEAVA) Fodder beet (BEAVC)	F	TTTMM, TTTDD	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS
25	CZE	Sugar beet (BEAVA)	F	TTTMM, TTTDD	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS

26	HUN	Sugar beet (BEAVA)	F	TTTMM, TTTDD	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS
27	SVK	Sugar beet (BEAVA)	F	GGGAN, BBBAN	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS
28	GBR	Sugar beet (BEAVA) Fodder beet (BEAVC)	F	ECHCG, MERAN, POLCO, SOLNI, AMARE, STEME, FUMOF, CHEAL, VIOAR, THLAR, POLAV, CHEPO, CHEHY, POLLA, LAMPUR, POLPE, MATCH, BRNN	spraying (broadcast, overall)	14-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	150-300	as per growth stage		To be confirmed by cMS
29	NLD	Sugar beet (BEAVA) Fodder beet (BEAVC) only ALS tolerant varieties	F	GGGAN, BBBAN	spraying (broadcast, overall)	10-18 March - June	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	80-300	as per growth stage		To be confirmed by cMS
30	ROU	Sugar beet (BEAVA)	F	ECHCG, ALOMY, POAAN, PANMI, AMARE, CVCCA, FUMOF, GALAP, LAMPUR, MATCH, PAPRH, SOLNI, STEME, VIOAR, THLAR, POLSS, CHESS, LOLSS	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	200-300	as per growth stage		To be confirmed by cMS
31	IRE	Sugar beet (BEAVA) Fodder beet (BEAVC)	F	ECHCG, POAAN, AMARE, MERAN, POLCO, SOLNI, SINAR, STEME, GALAP, PAPRH, CHEAL, CVCCA, VIOAR, THLAR, FUMOF, CHEHY, POLAV, POLLA, LAMPUR, POLPE, MATCH, CAPBP, BRNN	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS
32	POL	Sugar beet (BEAVA)	F	AETCY, ECHCG, VIOAR, STEME, LAMPUR, MAT- IN, CHEAL, GALAP, POLCO, POLAV, POLPE, BRNN, VERAR, THLAR, POAAN, VERPE	spraying (broadcast, overall)	10-18 B1: 10-12 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage		Acceptable

33	AUT	Sugar beet (BEAVA)	F	GGGAN, BBBAN	spraying (broadcast, overall)	10-18 B1: 10-14 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS
34	BEL	Sugar beet (BEAVA), Fodder beet (BEAVC)	F	TTTMM, TTDD	spraying (broadcast, overall)	10-18 B1: 10-14 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS
35	CZE	Sugar beet (BEAVA)	F	TTTMM, TTDD	spraying (broadcast, overall)	10-18 B1: 10-14 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS
36	SVK	Sugar beet (BEAVA)	F	GGGAN, BBBAN	spraying (broadcast, overall)	10-18 B1: 10-14 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS
37	NLD	Sugar beet (BEAVA) Fodder beet (BEAVC) only ALS tolerant varieties	F	GGGAN, BBBAN	spraying (broadcast, overall)	10-18 Application 1: BBCH 10-14 (spring, March- June) Application 2: BBCH 12-18 (spring, March- June) B1: 10-14 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	80-300	as per growth stage	.	To be confirmed by cMS
38	ROU	Sugar beet (BEAVA)	F	ECHCG, ALOMY, POAAN, PANMI, AMARE, CVCCA, FUMOF, GALAP, LAMPU, MATCH, PAPRH, SOLNI, STEME, VIOAR, THLAR, POLSS, CHESS, LOLSS	spraying (broadcast, overall)	10-18 B1: 10-14 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	200-300	as per growth stage		To be confirmed by cMS

39	HUN	Sugar beet (BEAVA)	F	TTTMM, TTTDD	spraying (broadcast, overall)	10-18 B1: 10-14 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	200-300	as per growth stage		To be confirmed by cMS
40	IRE	Sugar beet (BEAVA) Fodder beet (BEAVC)	F	ECHCG, POAAN, AMARE, MERAN, POLCO, SOLNI, SINAR, STEME, GALAP, PAPRH, CHEAL, CVCCA, VIOAR, THLAR, FUMOF, CHEHY, POLAV, POLLA, LAMPU, POLPE, MATCH, CAPBP, BRSNN	spraying (broadcast, overall)	10-18 B1: 10-14 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage		To be confirmed by cMS
Zonal uses (indoor)														
-	-	-	-	-	-	-	-	-	-	-	-	-	-	

* 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

3.2 Efficacy data (KCP 6)

Introduction

This draft registration report is a zonal core dossier following the frame of Art.43 for the re-registration of **FSN+TCM OD 80** in the Central administrative zone. Poland is the zRMS for the re-registration of the product in Poland, Austria, Belgium, Czech Republic, Hungary, Slovakia, The Netherlands, The United Kingdom, Romania and Ireland. **FSN+TCM OD 80** is already registered in these countries (except in Slovakia for which the registration process is still on going and emergency authorisations have been granted so far) for several years.

Warning: this concept is based on two specific components:

- A specific plant protection product **FSN+TCM OD 80** mainly named “Convise One”
- Varieties tolerant to ALS inhibiting herbicides (named with the suffix “smart” varieties)

In the rest of this document each time we refer to beet crops, it implies these specific herbicide tolerant “smart” varieties. One should remember that all the other commercial varieties are highly sensitive to this product. “Smart” varieties developed by the company KWS are currently under specific registration process so that no final name is given yet. These varietal aspects will be addressed in the specific procedure for variety inscriptions. Here we are focussing only on the herbicide part of the concept.

As basic principle, following Art.43, no significant change of GAP should be requested for renewal of authorization compared to previous authorization, therefore limited new information is required in term of the efficacy section. Nevertheless, GAPs modifications are deemed to be acceptable when necessary and with appropriate justification (*eg* new endpoints, conditions or restrictions in the renewal regulation...). In other case when there’s no appropriate justification, formalistically, other application such as Art.33 or Art.45 should be used, which have different timelines and procedures from Art.43.

Concerning the formulation **FSN+TCM OD 80**, no new data concerning efficacy or adverse effects are provided in this document. However, the analysis of the resistance risk has been updated in accordance with the EPPO method PP 1/213: “*Resistance risk analysis*” and is submitted in this document.

Furthermore, no national addenda (Section 3) is submitted in the frame of this re-registration.

c-MS	Nat Add (Y/N)	Justification for Nat Add
Poland	N	
Austria	N	
Belgium	N	
The Czech republic	N	
The Netherlands	N	
The United Kingdom	N	
Hungary	N	
Romania	N	
Slovakia	N	
Ireland	N	

Description of active ingredients

Foramsulfuron	existing
Thiencarbazone-methyl	existing

FSN+TCM OD 80 is a wide spectrum post-emergence herbicide developed by Bayer CropScience for the control of grass weeds and broad-leaved weeds in beet crops. It is a oil dispersion formulation (OD) containing the active substances foramsulfuron (FSN, 50 g/l) and thiencarbazone-methyl (TCM, 30 g/l). The active substances are used for several years and widely available in many formulations across Europe. Foramsulfuron belongs to the sulfonyl urea chemical class and thiencarbazone-methyl to the sulfonyl-amino-carbonyl triazolinone chemical class.

Foramsulfuron

Foramsulfuron was included into Annex I of Directive 91/414 in 2003 via Directive 2003/23/EC. In the Annex I Inclusion Directive for foramsulfuron there were no specific provisions under Part B which needed to be considered related to the efficacy data.

Foramsulfuron was EU re-approved via the Commission Implementing Regulation (EU) 2020/616 of 5th of May 2020 - Date of EU approval: 1st of June 2020. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on foramsulfuron, and in particular Appendices I and II thereto, shall be taken into account.

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

- the risk to consumers and operators
- the risk to aquatic organisms and non-target plants

Conditions of use shall include risk mitigation measures, where appropriate.

No specific provisions under Part B are therefore needed to be considered related to the efficacy data.

Thiencarbazone-methyl

Thiencarbazone-methyl is a new active substance which was submitted in 2007, to the UK authorities as RMS, for the inclusion into Annex I of Directive 91/414. Thiencarbazone-methyl was part of an OECD Joint Review. Thiencarbazone was voted for approval at European level in the Standing Committee in December 2013. The Regulation for EU Approval of thiencarbazone-methyl is 145/2014/EC dated 14th of February 2014 (entry into force: 1st of July 2014). In the EU approval regulation, there are no specific provisions under Part B which need to be considered related to the efficacy data. The EFSA conclusions on the peer review for thiencarbazone-methyl (EFSA Journal 2013; 11(7): 3270, June 2013) is considered to provide the relevant scientific information for the review of the product.

Information which is considered to be confidential, for example the detailed composition of the plant protection product or bridging statements, can be found in the confidential section of this submission (Registration Report - Part C).

Mode of action and biological activity

FSN+TCM OD 80 is a oil dispersion formulation (OD) containing the active substance foramsulfuron (FSN, 50 g/L) and thien carbazon-methyl (TCM, 30 g/L).

A summary of the main characteristics of the active ingredients is presented in Table 3.2/1 below.

Table 3.2/1: Details of the active ingredients

Active substance	FSN Foramsulfuron	TCM Thien carbazon-methyl
Concentration (Unit: g/kg or g/L...)	50 g/L	30 g/L
Chemical group	Sulfonyl-urea (HRAC B)	Sulfonyl-amino-carbonyl-triazolinone (SACT) (HRAC B)
Mode of action	Inhibition of acetolactate synthase (ALS)	Inhibition of acetolactate synthase (ALS)
Biological action	Post-emergence herbicide	Post-emergence herbicide

For further physico-chemical properties, reference should be made to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Foramsulfuron (FSN) belongs to the sulfonyl-urea chemical family. Conducted by the xylem and the phloem, foramsulfuron acts by the inhibition of the acetolactate synthase ALS (acetohydroxyacid synthase AHAS). It is mainly absorbed through the foliage of weeds. Absorption by roots makes only a minor contribution to the overall efficacy. This active ingredient controls many annual broad leaved weeds and grass weeds already established when the product is applied.

At 45-60 g ai/ha, foramsulfuron has a competitive grass weed spectrum covering species of major economic importance such as *Echinochloa crus galli*, *Digitaria sanguinalis*, *Poa annua*, *Lolium multiflorum*, *Setaria* sp., *Agropyron repens*, *Sorghum halepense*. A broad spectrum of dicotyledonous weeds is also controlled by foramsulfuron: *Amaranthus* sp., *Chenopodium* sp., cruciferous weeds, *Galinsoga* sp., *Mercurialis annua*, *Solanum nigrum*, *Stellaria media* and many others.

Thien carbazon-methyl belongs to the sulfonyl-amino-carbonyl-triazolinone (SACT) chemical family. and acts on the inhibition of the acetolactate synthase ALS. After an application in either pre-emergence or early post-emergence of weeds, this active substance is rapidly absorbed by leaves and roots, and then conducted by the xylem and the phloem. Translocation by phloem is very important because it allows the transport of the herbicide from mature leaves to newly-grown shoots and roots.

Thien carbazon-methyl controls a wide number of monocotyledonous and dicotyledonous weeds. Weeds sensitive to thien carbazon-methyl stop growing and after few days, leaves show some yellowing and then necroses. After 2 to 4 weeks, weeds die.

According to the knowledge acquired during the development of this active substance, its relevant dose rate is 10-30 g a.i/ha in post emergence, depending on the weeds. Moreover, efficacy depends from the weeds growth stage at the application.

Tableau **3.2/2**: Thiencarbazone-methyl spectrum of action
(*Source: European registration dossier for the active substance*)

Very good control	Good control	Satisfactory control
<i>Polygonum convolvulus</i> <i>Polygonum lapathifolium</i> , <i>Polygonum persicaria</i> , <i>Polygonum aviculare</i> <i>Solanum nigrum</i> <i>Stellaria media</i> <i>Atriplex patula</i> <i>Matricaria chamomilla et inodora</i> <i>Viola arvensis</i> <i>Amaranthus retroflexus et blitoides</i> <i>Portulaca oleracea</i> <i>Galium aparine</i> <i>Capsella bursa-pastoris</i> <i>Echinochloa crus-galli</i> <i>Setaria viridis</i> <i>Panicum dichotomiflorum</i> <i>Lamium purpureum</i>	<i>Chenopodium album</i> <i>Anagallis arvensis</i> <i>Abuthilon spp.</i> <i>Panicum miliaceum</i> <i>Poa annua</i>	<i>Chenopodium ficifolium</i> <i>Xanthium strumarium</i> <i>Mercurialis annua</i> <i>Digitaria sanguinalis</i> <i>Pennisetum glaucum</i>

Description of the plant protection product

In the Central administrative zone, **FSN+TCM OD 80** is currently registered in Poland, Austria, Belgium, the Czech Republic, the Netherlands, The United Kingdom, Hungary, Slovakia (emergency authorisation), Romania and Ireland. under the main trade name CONVISO ONE. **FSN+TCM OD 80** is a herbicide for the control of monocotyledonous/grass weeds and dicotyledonous/broad-leaved weeds in beet crop fields. It is to be applied at the 1 l/ha dose rate in one single application or, in most of the countries, in split application (0.5+0.5 l/ha) without exceeding 1 l/ha per season.

In Austria, **FSN+TCM OD 80** has been registered since February 2019 under the trade name CONVISO ONE for use on sugar beet. **FSN+TCM OD 80** is to be applied against annual grasses and annual broad-leaved plants at the 1 l/ha dose rate, in one single application, from BBCH 10 to BBCH 18 or in split application (0.5+0.5 l/ha). In case of split application, the first application is to be done between BBCH 10 and BBCH 14 and the second application between BBCH 12 and BBCH 18. The minimum spraying interval between application is 10 days.

In Belgium, **FSN+TCM OD 80** has been registered since September 2018 under the trade name CONVISO ONE for use on sugar and fodder beet. **FSN+TCM OD 80** is to be applied against monocotyledonous weed plants and dicotyledonous weed plants at the 1 l/ha dose rate, in one single application, from BBCH 10 to BBCH 18 or in split application (0.5+0.5 l/ha). In case of split application, the first application is to be done between BBCH 10 and BBCH 14 and the second application between BBCH 12 and BBCH 18. The minimum spraying interval between application is 10 days.

In the Czech Republic, **FSN+TCM OD 80** has been registered since July 2018 under the trade name CONVISO ONE for use on sugar beet. **FSN+TCM OD 80** is to be applied against monocotyledonous weed plants and dicotyledonous weed plants at the 1 l/ha dose rate, in one single application, from BBCH 10 to BBCH 18 or in split application (0.5+0.5 l/ha). In case of split application, the first application is to

be done between BBCH 10 and BBCH 14 and the second application between BBCH 12 and BBCH 18. The minimum spraying interval between application is 10 days.

In Hungary, **FSN+TCM OD 80** has been registered since November 2018 under the trade name CONVISO ONE for use on sugar beet. **FSN+TCM OD 80** is to be applied against monocotyledonous weed plants and dicotyledonous weed plants at the 1 l/ha dose rate, in one single application, from BBCH 10 to BBCH 18 or in split application (0.5+0.5 l/ha). In case of split application, the first application is to be done between BBCH 10 and BBCH 14 and the second application between BBCH 12 and BBCH 18. The minimum spraying interval between application is 10 days.

In Slovakia, **FSN+TCM OD 80** has been granted emergency authorization under the trade name CONVISO ONE for use on sugar beet. **FSN+TCM OD 80** is to be applied against annual grasses and annual broad-leaved plants at the 1 l/ha dose rate, in one single application, from BBCH 10 to BBCH 18 or in split application (0.5+0.5 l/ha). In case of split application, the first application is to be done between BBCH 10 and BBCH 14 and the second application between BBCH 12 and BBCH 18. The minimum spraying interval between application is 10 days.

In The United Kingdom, **FSN+TCM OD 80** has been registered since March 2019 under the trade name CONVISO ONE for use on sugar and fodder beet. **FSN+TCM OD 80** is to be applied against *Amaranthus retroflexus*, *Brassica napus*, *Chenopodium album*, *Chenopodium hybridum*, *Chenopodium polyspermum*, *Fumaria officinalis*, *Lamium purpureum*, *Matricaria chamomilla*, *Mercurialis annua*, *Polygonum aviculare*, *Fallopia convolvulus*, *Polygonum lapathifolium*, *Polygonum persicaria*, *Solanum nigrum*, *Stellaria media*, *Thlaspi arvense*, *Viola arvensis* and *Echinochloa crus-galli*. It is to be used at the 1 l/ha dose rate, in one single application, from BBCH 14 to BBCH 18

In the Netherlands, **FSN+TCM OD 80** has been registered since November 2018 under the trade name CONVISO ONE for use on sugar and fodder beet. **FSN+TCM OD 80** is to be applied against annual grasses and annual broad-leaved plants at the 1 l/ha dose rate, in one single application, from BBCH 10 to BBCH 18 (March-June) or in split application (0.5+0.5 l/ha). In case of split application, the first application is to be done between BBCH 10 and BBCH 14 (March-June) and the second application between BBCH 12 and BBCH 18 (March-June). The minimum spraying interval between application is 10 days.

In Romania, **FSN+TCM OD 80** has been registered since March 2019 under the trade name CONVISO ONE for use on sugar beet. **FSN+TCM OD 80** is to be applied against *Amaranthus retroflexus*, *Chenopodium* sp., *Cuscuta campestris*, *Fumaria officinalis*, *Galium aparine*, *Lamium purpureum*, *Matricaria chamomilla*, *Papaver rhoeas*, *Polygonum* sp., *Solanum nigrum*, *Stellaria media*, *Thlaspi arvense*, *Viola arvensis*, *Alopecurus myosuroides*, *Echinochloa crus-galli*, *Lolium* sp., *Panicum miliaceum* and *Poa annua*. It is to be used at the 1 l/ha dose rate, in one single application, from BBCH 10 to BBCH 18 or in split application (0.5+0.5 l/ha). In case of split application, the first application is to be done between BBCH 10 and BBCH 14 and the second application between BBCH 12 and BBCH 18. The minimum spraying interval between application is 10 days.

In Ireland, **FSN+TCM OD 80** has been registered since May 2019 under the trade name CONVISO ONE for use on sugar and fodder beet. **FSN+TCM OD 80** is to be applied against *Amaranthus retroflexus*, *Brassica napus*, *Chenopodium album*, *Chenopodium hybridum*, *Capsella bursa-pastoris*, *Cuscuta campestris*, *Fumaria officinalis*, *Lamium purpureum*, *Matricaria chamomilla*, *Mercurialis annua*, *Polygonum aviculare*, *Fallopia convolvulus*, *Polygonum lapathifolium*, *Polygonum persicaria*, *Sinapis arvensis*, *Solanum nigrum*, *Stellaria media*, *Galium aparine*, *Papaver rhoeas*, *Thlaspi arvense*, *Viola arvensis*, *Poa annua* and *Echinochloa crus-galli*. It is to be used at the 1 l/ha dose rate, in one single application, from BBCH 10 to BBCH 18 or in split application (0.5+0.5 l/ha). In case of split application, the first application is to be done between BBCH 10 and BBCH 14 and the second application between BBCH 12 and BBCH 18. The minimum spraying interval between application is 10 days.

In Poland, **FSN+TCM OD 80** has been registered since October 2017 under the trade name CONVISO ONE for use on sugar beet. **FSN+TCM OD 80** is to be applied against *Aethusa cynapium*, *Brassica napus*, *Chenopodium album*, *Lamium purpureum*, *Tripleurospermum inodorum*, *Polygonum aviculare*, *Fallopia convolvulus*, *Polygonum persicaria*, *Stellaria media*, *Galium aparine*, *Thlaspi arvense*, *Veronica arvensis*, *Veronica persica*, *Viola arvensis*, *Poa annua* and *Echinochloa crus-galli*. It is to be used at the 1 l/ha dose rate, in one single application, from BBCH 10 to BBCH 18 or in split application (0.5+0.5 l/ha). In case of split application, the first application is to be done between BBCH 10 and BBCH 14 and the second application between BBCH 12 and BBCH 18. The minimum spraying interval between application is 10 days.

Table 3.2/3: Administrative details of the current registration in the Central Administrative zone for **FSN+TCM OD 80** (specification SP102000025743)

Products trade names	Member State	Authorisation No.	Date of initial registration
CONVISO ONE	Poland	R-40/2017 wu	2017-10-20
CONVISO ONE	Austria	4004	2019-02-15
CONVISO ONE	The Czech Republic	5629-0	2018-07-04
CONVISO ONE	The Netherlands	15728N	2018-11-02
CONVISO ONE	The United kingdom	MAPP 19036	2019-03-14
CONVISO ONE	Hungary	04.2/709-2/2018 NEBIH	2018-11-19
CONVISO ONE	Slovakia	59352/2019	2019-12-09
CONVISO ONE	Romania	508PC/14.03.2019	2019-03-14
CONVISO ONE	Belgium	10827P/B	2018-09-03
CONVISO ONE	Ireland	PCS No 06436	2019-05-24

Bayer Cropscience claims for the re-registration of **FSN+TCM OD 80** in the concerned countries of the Central administrative zone. **FSN+TCM OD 80** is proposed for the control of monocotyledonous/grass weeds and dicotyledonous/broad leaved weeds at the 1 l/ha in one single application or in split application (0.5+0.5 l/ha). It is to be used in beet crop fields. Further details concerning the claimed uses for the re-registration are given in Table 3.2/4 below.

Table 3.2/4: Simplified table of currently registered and intended uses
for **FSN+TCM OD 80**

Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments / Other relevant details on GAPs
Crop	Target(s)				
Sugar beet (BEAVA)	Annual grasses (GGGAN), Annual broad-leaved plants (BBBAN) (see details on the label)	AUT	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	
Sugar beet (BEAVA) Fodder beet (BEAVC)	Monocotyledonous weed plants (TTTMM), Dicotyledonous weed plants (TTTDD) (see details on the label)	BEL	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	

Further details are in the table "All intended uses" in Part B - Section 0.

Table 3.2/4: Simplified table of currently registered and intended uses
for **FSN+TCM OD 80 (continued)**

Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments / Other relevant details on GAPs
Crop	Target(s)				
Sugar beet (BEAVA)	Monocotyledonous weed plants (TTTMM), Dicotyledonous weed plants (TTTDD) (see details on the label)	CZE	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	
Sugar beet (BEAVA)	Monocotyledonous weed plants (TTTMM), Dicotyledonous weed plants (TTTDD) (see details on the label)	HUN	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	

Further details are in the table "All intended uses" in Part B - Section 0.

Table **3.2/4:** Simplified table of currently registered and intended uses
for **FSN+TCM OD 80 (continued)**

Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments / Other relevant details on GAPS
Crop	Target(s)				
Sugar beet (BEAVA)	Annual grasses (GGGAN), Annual broad-leaved plants (BBBAN) (see details on the label)	SVK	<p>1 l/ha max per crop cycle</p> <p>One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i></p> <p>Split application (0.5+0.5 l/ha) 1st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i></p> <p>2nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i></p> <p>10 days minimum spraying interval between applications</p>	<p>1 l/ha max per crop cycle</p> <p>One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i></p> <p>Split application (0.5+0.5 l/ha) 1st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i></p> <p>2nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i></p> <p>10 days minimum spraying interval between applications</p>	
Sugar beet (BEAVA) Fodder beet (BEAVC)	CHEAL, VIOAR, THLAR, POLAV, CHEPO, CHEHY, POLLA, LAMPU, POLPE, MATCH, BRSNN, ECHCG, MERAN, POLCO, SOLNI, AMARE, STEME, FUMOF (see details on the label)	GBR	<p>1 l/ha max per crop cycle</p> <p>One single application in post-emergence BBCH 14-18 <i>Weeds not bigger than BBCH 14</i></p>	<p>1 l/ha max per crop cycle</p> <p>One single application in post-emergence BBCH 14-18 <i>Weeds not bigger than BBCH 14</i></p>	

Further details are in the table "All intended uses" in Part B - Section 0.

Table 3.2/4: Simplified table of currently registered and intended uses
for **FSN+TCM OD 80 (continued)**

Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments / Other relevant details on GAPs
Crop	Target(s)				
Sugar beet (BEAVA) Fodder beet (BEAVC)	Annual grasses (GGGAN), Annual broad-leaved plants (BBBAN) (see details on the label)	NDL	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 (March-June) <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 (March-June) <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 (March-June) <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 (March-June) <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 (March-June) <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 (March-June) <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	
Sugar beet (BEAVA)	ECHCG, LOLSS, ALOMY, POAAN, PANMI, AMARE, CHESS, CVCCA, FUMOF, GALAP, LAMPU, MATCH, POLSS, PAPRH, SOLNI, STEME, VIOAR, THLAR (see details on the label)	ROU	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	

Further details are in the table "All intended uses" in Part B - Section 0.

Table 3.2/4: Simplified table of currently registered and intended uses
for **FSN+TCM OD 80 (continued)**

Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments / Other relevant details on GAPs
Crop	Target(s)				
Sugar beet (BEAVA) Fodder beet (BEAVC)	ECHCG, POAAN, AMARE, MERAN, POLCO, SOLNI, SINAR, STEME, GALAP, PAPRH, CHEAL, CVCCA, VIOAR, THLAR, FUMOF, CHEHY, POLAV, POLLA, LAMPU, POLPE, MATCH, CAPBP, BRSNN (see details on the label)	IRE	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 (March-June) <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 (March-June) <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 (March-June) <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 (March-June) <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 (March-June) <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 (March-June) <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	
Sugar beet (BEAVA)	AETCY, ECHCG, VIOAR, STEME, LAMPU, MATIN, CHEAL, GALAP, POLCO, POLAV, POLPE, BRSNN, VERAR, THLAR, POAAN, VERPE (see details on the label)	POL	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	1 l/ha max per crop cycle One single application in post-emergence BBCH 10-18 <i>Weeds not bigger than BBCH 14</i> Split application (0.5+0.5 l/ha) 1 st appl BBCH 10 to 14 <i>Weeds not bigger than BBCH 12-14</i> 2 nd from BBCH 12 to 18 <i>Weeds not bigger than BBCH 12-14</i> 10 days minimum spraying interval between applications	

Further details are in the table "All intended uses" in Part B - Section 0.

Description of the target pests

Beet is a crop which grows slowly, compared to other crops such as cereals for instance, the rhythm of its growth depending on soil type and climatic conditions: thus row closure may occur only three months after sowing. Therefore weeds can easily develop and severely compete with beet for nutrients, water and light during a long period of time. Yield losses from weed competition depend on their competitiveness (species dependent), density and how long they are present. Weeds that emerge early and grow taller than the crop are the most competitive and, if present in high density, can cause very severe yield loss, up to 50% and even 100%, according to technical literature.

Experiments conducted in the UK have shown that just one tall weed per square metre can reduce yield by 10% or more. In the past, growers might leave a few weeds in the crop but this is no longer acceptable for those now pushing for the high yields required for profitable production. Weeds in beet can produce a large number of viable seeds ranging from around 150 per plant from species such as *Anagallis arvensis* to over 70,000 per plant from *Chenopodium album* L. (CHEAL).

The main weeds found in beet crops in Europe include common annual dicot weeds *Chenopodium album*, *Polygonum aviculare*, *Matricaria chamomilla*, *Fallopia convolvulus*, *Sinapis arvensis* and *Stellaria media*. Besides some grass weeds can emerge like *Alopecurus myosuroides*, *Apera spica-venti* or *Echinochloa crus-galli* also some perennial species like *Agropyron repens* and *Cirsium arvense* can also be found. In many countries volunteers of potatoes and oilseed rape are present. In the absence of any treatment the total potential losses from weeds would be between 50 and 100% of the potential crop yield.

The weed spectrum of **FSN+TCM OD 80** covers a large spectrum of important grass weeds and broad leaved weeds. A description of the main weeds is summarized below.

***Echinochloa crus-galli* (ECHCG)**

Echinochloa crus-galli is considered as one of the world's worst weed. *Echinochloa crus-galli* can be a very serious weed in rice, maize, soya bean, lucerne, vegetables, root crops, orchards and vineyards. This species has the capability to reduce crop yields and cause forage crops to fail by removing up to 80% of the available soil nitrogen. When growing under suitable environmental conditions (i.e., moist soils), it spreads rapidly and produces large amounts of seeds which can germinate or remain in the seed bank for several years. *E. crus-galli* spreads only by seed, and its high capacity for seed production allows large populations to rapidly establish. Seeds can be dispersed by wind, water or as a contaminant in soil, seed crops, and agricultural machinery. The economic impact is estimated between 6 and 80 % depending on early or late weed emergence.

***Setaria viridis* (SETVI)**

Setaria viridis is a tufted annual grass, with many culms, more-or-less erect, up to 70 cm (rarely 100 cm) high. The leaves are about 20 cm (2-40 cm) long by 10 mm (4-25 cm) wide, flat, acuminate, light green, drooping, distinctly, but finely veined with prominent mid-vein below, scabrous above, usually glabrous below. In Europe, *Setaria viridis* is present in a lot of countries and is one of the most abundant of all weeds. *Setaria viridis* is an annual plant, reproducing only by seed. Freshly shed seed may be capable of germinating immediately, or there may be a short period of dormancy of some weeks or months, readily

broken by moist storage for a few weeks. The development of *Setaria viridis* seedlings is critically affected by light and temperature.

Its importance as a weed relates to its heavy seed production and dense competitive stands which occur largely in spring-sown crops such as beet crop. Individually, *Setaria viridis* plants may not be highly competitive, but population densities can reach 3000 plants/m².

Digitaria sanguinalis (DIGSA)

Digitaria. sanguinalis is an annual, late spring-and summer-germinating plant. Tillering initiates after emergence of the fourth leaf. Mature plants cover extensive areas developing a 'mulch' or 'tuft' 40-60 cm deep (Kissman and Groth, 1993). One isolated plant can bear more than 150,000 'seeds' (caryopses). Seeds are dormant when shed. Seedling emergence can occur from 6 cm depth in the soil; seed-germination is not light-sensitive, but is favoured by alternating temperatures (Holm et al., 1977).

Digitaria sanguinalis is highly competitive in some spring crops, especially in the few weeks following the sowing. *Digitaria sanguinalis* is highly adaptable to different environments, mobile locally, has a high reproductive potential and also has propagules that can remain viable for more than one year.

Sorghum halepense (SORHA)

Sorghum. halepense is a perennial grass which can be cultivated for fodder, but is also an extremely invasive weed with a worldwide distribution. Its extensive spreading rhizome and shoot system and high rate of seed production make it extremely invasive and difficult to eradicate. The species has a number of detrimental effects including: toxicity to grazing stock, fire risk during summer and competitive exclusion of other plants. It reduces soil fertility, acts as a host for crop pathogens and is a known allergen. It is regarded as a serious weed in some European countries and in a wide range of field crops, including beet crop.

Agropyron repens or *Elymus repens* (AGRRE)

Agropyron repens is a rhizomatous perennial grass with both vegetative and sexual reproduction. It propagates easily by the rhizomes, even short fragments of which are regenerative if they include a node. The plant can therefore be rapidly spread and multiplied by soil cultivation, and where competition from other plants is not too strong, undisturbed plants can develop rapidly extending clones. In a short-term perspective, vegetative propagation dominates quantitatively and contributes to the special character of the species as a weed. However, following very thorough control of this weed in the field, surviving seeds will be important (together with surviving rhizome fragments) for initiating a new weed population.

Agropyron repens is a competitive weed, being able to reduce growth and production in any crop, including competitive crops such as cereals. Many shoots of this grass are often still green when the crop is ripe. At mechanical harvest of cereals and other crops, these shoots can cause technical problems and result in yield losses.

Cirsium arvense (CIRAR)

Cirsium arvense is a tenacious and economically important agricultural weed. It has a fibrous taproot and is capable of sending out lateral roots as deep as 90 cm below ground, from which shoots sprout up at frequent intervals. It also readily regenerates from root fragments less than 2.5 cm in length. This vegetative way of propagation results in the formation of “hot spots” in infested fields which rapidly expand, if not adequately controlled. *Cirsium arvense* is an aggressive species having the ability to germinate at similar rates during the entire growing season and across a broad range of soil moisture conditions.

Amaranthus retroflexus (AMARE)

Amaranthus retroflexus is a monoecious, erect, finely hairy, freely-branching, herbaceous annual growing to 2 m tall. *Amaranthus retroflexus* is widely spreaded throughout Europe and is a common weed of most field and horticulture row crops including beet crop. *Amaranthus retroflexus* is found on a wide variety of soil types and textures. It grows particularly well in fertile soils and has a high N requirement. *A. retroflexus* is an annual that reproduces solely by seed. It is a prolific seed producer, with single vigorous plants capable of producing between 230,000 and 500,000 seeds

Amaranthus retroflexus is an aggressive and competitive weed in a variety of row crops. It causes substantial yield loss in soyabean, maize, cotton, sugarbeet, sorghum, and many vegetable crops. It has been reported to have allelopathic effects on both weeds and crops and has the capacity to accumulate and concentrate nitrates in stems and branches in amounts which are poisonous to livestock. Leaves have been reported to have oxalate levels as high as 30% (Nuss and Loewus , 1978). *Amaranthus* species can cause allergic reactions in humans, primarily due to wind-borne pollen. *A. retroflexus* is an alternative host for a number of crop pests and diseases.

Matricaria Chamomilla (MATCH)

Matricaria chamomilla is a major annual dicotyledon weed in Northern Europe with a deep root system. Scented mayweed competes for water and light, interferes with combine harvesting and therefore greatly reduces yield. *Matricaria chamomilla* can grow in poor and disturbed soils, with moderate salinity and acidity with it often growing near roads and in cultivated fields as a weed. It infests both winter and spring crops, which makes long-term management without herbicide difficult.

Chenopodium album (CHEAL)

This annual dicotyledon is one of the most important and widespread of all weeds. Primarily it is a spring weed of broadleaved crops such as sugar beet and other open row crops. Seeds may germinate in autumn but only spring germinating seedlings go on to flower and set seed. Seeds are spread by crop contamination and dispersed by birds and mammals; about 20% germinate immediately. *Chenopodium album* extracts large quantities of nutrients from the soil. It has a highly persistent seedbank and seeds can remain dormant in the soil for many years.

Galium aparine (GALAP)

Annual or perennial climbing weed, belonging to the Rubiaceae family, *Galium aparine* prefers fertile, humus-rich, nutrient-rich (high nitrogen content) soil and soils with a high loam or clay content. The propagation occurs by seed (approx. 100-500 per plant), which can remain viable for 7-8 years. Germination is light-independent and emergence occurs generally from a depth of 1-5 cm, however germination from a soil depth of 10 cm is possible. *Galium aparine* is very competitive in fields with high nitrogen input since it impedes in harvest; therefore, the economic weed threshold is very low. Adult plants can be very large and can choke crops by growing over the top of the canopy effecting harvest. Due to their growth, *Galium aparine* can also have a negative influence on harvest technique.

Mercurialis annua (MERAN)

Mercurialis annua is annual weed, frequently found in some crops such as sugarbeet or maize and other open row crops. It can grow in a lot of soils. It grows particularly well in fertile soils, with a lot of nitrogen. In the field, seed germination occurs intermittently from May to September. Under field conditions first plants of *Mercurialis annua* can be detected during the April. The peak of emergence comes in May and June. The emergence is not fixed to spring only. There can be identified several waves of emergence, which are not too distinct and the emergence dynamic is influenced by weather conditions, especially by precipitation. Seeds can remain viable in soil for 6-7 years. *Mercurialis annua* can produce up to 20 000 seeds per square meter - with dependence on the intensity of weediness and germination date.

Mercurialis annua can be a highly competitive weed in a variety of row crops and difficult to control due to its several waves of emergence. Mineral uptake at early growth stages is relatively high, an important factor in plant competition. The plant is poisonous if eaten by livestock. The seeds are the most poisonous part. It could be problematic for the silage maize production. *Mercurialis annua* can be mostly controlled with a post-emergence application.

Solanum nigrum (SOLNI)

Solanum nigrum is a very variable ephemeral, annual or sometimes biennial herb, 0.2–1.0 m tall, reproducing only by seed. It has a strong white taproot, with many lateral roots being produced in moist and fertile surface soils. *Solanum nigrum* thrive under disturbed moist warm fertile conditions with full or partial sunlight, becoming less competitive where soils are drier, cooler and less fertile or where there is heavy shade from taller crops. It is best adapted to fertile soils, especially those high in nitrogen and phosphorus.

Solanum nigrum is a serious competitor with the seedling stages of many horticultural and agricultural crops for water, light and nutrients, especially with spring crops such as sugarbeet, maize, potato and with widely spaced and low-growing horticultural crops such as tomato.

Polygonum persicaria (POLPE)

Polygonum persicaria is common annual weed of arable land, particularly damp but well aerated loams and sandy soils rich in nutrients. During cultivations plant fragments can root at the nodes. *Polygonum persicaria* can be very competitive with crop plants, particularly in moist areas, and has an ability to spread rapidly once germinated.

Fallopia convolvulus (POLCO)

Polygonum convolvulus is a summer annual that scrambles as high as the supporting vegetation will allow. It is one of the most common weeds found in the main rotational crops; cereals, potato, sugar beet and maize crops. It grows rapidly from large seedlings mainly germinating in spring and is deep rooting.

Polygonum aviculare (POLAV)

Polygonum aviculare is typically a weed of spring crops. It is one of the relatively few weeds that are equally abundant in both cereals and broad-leaved crops and is a principal or serious weed of a wide range of crops in temperate climates, especially in maize fields.

Polygonum aviculare regenerates exclusively by seed and is often one of the most abundant species in seed banks of cultivated soils in temperate Europe. Densities as high as 200 to 5000 seeds/m² are common, with most seeds being buried in the upper 5 cm of soil. *Polygonum aviculare* usually germinates in a single flush during a short period early in the spring.

The first seeds are usually shed two months after emergence, and can be produced over an extended period of time (up to 6 months or more unless the plant is killed by frost). A single plant can produce up to 6000 seeds, but this number is highly variable, depending on competition and resource availability

In spite of its short stature, *Polygonum aviculare* has a significant competitive effect on several crops, including maize. It competes primarily for soil resources.

Stellaria media (STEME)

Because of its ability to produce large numbers of seeds under cool temperatures, *Stellaria media* rapidly colonizes any cool, moist area before winter or spring crops can become competitive. In commercial situations common chickweed can limit winter vegetable production by competing for space, light, and nitrogen. Plants can produce large numbers of seeds, potentially up to 15,000 seeds per plant (HANF; 1991). Additionally, *Stellaria media* can serve as a host for insect pests such as lygus bugs and thrips as well as a reservoir host for tomato spotted wilt virus (TSWV) and cucumber mosaic virus (CMV).

Sinapis arvensis (SINAR)

Sinapis arvensis is an annual weed belonging to the Brassicaceae family that occurs in nutrient-rich and usually also lime-rich soils. It propagates by seeds that germinates in spring from a soil depth up to 2 cm. *S. arvensis* produces 200-2000 seeds/plant, which can remain viable for more than 35 years due to their high oil content. It is often found in high densities in cereals crops, and this causes a strong competition for soil nutrients and yield reduction.

Viola arvensis (VIOAR)

This weed belongs to Violaceae family and is very frequent in European countries. It is 10-20 cm height and usually stays in lower canopy in grown fields. *Viola arvensis* very often germinates in huge numbers and if a young crop is weak in competition with this weed it can lead to huge yield losses. This is why chemical control measures have to be implemented at early development stages of this target weed. Up to 2,500 seeds can be produced by one plant (HANF; 1999).

Table 3.2/5: Glossary of weeds mentioned in the dossier

EPPO code	Scientific name	EPPO code	Scientific name
ABUTH	<i>Abuthilon theophrasti</i>	LAMAM	<i>Lamium amplexicaule</i>
AETCY	<i>Aethusa cynapium</i>	LOLMU	<i>Lolium multiflorum</i>
AGRRE	<i>Agropyron repens</i>	LOLSS	<i>Lolium</i> sp.
ALOMY	<i>Alopecurus myosuroides</i>	MATCH	<i>Matricaria chamomilla</i>
AMABL	<i>Amaranthus blitoides</i>	MATIN	<i>Tripleurospermum inodorum</i>
AMARE	<i>Amaranthus retroflexus</i>	MATMA	<i>Matricaria maritima</i>
AMASS	<i>Amaranthus</i> sp	MATSS	<i>Matricaria</i> sp.
AMIMA	<i>Ammi majus</i>	MERAN	<i>Mercurialis annua</i>
ANGAR	<i>Annagalis arvensis</i>	PANDI	<i>Panicum dichotomiflorum</i>
ANTAR	<i>Anthemis arvensis</i>	PANMI	<i>Panicum miliaceum</i>
APESV	<i>Apera spica-venti</i>	PAPRH	<i>Papaver rhoeas</i>
ATXPA	<i>Atriplex patula</i>	PESGL	<i>Pennisetum glaucum</i>
BBBAN	Annual broad leaved plants	POAAN	<i>Poa annua</i>
BRSNN	<i>Brassica napus</i>	POASS	<i>Poa</i> sp.
CAPBP	<i>Capsella bursa-pastoris</i>	POLAV	<i>Polygonum aviculare</i>
CERAR	<i>Cerastium arvense</i>	POLCO	<i>Fallopia convolvulus</i>
CHEAL	<i>Chenopodium album</i>	POLLA	<i>Polygonum lapathifolium</i>
CHEFI	<i>Chenopodium ficifolium</i>	POLPE	<i>Polygonum persicaria</i>
CHEHY	<i>Chenopodium hybridum</i>	POROL	<i>Portulaca oleracea</i>
CHEPO	<i>Chenopodium polyspermum</i>	SORHA	<i>Sorghum halepense</i>
CHES	<i>Chenopodium</i> sp	SENVU	<i>Senecio vulgaris</i>
CIRAR	<i>Cirsium arvense</i>	SETSS	<i>Setaria</i> sp
CVCCA	<i>Cuscuta campestris</i>	SETVI	<i>Setaria viridis</i>
DIGSA	<i>Digitaria sanguinalis</i>	SINAR	<i>Sinapis arvensis</i>
ECHCG	<i>Echinochloa crus galli</i>	SOLNI	<i>Solanum nigrum</i>
FAGES	<i>Fagopyrum esculentum</i>	STEME	<i>Stellaria media</i>
FUMOF	<i>Fumaria officinalis</i>	THLAR	<i>Thlaspi arvense</i>
GALAP	<i>Galium aparine</i>	TTTDD	Dicotyledonous weed plants
GASSS	<i>Galinsoga</i> sp	URTUR	<i>Urtica urens</i>
GASCI	<i>Galinsoga ciliata</i>	VERPE	<i>Veronica persica</i>
GGGAN	Annual grass weeds	VIOAR	<i>Viola arvensis</i>
GGGGG	Grasses	XANST	<i>Xanthium strumarium</i>
LAMPU	<i>Lamium purpureum</i>		

Major / minor status of intended uses

The status of the uses is summarized in **Table 3.2/6** below.

Table 3.2/6: Status of the uses according to the country

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Sugar beet (BEAVA)	BEL, GBR, IRE, NLD, SVK, HUN, POL, AUT, ROU, CZE		Grass weeds and broad leaved weeds	BEL, GBR, IRE, NLD, SVK, HUN, POL, AUT, ROU, CZE	-
Fodder beet (BEAVC)	BEL, GBR, IRE, NLD				

A master draft label is prepared here to facilitate the understanding on the product and help in the construction of the country label that is submitted into Part A.

FSN+TCM OD 80

An oil dispersion formulation (OD) containing the active substances foramsulfuron (FSN 50 g/l) and thiencarbazone-methyl (30 g/l).

CROPS

For use on sugar and fodder beet

TARGETS

For control of some grass weeds and broad-leaved weeds such as: ECHCG, ALOMY, LOLSS, POAAN, DIGSA, PANDI, PANMI, STESS, AGRRE, AETCY, AMASS, BRSNN, CHESS, CIRAR, CERAR, GASSS, CVCCA, FUMOF, GALAP, LAMSS, MATSS, MERAN, PAPRH, POLSS, SENVU, SINAR, SOLNI, STEME, THLAR, VIOAR.... *(see details on the label)*

APPLICATION TIMING

Single application: BBCH 10 to BBCH 18 (weeds not bigger than BBCH 14)

Split application: BBCH 10-14 for the 1st application (weeds not bigger than BBCH 12-14) and BBCH 12-18 for the 2nd application (weeds not bigger than BBCH 12-14). 10 days minimum spraying interval between applications

NUMBER OF APPLICATIONS

One single application or split application

RATE & WATER VOLUME

1 l/ha for the single application. 2*0.5 l/ha for the split application

Water volume: 80 to 300 l/ha in the Netherlands, 100-300 l/ha Poland, Austria, Belgium, the Czech Republic, Slovakia, Ireland and Hungary, 150-300 l/ha in The United Kingdom, 200-300 in Romania.

APPLICATION DETAILS:

Spraying

Compliance with the Uniform Principles

Apart from the resistance statement, no new biological data are presented in this dossier. The overall assessment is performed according to the uniform principles.

Information on trials submitted (3.1 Efficacy data)

No new trials are submitted within this application.

Comments of zRMS:	<p>All necessary information's were provided above by Applicant. This document summarises the information related to the efficacy of the plant protection product – FSN+TCM OD 80 (product code: 102000025743).</p> <p>The data presented in this dossier fully support the renewal under Article 43 of FSN+TCM OD 80 for the control of weeds in sugabeet and fodder beet. In Poland (ZRMs) FSN+TCM OD 80 was registered under trade name: Conviso One (R-40/2017 wu dated 20.10.2017) and now it can be re-registered. In our opinion each cMS should decide if presented documentation is sufficient for re-registered FSN+TCM OD 80.</p>
-------------------	---

3.2.1 Preliminary tests (KCP 6.1)

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	<p>Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.</p>
-------------------	---

3.2.2 Minimum effective dose tests (KCP 6.2)

The submission of **FSN+TCM OD 80** or re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	<p>Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.</p>
-------------------	---

3.2.3 Efficacy tests (KCP 6.2)

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

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

Reference:	KCP 6.3/01
Title:	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product - FSN+TCM OD 80 (50+30 g/L)
Report:	Collavo, A.; Kaiser, J.; 2020; M-685081-01-1
Authority registration No:	
Guideline(s):	EU Directive 1107/2009 EEC According to OECD format guidance for industry data submissions on plant protection products and their active substances According to EPPO-Guideline PP 1/213 (4)
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study):	

An analysis of the resistance risk has been updated, in accordance with the EPPO method PP 1/213: “*Resistance risk analysis*”. EPPO Standard PP 1/213(3) EPPO Standard PP 1/213(4) ‘Resistance Risk Analysis’ provides a framework for resistance risk assessment and resistance risk management (Anonymous, 2015). To a great extent the resistance risk assessment considers the inherent risk of resistance evolution and depends on various factors, some of which are associated with the product and others with the weed. A detailed analysis of the risk of resistance and its management has been prepared and this document follows the framework presented within the guideline PP1/213(4). A summary is presented below.

Abstract

The product **FSN+TCM OD 80** is a mixture containing the following active ingredients:

- Foramsulfuron (FSN)
- Thienencarbazone-methyl (TCM)

The herbicide **FSN+TCM OD 80** is a product for the control of a wide range of annual grasses and dicotyledonous weeds in ALS-tolerant sugar beet. It is a foliar applied herbicide formulated as an oily disper-

sion (OD) with the two different active ingredients foramsulfuron (50 g/l) and thien carbazon (30 g/l). The proposed usage is either a single spray of maximum 0.75-1 L/ha or 2 applications of 0.375-0.5 L/ha in a spray interval of 10-14 days according to the country of registration. The development of the weeds at the time of herbicide application should not be bigger than 4-leaf stage. Foramsulfuron belongs to the chemical group of the Sulfonylureas (SU) and thien carbazon to the chemical group of the sulfonyl-amino-carbonyl-triazolinone (SACT) herbicides. Both compounds are very effective inhibitors of the enzyme acetolactate synthase (ALS). Both active ingredients are part of various products registered for many years in European countries as well as in the USA and other countries.

FSN+TCM OD 80 is proposed for the use in ALS tolerant sugar beet as post emergence spring treatment for controlling a wide spectrum of annual broad leaved weeds and grasses (for example *Aethusa cynapium*, *Alopecurus myosuroides*, *Amaranthus retroflexus*, *Ambrosia* sp., *Brassica napus*, *Chenopodium album*, *Chenopodium hybridum*, *Convolvulus arvensis*, *Cuscuta campestris*, *Echinochloa crus-galli*, *Fallopia convolvulus*, *Fagopyrum esculentum*, *Fumaria officinalis*, *Gallium aparine*, *Lamium purpureum*, *Lolium* sp., *Matricaria chamomilla*, *Mercurialis annua*, *Panicum* sp., *Papaver rhoeas*, *Persicaria lapathifolia*, *Poa annua*, *Polygonum aviculare*, *Sinapis arvensis*, *Solanum nigrum*, *Sorghum halepense*, *Stellaria media*, *Thlaspi arvensis*, *Tripleurospermum inodorum*, *Veronica persica*, *Viola arvensis*).

Mode of Action

Foramsulfuron and thien carbazon-methyl inhibit the acetolactate synthase enzyme (ALS) and as a result both prevent the formation of branched chain amino acids (leucine, isoleucine and valine). Branched-chain amino acids, like valine, leucine and isoleucine are required components of the growth processes. By blocking ALS and preventing branched-chain amino acid production, these herbicides rapidly inhibit cell division at the root and shoot tips. After application of the product, sensitive grasses and broad-leaved weeds do not develop any significant further growth - therefore weed competition stops - and die three to six weeks later. According to the Herbicide Resistance Action Committee (HRAC), foramsulfuron and thien carbazon-methyl are classified as Group B herbicides. This chemical group contains five different chemical subgroups, which differentiate in patterns of resistance development and cross-resistance patterns.

Mechanism of Resistance

The major resistance mechanisms reported in literature for ALS inhibiting herbicides are due to target site mutations and herbicide metabolism. Taking in account target site resistance mechanism to ALS, 18 amino acid residues are involved in herbicide binding, structurally different ALS herbicides orientate differently in the herbicide binding domain, with partial overlap. Thus, a particular amino acid substitution within the herbicide binding domain can confer resistance to some but not to all ALS herbicides (Powles and Yu, 2010). Metabolic resistance is less predictable and therefore the cross-resistance patterns vary more among different resistant weeds (Delye et al., 2013).

Fitness cost is associated to some of the amino acid substitution involved in target site resistance (Vila-Aiub et al., 2009). Thien carbazon-methyl can be affected by target site and metabolic resistance mechanisms while foramsulfuron is reported to be only affected by target site resistance mechanism due to amino acid substitutions in the ALS gene at position 574. Foramsulfuron is reported to be only affected by target site resistance mechanism due to amino acid substitutions in the ALS gene at position 574 and

can control ALS metabolic resistant biotypes as well as grasses carrying an amino acid substitutions in the ALS gene at position 197. Therefore foramsulfuron can still be used to control certain weeds resistant to other ALS-inhibiting compounds.

Cross Resistance

Cross-resistance among ALS inhibitors and to different mode of action is quite common worldwide as reported in Tables 3.1 and 3.2. The tables summarise all cases officially reported in the global database of herbicide resistance. Entries in this database follow a certain quality check while for other suspected cases the background is not always clear.

Evidence of Resistance, Sensitivity Data and Resistance Risk

ALS inhibitors have selected more resistant weeds than any other herbicide group mainly because of three reasons: there are many ALS inhibitor herbicides (over 55 actives in 5 chemical classes, twice as many as any other herbicide group), they are used extensively for more than 30 years and they are used on a greater area annually than any other herbicide group. Moreover, ALS inhibitors exert a strong selection pressure because they have very high activity on sensitive biotypes and they also have soil residual activity (Heap, 2014). There are now 165 weed species that have evolved resistance to the diverse ALS inhibitors, 22 cases involving foramsulfuron and only 2 cases regarding thien carbazon-methyl (Heap, 2020). Thien carbazon-methyl is usually found in mixture with other ALS inhibitors and cross-resistance is common. In Europe, to date, five resistance cases have been reported for the following species: *Digitaria sanguinalis*, *Echinochloa crus-galli*, *Echinochloa phyllopogon*, *Sorghum halepense* and *Setaria viridis* in corn and rice crop against foramsulfuron. A case of thien carbazon resistant *Senecio vulgaris* has been reported in France and it has been found in grapes and wheat. Due to long use of ALS inhibitors in Europe and therefore the long exposure of key weeds to these herbicides, data on initial sensitivity are not available. The information available on the diffusion of resistance among ALS-inhibiting herbicides leads to suggest a high inherent risk.

FSN+TCM OD 80 is a mixture of two compounds with the same mode of action. The resistance risk and resistance dynamics in weeds are determined by a range of factors, which will be described in the following sections as far as they are relevant and known. It is of considerable importance to resistance evolution whether a target organism already has evolved a resistance mechanism against the new compound and/or if cross-resistance to other compounds or mode of action groups has to be taken into account.

Depending on the weed phenological stage, **FSN+TCM OD 80** is a powerful herbicide to give effective control in sugar beet to a wide range of broadleaves and some grasses. No sensitivity data are available for **FSN+TCM OD 80**. Field efficacy data demonstrate the efficacy of the product under near-practical conditions and the field data will be considered a measure of sensitivity for future reference (Anonymous, 2015).

The information available on the diffusion of resistance among ALS inhibitors and the cross-resistance pattern lead to suggest a high inherent risk for monocotyledonous weeds and a medium risk for dicotyledonous species found in different crops.

A reduced practical risk of selecting resistant biotypes is estimated when the product is used following the good agronomic practices.

The information available on the diffusion of resistance among the two herbicides alone and the cross-resistance lead to suggest a high inherent risk but a reasonable practical risk of selecting resistant biotypes when the product is used following the good agronomic practices.

Acceptability of the Resistance Risk

The resistance risk analysis takes in account the inherent risk of selecting resistant weeds to the product under unrestricted conditions as well as the effect of appropriate measures to be implemented to mitigate the resistance risk (based on EPPO Standard PP 1/213(4) ‘Resistance Risk Analysis’; Anonymous, 2015). When the product is used following the label indications (i.e. maximum two application per crop/season according to the biological dossier and maximum 1 L/ha per crop/season) and rotated with herbicides having different modes, the selection pressure exerted by FSN+TCM OD 80 will be extremely reduced. Based on these assumptions and according to the section 5.2 of the EPPO Standard PP 1/213(4) ‘Resistance Risk Analysis’ (Anonymous, 2015), the magnitude of the risk of resistance is considered acceptable when the product is used following the label indications.

For the estimation of the risk of a possible resistance development for the product **FSN+TCM OD 80**, it is important to consider the inherent risk of the single active ingredient along with the whole crop rotation system in which the ALS-tolerant sugar beet is grown.

Two basic conditions are necessary to increase the selection pressure and consequently favor the development of resistance:

- The product used must have in the field conditions a relevant activity against the weed species aimed to be controlled.
- The weed species concerned must get in contact with the product.

The analysis of the impact of the introduction of ALS-tolerant sugar beet varieties treated with and **FSN+TCM OD 80** replacing the current commercialized and registered sugar beet varieties treated with non-ALS herbicides should be analyze according to these parameters.

More precisely relevant factors to be considered:

- Rotation with crops with intensive ALS use
- Overlap in area grown
- Weed spectrum overlap
- “Resistant -risky” weeds and their biology
- Soil cultivation methods

In this respect the three (3) -years crop rotation, i.e. ALS-tolerant sugar beet - winter wheat - winter wheat, can be considered as the most risky since winter wheat will usually receive ALS-inhibiting herbicides for the control of grass and dicotyledonous weeds. This fact is reflected in the number of ALS-resistance reports shown for winter wheat in table 3.1 and 3.2.

The most critical weeds for the potential development of ALS-resistance are the “risky” grass weeds *Alopecurus myosuroides* and *Apera spica-venti* which are major weed in winter wheat often grown in rota-

tion with sugar beet. To appreciate the potential risk increase of ALS-resistance development on “risky grasses” such as *Alopecurus myosuroides* and *Apera spica-venti* it should be noted that the sugar beet growing area is ca. 1.6 million hectares - rather low in comparison to winter wheat which is grown on ca. 23 million hectares in Europe, i.e. the overlap of area grown is limited and less than 7% of the overall winter-wheat growing area. Furthermore taking into account the entire winter cereals (40 million ha) the potentially affected winter cereal area is even less (< 5%).

In Europe actual soil cultivation prior sugar beet includes usually thorough soil cultivation (ploughing) in spring or at least the use of glyphosate as a pre-seed treatment. This fact combined to the biology of the “risky” grassy weeds *Alopecurus myosuroides* and *Apera spica-venti* which are mainly/only germinating in autumn, explains the usually very low infestations of those grassy weeds in sugar beet. These autumn emerging weeds are destroyed by the soil cultivation measures in autumn and/or spring before sowing sugar beet.

Therefore, due to the very low importance and occurrence of the “risky” grassy weeds *Alopecurus myosuroides* or *Apera spica-venti* in sugar beet the additional selection pressure towards ALS resistance induced by the use of **FSN+TCM OD 80** in sugar beet can be considered as low.

The overlap of dicotyledonous weed species between sugar beet and winter wheat (usually grown before sugar beet in crop rotation), is rather limited.

For instance, the most important weed species in European sugar beet is *Chenopodium album* which is of absolute no relevance in winter cereals. Other major sugar beet weeds such as *Mercurialis annua*, *Polygonum* spp., or *Aethusa cynapium* do not play any role in winter wheat either. Nevertheless, some weeds species such as *Matricaria* and *Stellaria* can be found both in sugar beet and winter wheat.

Overall, four facts leads to the conclusion that the use of **FSN+TCM OD 80** in ALS-tolerant sugar beet varieties will not significantly increase the risk of ALS-resistance development:

- already today’s sugar beet is not an ALS-free crop, triflurosulfuron is widely used (currently average half of European sugar beet area grown is treated twice with triflurosulfuron);
- the overlap with cereals of the area grown is rather low;
- the number of annual grass and dicotyledonous weed species that need to be controlled in both sugar beet and winter wheat is limited;
- the thorough soil cultivation including ploughing prior planting.

Resistance Management Strategy and Use Pattern

In terms of resistance management it is advisable to diversify the tactics and the herbicides used for controlling weeds. Depending on the population size, resistance to an herbicide naturally occurs in few rare individuals within a weed population. Nevertheless, in terms of probability it is unlikely to find an individual plant that can survive two or more herbicides belonging to different mode of action. Therefore, to decrease the risk of selecting resistant weeds, the application of an additional herbicide belonging to a different mode of action and having high efficacy on the species to be controlled is recommendable. In this context the use of **FSN+TCM OD 80** is suitable for a resistance management strategy considering the product already registered in sugar beet.

In particular the following recommended resistance management measures need to be followed:

- Thorough soil cultivation including ploughing needs be included if not prior Sugar beet planting during the course of the rotation.
- At least once in a 3-year crop rotation, use glyphosate as a pre-seed treatment after allowing emergence of weeds (stale seedbed).
- An efficacy level as high as possible should always be targeted in order to keep the seed bank as low as possible in this respect, the recommended dose rate should not be reduced.
- In the subsequent winter cereal in a 3-year crop rotation, use at least once a pre-emergence/early post-emergence non-ALS inhibiting herbicide active on monocotyledonous grasses and dicotyledonous weeds with residual efficacy to control particularly the risky grasses *Alopecurus myosuroides* and *Apera spica-venti* and also dicotyledonous weeds.
- Crop competition should be favoured as much as possible by the choice of appropriate sowing time and crop management measures.
- The infestation of monocotyledonous grasses and dicotyledonous weed species from the edge biotopes or from untreated field borders should be prevented. To this end the crops should be treated up to the field borders, with the recommended dose rates, wherever possible.

Considering the resistance situation in Europe, the low overlap of area grown between sugar beet and winter wheat, the clearly different weed spectra sugar beet being a summer crop whereas wheat is a winter crop and the commonly used thorough soil cultivation before sugar beet is sown (controlling autumn emerged weeds very effectively), the use of **FSN+TCM OD 80** in the requested application for the control of annual monocotyledonous and dicotyledonous weeds can be safely supported.

Since the inherent resistance risk of **FSN+TCM OD 80** can be considered high, it is recommended to use the product in alternation or in combinations with compounds having a different mode of action. To avoid the selection of resistance it is recommended to perform one or two applications of **FSN+TCM OD 80** at the recommended dose per season according to the biological dossier.

Communication and Implementation of the Management Strategy

The anti-resistance strategy for the product **FSN+TCM OD 80** communicated to the advisory and at farmer's level essentially on the label. In addition, leaflets and brochures that describe the product properties in a detailed manner contain the essential anti-resistance strategy points.

Comments of zRMS:	<p>Applicant presented an analysis of the resistance risk, in accordance with the EPPO method PP 1/213: “Resistance risk analysis”.</p> <p>Resistance against B/2 herbicides is known for various species. In the data-base of www.weedscience.org, 24 25 cases of resistance against foramsulfuron and 2 4 cases against thiencarbon-methyl are momentarily documented.</p> <p>Group B/2 herbicides bind to the substrate binding site of the acetolactate synthase (ALS) enzyme, thus preventing the production of essential amino acids, and without these amino acids, the plant eventually dies. The mechanism of resistance found against sulfonylureas is a so-called target site mechanism. Target site resistance is caused by a mutation on the enzyme at the site where the herbicide</p>
-------------------	--

molecule binds, thus stopping the plant's normal biochemical processes.

Foramsulfuron (FSN) belongs to the sulfonyl-urea chemical family. Conducted by the xylem and the phloem, foramsulfuron acts by the inhibition of the acetolactate synthase ALS (acetoxyacid synthase AHAS). It is mainly absorbed through the foliage of weeds. Absorption by roots makes only a minor contribution to the overall efficacy. This active ingredient controls many annual broad leaved weeds and grass weeds already established when the product is applied.

Thiencarbazon-methyl belongs to the sulfonyl-amino-carbonyl-triazolinone (SACT) chemical family. and acts on the inhibition of the acetolactate synthase ALS. After an application in either pre-emergence or early post-emergence of weeds, this active substance is rapidly absorbed by leaves and roots, and then conducted by the xylem and the phloem. Translocation by phloem is very important because it allows the transport of the herbicide from mature leaves to newly-grown shoots and roots.

Table: Overview of the resistance cases for foramsulfuron

#	Year	Species	Country	MOAs	Actives	Situations
1	2017	Poa annua	Australia (New South Wales)	ALS inhibitors (B/2)	bispyribac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
2	2017	Poa annua	Australia (New South Wales)	ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), Microtubule Assembly inhibitors (K1/3), Photosystem II-Serine 264 Binders (C1/5), Unknown (Z/27)	endothall, bispyribac-sodium, rimsulfuron, simazine, glyphosate, propyzamide = pronamide, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
3	2017	Poa annua	Australia (South Australia)	ALS inhibitors (B/2)	bispyribac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
4	2017	Poa annua	Australia (Victoria)	ALS inhibitors (B/2)	bispyribac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
5	2019	Apera spica-venti	Belgium	ALS inhibitors (B/2)	iodosulfuron-methyl-sodium, foramsulfuron, mesosulfuron-methyl	Wheat
6	2004	Parthenium hysterophorus	Brazil	ALS inhibitors (B/2)	imazethapyr, chlormuron-ethyl, cloransulam-methyl, iodosulfuron-methyl-sodium, foramsulfuron	Soybean
7	2006	Bidens subalternans	Brazil	ALS inhibitors (B/2), Photosystem II- Serine 264 Binders (C1/5)	atrazine, iodosulfuron-methyl-sodium, foramsulfuron	Corn (maize)
8	2011	Setaria viridis	France	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize)

	9	2013	Echinochloa crus-galli var. crus-galli	France	ALS inhibitors (B/2)	foramsulfuron, penox-sulam	Corn (maize), Rice
	10	2015	Digitaria sanguinalis	France	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize)
	11	2009	Echinochloa phyllopogon (=E. oryzicola)	Greece	ALS inhibitors (B/2)	bispyribac-sodium, nicosulfuron, rimsulfuron, imazamox, foramsulfuron, penox-sulam	Rice
	12	2015	Sorghum halepense	Hungary	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize), Fallow
	13	2008	Amaranthus palmeri	Israel	ALS inhibitors (B/2)	pyrithiobac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron, trifloxysulfuron-sodium, mesosulfuron-methyl	Corn (maize), Cotton, Watermelon
	14	2019	Amaranthus tuberculatus (=A. rudis)	Israel	ALS inhibitors (B/2)	pyrithiobac-sodium, foramsulfuron, trifloxysulfuron-sodium	Corn (maize), Cotton, Sunflower
	15	2009	Sorghum halepense	Mexico	ALS inhibitors (B/2)	nicosulfuron, rimsulfuron, primisulfuron-methyl, foramsulfuron	Corn (maize)
	16	2012	Poa annua	United States (Alabama)	ALS inhibitors (B/2)	imazaquin, bispyribac-sodium, foramsulfuron, trifloxysulfuron-sodium	Turf
	17	2006	Sorghum bicolor	United States (Indiana)	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize), Soybean
	18	2006	Sorghum halepense	United States (Kentucky)	ALS inhibitors (B/2)	nicosulfuron, primisulfuron-methyl, foramsulfuron	Corn (maize)
	19	2006	Setaria faberi	United States (Michigan)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron, foramsulfuron	Corn (maize), Soybean
	20	2014	Poa annua	United States (Mississippi)	ALS inhibitors (B/2)	foramsulfuron	Golf courses
	21	2004	Setaria faberi	United States (Pennsylvania)	ALS inhibitors (B/2)	nicosulfuron, imazamox, foramsulfuron	Corn (maize)
	22	2013	Poa annua	United States (Tennessee)	ALS inhibitors (B/2), Photosystem II- Serine 264 Binders (C1/5)	simazine, foramsulfuron, trifloxysulfuron-sodium	Golf courses, Turf
	23	2004	Rottboellia cochinchinensis (=R. exaltata)	Venezuela	ALS inhibitors (B/2)	nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Corn (maize)
	24	2010	Sorghum halepense	Venezuela	ALS inhibitors (B/2)	nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Corn (maize)
	25	2020			Inhibition of	imazethapyr, thifensulfuron-methyl, tribenuron-methyl	

		<i>Amaranthus retroflexus</i>	Ukraine	Acetolactate Synthase HRAC Group 2 (Legacy B)	ron-methyl, flumetsulam, imazamox, florasulam, iodosulfuron-methyl-Na, foramsulfuron, thiencazone-methyl	Corn (maize),
--	--	-------------------------------	---------	---	--	---------------

Table: Overview of the resistance cases for thiencazone-methyl

#	Year	Species	Country	MOAs	Actives	Situations
1	2009	<i>Senecio vulgaris</i>	France	ALS inhibitors (B/2)	tribenuron-methyl, prosulfuron, metsulfuron-methyl, flazasulfuron, imazamox, florasulam, iodosulfuron-methyl-sodium, mesosulfuron-methyl, thiencazone-methyl	Grapes, Wheat
2	2011	<i>Conyza canadensis</i>	United States (Kansas)	ALS inhibitors (B/2)	thifensulfuron-methyl, chlorsulfuron, tribenuron-methyl, metsulfuron-methyl, rimsulfuron, iodosulfuron-methyl-sodium, thiencazone-methyl	Corn (maize), Cotton, Soybean, Wheat
3	2019	<i>Ambrosia artemisiifolia</i>	Serbia	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, imazamox, thiencazone-methyl	Corn (maize), Soybean, Sugar beets, Sunflower
4	2020	<i>Amaranthus retroflexus</i>	Ukraine	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	imazethapyr, thifensulfuron-methyl, tribenuron-methyl, flumetsulam, imazamox, florasulam, iodosulfuron-methyl-Na, foramsulfuron, thiencazone-methyl	Corn (maize), Sunflower

However, several dicotyledonous weeds species have been reported with resistance to ALS inhibitors worldwide and also in Europe. Most of these were found to be resistant to sulfonylureas. The inherent risk of thiencazone-methyl and foramsulfuron has to be classified as **medium to high**:

- inherent risk related to active substance is considered to be high for the application of Conviso One in sugar beet.
- inherent risk related to target weeds is considered to be high for the application of Conviso One in sugar beet.
- agronomic risk) is considered to be high for the application of Conviso One in sugar beet.

Applicant did not present any sensitivity data (neither historical baseline sensitivity data from the initial registration nor e.g. sensitivity data produced from typical field populations-even if these have been exposed to the selection pressure). So, in the opinion of ZRMs the EPPO requirements of PP 1/213(4) are not fulfilled. However, taking into account that both a.s. foramsulfuron and thiencazone are high risk a.s. anyway, it may be acceptable to waive the sensitivity data.

Analysis of the inherent risk:

Both active substances belong to HRAC group B/2 which exhibits a very high resistance risk. The original target organisms of CONVISO ONE are a wide range of dicotyledonous weed species, *Alopecurus myosuroides*, *Echinochloa crus-galli* and *Poa annua*. A number of resistance cases against HRAC group B/2 herbicides have been reported for grasses such as *Alopecurus myosuroides* and *Apera spica-venti* in various European countries including Germany, UK, France and Poland mainly in winter cereals. In addition, some cases of ALS resistance are reported for *Lolium species*, *Avena species* and *Echinochloa species* in cereals, maize and rice. For *Avena fatua*, resistance to ALS inhibitors has already been reported in Germany. Regarding grass weed species, particularly *Alopecurus myosuroides* and *Echinochloa species* can be considered to have a high risk to develop resistance against ALS inhibiting herbicides in general or CONVISO ONE in specific. In addition, numerous dicotyledonous biotypes have been reported with resistance to ALS inhibitors in Europe and in the Central Zone. Most of these biotypes were found to be resistant to sulfonylureas. Regarding the existing dicotyledonous biotypes with resistant to ALS inhibitors, *Matricaria spp.*, *Kochia scoparia*, *Stellaria media* and *Papaver rhoeas* are the dicotyledonous weeds most likely to develop resistance as many resistance cases have been reported for these species in the Central Zone. Regarding crop sugar beets, mainly *Chenopodium album*, *Matricaria species*, *Stellaria media*, *Mercurialis annua*, *Amaranthus retroflexus*, *Polygonum spp.* or *Aethusa cynapium* are of importance in the Central Zone. Of those species especially *Matricaria species* and *Stellaria media* exhibit a high resistance risk. The inherent risk of both two active substances therefore has to be classified as high regarding both dicotyledonous and grass species. The applicant has not provided data on the sensitivity variation of the target species.

Agronomic risk:

The herbicide CONVISO ONE is intended to be used post-emergent for the control of dicotyledonous weed species, *Alopecurus myosuroides*, *Echinochloa crus-galli* and *Poa annua* in ALS tolerant sugar beet varieties. It seems that the use of CONVISO ONE in ALS tolerant sugar beet varieties does not lead to a significantly higher risk of ALS resistance development of monocotyledonous weeds because of the very low importance and appearance of the high risk grass weeds *Alopecurus myosuroides* and *Apera spica-venti* in sugar beets. This conclusion cannot be followed. Although the two species are of higher importance in winter cereals, especially *Alopecurus myosuroides* is also frequently found in sugar beets and is therefore prone to resistance evolution. Due to the narrow efficacy spectrum these triflurosulfuron herbicides, they are used as part of herbicides regimes comprising of a high number of additional active substances from differing MoA groups for the control of the target weeds so that the selection pressure by ALS herbicides is considerably low in conventional sugar beet varieties so far. The agronomic risk of CONVISO ONE therefore has to be assessed as being high. However, the design of the respective crop rotations and the associated frequency of application of CONVISO ONE may differ in the various Member States in the Central Zone and a national specific assessment of the agronomic risk is therefore recommended. The applicant has not provided any information on the individual resistance risk within the different Member States in the Central zone.

In order to minimize the risk of occurrence and development of herbicide weed resistance we should follow Good Agricultural Practice:

- ✓ follow strictly the directions on the plant protection product label,
- ✓ apply the product at the recommended dose and within the recommended time frame to ensure optimal weed control weeds,
- ✓ adjust the choice of the herbicide and the decision as to whether or not to carry

	<p>out the treatment to the prevailing weed infestation</p> <ul style="list-style-type: none"> ✓ adapt the choice of herbicide and the decision on treatment to the prevailing (or potential) weed infestation, taking into account the dominant species and damage thresholds and pest thresholds, ✓ use a rotation of herbicides (active substances) with different mechanisms of action ✓ use a mixture of herbicides with different mechanisms of action, ✓ use in rotation and/or in a mixture herbicides affecting several weed life processes with different mechanisms of action, ✓ use herbicides with a particular mechanism of action only once during the growing season, ✓ adjust tillage measures to field conditions, especially to the type and intensity of weeds, ✓ use various methods of weed control, including crop rotation, etc, ✓ use certified seed, ✓ clean agricultural machinery to prevent weed propagation material from being transferred to other sites, ✓ destroy weeds at field edges and baulks, ✓ inform the permit holder if weed control is not satisfactory, ✓ for more information, contact your advisor, the permit holder, or the permit holder's. <p>Resistance management strategy proposed by the applicant is acceptable. However, in the opinion of Evaluator each of cMS can change or adjust risk assessment considering the national requirements and may designate additional measures relating to resistance prevention on the national level.</p> <p>Also, cMS should remember that design of the respective crop rotations and the associated frequency of application of CONVISO ONE may differ in the various Member States in the Central Zone and a national specific assessment of the agronomic risk is therefore recommended. In the opinion of Evaluator, each cMS should do this separately at national level.</p> <p>To avoid the selection of herbicide resistant biotypes, pre-launch programs have been established to define different anti-resistance management strategies for the ALS-tolerant sugar beet. The strategies adopted rely on pro-active resistance management by defining main crop rotations and associated weed control measures. Thus, strategies focus on diversity in the cropping system and monitoring suspected herbicide failures. The stewardship developed to support the herbicide tolerant sugar beet variety includes diagnostic support by scrutinizing complaints and potentially resistant weeds as well as to provide tailor-made management advice based on investigations of possible herbicide resistance mechanism(s). Applying the above mentioned IWM stewardship measures will allow the sustainable use ALS tolerant sugar beet and to provide a new weed management option to farmers.</p>
--	---

3.4 Adverse effects on treated crops (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be sup-

ported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

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

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

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

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

3.4.4 Effects on transformation processes (KCP 6.4.4)

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

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

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data require-

ments and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

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

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

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

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be supported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

3.6 Other/special studies

The submission of **FSN+TCM OD 80** for re-registration is made under Article 43. As the uses to be sup-

ported are the same as the currently registered ones, this does not trigger the needs for new data requirements and therefore, no additional information is provided under this chapter.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.
-------------------	--

3.7 List of test facilities including the corresponding certificates

Not relevant.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 6.3 / 01	Collavo, A.; Kaiser, J.	2020	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product - FSN+TCM OD 80 (50+30 g/L) Report No.: M-685081-01-1 Bayer AG, Crop Science Division, Frankfurt am Main, Germany GLP/GEP: n.a. unpublished	No	Bayer