REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: FLUDIOXONIL 100FS/GLOB182F

Product name(s): SURRENDER

Chemical active substance:

Fludioxonil 100 g/L

Interzonal

Zonal Rapporteur Member State: PL

Applicant: Globachem N.V.

Submission date: January 2021

MS Finalisation date: August 2021 (initial Core Assessment)

March 2022 (final Core Assessment)

Version history

When	What
January 2021	Initial dRR – Globachem NV
August 2021	Dossier update by the applicant: corrected water volume for the seed treatment, and separate dose rate established for sunflower in Germany, due to different seed planting rate (DE was removed from the use no 4, the use no 6 was added for DE alone).
August 2021	Initial izRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the izRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
March 2022	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the izRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow.

Table of Contents

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

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

Abstract

Abstract by zRMS:

Introduction
According to the applicant`s statement, the present dossier "*summarises the information related to the efficacy of the plant protection product Surrender, further referred to as GLOB182F or Fludioxonil 100 FS in this dossier, containing the active ingredient fludioxonil as a seed treatment fungicide in maize and sunflower.*" Fludioxonil belongs to the MoA group E2 (Phenylpyrroles), and represents one of just two actives in this group, the other one being fenpiclonil, currently not approved (EU Pesticide Database, July 2021).
The applicant has submitted **23 efficacy trials in maize**, including 8 - in the Maritime EPPO zone (BE, CZ, FR, NL), 8 - in the NE EPPO zone (PL), 3 - in the SE EPPO zone (HU) and 4 -in the Mediterranean Zone (ES, IT), and **27 efficacy trials in sunflower**, including 1 - in the Maritime EPPO zone (NL), 2 - in the NE EPPO zone (PL), 7 - in the SE EPPO zone (HR, HU) and 17 -in the Mediterranean Zone (ES, IT). **Five** trials in maize **and eleven** trials in sunflower include at least one lower dose, in order to determine the **MED**. The authorization is sought according to the article 33 of the the Regulation No 1107/2009.

MED in maize
The data presented by the applicant demonstrate that the dose rate of 0.5 L/t seeds of Fludioxonil 100 FS is justified as the minimum effective dose to provide disease reduction. The claim is based on 5 trials testing efficacy of the target dose and lower dose rates against *Fusarium* sp. in maize crop.

MED in sunflower
The dose rate of 1.5 L/t seeds should be considered the MED for sunflower. The claim is based on 11 trials testing efficacy of the dose **range** targeted by the applicant (1.25-1.50L/t seeds) plus one more lower dose, against *Fusarium* sp. and *Botrytis cinerea* in sunflower crop. The details concerning the dose range claim for the SE zone are discussed by zRMS following the MED chapter, and following the Efficacy chapter.

Efficacy and yield in the efficacy trials - maize
Majority of trials demonstrate positive, or the level of standard reference, effect of the test item at the target dose rate of 0.5L/t seeds, on plant emergence, compared to the untreated plots. As, to the zRMS knowledge, no separate criteria exist for the efficacy assessment in seed treatments, it must be concluded that, in light of the data submitted by the applicant, the efficacy of Fludioxonil 100 FS against the target pathogens in maize: *Fusarium* and *Pythium*, at the target dose rate of 0.5L/t seeds, is moderate. The efficacy was nevertheless shown to be at least comparable to the reference standards in most of the submitted trials, and the test item shows no negative effect on seed germination either. Yield of maize treated with the test item at 0.5L/t seeds was on average slightly higher numerically, but comparable statistically to that obtained from the reference-treated plots. The same is true for TKW and moisture content. More details are available in commenting boxes placed within and following the Efficacy chapter.

Efficacy and yield in the efficacy trials - sunflower
Majority of trials demonstrate positive, or the level of standard reference, effect of the test item at the dose range targeted by the applicant: 1.25-1.50 L/t seeds, on plant emergence, compared to the untreated plots. It is concluded that the efficacy of Fludioxonil 100 FS in sunflower against *P. halstedi*, *B. cinerea* and *Fusarium* sp. at the dose rate of 1.50L/t seeds is good. However, the lower dose rate: 1.25L/t, is not universally efficient against all the targets in sunflower. Only in case of *Fusarium* sp. the lower dose rate is indeed comparable to the higher dose. Therefore, while the dose range of 1.25-1.50L/t may be recommended, the label for the Member States of the SE EPPO zone should contain the information that the efficacy of the 1.25L/t dose against *B. cinerea* and *P. halstedii* is moderate. The concerned MSs in the SE zone are also kindly advised to consider individually, whether the dose range approach is acceptable for them. The yield of sunflower treated with the test item at 1.25-1.50 L/t seeds was significantly higher compared to the UNCK and on average comparable between the test item and the reference standards, at their equivalent dose rates. The fresh weight of plants was higher, in majority of trials, from the plots treated with both rates of the test item, compared to the UNCK. This effect was comparable to the plots treated with standards. Moisture content in seeds is unaffected by the application of Fludioxonil 100 FS, as compared to the

standard products and to the UNCK. More details are available in commenting boxes placed within and following the Efficacy chapter.

Resistance management
As the foliar uses of fludioxonil are registered neither for maize, nor for the sunflower, one may admit that the resistance management strategy might be to date unnecessary. The zRMS reasoning, based on a modest data available on target and related pathogens, and considering FRAC statement on the MoA group E2, is presented in the commenting box following the Resistance Risk chapter. However, in case foliar applications of the same active are proposed in maize or sunflower in the future, these should be considered more carefully, particularly with respect to sunflower, the host to the high-risk pathogen *Botrytis cinerea*.

Phytotoxicity
Altogether 18 selectivity field trials were carried out, including 10 in maize and 8 in sunflower crop. The trials in maize were carried out in CZ, DK, FR(Mediterr. zone), HU, IT, LV(2), NL, PL and SE. The trials in sunflower were carried out in CZ(3), DE(2), FR, IT and RO. In one of the 10 selectivity trials in maize, although the seed germination was not affected, the canopy thinning was observed, of the intensity higher compared to the reference standards, on the same assesment dates. Otherwise no specific phytotoxicity symptoms were observed in any of the remaining selectivity trials in maize or sunflower. As observed **in maize**, the emergence was on average higher compared to UNCK, and higher compared to that observed in the reference treatments. However, from the split data summaries it is clear that emergence rates vary depending on trial aggregation by EPPO zones. Plant emergence observed **in sunflower** seems equivalent to that in the UNCK, and to the emergence observed in plots treated with reference standards. Details are available in the commenting boxes following the respective chapters. Only 4 selectivity trials in maize and none of the selectivity trials in sunflower included germination test of the harvested seeds. The details are available in the commenting box following the 3.4.5 chapter.

Yield in selectivity trials
The data presented allow to conclude that the test item does not affect negatively the yield amount, compared to the untreated check and to the reference standards, neither in maize nor in sunflower crops. The moisture content in grain of both crops, as well as their TKW were comparable to the untreated check and to the reference standards. The oil content in the seeds of sunflower was shown to be, on average, lower compared to the average of the reference standards. At the same time the oil content was on average higher compared to the untreated check. Details are available in the commenting boxes following the respective chapters.

Succeeding crops
The calculated TER > 1 (as based on the initial PEC_{soil} calculation (in the present dossier, Section 8) and on the laboratory tests on toxicity to plants, carried out in 2002 (summary available in DAR for fludioxonil, 2005)) allows to conclude, according to the EPPO guidance PP 1/207 (2) *Effects on succeeding crops*, that no field testing is needed, as the application of the test item poses no risk for succeeding crops. Details are available in the commenting box following the chapter 3.5.1.

As the result of the initial evaluation by the zRMS PL, Fludioxonil 100FS / GLOB182F / Surrender has been considered as useful and worth of authorization in spite of its moderate efficacy in control of the target pathogens in maize. Nevertheless, the comments received from the concerned Member States have shown the lack of acceptance for some of the uses claimed by the applicant, for the reasons of low too the efficacy level, inadequate the target spectrum claimed in the trials (FUSASP), too low a number of trials (PYTHSP), the inconsistency of the reported efficacy level with the scientific evidence on the active not acting against specific targets (PLASHA in sunflower), or a number of such circumstances combined. Moreover, some comments have raised judicious doubts as to the acceptability of the use in sweet corn in the absence of specific selectivity trials. The latter makes also the zRMS themselves to re-define their decision as to the authorization of this particular use. Therefore the zRMS has decided to enable the cMSs to fine-tune the authorization conditions to their local requirements, agronomic practice and other circumstances. In order to do that, in the GAP table the initial phrase “Acceptable” has been changed, for a number of aspects, into the phrase “To be confirmed by cMS”.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L/ton seeds a) max. rate per appl. b) max. total rate per crop/season	Kg a.s./ton seeds a) max. rate per appl. b) max. total rate per crop/season	Water L/ton seeds min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL, LV, HU, RO, AT, SI, DE, FR, IT, ES	Maize (forage)	I (treatment seeds) F (sowing)	*Fusarium* sp. FUSASP *Pythium sp.* PYTHSP	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 0.5 b) 0.5	a) 0.050 b) 0.050	4-8 L (incl. product)	N/A	TGW: 240-380 Sowing density: 100,000-125,000 12-23.75 mL product/ha	A *Fusarium* sp., PL N *Pythium* sp., FR, PL C both target pathogens, other cMSs
2	PL, LV, HU, RO, AT, SI, DE, FR, IT, ES	Maize (grain)	I (treatment seeds) F (sowing)	*Fusarium* sp. FUSASP *Pythium sp.* PYTHSP	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 0.5 b) 0.5	a) 0.050 b) 0.050	4-8 L (incl. product)	N/A	TGW: 240-380 Sowing density: 80,000-90,000 9.6-17.1 mL product/ha	A *Fusarium* sp., PL N *Pythium* sp., FR, PL C both target pathogens, other cMSs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L/ton seeds a) max. rate per appl. b) max. total rate per crop/season	Kg a.s./ton seeds a) max. rate per appl. b) max. total rate per crop/season	Water L/ton seeds min / max			
3	PL, LV, HU, RO, AT, SI, DE, FR, IT, ES	Sweet corn	I (treatment seeds) F (sowing)	*Fusarium* sp. FUSASP *Pythium sp.* PYTHSP	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 0.5 b) 0.5	a) 0.050 b) 0.050	4-8 L (incl. product)	N/A	TGW: 90-220 Sowing density: 65,000-75,000 2.93-8.25 mL product/ha;	N, sweet corn, PL C, other cMSs
4	PL, AT, FR, IT, LV, ES	Sunflower	I (treatment seeds) F (sowing)	*Botrytis cinerea* BOTRCI *Fusarium sp.* FUSASP *Plasmopara halstedii* PLASHA	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 1.5 b) 1.5	a) 0.150 b) 0.150	4-8 L (incl. product)	N/A	TGW: 20-50 Sowing density: 175,000-225,000 5.25-16.88 mL product/ha	A
5	HU, RO, SI	Sunflower	I (treatment seeds) F (sowing)	*Botrytis cinerea* BOTRCI *Fusarium sp.* FUSASP *Plasmopara halstedii* PLASHA	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 1.25 - 1.5 b) 1.25 - 1.5	a)0.125 - 0.150 b) 0.125 - 0.150	4-8 L (incl. product)	N/A	TGW: 20-50 Sowing density: 175,000-225,000 4.375-16.88 mL product/ha	A C *Plasmopara halstedii*, HU

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L/ton seeds a) max. rate per appl. b) max. total rate per crop/season	Kg a.s./ton seeds a) max. rate per appl. b) max. total rate per crop/season	Water L/ton seeds min / max			
6	DE	Sunflower	I (treatment seeds) F (sowing)	*Botrytis cinerea* BOTRCI *Fusarium sp.* FUSASP *Plasmopara halstedii* PLASHA	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 1.5 b) 1.5	a) 0.150 b) 0.150	4-8 L (incl. product)	N/A	TGW: 60-90 Sowing density: 75,000-85,000 6.75-11.48 mL product/ha	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

3.2 Efficacy data (KCP 6)

Introduction

This core assessment dossier summarises the information related to the efficacy of the plant protection product Surrender, further referred to as GLOB182F or Fludioxonil 100 FS in this dossier, containing the active ingredient fludioxonil as a seed treatment fungicide in maize and sunflower. Poland is considered to be the zRMS of this dossier and belongs to the Central EU zone according to the Regulation No 1107/2009. However, since this product is a seed treatment, an Interzonal dossier is submitted to the zRMS Poland. cMSs for this product are Northern zone: Latvia; Central zone: Hungary, Romania, Austria, Slovenia, Germany; Southern zone: France, Italy, Spain.
The evaluation of the product will be valid for the whole EPPO-zone (EPPO standard PP1/241). Consequently in this dRR trials are performed in all EPPO Zones where registration is requested.
Fludioxonil was approved on 1 November 2008 under Directive 2007/76/EC of 20 December 2007, amended by the Annex to Commission Implementing Regulation (EU) No 540/2011. The SANCO reports for fludioxonil (SANCO/2818/07-rev.2 – 10/09/2007) were considered to provide the relevant review information or a reference to where such information can be found.
The Annex I Inclusion Directive for fludioxonil (2007/74/EC) provide specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fludioxonil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 09/10/2007 (fludioxonil) shall be taken into account. In this overall assessment:

On the basis of the proposed uses and the supported uses, for uses other than seed treatment, Member States, in the framework of any authorisations to be granted, varied or withdrawn, must pay particular attention to the potential for groundwater contamination, in particular from the soil photolysis metabolites CGA 339833 and CGA 192155, in vulnerable zones and must pay particular attention to the protection of fish and aquatic invertebrates. In this overall assessment there are however no efficacy related concerns.

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

Description of active substances

The product Fludioxonil 100 FS contains 100 g/L fludioxonil, a well known active registered in many EU countries and used as both a seed treatment product and as a fungicide in foliar sprays in a myriad of crops. In most EU countries, one or more products based on fludioxonil are approved.

Mode of action

Fludioxonil is a fungicide of the class of the phenylpyrroles and intereferes with the osmotic regulation of fungi. It is a non-systemic active ingredient mainly inhibiting the germination of fungal spores.

Table 3.2-1: Details of the active substance in Fludioxonil 100 FS

Active substance	Fludioxonil
Concentration (Unit: g/kg or g/L...)	100 g/L
Chemical group	Phenylpyrrole
Mode of action	Non systemic fungicide interfering* with fungal osmotic signaling
Biological action	Seed treatment product cereals

"*The HOG pathway is a branched mitogen activated protein kinase (MAPK) signal transduction system that has been well characterised in Saccharomyces cerevisiae. The major role of this pathway is to adapt fungi to the osmolarity of the surrounding environment. Increased osmolarity in the environment leads to water loss and cell shrinkage. To compensate for this, the HOG pathway stimulates production of intracellular glycerol to draw in more water.*
[…]
Fludioxonil is one of two commercial fungicides, the other being fenpiclonil, derived from the compound pyrrolnitrin, which was first isolated from bacteria in the genus Pseudomonas. It is a broad-spectrum fungicide used to control many crop pathogens before and after harvest. It inhibits fungal growth by over-stimulating the high osmolarity glycerol (HOG) pathway to induce hyphal swelling and bursting."

Please note: the two paragraphs above are *verbatim* quotation from: Akeem O. Taiwo, Lincoln A. Harper and Mark C. Derbyshire 2021. Impacts of fludioxonil resistance on global gene expression in the necrotrophic fungal plant pathogen Sclerotinia sclerotiorum. BMC Genomics (2021) 22:91 https://doi.org/10.1186/s12864-021-07402-x

Description of the plant protection product
Fludioxonil 100 FS, is a red, flowable suspension with a neutral odor. The product contains 100 g/L fludioxonil.

Information on the detailed composition can be found in the confidential dossier of this submission (Registration Report - Part C).

Table 3.2-2: Simplified table of requested additional uses for Fludioxonil 100 FS.

Uses		Member State	Currently registered rate(s) of analogous products	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)				
Maize (forage)	FUSASP PYTHSP	PL, LV, HU, RO, AT, SI, DE, FR, IT, ES	-	0.5 L/ton	-
Maize (grain)					
Sweet corn					
Sunflower	BOTRCI PLASHA FUSASP	PL, LV AT, DE, FR, IT, ES	-	1.5 L/ton	-
		HU, SI and RO		1.25 – 1.50 L/ton	-

Description of the target pests
Below in table Table 3.2-3 a list of all pests mentioned in this dossier is shown.

Table 3.2-3: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
BOTRCI	*Botrytis cinerea* (preferred name) *Botryotinia fuckeliana* *Botrytis cinerea* (anamorph)	Browning-grey mildew, grey mould
FUSAOX	*Fusarium oxysporum*	Foot rot, root rot, seedling wilt, wilt

EPPO code	Scientific name	Common name
FUSACU	*Fusarium culmorum*	Foot rot, root rot
FUSASM	*Fusarium sporotrichioides*	Kernel rot
FUSASP	*Fusarium* sp.	-
GIBBZE	*Fusasium graminearum*	Ear rot, stalk rot, blight
GIBBIN	*Fusarium equiseti*	Stalk rot
PLASHA	*Plasmopara halstedii*	~~Downet~~ Downy mildew of sunflower
PYTHSP	*Pythium* sp.	Maize root rot

Maize

***Fusarium spp.* (FUSASP)**

Fusarium ear rot is the most common maize ear disease worldwide, caused by several fungi in the genus *Fusarium* (FUSASP). Symptoms are a white to pink or salmon-colored, cottony mold that occurs on single or multiple kernels scattered or clustered on the ear. Decay often begins with insect-damaged kernels. Infected kernels are frequently tan or brown or have white streaks.

Fusarium stalk rot is caused by multiple fungal pathogens in the *Fusarium* genus (FUSASP). It is among the most common stalk rots. Affected plants have shredded pith that may be a whitish-pink to salmon color and die prematurely. Brown streaks may be observed on the lower internodes.

Causal fungi overwinter in maize residue and on dead, grassy weeds. Fusarium spores are spread by wind and splashing rain to silks. Infections also occur through wounds made by insects or other types of wounds in kernels, stalks or leaves. Disease is favored by hot and dry weather during and after silking. Stalk and ear rot results in yield losses due to impaired grain filling, premature senescence, and lodging, which limits production and harvesting of ears. In addition, several Fusarium species also can produce harmful mycotoxins, so caution should be used when feeding moldy maize to animals. Moldy corn should be tested for mycotoxin contamination prior to feeding.

Scouting prior to physiological maturity is important to identify areas with mold problems. These areas should be harvested as soon as possible to prevent further mold development. Harvested grain should be cooled, dried, and cleaned immediately after harvest, and stored apart from grain harvested from healthy fields (cropprotectionnetwork.org).

***Pythium spp.* (PYTHSP)**

Pythiums are a common cause of seedling blight (damping off) and seed rot in maize, destroying seeds before germination or killing seedlings after emergence.

Pythium is a soilborne fungal-like organism that is able to survive in the soil for many years as oospores. Under favorable environmental conditions, the oospores are able to germinate and produce small zoospores that swim in soil water following root exudates to infect emerging seedlings. Once root systems have developed, seedlings can usually only survive mild Pythium infections. Seed treatments can provide some protection for up to 10-14 days after planting, and can be helpful for improving seedling emergence and reducing pre-emergent damping off. Symptoms can include stunted, slower growing plants, to severely infected, dead plants. Infected plants typically have brown, rotted roots and mesocotyl. In severely infected plants, the top of the plant may be completely separated from the root system, resulting in plant death. Damping off from Pythium is common in low field areas that hold more moisture, but wet, cool spring conditions favor the development. (https://sites.udel.edu Pythium causing damping off).

Sunflower

***Plasmopara halstedii*. (PLASHA)**

Downy mildew (*Plasmopara halstedii*; PLASHA) is a common and economically important sunflower disease found in most common sunflower production regions around the world and is capable of killing or stunting plants, reducing stands and causing yield loss. When downy mildew is sporadic throughout the field, sunflowers are able to compensate for the infected plants and limit the amount of yield loss. However, downy mildew often occurs in heavily diseased patches, which limits the plantss abilities to compensate for the infected areas on a fieldwide scale and causing big yield losses (Plant disease management NDSU). The pathogen is host specific and soil-borne, and can survive many years in the soil. The disease is favored by cool and wet/waterlogged soil conditions when the seeds are germinating and seedlings are emerging. Infection begins when motile zoospores, which swim in water, infect the roots of germinating seeds. Infected seedlings may die pre- or postemergence.
Surviving plants display systemic chlorosis on the upper side of emerging leaves (National sunflower association).

***Fusarium spp.* (FUSASP)**

Fusarium root and stem rot is becoming an emerging problem in more and more sunflower producing countries. Fusarium root and stem rot is caused by multiple species of Fusarium (FUSASP) in sunflower, which are soil- or residue-borne and can infect plants through the roots. Conditions favoring disease development are dry weather early in the season, followed by wet weather conditions during mid-season and warm/hot temperatures. Infection results in pinkish to reddish-brown colored symptoms on or inside the roots or shoot of the plants. Additionally, premature senescence and browning of the outside of the stem can be observed on plants that are severely infected. Because of the infection, the vascular system can be constricted and the water transport capacity of the plants can be limited. Fusarium stem rot is also associated with charcoal rot, which complicates the economic importance of this disease.

***Botrytis cinerea* (BOTRCI)**

Botrytis blight, caused by *Botrytis cinerea* (BOTRCI) can be so destructive that it can be a limiting factor in crop production. *Botrytis cinerea* attacks seeds, seedlings, flowers, flower stalks, foliage, crowns, and stubs left after harvesting flowers. The disease can originate from contaminated seed and be transferred from seedlings to the field on infected plants. Disease spreads by air-borne spores in the field. After the disease becomes well established it is extremely difficult, or impossible, to control, especially when climatic conditions are favorable for development of the pathogen (oregonstate.edu).
On sunflower it causes a bud blast or flower blight, causing rotting of seed heads. Information on percentage seed infected in Russia was given for two years (Piven et al., 2010) and in Bangdadesh B. cinerea was second in order of prevalence and second in order of predominance out of the nine fungi recorded on seed samples (Rahman & Fakir, 2007). *Botrytis cinerea* was detected on sunflower and safflower seed imported from the USA and Germany to India (Chakrabarty et al., 2004).
This pest is quoted in general terms in some abstracts as causing severe head infection in Croatia, Russia and UK where early maturity is desired to avoid high losses due to wetter weather. In a UK trial some early maturing cultivars were particularly susceptible with > 50% of the heads destroyed before harvest, others however, had < 5% of completely infected heads (rnqp.EPPO.int)

The efficacy scale used in this dossier and the status of all intended uses are shown in Table 3.2-4 and **Błąd! Nie można odnaleźć źródła odwołania.** below.

~~**Table 3.2-4 Efficacy scale**~~

~~**Weed species susceptibility**~~	~~**Level of control**~~
~~Control (C)~~	~~> 80%~~
~~Partial/moderate control (MC)~~	~~60 – 80 %~~
~~Some control (SC)~~	~~40 – 60 %~~

Table 3.2-4 Efficacy scale

Level of control	Efficacy description
> 80%	Control (C)
60 - 80 %	Moderate control (MC)
40 - 60 %	Low level of control (LC) / ability to contain disease

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS)*
HU

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Maize (forage)	PL, LV, HU, RO, AT, SI, DE, FR, IT, ES	-	FUSASP & PYTHSP	PL, LV, HU, RO, AT, SI, DE, FR, IT, ES	-
Maize (grain)					
Sweet corn	HU	PL, LV, RO, AT, SI, DE, FR, IT, ES			
Sunflower	HU, RO, AT, SI, DE, FR, IT, ES	PL, LV	BOTRCI & PLASHA & FUSASP		

Compliance with the Uniform Principles
All data submitted in this Biological assessment dossier are in compliance with the Uniform Principles.

Information on trials submitted (3.2 Efficacy data)
All trials presented in this dossier were carried out by the applicant, the number of trials is presented in Table 3.2-6 below.

Table 3.2-6: Presentation of trials (efficacy trials~~, preliminary trials...~~)

Crop *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***
					Mar zone	N-E zone	S-E zone	Med zone	GEP
Maize	FUSASP + PYTHSP	FR	2019	E	1	-	-	-	**GEP**
		NL	2018	MED + E	2	-	-	-	**GEP**
			2019	MED + E	3	-	-	-	**GEP**
		PL	2019	E	-	3	-	-	**GEP**
			2020	E	-	5	-	-	**GEP**
		CZ	2019	E	1	-	-	-	**GEP**
		HU	2019	E	-	-	1	-	**GEP**
			2020	E	-	-	2	-	**GEP**
		ES	2020	E	-	-	-	1	**GEP**
		IT	2020	E	-	-	-	2	**GEP**
				TOTAL	**7**	**8**	**3**	**3**	**21**
Sunflower	BOTRCI (11 trials) + PLASHA (16 trials) + FUSASP (6 trials)****	HU	2020	MED + E	-	-	2	-	**GEP**
		IT	2020	MED (3) + E	-	-	-	12	**GEP**
		ES	2020	MED (2) + E	-	-	-	5	**GEP**
		PL	2020	MED + E	-	2	-	-	**GEP**
		NL	2020	MED + E	1	-	-	-	**GEP**
		HR	2020	MED (1) + E	-	-	5	-	**GEP**
				TOTAL	**1**	**2**	**7**	**17**	**27**
OVERALL TOTAL					**8**	**10**	**10**	**20**	**48**

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

**** Some trials assessed > 1 target pathogen, therefore the overall total no. of trials is < compared to the sum of trials counted for each target separately.

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials ~~– preliminary trials…~~)

Crop(s)	Reference standard	Country(ies) where the product is registered [1]	Authorization number	Active substance(s)	Formulation		Registered application rate[3]	Application rate in trials (per treatment)	Remark [4]
					Type[2]	Concentration of a.s.			
Maize	Maxim XL/ Influx XL/ Celest XL	NL	12302 N	Fludioxonil Metalaxyl-m	FS	25 g/L 9,7 (10) g/L	12.5 mL/ 50000 seeds OR 1L/t seeds OR 25 mL/100000 seeds	1L/ton	/
		PL	222/2020d					1L/ton	/
		FR	9800344					1L/ton	/
		HU	6300/19880-3/2019					1L/ton	/
		ES	22361					1L/ton	/
		IT	10110					25mL/100000	/
Sunflower	Maxim 25 FS/ Celest FS/ Celest Formula M	ES	20006	Fludioxonil	FS	25 g/L	6L/ton	6L/ton	/
		IT	9288					6L/ton	/
		NL	/					6L/ton	/
		PL	563/2020d					6L/ton	/
		HR	/				5L/ton	5L/ton	/
		HU	6300/13711-1/2019					5L/ton	/
	Apron XL	IT	10109	Metalaxyl-M	FS	340 g/L	3L/ton	3L/ton	/
		ES	22194					3L/ton	/
		HR	/					3L/ton	/

(1) only on use(s) applied for (with the test product).
(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country.
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

3.2.1 Preliminary tests (KCP 6.1)

No preliminary tests ~~have~~ are deemed necessary, since fludioxonil is already registered for many years as a seed treatment for cereals, in many countries.

3.2.2 Minimum effective dose tests (KCP 6.2)

Maize

During the first year of trials in maize 2018, it was not 0.5 L/ton of Fludioxonil 100 FS that was tested but 2.0L/ton of Fludioxonil 25 FS (2 trials in the Netherlands). Both products are based on the same recipe and as a consequence the seeds are coated with the same amount of Fludioxonil. In these 2 trials a lower dose of 1L/ha Fludioxonil 25 FS was also tested. These 2 trials are only used in the MED section. Further, in 2019 a dose rate of 0.3 L/ton (60% of the minimum requested dose rate) of Fludioxonil 100 FS was included in 3 efficacy trials to establish 1 L/ton of Fludioxonil 100 FS as the minimum effective dose rate in maize. The results of those trials are summarized in Table 3.2-8 a ~~b~~.

The parameter used to determine the minimum effective dose is the disease index (root injury).
This may be done by assessing disease severity on each plant and calculating the disease index as in the following example:
1 = no symptoms on the root, healthy;
2 = 0–25% of the root with brown lesions;
3 = 25–50% of the root with brown lesions;
4 = 50–75% of the root with brown lesions;
5 = 75–100% of the root with brown lesions.

Disease index:

$$x = \frac{(a \times 1) + (b \times 25) + (c \times 50) + (d \times 75) + (e \times 100)}{T = \text{total number of plants}}$$

where a, b, c, d and e are numbers of plants in groups 1–5 as indicated from the assessment, whereas T is the total number of plants in this assessment. The index values (x) can vary from 1 to 100.

Comments of zRMS on the SEVIND calculation by the testing units:

The disease index formula, called "severity index" further in the dRR text and abbreviated SEVIND in the trial reports:

$$x = \frac{(a \times 1) + (b \times 25) + (c \times 50) + (d \times 75) + (e \times 100)}{T = \text{total number of plants}} \qquad (1)$$

was used in the assessment of infection severity by *Fusarium* sp. in both maize and sunflower, as well as *Pythium* sp. in maize and *P. halstedii* and *B. cinerea* in sunflower. The index formula origins in the EPPO 1/125(4) guide. It has been noted that not all of the experimental units applied the formula uniformly. In some trials, like the KCP 6.2-01, SEVIND was calculated according to:

$$x = \frac{(a \times 1) + (b \times \mathbf{2}) + (c \times \mathbf{3}) + (d \times \mathbf{4}) + (e \times \mathbf{5})}{T = \text{total number of plants}} \qquad (2),$$

and sometimes, as in the KCP 6.2-02, the formulae (1) or (2) were used alternately in the same trial report, depending on the assessment date. As the values calculated using formulae (1) or (2) vary by order of magnitude (e.g. 37,56 *vs* 3,13), thus making summaries based on many trials unreliable, the SEVIND was recalculated by the zRMS where necessary, using only the formula (1), and the resultant efficacy values were amended respectively.

~~**Table 3.2-8a Minimum effective dose. Efficacy of Fludioxonil 100 FS at proposed label rate, at 50% and 60% dose rates in Maize against FUSASP**~~

~~Disease~~	~~Number of trials~~	~~Severity Index of the control~~		~~% control with Fludioxonil 100 FS or Fludioxonil 25 FS (Severity Index %UNCK)~~					
				~~0.25 L/t seeds 1L of Fludioxonil 25 FS~~		~~0.3 L/t seeds~~		~~0.5 L/t seeds or 2 Fludioxonil 25 FS*~~	
		~~Mean~~	~~Min & Max~~	~~Mean~~	~~Min & Max~~	~~Mean~~	~~Min & Max~~	~~Mean~~	~~Min & Max~~
~~FUSASP~~	~~2~~	~~20,3~~	~~3,13 & 37,56~~	~~26,23~~	~~23,23 & 29,22~~	~~-~~	~~-~~	~~37,32*~~	~~36,96 & 37,67*~~
~~FUSASP~~	~~3~~	~~25~~	~~24 & 25~~	~~-~~	~~-~~	~~27~~	~~17 & 34~~	~~46,33~~	~~34 & 61~~
~~FUSASP~~	~~5~~	~~22,9~~	~~3,13 & 37,56~~	~~-~~	~~-~~	~~-~~	~~-~~	~~42,73~~	~~34 & 61~~

Comments of zRMS :

The table 3.2-8a has been explained insufficiently in its header. Moreover, the Severity Index for the UNCK and the efficacy means based on it are produced using two different SEVIND formulae (see the commenting box above). Therefore the amended version of the table is presented below.

Table 3.2-8a Minimum effective dose. Efficacy of Fludioxonil 100 FS at the proposed rate and 60% label rate. Efficacy of Fludioxonil 25 FS at the proposed rate and 50% dose rate.
Use against FUSASP in maize, 35-83 DAA.

Pathogen	**No of trials, year KCP**	**Severity Index; UNCK**		**% control with Fludioxonil 100 FS or Fludioxonil 25 FS (Severity Index %UNCK)**						
				1L of Fludioxonil 25 FS (2018) 25 g active, 50% target rate		**0.3 L/t seeds Fludioxonil 100 FS (2019) 30 g active, 60% target rate**		**0.5 L/t seeds Fludioxonil 100 FS (2019), 2.0 L/t seeds Fludioxonil 25 FS (2018) 50 g active, 100% target rate**		**assessment:**
		Mean	**Min - Max**	**Mean**	**Min - Max**	**Mean**	**Min - Max**	**Mean**	**Min - Max**	**DAA**
FUSACU FUSACU	2, **2018** KCP 6.2-01, NL, KCP 6.2-02 BE	**39.9**	37.6 – 42.3	**22.6**	16.0 – 29.2	–	–	**34.4**	31.9 – 37.0	35 – 48
FUSAOX FUSACU FUSACU	3, **2019** KCP 6.2-04, KCP 6.2-07, KCP 6.2-09, all NL	**23.9**	18.5 – 26.6	–	–	**46.9**	16.9 – 91.1	**53.4**	29.7 – 93.3	47 – 83
FUSASP	5	**30.3**	18.5 – 42.3	–	–	–	–	**45.8**	29.7 – 93.3	35 – 83

The table above demonstrates that a dose rate of 0.5 L/ton of Fludioxonil 100 FS is required and provides a much higher efficacy compared to the lower dose rates.

Sunflower

A dose rate of 0.75 L/ton (50% of the minimum requested dose rate) of Fludioxonil 100 FS was included in 11 efficacy trials to establish 1.50 L/ton of Fludioxonil 100 FS as the minimum effective dose rate in sunflower. The results of those trials are summarized in Table 3.2-8b.

Table 3.2-8~~a~~b Minimum effective dose. Efficacy of Fludioxonil 100 FS at proposed label rate, at 50% of the minimum effective dose rate in sunflower against FUSASP & BOTRCI

Disease	Number of trials	% infestation		% control with Fludioxonil 100 FS (%UNCK)					
				0.75 L/ton seeds		1.25 L/ton seeds		1.50 L/ton seeds	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
~~FUSASP (PESINC)~~	~~4~~	~~27~~	~~11 & 47~~	~~59 b~~	~~35 & 81~~	~~68 a~~	~~40 & 85~~	~~72 a~~	~~27 & 96~~
FUSASP (PESINC)	4 ES(2), HR(1), IT(1)	21	11 & 29	65	48 & 81	78	68 & 85	90	81 & 100
BOTRCI (PESSEV)	9 ES(1), HU(1), HR(2), IT(2), NL(1), PL(2)	22	5 & 93	56 d	14 & 93	67 c	27 & 98	76 b	39 & 100

The table above demonstrates that a minimum dose rate of 1.50 L/ton of Fludioxonil 100 FS is required to reach a good efficacy of efficacy and provides a much higher efficacy compared to the lower dose rate. However in the countries of the South-East EPPO zone, a range of 1.25 – 1.50 L/ton seeds is applied for in Sunflower. It can be observed that this dose rate also provide a higher efficacy compared to the 0.75 L/ton, and could be sufficient in less severe and challenging situations.

Comments of zRMS on the MED:

Maize
The data presented by the applicant, as summarized in the Table 3.2-8a by the zRMS, demonstrate that the dose rate of 0.5 L/t seeds of Fludioxonil 100 FS is indeed indispensable to provide disease reduction, or, according to the original efficacy scale (Table 3.2-4), to provide "some control". The dose response is seen, but the level of efficacy observed is lower than satisfactory (<60%). However, the data set justifying the MED in maize crop is limited, including one group of targets only. On the other hand, the efficacy of the target dose rate is demonstrated and justified better in the Efficacy tests chapter, where the data are more extensive.

Sunflower
The zRMS agrees with the applicant that the 1.5 L/ton seed dose rate should be considered the MED for sunflower.
Regarding the SE zone: the zRMS assumes that the applicant`s statement concerning 1.25 – 1.50 L dose range is based on their previous experience with fludioxonil in that zone. It must be noted, however, that in the MED data set the 1.25 L dose rate it is represented by just two trials from Croatia and Hungary, that are either averaged together with 7 other trials from the Mar, Mediterr. and the NE zones - as for BOTRCI, or summarized jointly with 3 other trials – as for FUSASP.
Although the 1.25 L/t dose rate appears in 16 other trials, it only occurs in 4 trials from the SE zone: one from Hungary and three from Croatia. The dose range recommendation should be based on these data as well, therefore the zRMS refers the reader to Efficacy chapter for the more complete information on efficacy of the lower dose.

3.2.3 Efficacy tests (KCP 6.2)

The trials provided in this dossier demonstrate the efficacy of Fludioxonil 100 FS against fungal pathogens on seeds maize and sunflower. This dossier aims to register the use of Fludioxonil 100 FS on these crops. The trials were performed in a range of different climates spread over the regions where registration is requested. Some of the trials were performed in a greenhouse (indicated in final column of Table 3.2-5). This approach is allowed and sometimes preferred according to EPPO PP 1/125(4).

In total 8 efficacy trials were performed in the Maritime zone, 10 in the North-East, 10 in the South-East and 20 in the Southern EPPO Zone. All of these trials were carried out between 2018 and 2020 by GEP certified research institutions. The trials methodology, crop species, trial site information, application details, location and soil type are presented in

Table 3.2- and Table 3.2-5 below.

Table 3.2-9a: Details on trial methodololgy in Maize

Guidelines	General guidelines	**EPPO PP 1/152 (4), 1/135 (4), 1/181 (4)**
	Specific guidelines	**PP 1/125(4)** Seed treatments against seedling diseases (trials under controlled conditions) **PP 1/19(4)** Seed-borne cereal fungi.
Experimental design	Plot design	Randomized Complete Block
	Plot size	20-42 m² (field trials) / ~~0.75-2.4~~ 0.24 – 2.4 m² (greenhouse trials)
	Number of replications	4
Crop	Trials per crop	23 trials (9 varieties: Galactus, Jubilat, Konkurent, LG90211, Like it, Mantilla, Opoka, Parel, Rywal)
Application	Crop stage (BBCH) at application	Seed treatment
	Number of applications Intervals	1
	Spray volumes	5-8 L/ton
Assessment	Assessment types	COUPLA: number of emerged plants PESSEV: pest severity PESINC: pest incidence INFEST: infestation SEVIND: severity index On plant & roots Phytotoxicity Sometimes also yield, moisture content, TKW and germination rates
	Assessment dates	From sowing until after harvest
	Field / Greenhouse...	Field trials / ~~green house~~ greenhouse trials
	GEP	All trials were performed according to GEP

Table 3.2-9b: Details on trial methodololgy in Sunflower

Guidelines	General guidelines	**EPPO PP 1/152 (4), 1/135 (4), 1/181 (4)**
	Specific guidelines	**PP 1/125(4)** Seed treatments against seedling diseases (trials under controlled conditions) **PP 1/19(4)** Seed-borne cereal fungi.
Experimental design	Plot design	Randomized Complete Block
	Plot size	11,25-30 m² (field trials) / ~~0.75- 2.4~~ 0.75-2.5 m² (greenhouse trials)
	Number of replications	4
Crop	Trials per crop	27 trials (2 varieties: Peredovick, Słonecznik Czarny)
Application	Crop stage (BBCH) at application	Seed treatment
	Number of applications Intervals	1
	Spray volumes	8 L/ton
Assessment	Assessment types	COUPLA: number of emerged plants PESSEV: pest severity PESINC: pest incidence SEVIND: severity index On plant & roots Phytotoxicity Sometimes also yield, moisture content, HLW and germination rates
	Assessment dates	From sowing until after harvest
	Field / Greenhouse...	Field trials / ~~green house~~ greenhouse trials
	GEP	All trials were performed according to GEP

Table 3.2-5a: Summary form of information concerning trial sites and application details in maize

Type of trials	Effectiveness
Identity of the product under test	Fludioxonil 100 FS
Crop	Maize (ZEAMX)
Harmful organism	Seedborne diseases
	Responsible body for reporting trial See second column
Date of submission	December 2020

~~Reference is made to the BAD.~~

zRMS: For completeness, the respective table has been restored from BAD:

Trial reference	Testing unit	Trial location Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)
				Date (1st and last), interval	Method, applic. Amount	Applic. Technique		
KCP 6.2-01	Proeftuin Zwaagdijk	Wieringerwerf (NL) Sandy Clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 24 m²	01/05/2018	Seed treatment, 5 L/ton (Fludio 25 FS)	Rotostat	Seed treatment	Maize LG90211
KCP 6.2-02	Proeftuin Zwaagdijk	Meerdonk (BEL) Loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 24 m²	01/05/2018	Seed treatment, 5 L/ton (Fludio 25 FS)	Rotostat	Seed treatment	Maize Mantilla
KCP 6.2-03	Promo-Vert	Miossens (FR/MAR)	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 25.6 m²	06/06/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Opoka
KCP 6.2-04	Proeftuin Zwaagdijk	Wieringerwerf (NL) Sandy Clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 30 m²	10/04/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize SM Jubilat
KCP 6.2-05	Inhort	Skierniewice (PL) Sandy Clay Loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 20 m²	09/04/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Konkurent
KCP 6.2-06	Syntech Research	Bagamer (HU) Loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 42 m²	10/04/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Rywal
KCP 6.2-07	Proeftuin Zwaagdijk	Zwaagdijk (NL) Clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 30 m²	10/04/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Opoka
KCP 6.2-08	Kromeriz	Kromeriz (CZ) Loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	10/04/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Konkurent

Trial reference	Testing unit	Trial location Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)
				Date (1st and last), interval	Method, applic. Amount	Applic. Technique		
KCP 6.2-09	Proeftuin Zwaagdijk	Wieringerwerf (NL) Sandy Clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 30 m²	10/04/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize SM Jubilat
KCP 6.2-10	GMW	Alberic (ES) Loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	15/04/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Like it
KCP 6.2-11	SAGEA	Castagnito d'Alba (IT) Loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	15/04/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Galactus
KCP 6.2-12	Staphyt	Rocca de Baldi (IT) Loamy sand	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	15/04/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Like it
KCP 6.2-13	CPR	Zsennye (HU) Clay Loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 30 m²	15/04/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Galactus
KCP 6.2-14	CPR	Gyekenyes (HU) Clay Loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 30 m²	15/04/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Galactus
KCP 6.2-15	Inhort	Skierniewice (PL) Sandy Clay Loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 0.75 m²	11/04/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Like it (Greenhouse)
KCP 6.2-16	Instytut Ochrony Roslin	Sosnicowice (PL) Peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2,4 m²	15/04/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Galactus (Greenhouse)
KCP 6.2-17	Instytut Ochrony Roslin	Sosnicowice (PL) Peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2,4 m²	15/04/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Like it (Greenhouse)
KCP 6.2-18	Proeftuin Zwaagdijk	Zwaagdijk (NL) Seeding soil	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 0.24 m²	05/08/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Parel (Greenhouse)
KCP 6.2-19	Ochrony Roslin	Sosnicowice (PL) Peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2,4 m²	22/05/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Rywal (Greenhouse)
KCP 6.2-20	Instytut Ochrony Roslin	Sosnicowice (PL) Peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2,4 m²	22/05/2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Jubilat (Greenhouse)
KCP 6.2-21	SAGEA	Castagnito d'Alba (IT) Peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 1,2 m²	11/03/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Opoka (Greenhouse)

Trial reference	Testing unit	Trial location Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)
				Date (1st and last), interval	Method, applic. Amount	Applic. Technique		
KCP 6.2-22	Instytut Ochrony Roslin	Sosnicowice (PL) Peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2,4 m²	11/03/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Konkurrent (Greenhouse)
KCP 6.2-23	Instytut Ochrony Roslin	Sosnicowice (PL) Peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2,4 m²	11/03/2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Maize Konkurrent (Greenhouse)

Table 3.2-10~~a~~b: Summary form of information concerning trial sites and application details in ~~maize~~ sunflower

Type of trials	Effectiveness
Identity of the product under test	Fludioxonil 100 FS
Crop	Sunflower (HELAN)
Harmful organism	Seedborne diseases
	Responsible body for reporting trial See second column
Date of submission	December 2020

~~Reference is made to the BAD.~~

zRMS: For completeness, the respective table has been restored from BAD:

Trial reference	Testing unit	Trial location	Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)	Indoor/ outdoor
					Date (1st and last), interval	Method, applic. Amount	Applic. Technique			
KCP 6.2-24	Sagea	Castagnito (IT)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 1,2 m²	Mar-19-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	GREENH
KCP 6.2-25	Sagea	Castagnito (IT)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 1,2 m²	Mar-19-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	GREENH
KCP 6.2-26	CPR Europe Kft.	Hódmezővásárhely (HU)	clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 11,25 m²	Mar-25-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.2-27	Sagea	Castagnito d'Alba (IT)	silt loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	Mar-25-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.2-28	GMW Bioscience	Anna (ES)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2 m²	Jun-24-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	GREENH
KCP 6.2-29	GMW Bioscience	Anna (ES)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2,5 m²	Jun-24-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	GREENH
KCP 6.2-30	Research Institute of Horticulture	Skierniewice (PL)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 0,75 m²	Jun-2-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Słonecznik Czarny	GREENH
KCP 6.2-31	Research Institute of Horticulture	Skierniewice (PL)	torf	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 0,75 m²	Apr-11-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Słonecznik Czarny	GREENH

Trial reference	Testing unit	Trial location	Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)	Indoor/ outdoor
					Date (1st and last), interval	Method, applic. Amount	Applic. Technique			
KCP 6.2-32	GMW Bioscience	Anna (ES)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Stonecznik Czarny	GREENH
KCP 6.2-33	Proeftuin Zwaagdijk	Zwaagdijk (NL)	organic	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2,4 m²	Jun-24-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Stonecznik Czarny	GREENH
KCP 6.2-34	Sagea	Castagnito (IT)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 1,2 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Slonecznik Czarny	GREENH
KCP 6.2-35	Sagea	Castagnito (IT)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 1,2 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	GREENH
KCP 6.2-36	Pest Pro d.o.o.	Umag (HR)	clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 25,2 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Slonecznik Czarny	FIELD
KCP 6.2-37	Pest Pro d.o.o.	Beravci (HR)	sandy clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 25,2 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.2-38	CPR Europe Kft.	Vasboldogasszony (HU)	clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 30 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Słonecznik Czarny	FIELD
KCP 6.2-39	Sagea	Castiglione Torinese (IT)	loamy sand	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Slonecznik Czarny	FIELD
KCP 6.2-40	GMW Bioscience	Alpera (ES)	sandy clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 20,25 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Prededovik	FIELD
KCP 6.2-41	SAGEA Iberia S.L.	Torralba (ES)	clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	May-6-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.2-42	Pest Pro d.o.o.	Beravci (HR)	sandy clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 25,2 m²	May-6-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.2-43	Pest Pro d.o.o.	Borovo (HR)	sandy clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 25,2 m²	May-6-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.2-44	Sagea	Castagnole Piemonte (IT)	loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	May-6-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD

Trial reference	Testing unit	Trial location	Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)	Indoor/ outdoor
					Date (1st and last), interval	Method, applic. Amount	Applic. Technique			
KCP 6.2-45	Sagea	Poirino (IT)	loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	May-6-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Slonecznick Czarny	FIELD
KCP 6.2-46	Sagea	San Maurizio C.se (IT)	loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	May-6-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Pederovick	FIELD
KCP 6.2-47	Pest Pro d.o.o.	Velika Kosnica, Zagreb (HR)	sandy clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 2,4 m²	Oct-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	GREENH
KCP 6.2-48	Sagea	Castagnito (IT)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 1,2 m²	Oct-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	GREENH
KCP 6.2-49	Sagea	Castagnito (IT)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 1,2 m²	Oct-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	GREENH
KCP 6.2-50	Sagea	Castagnito (IT)	peat	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 1,2 m²	Oct-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Slonecznik Czarny	GREENH

zRMS: The table directly below, now struck through, had been pasted mistakenly by zRMS, during the evaluation.
The correct place for this table is in the page 55, as Table 3.4-5, where it belongs to the selectivity data section.

~~Trial reference~~	~~Testing unit~~	~~Trial location~~	~~Soil type~~	~~Test method, plot size~~	~~Application details~~			~~Growth stage crop~~	~~Remarks (variety)~~	~~Indoor/ outdoor~~
					~~Date (1st and last), interval~~	~~Method, applic. Amount~~	~~Applic. Technique~~			
~~KCP 6.4-01 Maize~~	~~Agrolab A/S~~	~~Middelfart (DK)~~	~~sandy loam~~	~~PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 12 m²~~	~~Apr-10-2019~~	~~Seed treatment, 8 L/ton~~	~~Rotostat~~	~~Seed treatment~~	~~Opoka~~	~~FIELD~~
~~KCP 6.4-02 Maize~~	~~SynTech~~	~~Gyékényes (HU)~~	~~loam~~	~~PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 30 m²~~	~~Apr-10-2019~~	~~Seed treatment, 8 L/ton~~	~~Rotostat~~	~~Seed treatment~~	~~Rywal~~	~~FIELD~~
~~KCP 6.4-03 Maize~~	~~AgroResearch Sp. z o. o.~~	~~Wielgie (PL)~~	~~loamy sand~~	~~PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 12 m²~~	~~Apr-10-2019~~	~~Seed treatment, 8 L/ton~~	~~Rotostat~~	~~Seed treatment~~	~~Konkurent~~	~~FIELD~~

Trial reference	Testing unit	Trial location	Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)	Indoor/ outdoor
					Date (1st and last), interval	Method, applic. Amount	Applic. Technique			
KCP 6.4.04 Maize	Proefruin Zwaagdijk	Wieringerwerf (NL)	sandy clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 24 m²	Apr 10 2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Jubilat	FIELD
KCP 6.4.05 Maize	ZZS Kujavy	Kujavy (CZ)	loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 23 m²	Apr 15 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Like it	FIELD
KCP 6.4.06 Maize	HUSEC	Kristianstad (SE)	sandy loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 15 m²	Apr 15 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Like it	FIELD
KCP 6.4.07 Maize	Staphyt	Marsillargues (FR)	silty clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 24 m²	Apr 15 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Calactus	FIELD
KCP 6.4.08 Maize	Staphyt	Rocca de Baldi (IT)	loamy sand	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	Apr 15 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Calactus	FIELD
KCP 6.4.09 Maize	LAAPC	Vecauce (LV)	calcareous sandy loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 28 m²	Apr 15 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Like it	FIELD
KCP 6.4.10 Maize	LAAPC	Vecauce (LV)	sandy clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 28 m²	Apr 15 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Calactus	FIELD
KCP 6.4.11 Sunflower	ZZS Kujavy	Kujavy (CZ)	loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 27.5 m²	Apr 22 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	LG50 635CLP	FIELD
KCP 6.4.12 Sunflower	Agritec	Šumperk (CZ)	clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 30 m²	Apr 23 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Predovick	FIELD
KCP 6.4.13 Sunflower	InTec Agro Trials, s.r.o.	Uhersky Ostroh (CZ)	silty clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 42 m²	Apr 22 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.4.14 Sunflower	Field Research Support	Kolenfeld (DE)	silt loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	Apr 22 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	LG50 635CLP	FIELD
KCP 6.4.15 Sunflower	Agrartest GmbH	Rosenow (DE)	sandy loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 22.5 m²	Apr 23 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.4.16 Sunflower	Staphyt	Marsillargues (FR)	silty clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 24 m²	Apr 22 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	LG50 635CLP	FIELD

Trial reference	Testing unit	Trial location	Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)	Indoor/ outdoor
					Date (1st and last), interval	Method, applic. Amount	Applic. Technique			
KCP 6.4.17 Sunflower	SAGEA	Castagnito d'Alba (TT)	loam	pp 1/135 (4); pp 1/152 (4); pp 1/181 (4); pp 1/125 (4) Plot: 21 m²	Apr 23 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Pederovick	FIELD
KCP 6.4.18 Sunflower	Biotek	Fantanele (RO)	clay-loam	pp 1/135 (4); pp 1/152 (4); pp 1/181 (4); pp 1/125 (4) Plot: 32 m²	Apr 23 2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Perodovick	FIELD

Table 3.2-10 c Information on the type of trial inoculation (natural – N *vs* artificial – A)

Trial reference	Inoculation (N/A)	type (F/G)	Trial reference	Inoculation (N/A)	type (F/G)	Trial reference	Inoculation (N/A)	type (F/G)
KCP 6.2-01	A	Field	KCP 6.2-19	A	greenhouse	KCP 6.2-35	A	greenhouse
KCP 6.2-02	A	Field	KCP 6.2-20	A	greenhouse	KCP 6.2-36	N	Field
KCP 6.2-03	no symptoms, no info on artificial inoculation, efficacy not assessed	Field	KCP 6.2-21	A	greenhouse	KCP 6.2-37	N	Field
KCP 6.2-04	A	Field	KCP 6.2-22	A	greenhouse	KCP 6.2-38	N	Field
KCP 6.2-05	N	Field	KCP 6.2-23	A	greenhouse	KCP 6.2-39	N	Field
KCP 6.2-06	N	Field	KCP 6.2-24	A	greenhouse	KCP 6.2-40	N	Field
KCP 6.2-07	A	Field	KCP 6.2-25	A	greenhouse	KCP 6.2-41	N	Field
KCP 6.2-08	A	Field	KCP 6.2-26	A	Field	KCP 6.2-42	N	Field
KCP 6.2-09	A	Field	KCP 6.2-27	N	Field	KCP 6.2-43	N	Field
KCP 6.2-10	N	Field	KCP 6.2-28	N	greenhouse	KCP 6.2-44	N	Field
KCP 6.2-11	N	Field	KCP 6.2-29	N	greenhouse	KCP 6.2-45	N	Field
KCP 6.2-12	N	Field	KCP 6.2-30	N	greenhouse	KCP 6.2-46	N	Field
KCP 6.2-13	N	Field	KCP 6.2-31	A	greenhouse	KCP 6.2-47	A	greenhouse
KCP 6.2-14	N	Field	KCP 6.2-32	A	greenhouse	KCP 6.2-48	A	greenhouse
KCP 6.2-15	A	greenhouse	KCP 6.2-33	A	greenhouse	KCP 6.2-49	A	greenhouse
KCP 6.2-16	A	greenhouse	KCP 6.2-34	A	greenhouse	KCP 6.2-50	A	greenhouse
KCP 6.2-17	A	greenhouse						
KCP 6.2-18	A	greenhouse						

Details of the formulations tested and the dose rates of all treatments are provided in Table 3.2-6 and Table 3.2-7, respectively.

Table 3.2-61: Formulations included in efficacy trials

Product	Active substance	Active substance content	Formulation type
Fludioxonil 25 FS	Fludioxonil	25 g/L	FS
Fludioxonil 100 FS	Fludioxonil	100 g/L	FS
Celest/Influx/Maxim XL	Fludioxonil Metalaxyl-M	25 g/L 10 (9,7) g/L	FS
Maxim 25 FS/ Celest FS/ Celest Formula M	Fludioxonil	25 g/L	FS
Apron XL	Metalaxyl-M	340 g/L	FS

* Products not relevant, are not included the tables below

Table 3.2-7: Formulations included in efficacy trials

Trial reference number	Product	Application rate	
		g as/ton	L/ton
KCP 6.2-1 - 2	Fludioxonil 25 FS Fludioxonil 25 FS Maxim XL	25 50 70	1 2 2
KCP 6.2-4, 7, 9	Fludioxonil 100 FS Fludioxonil 100 FS Maxim XL	30 50 35	0,3 0,5 1
KCP 6.2-3, 5, 6, 8, 10 – 23	Fludioxonil 100 FS Celest/Influx/Maxim XL	50 35	0.5 1
KCP 6.2-24 – 29 KCP 6.2-41 – 50	Fludioxonil 100 FS Fludioxonil 100 FS Apron XL	125 150 1200	1,25 1,50 3
KCP 6.2-30 – 35 KCP 6.2-39 – 40	Fludioxonil 100 FS Fludioxonil 100 FS Fludioxonil 100 FS Maxim 25 FS/ Celest FS/ Celest Formula M	75 125 150 150	0,75 1,25 1,50 6
KCP 6.2-36 – 38	Fludioxonil 100 FS Fludioxonil 100 FS Fludioxonil 100 FS Maxim 25 FS/ Celest FS/ Celest Formula M Maxim 25 FS/ Celest FS/ Celest Formula M	75 125 150 125 150	0,75 1,25 1,50 5 6

Trial results

Below all efficacy results are summarized per crop in separate sections. The countries are mentioned after the KCP numbers providing the information that trias have been performed in all different EPPO Zones. However, KCP 6.2-15-23 for maize and KCP 6.2-24,25; KCP 6.2-28-35; KCP 47-50 for sunflower (which is approximately 50% of all sunflower trials) were perfomed in the greenhouse and are therefore not zone-specific. Since Fludioxonil 100 FS is a seed treatment, all results have been grouped in an interzonal assessment. Furthermore, Fludioxonil is known to work against these different diseases in other crops such as cereals and vegetables.

The summaries show the final assessment of each trial. For the untreated the absolute results are given.

The infestation, disease index (as explained in the MED section) and pest incidence/severity is shown. Only trials with infestation levels higher than 5% are taken into account.

3.2.3.1 Efficacy results of trials performed in maize

Table 3.2-13a The number of emerged plants relative to the untreated

Number of plants				KCP 6.2-4 (NL)	KCP 6.2-5 (PL)	KCP 6.2-6 (HU)	KCP 6.2-7 (NL)	KCP 6.2-8 (CZ)	KCP 6.2-9 (NL)	KCP 6.2-10 (ES)	KCP 6.2-11 (IT)	KCP 6.2-12 (IT)
Days after application				72 DA-A	84 DA-A	77 DA-A	62 DA-A	78 DA-A	104 DA-A	75 DA-A	53 DA-A	71 DA-A
Days after emergence				46 DE-1	42 DE-1	34 DE-1	14 DE-1	41 DE-1	48 DE-1	28 DE-1	35 DE-1	41 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Untreated Check (absolute #)*			*89 a*	*36 b*	*53 a*	*72 a*	*60 a*	*83 a*	*133 a*	*116 a*	*94 b*
2	Fludioxonil 100 FS	0,5	L/ton	101 a	122 a	102 a	101 a	99 a	100 a	101 a	100 a	128 a
3	Celest/Maxim/Influx XL	1	L/ton	110 a	119 a	100 a	103 a	106 a	98 a	102 a	101 a	128 a

Number of plants				KCP 6.2-12 (IT)	KCP 6.2-13 (HU)	KCP 6.2-14 (HU)	KCP 6.2-15 (PL)	KCP 6.2-16 (PL)	KCP 6.2-17 (PL)	Summary					
Days after application				71 DA-A	70 DA-A	54 DA-A	100 DA-A	138 DA-A	111 DA-A						
Days after emergence				41 DE-1	41 DE-1	35 DE-1	30 DE-1	34 DE-1	31 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (absolute #)*			*94 b*	*92 b*	*111 a*	*96 a*	*88 b*	*64 b*	*85*	*14*	-	-	-	-
2	Fludioxonil 100 FS	0,5	L/ton	128 a	106 a	100 a	100 a	113 a	122 a	107	14	99	128	10,08	101
3	Celest/Maxim/Influx XL	1	L/ton	128 a	107 a	102 a	101 a	112 a	106 b	107	14	98	128	8,267	104,5

zRMS:
The first column in the second (lower) part of the Table 3.2-13a is redundant – it is a duplicate of the last column in the upper part (KCP 6.2-12 (IT).
Please note that of all maize trials in efficacy, the trials KCP 6.2-15 – KCP 6.2-23 are greenhouse trials.

Table 3.2-13b Efficacy in maize against FUSASP at the final assessment: plant infestation relative to the untreated

Plant infestation				KCP 6.2-4 (NL)	KCP 6.2-5 (PL)	KCP 6.2-6 (HU)	KCP 6.2-7 (NL)	KCP 6.2-8 (CZ)	KCP 6.2-9 (NL)	KCP 6.2-10 (ES)
Pest				FUSAOX	FUSAOX	FUSASP	FUSACU	FUSAOX	FUSACU	FUSAVR
Days after application				72 DA-A	84 DA-A	77 DA-A	62 DA-A	78 DA-A	104 DA-A	75 DA-A
Days after emergence				46 DE-1	42 DE-1	34 DE-1	14 DE-1	41 DE-1	48 DE-1	28 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Untreated Check (%)*			*12*	*29*	*11*	*13*	*14*	*10*	*32*
2	Fludioxonil 100 FS	0,5	L/ton	100 a	56 a	0 a	90 a	0 a	100 a	49 a
3	Celest/Maxim/Influx XL	1	L/ton	100 a	43 a	0 a	66 b	22 a	98 a	48 a

Plant infestation				KCP 6.2-12 (IT)	KCP 6.2-13 (HU)	KCP 6.2-14 (HU)	KCP 6.2-15 (PL)	KCP 6.2-16 (PL)	KCP 6.2-17 (PL)	Summary					
Pest				FUSAGR	GIBBZE	GIBBZE	FUSACU	GIBBZE	FUSACU						
Days after application				71 DA-A	70 DA-A	54 DA-A	100 DA-A	138 DA-A	111 DA-A						
Days after emergence				41 DE-1	41 DE-1	35 DE-1	30 DE-1	34 DE-1	31 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (%)*			*55*	*12*	*9*	*22*	*68*	*51*	*26*	*13*	-	-	-	-
2	Fludioxonil 100 FS	0,5	L/ton	59 a	37 a	46 a	62 a	53 a	48 a	54 b	13	0	100	31,45	53
3	Celest/Maxim/Influx XL	1	L/ton	43 b	40 a	59 a	82 a	52 a	25 b	52 b	13	0	100	29,18	48

Only in 2 trials a difference between Fludioxonil 100 FS and the reference product is observed (KCP 6.2-12 and KCP 6.2-17). In these trials Fludioxonil 100 FS outperforms the reference product.

Table 3.2-13c Efficacy in maize against FUSASP at the final assessment: severity index of the roots relative to the untreated

Severity index (roots)				KCP 6.2-4 (NL)	KCP 6.2-5 (PL)	KCP 6.2-7 (NL)	KCP 6.2-8 (CZ)	KCP 6.2-9 (NL)	KCP 6.2-11 (IT)	KCP 6.2-12 (IT)
Pest				FUSAOX	FUSAOX	FUSACU	FUSAOX	FUSACU	GIBBZE	FUSAGR
Days after application				72 DA-A	84 DA-A	98 DA-A	78 DA-A	104 DA-A	53 DA-A	71 DA-A
Days after emergence				46 DE-1	42 DE-1	50 DE-1	41 DE-1	48 DE-1	35 DE-1	41 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Untreated Check (absolute #)*			*37*	*8*	*30*	*23*	*36*	*26*	*27*
2	Fludioxonil 100 FS	0,5	L/ton	44 a	87 a	61 a	96 a	34 a	47 a	19 a
3	Celest/Maxim/Influx XL	1	L/ton	43 a	87 a	41 b	96 a	29 a	49 a	8 b

Severity index (roots)				KCP 6.2-13 (HU)	KCP 6.2-14 (HU)	KCP 6.2-15 (PL)	KCP 6.2-16 (PL)	KCP 6.2-17 (PL)	Summary					
Pest				GIBBZE	GIBBZE	FUSACU	GIBBZE	FUSACU						
Days after application				70 DA-A	54 DA-A	100 DA-A	138 DA-A	111 DA-A						
Days after emergence				41 DE-1	35 DE-1	30 DE-1	34 DE-1	31 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (absolute #)*			*23*	*11*	*5*	*35*	*32*	*24*	*12*	-	-	-	-
2	Fludioxonil 100 FS	0,5	L/ton	33 a	61 a	66 a	66 a	77 a	58 b	13	19	96	23	61
3	Celest/Maxim/Influx XL	1	L/ton	35 a	66 a	68 a	63 a	23 c	51 b	13	8	96	26	46

Only in 3 trials a difference between Fludioxonil 100 FS and the reference product is observed (KCP 6.2-7, KCP 6.2-12 and KCP 6.2-17). In these trials Fludioxonil 100 FS outperforms the reference product.

zRMS:
Twelve trials are included in this set as shown in the summary for UNCK (line 1), not thirteen, as shown for treated objects (line 2 and 3).
KCP 6.2-15 – KCP 6.2-17 are greenhouse trials.

Table 3.2-13d Efficacy in maize against FUSASP at the final assessment: pest incidence of the roots relative to the untreated

Pest incidence (roots)				KCP 6.2-4 (NL)	KCP 6.2-5 (PL)	KCP 6.2-6 (HU)	KCP 6.2-7 (NL)	KCP 6.2-8 (CZ)	KCP 6.2-9 (NL)	KCP 6.2-11 (IT)
Pest				FUSAOX	FUSAOX	FUSASP	FUSACU	FUSAOX	FUSACU	GIBBZE
Days after application				72 DA-A	84 DA-A	77 DA-A	98 DA-A	78 DA-A	104 DA-A	53 DA-A
Days after emergence				46 DE-1	42 DE-1	34 DE-1	50 DE-1	41 DE-1	48 DE-1	35 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Untreated Check*			*100*	*28*	*95*	*99*	*91*	*100*	*68*
2	Fludioxonil 100 FS	0,5	L/ton	9 a	100 a	0 a	40 a	100 a	3 a	52 b
3	Celest/Maxim/Influx XL	1	L/ton	14 a	100 a	7 a	21 ab	100 a	3 a	66 a

Pest incidence (roots)				KCP 6.2-12 (IT)	KCP 6.2-13 (HU)	KCP 6.2-14 (HU)	KCP 6.2-15 (PL)	KCP 6.2-16 (PL)	KCP 6.2-17 (PL)	Summary					
Pest				FUSAGR	GIBBZE	GIBBZE	FUSACU	GIBBZE	FUSACU						
Days after application				71 DA-A	70 DA-A	54 DA-A	100 DA-A	138 DA-A	111 DA-A						
Days after emergence				41 DE-1	41 DE-1	35 DE-1	30 DE-1	34 DE-1	31 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check*			*100*	*83*	*45*	*17*	*65*	*40*	*72*	*13*	-	-	-	-
2	Fludioxonil 100 FS	0,5	L/ton	12 ab	30 a	61 a	81 a	53 a	81 a	48 b	13	0	100	35,74	52
3	Celest/Maxim/Influx XL	1	L/ton	0 b	31 a	66 a	89 a	27 a	31 c	43 b	13	0	100	36,84	31

Only in 2 trials a difference between Fludioxonil 100 FS and the reference product is observed (KCP 6.2-11 and KCP 6.2-17). In KCP 6.2-11 the reference product performs somewhat better than Fludioxonil 100 FS and in KCP 6.2-17 Fludioxonil 100 FS outperforms the reference product.

Table 3.2-14a Efficacy in maize against PYTHSP at the final assessment: severity index of the roots relative to the untreated; greenhouse trials

Severity index (roots)				KCP 6.2-19 (PL)	KCP 6.2-21 (IT)	KCP 6.2-22 (PL)	KCP 6.2-23 (PL)	Summary					
Pest				PYTHUL	PYTHUL	PYTHUL	PYTHAR						
Days after aplication				63 DA-A	34 DA-A	57 DA-A	57 DA-A						
Days after emergence				32 DE-1	13 DE-1	31 DE-1	31 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (absolute #)*			*44*	*34*	*88*	*66*	*58*	*4*	-	-	-	-
2	Fludioxonil 100 FS	0,5	L/ton	81 a	65 a	14 b	4 b	41 b	4	4	81	38	39
3	Celest/Maxim/Influx XL	1	L/ton	69 b	63 a	58 a	60 a	62 a	4	58	69	5	61

In KCP 6.2-22 and 23 the reference product performs better than Fludioxonil 100 FS, while in KCP 6.2-19 Fludioxonil 100 FS outperforms the reference product.

~~**Table 3.2-14b Efficacy in maize against PYTHSP at the final assessment: pest incidence of the roots relative to the untreated; greenhouse trials**~~

Severity index (roots)				KCP 6.2-19 (PL)	KCP 6.2-21 (IT)	KCP 6.2-22 (PL)	KCP 6.2-23 (PL)	Summary					
Pest				PYTHUL	PYTHUL	PYTHUL	PYTHAR						
Days after aplication				63 DA-A	34 DA-A	57 DA-A	57 DA-A						
Days after emergence				32 DE-1	13 DE-1	31 DE-1	31 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (absolute #)*			*44*	*34*	*88*	*66*	*58*	*4*	-	-	-	-
2	Fludioxonil 100 FS	0,5	L/ton	81 a	65 a	14 b	4 b	41 b	4	4	81	38	39
3	Celest/Maxim/Influx XL	1	L/ton	69 b	63 a	58 a	60 a	62 a	4	58	69	5	61

zRMS:
Considered the table`s header, the Table 3.2-14b should demonstrate efficacy measured based on PESINC. Instead, it duplicates Table 3.2-14a, which shows efficacy based on SEVIND. The amended summary based on PESINC data was inserted by zRMS below. Nevertheless, the applicant`s comment to the original Table 3.2-14b remains valid for its amended version too.

Table 3.2-14b Efficacy in maize against PYTHSP at the final assessment: pest incidence of the roots relative to the untreated; greenhouse trials

Trial code	KCP 6.2-19 (PL)	KCP 6.2-21 (IT)	KCP 6.2-22 (PL)	KCP 6.2-23 (PL)	Summary:			
Pest	PYTHUL	PYTHUL	PYTHUL	PYTHAR				
DA-A	63	34	57	57				
DA-E	32	13	31	31				
Product /treatment:					mean	n (trials)	min	max
UNCK (PESINC, %)	43.8	52.7	100.0	93.1	72.4	4	43.8	100.0
Fludioxonil 100 FS 0.5 L/t	82.0	58.9	17.4	27.2	**46.4**	4	14.4	82.0
Influx XL 1.0 L/t	58.0	54.8	59.8	72.4	**61.3**	4	54.8	72.4

In KCP 6.2-22 and 23 the reference product performs better than Fludioxonil 100 FS, while in KCP 6.2-19 Fludioxonil 100 FS outperforms the reference product.

Quality parameters such as Yield, TKW and MOICON were also investigated in some efficacy trials. The results are shown in the tables below.

Table 3.2-15a Effect of Fludioxonil 100 FS on the yield of maize (T-MET) compared to the untreated check (%UNCK)

YIELD				KCP 6.2-4 (NL)	KCP 6.2-5 (PL)	KCP 6.2-6 (HU)	KCP 6.2-7 (NL)	KCP 6.2-8 (CZ)	KCP 6.2-9 (NL)	KCP 6.2-10 (ES)	KCP 6.2-12 (IT)	KCP 6.2-13 (HU)	KCP 6.2-14 (HU)
Days after application				189 DA-A	163 DA-A	169 DA-A	206 DA-A	211 DA-A	210 DA-A	196 DA-A	177 DA-A	190 DA-A	194 DA-A
Days after emergence				163 DE-1	121 DE-1	126 DE-1	158 DE-1	174 DE-1	154 DE-1	149 DE-1	147 DE-1	161 DE-1	175 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Untreated Check (T-MET)*			*33*	*20*	*7*	*32*	*13*	*38*	*33*	*8*	*7*	*9*
2	Fludioxonil 100 FS	0,5	L/ton	98 a	111 a	106 a	121 a	110 a	113 a	115 a	112 a	106 a	103 a
3	Celest/Maxim/Influx XL	1	L/ton	99 a	108 a	103 a	114 ab	107 a	107 a	122 a	112 a	108 a	104 a

YIELD				Summary					
Days after application									
Days after emergence									
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (T-MET)*			*20*	*10*	-	-	-	-
2	Fludioxonil 100 FS	0,5	L/ton	110 a	10	98	121	6	110
3	Celest/Maxim/Influx XL	1	L/ton	108 a	10	99	122	6	108

Table 3.2-15b Effect of Fludioxonil 100 FS on the TKW of maize (g) compared to the untreated check (%UNCK)

TKW				KCP 6.2-4 (NL)	KCP 6.2-5 (PL)	KCP 6.2-6 (HU)	KCP 6.2-8 (CZ)	KCP 6.2-10 (ES)	KCP 6.2-12 (IT)	KCP 6.2-13 (HU)	KCP 6.2-14 (HU)	Summary					
Days after application				195 DA-A	163 DA-A	173 DA-A	211 DA-A	196 DA-A	180 DA-A	190 DA-A	196 DA-A						
Days after emergence				169 DE-1	121 DE-1	130 DE-1	174 DE-1	149 DE-1	150 DE-1	161 DE-1	177 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (g)*			*372*	*423*	*301*	*347*	*275*	*377*	*310*	*303*	*100 a*	*8*	*100*	*100*	*0*	*100*
2	Fludioxonil 100 FS	0,5	L/ton	102 a	100 a	111 a	104 a	106 a	103 a	104 a	100 a	104 a	8	100	111	3	103
3	Celest/Maxim/Influx XL	1	L/ton	99 a	100 a	99 a	101 a	106 a	101 a	103 a	101 a	101 a	8	99	106	2	101

Table 3.2-15c Effect of Fludioxonil 100 FS on the moisture content of maize (%)

MOICON				KCP 6.2-4 (NL)	KCP 6.2-5 (PL)	KCP 6.2-6 (HU)	KCP 6.2-7 (NL)	KCP 6.2-8 (CZ)	KCP 6.2-9 (NL)	KCP 6.2-10 (ES)	KCP 6.2-12 (IT)	KCP 6.2-13 (HU)	KCP 6.2-14 (HU)
Days after application				189 DA-A	163 DA-A	169 DA-A	206 DA-A	211 DA-A	210 DA-A	196 DA-A	177 DA-A	190 DA-A	194 DA-A
Days after emergence				163 DE-1	121 DE-1	126 DE-1	158 DE-1	174 DE-1	154 DE-1	149 DE-1	147 DE-1	161 DE-1	175 DE-1
No.	Product			%	%	%	%	%	%	%	%	%	%
1	*Untreated Check*			*16 a*	*14 a*	*15 a*	*22 a*	*21 a*	*18 a*	*15 a*	*20 a*	*16 a*	*19 a*
2	Fludioxonil 100 FS	0,5	L/ton	16 a	14 a	15 a	22 a	20 a	19 a	14 a	20 a	16 a	19 a
3	Celest/Maxim/Influx XL	1	L/ton	15 a	14 a	14 b	23 a	22 a	18 a	14 a	20 a	16 a	19 a

MOICON				Summary					
Days after application									
Days after emergence									
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check*			*18 a*	*10*	*14*	*22*	*3*	*17*
2	Fludioxonil 100 FS	0,5	L/ton	17 a	10	14	22	3	17
3	Celest/Maxim/Influx XL	1	L/ton	17 a	10	14	23	3	17

Summary

The results summarized above demonstrate that Fludioxonil 100 FS has good efficacy which is comparable to the reference product when applied on maize seeds. A dose rate of 0.5 L/ton is demonstrated to have good performance in a wide range of conditions. Furthermore, no negative effect on the quality parameters caused by Fludioxonil 100 FS or the reference product were observed. The results were fully comparable. It also has to be taken into account that Metalaxyl-M containing products such as Celest/Maxim/Influx XL will be forbidden for outdoor use from 2022. Fludioxonil 100 FS provides a Metalaxyl-M free solution. Altogether, these results fully support the authorization of 0.5 L/ton seed of Fludioxonil 100 FS on maize.

3.2.3.2 Efficacy results of trials performed on sunflower

Contrary to maize summary tables, none of the tables summarizing efficacy in sunflower shows trial location. Therefore the zRMS indicates it for the cMSs in the table below, sorted by the trial KCP code (on the left), or by the MSs (on the right). Trials: KCP 6.2-24, 25, 28-35 and 47-50, are greenhouse trials.

trial code ↑	trial location / MS		trial code	trial location / MS ↑
KCP 6.2-24	IT		KCP 6.2-28	ES
KCP 6.2-25	IT		KCP 6.2-29	ES
KCP 6.2-26	HU		KCP 6.2-32	ES
KCP 6.2-27	IT		KCP 6.2-40	ES
KCP 6.2-28	ES		KCP 6.2-36	HR
KCP 6.2-29	ES		KCP 6.2-37	HR
KCP 6.2-30	PL		KCP 6.2-42	HR
KCP 6.2-31	PL		KCP 6.2-43	HR
KCP 6.2-32	ES		KCP 6.2-47	HR
KCP 6.2-33	NL		KCP 6.2-26	HU
KCP 6.2-34	IT		KCP 6.2-38	HU
KCP 6.2-35	IT		KCP 6.2-24	IT
KCP 6.2-36	HR		KCP 6.2-25	IT
KCP 6.2-37	HR		KCP 6.2-27	IT
KCP 6.2-38	HU		KCP 6.2-34	IT
KCP 6.2-39	IT		KCP 6.2-35	IT
KCP 6.2-40	ES		KCP 6.2-39	IT
KCP 6.2-41	IT		KCP 6.2-41	IT
KCP 6.2-42	HR		KCP 6.2-44	IT
KCP 6.2-43	HR		KCP 6.2-45	IT
KCP 6.2-44	IT		KCP 6.2-46	IT
KCP 6.2-45	IT		KCP 6.2-48	IT
KCP 6.2-46	IT		KCP 6.2-49	IT
KCP 6.2-47	HR		KCP 6.2-50	IT
KCP 6.2-48	IT		KCP 6.2-33	NL
KCP 6.2-49	IT		KCP 6.2-30	PL
KCP 6.2-50	IT		KCP 6.2-31	PL

Table 3.2-16a The number of emerged plants relative to the untreated

Number of plants				KCP 6.2-24	KCP 6.2-25	KCP 6.2-26	KCP 6.2-27	KCP 6.2-28	KCP 6.2-29	KCP 6.2-30	KCP 6.2-31	KCP 6.2-32	KCP 6.2-33
Days After Application				33 DA-A	33 DA-A	113 DA-A	50 DA-A	126 DA-A	126 DA-A	48 DA-A	53 DA-A	205 DA-A	61 DA-A
Days After Emergence				12 DE-1	12 DE-1	28 DE-1	32 DE-1	30 DE-1	30 DE-1	32 DE-1	35 DE-1	35 DE-1	17 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Untreated Check (absolute #)*			*84 b*	*82 b*	*56 b*	*77 a*	*14 a*	*14 b*	*90 b*	*89 b*	*87 a*	*95 a*
3	Fludioxonil 100 FS	1,25	L/ton	112 a	114 a	137 a	98 a	127 a	144 a	105 a	105 a	100 a	101 a
4	Fludioxonil 100 FS	1,5	L/ton	111 a	114 a	138 a	99 a	135 a	142 a	107 a	108 a	98 a	101 a
6	Maxim 025 FS	6	L/ton	-	-	-	-	-	-	108 a	107 a	104 a	101 a
7	Apron XL	3	L/ton	102 b	104 b	141 a	99 a	125 a	139 a	-	-	-	-

Number of plants				KCP 6.2-34	KCP 6.2-35	KCP 6.2-36	KCP 6.2-37	KCP 6.2-38	KCP 6.2-39	KCP 6.2-40	KCP 6.2-41	KCP 6.2-42	KCP 6.2-43
Days After Application				72 DA-A	72 DA-A	54 DA-A	56 DA-A	90 DA-A	54 DA-A	111 DA-A	91 DA-A	41 DA-A	48 DA-A
Days After Emergence				20 DE-1	20 DE-1	33 DE-1	34 DE-1	67 DE-1	40 DE-1	88 DE-1	26 DE-1	27 DE-1	34 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Untreated Check (absolute #)*			*93 a*	*93 a*	*109 b*	*109 b*	*59 a*	*116 a*	*89 a*	*113 a*	*107 b*	*109 b*
3	Fludioxonil 100 FS	1,25	L/ton	105 a	94 a	104 a	106 a	103 a	100 a	122 a	100 a	107 a	105 a
4	Fludioxonil 100 FS	1,5	L/ton	106 a	98 a	105 a	106 a	110 a	100 a	116 a	100 a	106 a	106 a
6	Maxim 025 FS	6	L/ton	106 a	82 b	104 a	106 a	109 a	100 a	111 a	-	-	-
7	Apron XL	3	L/ton	-	-	-	-	-	-	-	100 a	107 a	106 a

Number of plants				KCP 6.2-44	KCP 6.2-45	KCP 6.2-46	KCP 6.2-47	KCP 6.2-48	KCP 6.2-49	KCP 6.2-50	Summary					
Days After Application				92 DA-A	91 DA-A	92 DA-A	39 DA-A	42 DA-A	42 DA-A	42 DA-A						
Days After Emergence				30 DE-1	28 DE-1	29 DE-1	28 DE-1	28 DE-1	28 DE-1	28 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (absolute #)*			*116 a*	*113 a*	*117 a*	*98 a*	*71 b*	*66 b*	*74 b*	-	*27*	-	-	-	-
3	Fludioxonil 100 FS	1,25	L/ton	100 a	100 a	100 a	101 a	119 a	133 a	116 a	110 a	27	94	144	13	105
4	Fludioxonil 100 FS	1,5	L/ton	100 a	99 a	100 a	101 a	128 a	137 a	128 a	111 a	27	98	142	14	106
6	Maxim 025 FS	6	L/ton	-	-	-	-	-	-	-	103 b	11	82	111	8	106
7	Apron XL	3	L/ton	99 a	100 a	99 a	101 a	122 a	131 a	124 a	112 a	16	99	141	15	105

Table 3.2-16b Efficacy in sunflower leaves against PLASHA at the final assessment: pest severity relative to the untreated

Pest severity				KCP 6.2-24	KCP 6.2-25	KCP 6.2-26	KCP 6.2-27	KCP 6.2-41	KCP 6.2-42	KCP 6.2-43	KCP 6.2-44	KCP 6.2-45	KCP 6.2-46
Pest Code				PLASHA	PLASHA	PLASHA	PLASHA	PLASHA	PLASHA	PLASHA	PLASHA	PLASHA	PLASHA
Part Rated				LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Days After Treatment				33 DA-A	33 DA-A	113 DA-A	50 DA-A	107 DA-A	41 DA-A	48 DA-A	110 DA-A	109 DA-A	111 DA-A
Days After Emergence				12 DE-1	12 DE-1	28 DE-1	32 DE-1	42 DE-1	27 DE-1	34 DE-1	48 DE-1	46 DE-1	48 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Unreated Check*			*15 a*	*12 a*	*32 a*	*5 a*	*21 a*	*14 a*	*22 a*	*21 a*	*25 a*	*49 a*
3	Fludioxonil 100 FS	1,25	L/ton	55 c	48 c	79 c	51 b	67 a	91 a	93 a	67 a	52 b	55 c
4	Fludioxonil 100 FS	1,5	L/ton	78 b	74 b	86 b	73 a	68 a	94 a	93 a	68 a	65 a	67 b
7	Apron XL	3	L/ton	95 a	96 a	100 a	78 a	74 a	80 b	90 a	74 a	72 a	82 a

Pest severity				KCP 6.2-47	KCP 6.2-48	KCP 6.2-49	KCP 6.2-50	Summary					
Pest Code				PLASHA	PLASHA	PLASHA	PLASHA						
Part Rated				LEAF	LEAF	LEAF	LEAF						
Days After Treatment				39 DA-A	42 DA-A	42 DA-A	42 DA-A						
Days After Emergence				28 DE-1	28 DE-1	28 DE-1	28 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Unreated Check*			*73 a*	*22 a*	*16 a*	*27 a*	*25*	*14*	*5*	*73*	*17*	*22*
3	Fludioxonil 100 FS	1,25	L/ton	86 a	82 a	84 b	83 b	71 b	14	48	93	16	73
4	Fludioxonil 100 FS	1,5	L/ton	88 a	86 a	96 a	94 a	81 a	14	65	96	11	82
7	Apron XL	3	L/ton	69 b	85 a	81 b	97 a	84 a	14	69	100	10	82

It can be observed that 1.5 L/ton of Fludioxonil 100 FS performs on the same level as the reference product Apron XL against PLASHA. In trials KCP 6.2-24, 25, 26 and 46 Apron XL performs better while in trials KCP 6.2-42, 47 and 49 Fludioxonil 100 FS performs better. The 1.25 L/ton Fludioxonil 100 FS also provides moderate control against PLASHA.

zRMS comment to the Table 3.2-16 b:

Non-editable table. Corrections include:

1) KCP 6.2-26 was last assessed on 98 and not 113 DAA.
2) KCP 6.2-41: assessment 107 DAA: UNCK, Fludioxonil 1.25L, 1.50L and Apron XL 3.0L: 22%; 64%; 55% and 60 % respectively, according to trial report content.
3) Summary of efficacy in sunflower against PLASHA including correction to KCP 6.2-41 (pest severity on leaves relative to the untreated, n=14):

	mean	min	max
UNCK % PESSEV	25	5	73
Fludioxonil 100 FS 1.25 L/t; % UNCK	71	48	93
Fludioxonil 100 FS 1.50 L/t; % UNCK	**80**	**55**	96
Apron XL 3.0 L/t; % UNCK	**83**	**60**	100

It may be noted that on average 1.5 L/ton of Fludioxonil 100 FS controls PLASHA on the same efficacy level as the reference product Apron XL. The average minimum efficacy of the 1.5 dose rate is nevertheless lower than that of the standard reference (55% compared to 60%). Considered the individual trials, the test item outperforms the reference in 4 trials out of 14, and the efficacy of the 1.25L/t dose rate is significanly lower compared to 1.50L/t in 8 trials out of 14.

Table 3.2-16c Efficacy in sunflower roots against PLASHA at the final assessment: disease index relative to the untreated

Disease index				KCP 6.2-24	KCP 6.2-25	KCP 6.2-27	KCP 6.2-47	KCP 6.2-48	KCP 6.2-49	KCP 6.2-50	Summary					
Pest Code				PLASHA	PLASHA	PLASHA	PLASHA	PLASHA	PLASHA	PLASHA						
Part Rated				ROOT	ROOT	ROOT	ROOT	ROOT	ROOT	ROOT						
Days After Treatment				33 DA-A	33 DA-A	50 DA-A	39 DA-A	42 DA-A	42 DA-A	42 DA-A						
Days After Emergence				12 DE-1	12 DE-1	32 DE-1	28 DE-1	28 DE-1	28 DE-1	28 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Unreated Check*			*45 a*	*40 a*	*10 a*	*34 a*	*58 a*	*61 a*	*64 a*	*44 a*	*7*	*10*	*64*	*19*	*45*
3	Fludioxonil 100 FS	1,25	L/ton	62 a	58 a	49 a	77 a	45 c	60 b	58 a	58 b	7	45	77	10	58
4	Fludioxonil 100 FS	1,5	L/ton	63 a	51 a	48 a	78 a	74 a	75 a	81 a	67 a	7	48	81	13	74
7	Apron XL	3	L/ton	66 a	51 a	48 a	63 b	57 b	63 b	73 a	60 b	7	48	73	9	63

It can be observed that the lower dose rate of 1,25 L/ton of Fludioxonil 100 FS performs on the same level as the reference product Apron XL against PLASHA. In trial KCP 6.2-47 it performs better while in trial 6.2-48 the reference product has a higher efficacy.
The dose of 1,50 L/ton of Fludioxonil 100 FS has the highest efficacy against PLASHA in sunflower roots, ~~. O~~ outperforming the reference product~~ion~~ in trials KCP 6.2-47, 48 and 49.

Table 3.2-16d Efficacy in sunflower leaves against BOTRCI at the final assessment: pest severity relative to the untreated

Pest severity				KCP 6.2-30	KCP 6.2-31	KCP 6.2-32	KCP 6.2-33	KCP 6.2-34	KCP 6.2-35	KCP 6.2-36	KCP 6.2-37	KCP 6.2-40
Pest Code				BOTRCI	BOTRCI	BOTRCI	BOTRCI	BOTRCI	BOTRCI	BOTRCI	BOTRCI	BOTRCI
Part Rated				PLANT	PLANT	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Days After Treatment				48 DA-A	53 DA-A	205 DA-A	61 DA-A	72 DA-A	72 DA-A	54 DA-A	56 DA-A	111 DA-A
Days After Emergence				32 DE-1	35 DE-1	35 DE-1	17 DE-1	20 DE-1	20 DE-1	33 DE-1	34 DE-1	88 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Unreated Check*			*5 a*	*9 a*	*93 a*	*6 a*	*21 a*	*28 a*	*7 a*	*9 a*	*19 a*
3	Fludioxonil 100 FS	1,25	L/ton	84 b	98 a	27 b	37 a	54 ab	37 ab	98 a	90 a	78 b
4	Fludioxonil 100 FS	1,5	L/ton	93 a	100 a	46 a	39 a	74 a	56 a	99 a	94 a	86 a
6	Maxim 025 FS	6	L/ton	81 b	99 a	32 b	65 a	65 a	10 b	99 a	92 a	81 ab

Pest severity				Summary					
Pest Code									
Part Rated									
Days After Treatment									
Days After Emergence									
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Unreated Check*			*22*	*9*	*5*	*93*	*28*	*9*
3	Fludioxonil 100 FS	1,25	L/ton	67 c	9	27	98	28	78
4	Fludioxonil 100 FS	1,5	L/ton	76 b	9	39	100	24	86
6	Maxim 025 FS	6	L/ton	69 c	9	10	99	31	81

The dose rate of 1,25 L/ton of Fludioxonil 100 FS always performs on the same level as the reference product. It has to be noted that the reference product contains 150 g/ton of Fludioxonil while 1,25 L/ton of Fludioxonil contains 25 g less Fludioxonil. The higher dose rate (also containing 150 g/ton Fludioxonil) even performs better in trials KCP 6.2-30, 32 & 35 to provide control against BOTRCI.

zRMS comment to the Table 3.2-16 d:
The test item at 1.25L/t seeds does not always perform the level of the standard reference. See KCP 6.2-32 - 34, where it is inferior to Maxim at 6L/ton. In KCP 6.2-33 even the target dose, 1.50L/t, is inferior to the reference. KCP 6.2-35 (IT) should be excluded from the summary, for the extremely low performance of the standard reference, for which no reasons are given in the trial report. The summary after exclusion of KCP 6.2-35 reads as follows: 21.1%, **71.2**%, **78.8**% and 76.8% (respectively: UNCK PESSEV, **the test item at 1.25 and 1.50** L/ton, and the reference Maxim (7 trials) or Celest (1 trial) at 6.0L/ton). Only two trials in this summary come from the SE EPPO (Croatia) zone: KCP 6.2-36 and 37. Both are field trials.

Table 3.2-16e Efficacy in sunflower roots against FUSASP at the final assessment: pest incidence & disease index relative to the untreated

Pest incidence				KCP 6.2-36	KCP 6.2-37	KCP 6.2-39	KCP 6.2-40	KCP 6.2-42	KCP 6.2-43	Summary					
Pest Code				GIBBIN	GIBBIN	FUSASR	FUSAOX	GIBBIN	GIBBIN						
Part Rated				ROOT	ROOT	ROOT	ROOT	ROOT	ROOT						
Days After Treatment				54 DA-A	56 DA-A	54 DA-A	111 DA-A	41 DA-A	48 DA-A						
Days After Emergence				33 DE-1	34 DE-1	40 DE-1	88 DE-1	27 DE-1	34 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Unreated Check*			*21 a*	*29 a*	*11 a*	*47 a*	*26 a*	*33 a*	*28*	*6*	-	-	-	-
3	Fludioxonil 100 FS	1,25	L/ton	85 a	79 a	69 a	40 a	76 a	67 a	71 a	6	40	89	17	73
4	Fludioxonil 100 FS	1,5	L/ton	96 a	84 a	81 a	27 a	80 a	75 a	74 a	6	27	96	24	81
6	Maxim 025 FS	6	L/ton	94 a	86 a	67 a	29 a	-	-	69 a	4	29	94	29	77
7	Apron XL	3	L/ton	-	-	-	-	68 a	87 a	78 a	2	68	87	13	78

Disease index				KCP 6.2-36	KCP 6.2-37	KCP 6.2-39	KCP 6.2-40	KCP 6.2-42	KCP 6.2-43	Summary					
Pest Code				GIBBIN	GIBBIN	FUSASR	FUSAOX	GIBBIN	GIBBIN						
Part Rated				ROOT	ROOT	ROOT	ROOT	ROOT	ROOT						
Days After Treatment				54 DA-A	56 DA-A	54 DA-A	111 DA-A	41 DA-A	48 DA-A						
Days After Emergence				33 DE-1	34 DE-1	40 DE-1	88 DE-1	27 DE-1	34 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Unreated Check*			*5 a*	*9 a*	*5 a*	*17 a*	*7 a*	*12 a*	*9*	*6*	-	-	-	-
3	Fludioxonil 100 FS	1,25	L/ton	85 a	83 a	50 a	55 a	78 a	76 a	71 a	6	50	85	15	77
4	Fludioxonil 100 FS	1,5	L/ton	96 a	87 a	58 a	45 a	83 a	83 a	75 a	6	45	96	20	83
6	Maxim 025 FS	6	L/ton	94 a	88 a	47 a	51 a	-	-	70 a	4	47	94	24	70
7	Apron XL	3	L/ton	-	-	-	-	71 a	93 a	82 a	2	71	93	16	82

No differences can be observed in any of the trials between the reference product and both dose rates of Fludioxonil 100 FS regarding efficacy against FUSASP.

zRMS comment to the Table 3.2-16 e: All trials in this summary are field trials.

In the South-east EPPO Zone, Maxim 25 FS is authorized as 5L/ton of seeds, which is equivalent to 125 g/ton of seeds of Fludioxonil. As a results, we also apply for this dose, equivalent to 1,25 L/ton of Fludioxonil 100 FS in the countries of these EPPO zone, respectively HU, RO and SI. The 2 Hungarian* trials, KCP 6.2-36 & 37 also prove the equivalence between both products at this dose rate.

Pest severity				KCP 6.2-36	KCP 6.2-37
Pest Code				BOTRCI	BOTRCI
Part Rated				LEAF	LEAF
Days After Treatment				54 DA-A	56 DA-A
Days After Emergence				33 DE-1	34 DE-1
No.	Product			%UNCK	%UNCK
1	*Unreated Check*			*7 a*	*9 a*
3	Fludioxonil 100 FS	1,25	L/ton	98 a	90 a
5	Maxim 025 FS	5	L/ton	96 a	92 a

Disease index				KCP 6.2-36	KCP 6.2-37
Pest Code				GIBBIN	GIBBIN
Part Rated				ROOT	ROOT
Days After Treatment				54 DA-A	56 DA-A
Days After Emergence				33 DE-1	34 DE-1
No.	Product			%UNCK	%UNCK
1	*Unreated Check*			*5 a*	*9 a*
3	Fludioxonil 100 FS	1,25	L/ton	85 a	83 a
5	Maxim 025 FS	5	L/ton	85 a	77 a

Pest incidence				KCP 6.2-36	KCP 6.2-37
Pest Code				GIBBIN	GIBBIN
Part Rated				ROOT	ROOT
Days After Treatment				54 DA-A	56 DA-A
Days After Emergence				33 DE-1	34 DE-1
No.	Product			%UNCK	%UNCK
1	*Unreated Check*			*21 a*	*29 a*
3	Fludioxonil 100 FS	1,25	L/ton	85 a	79 a
5	Maxim 025 FS	5	L/ton	85 a	74 a

***zRMS comment:** Regarding BOTRCI: KCP 6.2-36 and 37 are Croatian trials, to be correct. To the opinion of zRMS, picking up just two trials in order to highlight a selected concept is inappropriate, and the larger data set shows contrary: See the "Summary" part of the Table 3.2-16d, where the applicant themselves demonstrates, based on 9 trials, that the 1.25 dose rate performs on average significantly lower compared to 1.5 L/t. Even after exclusion of KCP 6.2-35 from that set the difference is 7.6% to the detriment of the lower dose.

Quality parameters such as, Fresh weight, Yield, HLW and MOICON were also investigated in some efficacy trials. The results are shown in the tables below.

Table 3.2-16f Effect of Fludioxonil 100 FS on the fresh weight of sunflower (g) compared to the untreated check (%UNCK) greenhouse trials exclusively

Fresh weight				KCP 6.2-24	KCP 6.2-25	KCP 6.2-30	KCP 6.2-31	KCP 6.2-32	KCP 6.2-33	KCP 6.2-34	KCP 6.2-35	KCP 6.2-47	KCP 6.2-48	KCP 6.2-49	KCP 6.2-50
Days After Application				33 DA-A	33 DA-A	48 DA-A	53 DA-A	205 DA-A	65 DA-A	72 DA-A	72 DA-A	39 DA-A	42 DA-A	42 DA-A	42 DA-A
Days After Emergence				12 DE-1	12 DE-1	32 DE-1	35 DE-1	35 DE-1	21 DE-1	20 DE-1	20 DE-1	28 DE-1	28 DE-1	28 DE-1	28 DE-1
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	%UNCK
1	*Untreated Check (g)*			*161 c*	*183 a*	*271 a*	*468 c*	*90 b*	*314 a*	*53 c*	*81 b*	*1114 c*	*126 b*	*155 b*	*89 b*
3	Fludioxonil 100 FS	1,25	L/ton	114 ab	109 a	109 a	125 a	216 ab	101 a	246 a	188 a	394 a	133 a	180 a	148 a
4	Fludioxonil 100 FS	1,5	L/ton	126 a	118 a	112 a	128 a	321 a	106 a	262 a	198 a	403 a	147 a	200 a	159 a
6	Maxim 025 FS	6	L/ton	-	-	110 a	133 a	293 a	104 a	260 a	126 ab	-	-	-	-
7	Apron XL	3	L/ton	138 a	135 a	-	-	-	-	-	-	345 a	136 a	185 a	144 a

Fresh weight Days After Application Days After Emergence				Summary					
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (g)*			-	*12*	-	-	-	-
3	Fludioxonil 100 FS	1,25	L/ton	172 a	12	101	394	84	140
4	Fludioxonil 100 FS	1,5	L/ton	190 a	12	106	403	94	153
6	Maxim 025 FS	6	L/ton	171 a	6	104	293	83	130
7	Apron XL	3	L/ton	181 a	6	135	345	83	141

Table 3.2-16g Effect of Fludioxonil 100 FS on the yield of sunflower (T-MET) compared to the untreated check (%UNCK)

Yield				KCP 6.2-36	KCP 6.2-37	KCP 6.2-38	KCP 6.2-42	KCP 6.2-43	Summary					
Days After Application				128 DA-A	140 DA-A	146 DA-A	127 DA-A	125 DA-A						
Days After Emergence				107 DE-1	118 DE-1	123 DE-1	113 DE-1	111 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (T-MET)*			*1 a*	*1 a*	*2 c*	*2 b*	*2 b*	-	*5*	-	-	-	-
3	Fludioxonil 100 FS	1,25	L/ton	107 a	107 a	136 ab	115 a	120 a	117 a	5	107	136	12	115
4	Fludioxonil 100 FS	1,5	L/ton	108 a	111 a	135 ab	113 a	124 a	118 a	5	108	135	11	113
6	Maxim 025 FS	6	L/ton	113 a	116 a	134 ab	-	-	121 a	3	113	134	11	116
7	Apron XL	3	L/ton	-	-	-	116 a	117 a	117 a	2	116	117	1	117

Table 3.2-16h Effect of Fludioxonil 100 FS on the HLW of sunflower (kg) compared to the untreated check (%UNCK)

HLW				KCP 6.2-36	KCP 6.2-37	KCP 6.2-42	KCP 6.2-43	Summary					
Days After Application				128 DA-A	140 DA-A	127 DA-A	125 DA-A						
Days After Emergence				107 DE-1	118 DE-1	113 DE-1	111 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (kg)*			*35 a*	*37 a*	*35 b*	*38 b*	-	*4*	-	-	-	-
3	Fludioxonil 100 FS	1,25	L/ton	104 a	106 a	107 a	105 a	105 a	4	104	107	1	105
4	Fludioxonil 100 FS	1,5	L/ton	104 a	105 a	107 a	107 a	106 a	4	104	107	2	106
6	Maxim 025 FS	6	L/ton	104 a	106 a	-	-	105 a	2	104	106	2	105
7	Apron XL	3	L/ton	-	-	106 a	105 a	106 a	2	105	106	1	106

Table 3.2-16i Effect of Fludioxonil 100 FS on the moisture content of sunflower (%)

Moisture content				KCP 6.2-36	KCP 6.2-37	KCP 6.2-38	KCP 6.2-42	KCP 6.2-43	Summary					
Days After Application				128 DA-A	140 DA-A	146 DA-A	127 DA-A	125 DA-A						
Days After Emergence				107 DE-1	118 DE-1	123 DE-1	113 DE-1	111 DE-1						
No.	Product			%	%	%	%	%	Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check (%)*			*11 a*	*12 a*	*7 a*	*12 a*	*11 a*	*10 a*	*5*	*7*	*12*	*2*	*11*
3	Fludioxonil 100 FS	1,25	L/ton	12 a	11 a	7 a	11 a	11 a	10 a	5	7	12	2	11
4	Fludioxonil 100 FS	1,5	L/ton	11 a	11 a	6 b	11 a	10 a	10 a	5	6	11	2	11
6	Maxim 025 FS	6	L/ton	11 a	12 a	7 a	-	-	10 a	3	7	12	3	11
7	Apron XL	3	L/ton	-	-	-	10 a	10 a	10 a	2	10	10	0	10

Summary

The results summarized above demonstrate that Fludioxonil 100 FS at 1.5 L/ton has good efficacy which is comparable or even better than the reference product when applied on sunflower seeds.

It has to be noted that the reference product Maxim 25 FS is authorized as 5L/ton of seeds, comparable to 1,25 L/ton of seeds Fludioxonil FS in the South-eastern EPPO Zone countries. Therefore we also apply for the comparable dose in HU, RO and SI. The results show that this dose also provides moderate control, comparable to the reference product, against different diseases.

Furthermore, no negative effect on the quality parameters caused by Fludioxonil 100 FS or the reference product were observed. The results were fully comparable.

It also has to be taken into account that Metalaxyl-M containing products such as XL will be forbidden for outdoor use from 2022. Fludioxonil 100 FS provides a Metalaxyl-M free solution.

Altogether, these results fully support the authorization of 1,50 L/ton seed of Fludioxonil 100 FS on sunflower.

Comments of zRMS on Efficacy tests chapter:

Efficacy in maize
The applicant has submitted 23 efficacy trials in maize, including 8 - in the Maritime EPPO zone (BE, CZ, FR, NL), 8 - in the NE EPPO zone (PL), 3 - in the SE EPPO zone (HU) and 4 -in the Mediterranean Zone (ES, IT). Majority of trials demonstrate positive, or the level of standard reference, effect of the test item at the target dose rate of 0.5L/t seeds, on plant emergence, compared to the untreated plots. The mean effect on plant infestation by ***Fusarium* sp**. is, based on 13 trials, below the 60% efficacy treshold, even though on average 2% higher compared to the reference product. The same is concluded for efficacy against *Fusarium* sp. in plant roots, as quantified by severity index, although here the efficacy is on average 7% higher than that of standards. The average reduction of the incidence of *Fusarium* sp. is lower than 50%, but it is true that here majority of trials show there is no statistical significance between the test item and standard products. **Four trials only** (3 from PL and 1 from IT) demonstrate efficacy against ***Pythium* sp.**, as quantified first by severity index and then by pest incidence. The efficacy is < 50%, with standards performing > 60%, on average.
As to the zRMS knowledge no separate criteria exist for the efficacy assessment in seed treatments, it is concluded that the efficacy of Fludioxonil 100 FS against the target pathogens in maize: *Fusarium* and *Pythium*, at the target dose rate of 0.5L/t seeds, is **moderate**. It was nevertheless shown to be comparable to the reference standards in most of the submitted trials, and the test item shows no negative effect on seed germination either.

Yield in efficacy trials in maize
Yield of maize treated with the test item at 0.5L/t seeds was on average slightly higher numerically, but comparable statistically (insignificant differences) to that obtained from the reference-treated plots. The same is true for TKW and moisture content.

Efficacy in sunflower
The applicant has submitted 27 efficacy trials in sunflower, including 1 - in the Maritime EPPO zone (NL), 2 - in the NE EPPO zone (PL), 7 - in the SE EPPO zone (HR, HU) and 17 -in the Mediterranean Zone (ES, IT). Majority of trials demonstrate positive, or the level of standard reference, effect of the test item at the dose range targeted by the applicant: 1.25-1.50 L/t seeds, on plant emergence, compared to the untreated plots.
The mean efficacy against ***P. halstedii*** is > 80%, based on 14 trials, and comparable to the reference product, but the efficacy of the 1.25L/t dose rate is significanly lower compared to 1.50L/t in 8 trials. When quantified using the disease severity index on roots, the efficacy level is < 70% on average, it is nevertheless comparable to or higher than that of the reference products in individual trials, and significantly higher than that, when summarized across 7 trials (Table 3.2-16c). Still, the same as on leaves, the lower dose performs significantly lower, in 2 trials per 7, and also lower on average. The efficacy of the 1.50L/t dose rate against ***B. cinerea*** is quite good (79%), based on 8 valid trials. It is also signifcantly higher compared to both the reference standards and to the lower dose rate of the test item (71% at 1.25L/t) (see Table 3.2-16d and zRMS comment to it). The efficacy against ***Fusarium* sp.** is assessed as 74-75% on average, based on 6 trials, when measured as reduction in target incidence or infection severity. The efficacy level is comparable to the reference products, and **there is no significant difference between the 1.25 and 1.50 dose rates either**.
It is concluded that the efficacy of Fludioxonil 100 FS in sunflower against *P. halstedi*, *B. cinerea* and *Fusarium* sp. at the dose rate of 1.50L/t seeds is good. However, the applicant`s view that the lower dose rate: 1.25L/t, is universally efficient against all the targets in sunflower, is not justified by the submitted data. Only in case of *Fusarium* sp. the data show that the lower dose rate is indeed comparable to the higher dose. Therefore, to the opinion of zRMS, while the dose range of 1.25-1.50L/t may be recommended, for the Member States of the SE EPPO zone, the label should contain the information that the efficacy of the 1.25L/t dose against *Botrytis cinerea* and *P. halstedii* is moderate. The concerned MSs in the SE zone are thereby kindly advised to consider individually whether the dose range approach is acceptable for them.

Yield in efficacy trials in sunflower
The yield of sunflower treated with the test item at 1.25-1.50 L/t seeds was significantly higher compared to the UNCK and on average comparable between the test item and the reference standards at their equivalent dose rates. The fresh weight of plants was higher, in majority of trials, from the plots treated with both rates of the test item, compared to the UNCK. This effect was comparable to the plots treated with standards. Moisture content in seeds is unaffected by the application of Fludioxonil 100 FS, as compared to the standard products and to the UNCK.

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

Fludioxonil 100 FS consists of one active ingredient, fludioxonil.
Fludioxonil is a phenylpyrrole (PP fungicide) belonging to class E2 – Osmotic signal transduction MAP (mitogen activated protein) / histidine-kinase (os-2, HOG1). Only one other fungicide belongs to this group, fenpiclonil, however it was not included in Annex I of Directive 91/414 in 2002.

Resistance information is reported on the website of the Fungicide Resistance Action Committee (www.frac.info)

On the website two lists can be found:

- FRAC List of plant pathogenic organisms resistant to disease control agents – revised January 2013
- Pathogen Risk List (December 2005)

As mentioned in the pathogen risk list of the FRAC:

- soilborne diseases, smuts and bunts are plant pathogens which shows a low risk of resistance development.
- for fludioxonil, resistance is found sporadically, mechanism speculative. Low to medium risk. The observed resistance seems mainly related to foliar treatment on fruit, not to seed treatments.

Based on this information, a combined risk is calculated for fludioxonil when applied as a seed treatment: value 2 on a scale of 6 (with 6 maximum risk for resistance development).

Since there are no fludixonil-based foliar fungicides registered for use in maize or sunflower, multiple applications of the same active ingredient within the same growing season are excluded. Due to the fact the product is only used once a year, combined with the low medium risk for resistance development one can conclude that no resistance risk management measures are required.

Conclusion on the risk of resistance development related to the use of FLUDIOXONIL 100 FS as seed treatment:

There is a low risk for development of resistance related to the use of FLUDIOXONIL 100 FS, no anti-resistance measures are required.

Comments of zRMS :

The mode of action of fludioxonil plainly explained
"*The HOG pathway is a branched mitogen activated protein kinase (MAPK) signal transduction system that has been well characterised in Saccharomyces cerevisiae. The major role of this pathway is to adapt fungi to the osmolarity of the surrounding environment. Increased osmolarity in the environment leads to water loss and cell shrinkage. To compensate for this, the HOG pathway stimulates production of intracellular glycerol to draw in more water.*
[…]
Fludioxonil is one of two commercial fungicides, the other being fenpiclonil, derived from the compound pyrrolnitrin, which was first isolated from bacteria in the genus Pseudomonas. It is a broad-spectrum fungicide used to control many crop pathogens before and after harvest. It inhibits fungal growth by over-stimulating the high osmolarity glycerol (HOG) pathway to induce hyphal swelling and bursting."

(Please note: the two paragraphs above are verbatim quotation from Akeem O. Taiwo *et al*., 2021).

Resistance to fludioxonil in pathogens such as *B. cinerea*, or *S. sclerotiorum* and *A. alternata* (the latter two not targets in the present GAP, although efficacy in control of SCLESC was assessed in 1 HU sunflower trial and was shown to be poor) is a matter of debate, and the opinions vary about the relation between laboratory-observed, or even induced resistance, on the one hand, and the field incidence of resistant strains – on the other. There is in fact evidence of the fitness penalties in the resistant strains, partially explaining the lab vs field discrepancy (D-X. Wu *et*

al. 2015, Kilani and Fillinger 2016, Fernández-Ortuño 2016, Wang et al. 2021, Akeem et al. 2021).

Nevertheless, the applicant`s untroubled attitude towards the resistance issue seems a bit out of place. Fludioxonil is the **single active authorized**, and one of the total of **two** actives representing MoA E2(12). In the FRAC Code List of **2021** the full text pertaining to PP fungicides (group E2(12)) reads: "*Resistance found sporadically, mechanism speculative. Low to medium risk.* ***Resistance management required***." (bolding by zRMS). The sentence "*The observed resistance seems mainly related to foliar treatment on fruit, not to seed treatments.*", as quoted by the applicant, is found nowhere in the **2019 version** of the document. In the FRAC Pathogen List of **2019**, *Botrytis cinerea* and *Plasmopara viticola* are listed as high-risk pathogens, the fact ignored by the applicant despite *B. cinerea* being one target of those listed in GAP. Although a different *Plasmopara* species is concerned in sunflower crops, *P. halstedii* is member of the same genus and may be potentially regarded as high-risk pathogen either.
Following the simple, famous concept presented in the FRAC Pathogen List of 2019, p. 6-7, the combined risk for use **in sunflower**, against *B. cinerea* and *P. halstedii*, should be set at the level of 6 on a scale of 1 – 9 (diagram in Fig. 1) (medium, according to Brent and Hollomon 2007), or, more realistically, at the level of 3 on a scale of 0.25 - 18, when the low agronomic risk is assumed, resulting from the single use in a growth season (diagram in the Fig. 2). Conversely, considered low-risk pathogens (*Fusarium* and *Pythium*) and still single use in a growth season **in maize**, the combined risk for the use in maize may be set at the level of 2 on a scale of 1 – 9 (diagram in Fig. 1) ("low", according to Brent and Hollomon 2007), or at the level of 1 on a scale of 0.25 - 18, according to the diagram in the Fig 2 (FRAC Pathogen List 2019). The combined risk of resistance development can be thus concluded low for the use in maize and medium for the use in sunflower, which should have been demonstrated by the applicant themselves.
As the foliar uses of fludioxonil are registered for neither of the two crops (at least not in the zRMS country), one may admit that the necessary resistance management strategy might be hard to invent and is presently unnecessary. However, in case the foliar applications of the same active are proposed in maize or sunflower in the future, these should be considered more carefully, particularly with respect to sunflower, the host to the high-risk *B. cinerea*.

Brent K.J., Hollomon D.W., **2007**. FUNGICIDE RESISTANCE: THE ASSESSMENT OF RISK, FRAC Monograph No.2 second, (revised) edition.

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Akeem O. Taiwo, Lincoln A. Harper and Mark C. Derbyshire **2021**. Impacts of fludioxonil resistance on global gene expression in the necrotrophic fungal plant pathogen *Sclerotinia sclerotiorum*. BMC Genomics (2021) 22:91 https://doi.org/10.1186/s12864-021-07402-x

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3.4 Adverse effects on treated crops (KCP 6.4)

In accordance with EPPO Guideline 1/135(4) several selectivity trials were performed where a higher dose rate of Fludioxonil 100 FS was tested. Additionally selectivity data was gathered in the efficacy trials, which included treatment with the highest requested dose rate. The data from the efficacy trials can be regarded as confirmatory data. For more information on these trials reference is made to section 3.

In the tables below all informations on the selectivity trials is summarized.

Table 3.4-1 Presentation of selectivity trials

Crop *	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***
				Mar. zone	N-E zone	S-E zone	~~Med~~ Mediter. zone	GEP
Maize	DK (EU North zone)	2019	S+Y+Q	1	-	-	-	**GEP**
	LV (EU North zone)	2020	S+Y+Q	-	2	-	-	**GEP**
	HU	2019	S+Y+Q	-	-	1	-	**GEP**
	CZ	2020	S+Y+Q	1	-	-	-	**GEP**
	NL	2019	S+Y+Q	1	-	-	-	**GEP**
	SE (EU North zone)	2020	S+Y+Q	1	-	-	-	**GEP**
	FR (EU South zone)	2020	S+Y+Q	-	-	-	1	**GEP**
	IT (EU South zone)	2020	S+Y+Q	-	-	-	1	**GEP**
	PL	2019	S+Y+Q	-	1	-	-	**GEP**
	TOTAL			**4**	**3**	**1**	**2**	
Sunflower	FR (EU South zone)	2020	S+Y+Q	-	-	-	1	**GEP**
	IT (EU South zone)	2020	S+Y+Q	-	-	-	1	**GEP**
	RO	2020	S+Y+Q	-	-	1	-	**GEP**
	CZ	2020	S+Y+Q	3	-	-	-	**GEP**
	DE	2020	S+Y+Q	2	-	-	-	**GEP**
	TOTAL			**5**	**-**	**1**	**2**	
OVERALL TOTAL				**9**	**3**	**2**	**4**	**18**

* According to the GAP table
** S= selectivity trial, Y= trial with yield assessment, Q= trial with quality assessment

Table 3.4-2 Presentation of reference standards used in the selectivity trials

Crop(s)	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark (4)
					Type(2)	Concentration of a.s.			
Maize	Maxim XL/ Influx XL/ Celest XL	NL	12302 N	Fludioxonil Metalaxyl-m	FS	25 g/L 9,7 (10) g/L	12.5 mL/ 50000 seeds OR 1L/t seeds OR 25 mL/100000 seeds	1L/ton & double	/
		PL	222/2020d						/
		FR	9800344						/
		HU	6300/19880-3/2019						/
		DK	/						/
		LV	/						/
		SE	/						/
		CZ	4413-0						/
		IT	10110						/
Sunflower	Maxim 25 FS/ Celest FS/ Celest Formula M	FR	2030323	Fludioxonil	FS	25 g/L	6L/ton	6L/ton & double	/
		IT	9288						/
		RO	045PC/29092014						/
		CZ	/						/
		DE	/						/

The trial methodology and trial site information are presented in Table 3.4-3 and Table 3.4-5.

Table 3.4-3a Details on trial methodology in maize

Guidelines	General guidelines	**EPPO PP 1/152 (4), 1/135 (4), 1/181 (4)**
	Specific guidelines	**PP 1/125(4)** Seed treatments against seedling diseases (trials under controlled conditions)
Experimental design	Plot design	Randomized Complete Block
	Plot size	12-30 m²
	Number of replications	4
Crop	Trials per crop	10 trials (6 varieties: Galactus, Jubilat, Like it, Konkurent, Opoka, Rywal)
Application	Crop stage (BBCH) at application	Seed treatment
	Number of applications Intervals	1
	Spray volumes	8 L/ton
Assessment	Assessment types	Number of emerged plants Phytotoxicity Yield Moisture content TKW
	Assessment dates	From sowing until after harvest
	Field / Greenhouse...	Field trials
	GEP	All trials were performed according to GEP

Table 3.4-4a Details on trial methodology in sunflower

Guidelines	General guidelines	**EPPO PP 1/152 (4), 1/135 (4), 1/181 (4)**
	Specific guidelines	**PP 1/125(4)** Seed treatments against seedling diseases (trials under controlled conditions)
Experimental design	Plot design	Randomized Complete Block
	Plot size	21-42 m²
	Number of replications	4
Crop	Trials per crop	8 trials (2 varieties: LG50-635CLP, Peredovick)
Application	Crop stage (BBCH) at application	Seed treatment
	Number of applications Intervals	1
	Spray volumes	8 L/ton
Assessment	Assessment types	Number of emerged plants Phytotoxicity Yield Moisture content TKW Oil content
	Assessment dates	From sowing until after harvest
	Field / Greenhouse...	Field trials
	GEP	All trials were performed according to GEP

Table 3.4-5 Summary of trial site and application details for selectivity trials

Type of trials — Crop safety
Identity of the product under test — Fludioxonil 100 FS
Crop: — Maize (ZEAMX), Sunflower (HELAN)
Responsible body for reporting trial — See second column
Date of submission — December 2020
~~Reference is made to the BAD.~~

zRMS: For completeness, the respective table has been restored from BAD:

Trial reference	Testing unit	Trial location	Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)	Indoor/ outdoor
					Date (1st and last), interval	Method, applic. Amount	Applic. Technique			
KCP 6.4-01 Maize	Agrolab A/S	Middelfart (DK)	sandy loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 12 m²	Apr-10-2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Opoka	FIELD
KCP 6.4-02 Maize	SynTech	Gyékényes (HU)	loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 30 m²	Apr-10-2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Rywal	FIELD
KCP 6.4-03 Maize	AgroResearch Sp. z o. o.	Wielgie (PL)	loamy sand	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 12 m²	Apr-10-2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Konkurent	FIELD
KCP 6.4-04 Maize	Proeftuin Zwaagdijk	Wieringerwerf (NL)	sandy clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 24 m²	Apr-10-2019	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Jubilat	FIELD
KCP 6.4-05 Maize	ZZS Kujavy	Kujavy (CZ)	loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 23 m²	Apr-15-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Like it	FIELD
KCP 6.4-06 Maize	HUSEC	Kristianstad (SE)	sandy loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 15 m²	Apr-15-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Like it	FIELD
KCP 6.4-07 Maize	Staphyt	Marsillargues (FR)	silty clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 24 m²	Apr-15-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Galactus	FIELD
KCP 6.4-08 Maize	Staphyt	Rocca de Baldi (IT)	loamy sand	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	Apr-15-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Galactus	FIELD

Trial reference	Testing unit	Trial location	Soil type	Test method, plot size	Application details			Growth stage crop	Remarks (variety)	Indoor/ outdoor
					Date (1st and last), interval	Method, applic. Amount	Applic. Technique			
KCP 6.4-09 Maize	LAAPC	Vecauce (LV)	calcareous sandy loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 28 m²	Apr-15-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Like it	FIELD
KCP 6.4-10 Maize	LAAPC	Vecauce (LV)	sandy clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 28 m²	Apr-15-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Galactus	FIELD
KCP 6.4-11 Sunflower	ZZS Kujavy	Kujavy (CZ)	loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 27,5 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	LG50-635CLP	FIELD
KCP 6.4-12 Sunflower	Agritec	Šumperk (CZ)	clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 39 m²	Apr-23-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Predovick	FIELD
KCP 6.4-13 Sunflower	InTec Agro Trials, s.r.o.	Uhersky Ostroh (CZ)	silty clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 42 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.4-14 Sunflower	Field Research Support	Kolenfeld (DE)	silt loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	LG50-635CLP	FIELD
KCP 6.4-15 Sunflower	Agrartest GmbH	Rosenow (DE)	sandy loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 22,5 m²	Apr-23-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD
KCP 6.4-16 Sunflower	Staphyt	Marsillargues (FR)	silty clay	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 24 m²	Apr-22-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	LG50-635CLP	FIELD
KCP 6.4-17 Sunflower	SAGEA	Castagnito d'Alba (IT)	loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 21 m²	Apr-23-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Pederovick	FIELD
KCP 6.4-18 Sunflower	Biotek	Fantanele (RO)	clay loam	PP 1/135 (4); PP 1/152 (4); PP 1/181 (4); PP 1/125 (4) Plot: 32 m²	Apr-23-2020	Seed treatment, 8 L/ton	Rotostat	Seed treatment	Peredovick	FIELD

Details of the formulations tested are provided in Table 3.4-6. treatments and application rates of the different treatments are provided in Table 3.4-7.

Table 3.4-6 Formulations included in selectivity trials

Product	Active substance	Active substance content	Formulation type
Fludioxonil 100 FS	Fludioxonil	100 g/L	FS
Celest/Influx/Maxim XL	Fludioxonil Metalaxyl-M	25 g/L 10 (9,7) g/L	FS
Maxim 25 FS/ Celest FS/ Celest Formula M	Fludioxonil	25 g/L	FS

~~* Products not relevant, are not included the tables below~~

Table 3.4-7 Application rates in selectivity trials

Trial reference number	Product	Application rate	
		g as/ton	L/ton
KCP 6.4-1-10	Fludioxonil 100 FS	50	0,5
	Fludioxonil 100 FS	100	1
	Celest/Influx/Maxim XL	35	1
	Celest/Influx/Maxim XL	70	2
KCP 6.4-11 – 18	Fludioxonil 100 FS	150	1,50
	Fludioxonil 100 FS	300	3
	Maxim 25 FS/ Celest FS/ Celest Formula M	150	6
	Maxim 25 FS/ Celest FS/ Celest Formula M	300	12

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

In all trials, phytotoxicity on the seedlings emerging from seeds treated with Fludioxonil 100 FS has been assessed. ~~As shown in the tables below, in none of the trials a negative impact on seedlings could be indentified.~~ In one of the ten selectivity trials in maize, canopy thinning was observed on 69 DAA, with the intensity of 2.8% (test item, 1N) and 1.3% (standard reference, 1N), which receded completely, to 0.0%, until the 96 DAA in the reference standard, but remained at 2.0% level at the same time, in the plots treated with the test item. At 2 N dose rate in the same trial, the thinning by 7.0% was observed in the test item – treated plots, by the 69 DAA, and by the 3.5%, at the same time, in the plots treated with the reference standard. The symptoms receded slightly until the 96 DAA - to the level of 5.8% in the test item, and to 3.0% in the reference-treated plots (Table 3.4-7). Otherwise, no phytotoxicity symptoms were observed neither in any of the efficacy trials in maize, nor in the sunflower trials, whether they were of efficacy or selectivity type (Table 3.4-8).

Table 3.4-8 Phytotoxicity of Fludioxonil 100 FS in maize: highest phytotoxicity and phytotoxicity at final assessment

Number of trials with…		Selectivity trials (10)				Efficacy trials (23)	
		Fludioxonil 100 FS		Reference		Fludioxonil 100 FS	Reference
		N	2N	N	2N	N	N
Highest phytotoxicity	0%	9	9	9	9	23	23
	0% to 5%	~~10~~ 1	~~10~~ -	~~10~~ 1	~~10~~ 1	~~23~~ -	~~23~~ -
	>5% to 10%	-	1	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
Phytotoxicity at final assessment	0%	9	9	10	9	23	23
	0% to 5%	~~10~~ 1	~~10~~ -	~~10~~ -	~~10~~ 1	~~23~~ -	~~23~~ -
	>5% to 10%	-	1	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-

Table 3.4-9 Phytotoxicity of Fludioxonil 100 FS in sunflower: highest phytotoxicity and phytotoxicity at final assessment

Number of trials with…		Selectivity trials (8)				Efficacy trials (27)	
		Fludioxonil 100 FS		Reference		Fludioxonil 100 FS	Reference
		N	2N	N	2N	N	N
Highest phytotoxicity	0%	8	8	8	8	27	27
	0% to 5%	~~8~~ -	~~8~~ -	~~8~~ -	~~8~~ -	~~27~~ -	~~27~~ -
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
Phytotoxicity at final assessment	0%	8	8	8	8	27	27
	0% to 5%	~~8~~ -	~~8~~ -	~~8~~ -	~~8~~ -	~~27~~ -	~~27~~ -
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-

Number of trials with…		Selectivity trials (8)				Efficacy trials (27)	
		Fludioxonil 100 FS		Reference		Fludioxonil 100 FS	Reference
		N	2N	N	2N	N	N
	>15 %	-	-	-	-	-	-

Plant emergence: maize

~~Table 3.4-9 Number of emerged plants in all trials performed on maize~~

Number of plants (%UNCK)				Summary					
Days after application									
Days after emergence									
No.	Product			Mean	Trials	Min	Max	StDev	Median
~~*1*~~	~~*Untreated Check*~~			~~79~~	~~10~~	~~14~~	~~142~~	~~35~~	~~80~~
2	*Fludioxonil 100 FS*	*0,5*	*L/ton*	*105 a*	*10*	*84*	*120*	*10*	*107*
3	Fludioxonil 100 FS	1	L/ton	103 a	10	77	116	12	105
4	Celest/Maxim/Influx XL	1	L/ton	103 a	10	94	114	6	101
5	Celest/Maxim/Influx XL	2	L/ton	101 a	10	85	115	10	102

Table 3.4-9: Number of emerged plants in all trials performed on maize; the Central, the South and the North zones averaged; 47DAA - 71 DAA

No. of plants (in UNCK); % UNCK (in treatments)							
No.	Product			No of trials	Mean	Min	Max
1	Untreated Check			10	79,3	12,9	141,8
2	Fludioxonil 100 FS	0,5	L/ton	10	104,1	84,2	117,2
3	Fludioxonil 100 FS	1,0	L/ton	10	102,8	76,5	113,2
4	Celest/Maxim/Influx XL	1,0 or 25	L/ton or mL/ton	10	102,4	93,8	112,7
5	Celest/Maxim/Influx XL	1,0 or 25	L/ton or mL/ton	10	99,4	83,7	114,1

Table 3.4-9 a: Number of emerged plants in the Central Zone maize trials; 47-69 DAA; NL(1), CZ(1), PL(1), HU(1)

No. of plants (in UNCK); % UNCK (in treatments)							
No.	Product			No of trials	Mean	Min	Max
1	Untreated Check			4	79,7	52,0	141,8
2	Fludioxonil 100 FS	0,5	L/ton	4	99,2	84,2	112,3
3	Fludioxonil 100 FS	1,0	L/ton	4	97,5	76,5	111,6
4	Maxim XL	1,0	L/ton	4	102,2	93,8	112,7
5	Maxim XL	2,0	L/ton	4	100,8	83,7	114,1

Table 3.4-9 b: Number of emerged plants in the North Zone maize trials; 63-71 DAA; DK(1), LV(2), SE(1)

No. of plants (in UNCK); % UNCK (in treatments)							
No.	Product			No of trials	Mean	Min	Max
1	Untreated Check			4	74,8	12,9	112,3
2	Fludioxonil 100 FS	0,5	L/ton	4	107,6	102,8	117,2
3	Fludioxonil 100 FS	1,0	L/ton	4	107,6	102,3	113,2
4	Maxim XL	1,0	L/ton	4	104,4	102,2	107,4
5	Maxim XL	2,0	L/ton	4	99,2	88,9	106,3

Table 3.4-9 c: Number of emerged plants in the South Zone maize trials (EPPO Mediterr.); 50-63 DAA; FR(1), IT(1)

No. of plants (in UNCK); % UNCK (in treatments)							
No.	Product			No of trials	Mean	Min	Max
1	Untreated Check			2	87,6	79,8	95,3
2	Fludioxonil 100 FS	0,5	L/ton	2	93,7	87,0	100,3
3	Fludioxonil 100 FS	1,0	L/ton	2	91,2	80,0	102,3
4	Celest XL (IT) Influx XL 34,7 (FR)	25 1,0	mL/ton L/ton	1 1	99,0	98,4	99,6
5	Celest XL (IT) Influx XL 34,7 (FR)	50 2,0	mL/ton L/ton	1 1	96,9	89,2	104,6

Plant emergence: sunflower

Table 3.4-10 Number of emerged plants in all trials performed on sunflower

Number of emerged plants Days After Application Days After Emergence				Summary					
No.	Product			Mean	Trials	Min	Max	StDev	Median
~~*1*~~	~~*Untreated check*~~			~~*96*~~	~~*8*~~	~~*64*~~	~~*128*~~	~~*21*~~	~~*96*~~
2	Fludioxonil 100 FS	1,5	L/ton	102 a	8	91	115	8	101
3	Fludioxonil 100 FS	3	L/ton	102 a	8	96	109	4	101
4	Maxim 25 FS	6	L/ton	98 a	8	91	103	4	99
5	Maxim 25 FS	12	L/ton	101 a	8	93	112	6	101

Table 3.4-10: Number of emerged plants in all trials performed on sunflower; the Central and the South zones averaged; 36DAA - 70 DAA

No. of plants (in UNCK); % UNCK (in treatments)							
No.	Product			No of trials	Mean	Min	Max
1	Untreated Check			8	96,5	63,8	128,0
2	Fludioxonil 100 FS	1,5	L/ton	8	101,2	90,6	114,8
3	Fludioxonil 100 FS	3,0	L/ton	8	100,8	95,7	107,6
4	Maxim 25 FS (6 trials) / Celest (2 trials)	6	L/ton	8	97,5	91,0	102,1
5	Maxim 25 FS 6 trials) / Celest (2 trials)	12	L/ton	8	100,5	92,1	111,9

Table 3.4-10 a: Number of emerged plants in the Central zone sunflower trials; CZ(3), DE(2), RO(1); 42-70 DAA

No. of plants (in UNCK); % UNCK (in treatments)							
No.	Product			No of trials	Mean	Min	Max
1	Untreated Check			6	94,6	63,8	128,0
2	Fludioxonil 100 FS	1,5	L/ton	6	101,9	90,6	114,8
3	Fludioxonil 100 FS	3,0	L/ton	6	100,8	95,7	107,6
4	Maxim 25 FS	6	L/ton	6	96,8	91,0	102,1
5	Maxim 25 FS	12	L/ton	6	100,3	92,1	111,9

Table 3.4-10 b: Number of emerged plants in the South zone sunflower trials; FR, IT; 36–56 DAA

No. of plants (in UNCK); % UNCK (in treatments)							
No.	Product			No of trials	Mean	Min	Max
1	Untreated Check			2	120,3	91,8	112,8
2	Fludioxonil 100 FS	1,5	L/ton	2	98,9	97,1	100,8
3	Fludioxonil 100 FS	3,0	L/ton	2	101,1	100,2	102,0

No. of plants (in UNCK); % UNCK (in treatments)							
No.	Product			No of trials	Mean	Min	Max
4	Celest	6	L/ton	2	99,6	98,0	101,3
5	Celest	12	L/ton	2	101,3	100,5	102,0

Conclusion

In none of the selectivity trials performed with double the maximum requested dose rate or the efficacy trials performed with the maximum requested dose rate any phytotoxic effects, reduced emergence or reduced germination was observed. Therefore all trials demonstrate that Fludioxonil 100 FS is safe for use on maize and sunflower.

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

Yield amount was recorded in the selectivity trials and in some efficacy trials ~~(shown above)~~. All yield results of the selectivity trials in maize and sunflower are presented together in the tables below.

Table 3.4-11 Yield amount (ton/ha) results of the trials performed on maize relative to the control (%UNCK)

YIELD (T-MET) Days after application Days after emergence				Summary					
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check*			16	10	5	44	14	10
2	*Fludioxonil 100 FS*	*0,5*	*L/ton*	*107 a*	*10*	*97*	*119*	*7*	*105*
3	Fludioxonil 100 FS	1	L/ton	107 a	10	89	125	10	110
4	Celest/Maxim/Influx XL	1	L/ton	106 a	10	98	126	9	105
5	Celest/Maxim/Influx XL	2	L/ton	105 a	10	95	116	7	105

Table 3.4-12 Yield amount (ton/ha) results of the trials performed on sunflower relative to the control (%UNCK)

Yield Days After Application Days After Emergence				Summary					
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Untreated check*			*3*	*8*	*1*	*5*	*1*	*3*
2	Fludioxonil 100 FS	1,5	L/ton	103 a	8	97	110	5	102
3	Fludioxonil 100 FS	3	L/ton	102 a	8	99	109	4	101
4	Maxim 25 FS	6	L/ton	102 a	8	93	114	8	101
5	Maxim 25 FS	12	L/ton	104 a	8	97	112	5	103

* treatment 5 is Maxim 25 FS in 6 trials and Celest in 2 trials

Conclusion

In none of the selectivity trials performed with double the maximum requested dose rate any negative effects on yield amount were recorded, in many cases treatments with Fludioxonil 100 FS even resulted in an increased yield. Therefore all trials demonstrate that Fludioxonil 100 FS is safe for use on maize and sunflower.

3.4.3 Effect on the quality of plants or plant product (KCP 6.4.3)

Yield quality parameters were recorded in the selectivity trials and in some efficacy trials ~~(shown above)~~. ~~All results of these~~ Resuts from selectivity trials are presented together in the tables below.

Table 3.4-13 Moisture content in trials performed on maize (%)

MOICON				Summary					
Days after application									
Days after emergence									
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check*			34 a	10	16	70	20	25
2	*Fludioxonil 100 FS*	*0,5*	*L/ton*	*33 a*	*10*	*17*	*70*	*20*	*25*
3	Fludioxonil 100 FS	1	L/ton	34 a	10	17	70	20	26
4	Celest/Maxim/Influx XL	1	L/ton	34 a	10	17	70	20	26
5	Celest/Maxim/Influx XL	2	L/ton	33 a	10	16	70	20	25

Table 3.4-10 Thousend kernel weight (TKW in g) in trials performed on maize relative to the ~~untreatech~~ untreated check (%UNCK)

TKW (g)				Summary					
Days after application									
Days after emergence									
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Untreated Check*			391	8	235	722	150	356
2	*Fludioxonil 100 FS*	*0,5*	*L/ton*	*99 a*	*8*	*90*	*106*	*6*	*100*
3	Fludioxonil 100 FS	1	L/ton	96 a	8	72	105	10	97
4	Celest/Maxim/Influx XL	1	L/ton	98 a	8	89	107	6	99
5	Celest/Maxim/Influx XL	2	L/ton	99 a	8	87	107	7	98

Table 3.4-15 Moisture content in trials performed on sunflower (%)

Moisture content Days After Application Days After Emergence				Summary					
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Untreated check*			*16*	*8*	*12*	*26*	*5*	*15*
2	Fludioxonil 100 FS	1,5	L/ton	16 a	8	12	27	5	14
3	Fludioxonil 100 FS	3	L/ton	16 a	8	12	27	5	14
4	Maxim 25 FS	6	L/ton	17 a	8	12	29	6	16
5	Maxim 25 FS	12	L/ton	17 a	8	12	27	5	15

* treatment 5 is Maxim 25 FS in 6 trials and Celest in 2 trials

Table 3.4-16 Thousend kernel weight (TKW in g) in trials performed on sunflower relative to the untreatech check (%UNCK)

TKW Days After Application Days After Emergence				Summary					
No.	Product			Mean	Trials	Min	Max	StDev	Median
1	*Untreated check*			*65*	*8*	*38*	*83*	*14*	*65*
2	Fludioxonil 100 FS	1,5	L/ton	100 a	8	98	102	2	101
3	Fludioxonil 100 FS	3	L/ton	99 a	8	97	101	1	100
4	Maxim 25 FS	6	L/ton	101 a	8	98	105	2	100
5	Maxim 25 FS	12	L/ton	100 a	8	98	103	2	100

* treatment 5 is Maxim 25 FS in 6 trials and Celest in 2 trials

~~Table 3.4-17 Oil content in trials performed on sunflower~~

Oil content				KCP 6.4-11	KCP 6.4-12	KCP 6.4-14	KCP 6.4-15	KCP 6.4-16	Summary					
Days After Application				202 DA-A	187 DA-A	183 DA-A	162 DA-A	162 DA-A						
Days After Emergence				198 DE-1	143 DE-1	161 DE-1	125 DE-1	125 DE-1						
No.	Product			%UNCK	%UNCK	%UNCK	%UNCK	%UNCK	Mean	Trials	Min	Max	StDev	Median
~~*1*~~	~~*Untreated check*~~			~~*44*~~	~~*36*~~	~~*43*~~	~~*49*~~	~~*44*~~	~~*43*~~	~~*5*~~	~~*36*~~	~~*49*~~	~~*5*~~	~~*44*~~
2	Fludioxonil 100 FS	1,5	L/ton	103	104 a	99 a	100 a	100 a	101 a	5	99	104	2	100
3	Fludioxonil 100 FS	3	L/ton	87	99 a	98 a	100 a	100 a	98 a	5	87	100	6	99
4	Maxim 25 FS	6	L/ton	111	100 a	100 a	99 a	100 a	100 a	5	99	111	5	100
5	Maxim 25 FS	12	L/ton	87	105 a	99 a	100 a	99 a	100 a	5	87	105	7	99

Comments of zRMS on the oil content in sunflower seeds**:**

For no apparent reason the applicant has excluded the trial **KCP 6.4-13** from the above OILCON summary. The zRMS decided to include it. The amended treatment means from individual trials and the zonal mean values are available in the proper version of the table, added below. Using the occasion, the trial locations have been added (EPPO zone and MS).

Table 3.4-17 Oil content in trials performed on sunflower; % (UNCK) and %UNCK content (treatment 2-5)

No. of plants (in UNCK); % UNCK (in treatments)											
No.	Trial			KCP 6.4-11	KCP 6.4-12	**KCP 6.4-13**	KCP 6.4-14	KCP 6.4-15	*KCP 6.4-16	**Mean**	**Min**	**Max**
	DAA			202 DAA	187 DAA	**171 DAA**	183 DAA	162 DAA	162 DAA			
	EPPO / MS			Mar / CZ	Mar / CZ	**Mar / CZ**	Mar / DE	Mar / DE	Mediterr / FR			
1	Untreated Check			44,2	35,8	**44,6**	42,5	48,7	43,6	**43,2**	35,8	48,7
2	Fludioxonil 100 FS	1,5	L/ton	103,4	103,7	**103,8**	99,5	100,1	99,8	**101,7**	99,5	103,8
3	Fludioxonil 100 FS	3,0	L/ton	86,9	99,2	**104,3**	97,6	99,5	99,7	**97,9**	86,9	104,3
4	Maxim 25 FS / Celest Net*	6,0	L/ton	110,9	99,4	**105,6**	99,5	99,4	*99,9	**102,5**	99,4	110,9
5	Maxim 25 FS / Celest Net*	12,0	L/ton	86,7	104,7	**104,0**	98,9	99,8	*98,5	**98,8**	86,7	104,7

Conclusion

In none of the selectivity trials performed with double the maximum requested dose rate or the efficacy trials performed with the maximum requested dose rate any negative effects on different quality parameters were recorded. Therefore all trials demonstrate that Fludioxonil 100 FS is safe for use on maize and sunflower.

Comments of zRMS on the results of selectivity trials**:**

Altogether 18 selectivity trials were carried out, including 10 in maize and 8 in sunflower crop.

Canopy thinning
In one of the 10 selectivity trials in maize: KCP 6.4-03 (SFS-19-A-FDXLMIX-PL03, cv KONKURENT), canopy thinning was observed (for values see text preceding Table 3.4-7). Otherwise no specific phytotoxicity symptoms were observed in any of the remaining selectivity trials in maize or sunflower.

Plant emergence
As observed **in maize**, the emergence was on average higher compared to UNCK, and higher compared to that observed in the reference treatments. However, from the split data summaries (The amended Table 3.4-9 and Tables 3.4-9 a-c) it is clear that emergence rates vary depending on trial aggregation. It is the four trials of the North Zone that allow for this raised average, whereas the Central Zone trials show emergence at best comparable to that observed in the UNCK, and lower compared to the standard products. The reduced emergence is even more evident in two Mediterranean trials (FR, IT). Hence the concerned Member States in the Central Zone (CZ, HU, NL) should take a closer look particularly at the results in the **Table 3.4-9 a**.
Plant emergence observed **in sunflower** seems equivalent to that in the UNCK, and to the emergence observed in plots treated with reference standards.

Yield amount
The data presented allow to conclude that the test item does not affect negatively the yield amount, compared to the untreated check and to the reference standards, neither in maize nor in sunflower crops.

Yield quality
The moisture content in grain of both crops, as well as their TKW were comparable to the untreated check and to the reference standards. The oil content in the seeds of sunflower was shown to be, on average, lower by 0,8% at 1N and lower by 0,9% at 2N, compared to the average of the reference standards Maxim 25 FS (Maritime EPPO zone, 5 out of 6 trials) or Celest Net (Mediterranean EPPO zone, 1 out of 6 trials). At the same time the oil content was on average higher by 1,7% compared to the untreated check.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Fludioxonil is a well-known active substance on maize and sunflower. Effects on transformation processes are determined by the residue levels measured at harvest, which were not present in this case.
Currently registered products based on Fludioxonil (even with the same concentration), like the references used in this trial do not have negative effects on transformation processes. ~~Extrapolation to Fludioxonil 100 FS is therefore possible. Furthermore, because none of the active Therefore it can be concluded that Fludioxonil 100 FS is also safe when applied as recommended.~~

Comments of zRMS :

Although the yield of sunflower is not intended for any kind of processing that would involve microorganisms, the yield of maize may be used for silage. However, considered the long time elapsing since the seed treatment to the harvest, the non-submission of the trials concerning effect on transformation is acceptable.
The absence of residues at harvest cannot be verified with data required and submitted for the efficacy assessment. Instead, it may be verified based on the submission of data relevant for the residue section.
~~Extrapolation to …~~ : The irrelevant statemens and incomplete sentences have been removed.

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

As shown before, the application of Fludioxonil 100 FS on seeds is totally safe (reference is also made to the emergence results).

Comments of zRMS :

The reference to the emergence results is inappropriate under 3.4.5 paragraph, as 3.4.5 pertains to harvested seeds alone. Speaking of which, the germination tests of the seeds obtained at harvest of the treated crop have been summarized nowhere by the applicant. **Only 4 selectivity trials in maize** included germination test after harvest. These are KCP 6.4-01 – 6.4-04 (DK, HU, NL, PL). The tests were read on 206-240 DAA and the average results (n=4) are as follows:
UNCK: **95,8%**;
Fludioxonil 100 FS 0,5L/t: **96,3%**;
Fludioxonil 100 FS 1,0L/t: **96,5%**;
Maxim XL 1,0L/t: **96,7%**;
Maxim XL 2,0L/t: **96,0%**.
No germination tests after harvest were carried out within any of the 8 selectivity trials in sunflower, making the applicant`s statement non substantiated with reference to sunflower.

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

In none of the trials any undesirable or unintended side-effects were observed.

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Fludioxonil 100 FS is a fungicidal seed treatment, which by its chemical nature and method of application has a very narrow spectrum of biological impact. For this reason, no impact on succeeding crops is expected.

This worst-case PEC_{soil} value for the formulation has also been calculated for the risk envelope assuming a maximum sowing rate of 47,5 kg per ha and a formulation density of 1.05 g/mL (25.11 g formulation per ha), with a result of 0.033 mg/kg soil ~~for fludioxonil~~ f.p.

For fludioxonil, a study on seedling emergence was conducted on TRZAX, LACSA and RAPRA for the draft assessment report (Porch and Krueger, 2002). This study showed no effect up to the maximum dose rate of 0.261 mg fludioxonil per kg of soil. This is higher than the initial PEC_{soil} (0,033 mg/kg soil) which

confirms that there is no risk for following crops due to fludioxonil.
In conclusion, the GAP uses applicable for Fludioxonil 100 FS are considered to be safe for succeeding crops.

Comments of zRMS :

Although the risk to succeeding crops may seem of no concern in case of seed treatment, active substances are many and variable, so the origin of data which lead to such conclusion should be traceable for the reader. It is not the case with the section 3.5.1 in the present shape.

Exposure:

The PEC calculation for the **active** fludioxonil is presented **in the Section 8 (Environm. Fate and Behavior)** of the present dossier: in the chapter 8.7 *Predicted Environmental Concentration in soil (KCP 9.1.3)*. Assuming 2.375 g/ha application rate (resulting from 50 g a.s. / 1000 kg seeds and 47.5 kg / ha planting rate), the distribution at the soil depth of 5 cm, 0% canopy interception and the standard soil specific weight of 1.5 g / cm^3, it results in $PEC_{soil\ ini}$ = **0.0032** mg / kg fludioxonil. This calculation is not mentioned in the 3.5.1. chapter of the Section 3 (Efficacy).
Instead, "*This worst-case PEC_{soil} value*" (in the original Section 8.7.2.1 the wording is: "**An initial PEC_{soil} value for the formulation**") has been presented in the 3.5.1, for the GLOB 182F, assuming the same planting rate, and the formulation density of 1.05 g / mL (Table 8.7-4: PEC_{soil} for GLOB182F on maize, sunflower, Section B8, Environm. Fate, the same chapter). Therefore the value 0.033 mg/kg soil, given by the applicant above in the present section, refers to the formulated product and not to the active fludioxonil.

Toxicity:

The study quoted by the applicant as "Porch and Krueger **2002**" and titled: *A Toxicity Test to Determine the Effects of CGA 173506 025FS (A8207I) on Seedling Emergence and Growth of Terrestrial Plants*, has been reported in DAR **2005**, Vol 3_B9, p. 248. The study had used **CELEST 025 FS** (26,1 g/L fludioxonil) as the representative formulation. The concentrations used were 0.1; 1.0 and 10.0 mg of the formulated product *per* 1 kg dry soil, with 10.0 mg f.p. being equivalent to **0.261** mg fludioxonil. The authors of the study had concluded **EC50 > 0.261** mg **fludioxonil** / 1 kg soil, based on the assessment of the seedling emergence, survival and dry weight in the 3 plant species tested: TRZAX, LACSA and RAPRA, although some reduction (in most cases by < 10%, max. by 21%) was still seen in the parameters measured, at the 0.261 mg/kg concentration either.
Next, the applicant has compared the PEC value for the formulated product (0.033 mg/kg) instead of that for the active (**0.0032**), to the toxicity measure (EC50) reported for the active substance. In fact, the correctly calculated TER is more than 10 times higher (**0.261** / **0.0032** = **81.56**, instead of 7.9), allowing even more for the similar conclusion, yet being drawn in a proper manner: following the EPPO guidance PP 1/207 (2) *Effects on succeeding crops*.
According to the PP 1/207 (2) guidance, no further testing is needed and it may be concluded that the application of the test item poses no risk for succeeding crops.

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

Not applicable, Fludioxonil 100 FS is a flowable concentrate for seed treatment and therefore does not come into contact with adjacent crops.

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

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology). No negative effects of Fludioxonil 100 FS on beneficial or other non-target organisms were reported from the efficacy trials and there are also no unwanted effect indications from the past use of fludioxonil-based products from the market. Special tests to investigate this aspect of product use are not necessary. The results of the standard tests are presented in **Part B Section 6 (***Mammalian Toxicology*) and **Section 9** (*Ecotoxicology*) of the registration dossier for Fludioxonil 100 FS.

3.6 Other/special studies

No other studies were carried out.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

~~Reference is made to the BAD.~~

zRMS: For completeness, the respective table has been restored from BAD:

Test facility		Address	Certificate
Proeftuin Zwaagdijk		Tolweg 13 1681 ND Zwaagdijk-Oost The Netherlands	Yes
Agrolab		Røjleskovvej 18 5500 Middelfart Denmark	Yes
Field Research Support		Max-Planck-Straße 5 D-31515 Wunstorf Germany	Yes
Inhort		ul. Konstytucji 3 Maja 1/3 96-100 Skierniewice Poland	Yes
Institute of Plant Protection Sosnicowice Branch		ul. Gliwicka 29 44-153 Sosnicowice Poland	Yes
Agritec		Zemědělská 2520/16 787 01 Šumperk Czech Republic	Yes
Pest Pro		Stjepana Gradića 5, 10010 Zagreb Croatia	Yes
Latvian Plant Protection Research Centre Ltd.		Struktoru iela 14a Riga – 1039 Latvia	Yes
Syntech Research Hungary Kft.		Török Ignác u. 30. Szombathely Hungary	Yes
Syntech Research Poland Sp. Z. o.o.		69/1 Jagiellonska 85-027 Bydgoszcz Poland	Yes
Biotek Agriculture SP. z. o.o.		Gac 64 55-200 Olawa Poland	Yes
Zemedelska Zkusebni Stanice Kujavy		Kujavy 48 74244 Kujavy Czech Republic	Yes
Agrartest GmbH		Am Rehhagen 13 17091 Rosenow Germany	Yes
Sagea		Via San Sudario, 15 12050 Castagnito d'Alba (CN) Italy	Yes
CPR Europe Kft.		Török Ignác u. 30. Szombathely Hungary	Yes

Test facility		Address	Certificate
GMW Bioscience		Polígono Industrial SEPES C/Jornalers nº35 Alberic (Valencia) Spain	Yes
HUSEC		Borgeby Slottsväg 11 SE-237 91 Bjärred, SWEDEN	Yes
Staphyt FR		34590 Marsillargues France	Yes
Staphyt IT		12074 Rocca de Baldi Italy	Yes
Intec Agro		Blatnicka 179 687 24 Uhersky Ostroh Czech Republic	Yes

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 (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed	Owner
KCP 6.2	K. Schellingen	2020	Biological Assessment Dossier: Fludioxonil 100 FS-GLOB182F Sponsor: Globachem N.V. GEP, not published	N	Y	Globachem

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-