REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: **NORDOX 75 WG**

Product name(s): NORDOX 75 WG

Chemical active substance:

Copper (I) oxide 750 G/KG

Poland – Art. 43

CORE ASSESSMENT

(authorization)

Applicant: Nordox AS

Submission date: September 2022

Updated: November 2022

Evaluation date: December 2022

MS Finalisation date: dd/mm/yyyy

Version history

When	What
November 2022	Amendment of legal status of molecule and information regarding previous evaluations as per request of ZRMS
12/2022	Version evaluated by zRMS PL

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

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

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

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

Abstract

The dossier has been submitted to support the renewal of NORDOX 75WG in Poland (PL) which belongs to the North-East EPPO Climatic Zone and Hungary (HU) and Slovenia (SI) which belongs to the South-East EPPO Climatic Zone, according to Art.43 of Regulation (EC) No. 1107/2009, following the renewal of Copper compounds (Copper oxide) as active substances under Regulation (EC) No. 1107/2009.

This core assessment concerns the renewal of authorization of the uses of the protectant fungicide/bactericide, which is currently authorized under product names NORDOX 75WG in Poland (PL) which belongs to the North-East EPPO Climatic Zone and Hungary (HU) and Slovenia (SI) which belongs to the South-East EPPO Climatic Zone. NORDOX 75WG is formulated as a Wettable Granule (WG) and contains 86.2% of copper oxide i.e 750 g/kg of copper (as metal). The product is currently authorised for use as protectant fungicide/bactericide which prevents infection on plants, being active against a broad spectrum of plant pathogenic fungi.

The basis for renewal is an unchanged product (the formulation of the product remains the same) and an unchanged GAP and national label. The applicant provided a statement that this is the case for all CMS's. However, only an in-depth check has been performed for the PL uses in the GAP and the Polish label. Based on this check zRMS confirms that the PL-GAP has remained unchanged indeed. For all other cMS, it is left up to check and confirm if the submitted GAP and national label have remained unchanged indeed. In the case the GAP of an individual cMS has been changed, it is left up to the particular cMS to confirm zRMS conclusions on a national level.

The evaluation for renewal focuses on the resistance section. For evaluation of efficacy, reference can be made to evaluation and experience with the product in the past. Therefore efficacy does not need to be evaluated again. If no resistance has developed, it can be expected that the efficacy of the product is unchanged.

Table 3.1-1: ALL intended uses

GAP rev. 01, date: 2022-09-xx

PPP (product name/code):	Nordox 75 WG	Formulation type:	WG
Active substance 1:	Copper (I) oxide	Conc. of as 1:	750 [(c)]
Safener:	safener	Conc. of safener:	conc. [(c)]
Synergist:	synergist	Conc. of synergist:	conc. [(c)]
Applicant:	Nordox AS	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: Fungicide and bactericide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks: e.g. safener/synergist per ha**[(f)]	**zRMS conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Apple	F	*Venturia inaequalis*	Foliar spray	BBCH 03-BBCH 53	a) 2 b) 2	14	a) 1.0 b) 2.0	a) 0.75 b) 1.50	500-750	144		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks: e.g. safener/synergist per ha[f]**	**zRMS conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**			
2	HU	Pome fruits (Apple, Pear, Quince tree, nashi)	F	Bacteriosis *(Pseudomonas syringae pv.; Erwinia amylovora)* and other fungla diseases (except powdery mildew)	Foliar spay	At leaf fall (autumn) and before BBCH 54 (winter)	a) 2 b) 2	7-10	a) 2.6 b) 5.2	a) 1.95 b) 3.90	800-1500	-	1 appl at spring at dormancy and 1 appl at autumn. Effective dose range 2.0-2.6 kg product / ha	
3	HU	Pome fruits (Apple, Pear, Quince tree, nashi)	F	Apple Scab *(Venturia inaequalis) Erwinia, Pseudomonas, other bacteriosis*	Foliar spay	BBCH 01 - BBCH 56	a) 3 b) 3	7-10	a) 1.6 b) 4.8	a) 1.2 b) 3.6	800-1000	10	Effective dose range 1.2-1.6 kg product / ha Effective preventively	
4	SI	Pome fruits (Apple, Pear, Quince tree)	F	*Nectria galligena*	Foliar spay	BBCH 00 - BBCH 53 & from BBCH 91	a) 3 b) 3	14	a) 1.6 b) 4.8	a) 1.2 b) 3.6	500-1000	-		
5	HU	Stone fruits	F	Bacteriosis *(Pseudomonas syringae pv.) Xanthomonas arboricola)* Fungal diseases	Foliar spay	BBCH 00 - BBCH 09 and at leaf fall	a) 2 b) 2	14	a) 2.4 b) 4.8	a) 1.8 b) 3.6	800-1000	21	Concentration is 0.27 %-0.3 %	
6	HU	Stone fruits	F	*Stigmina carpophila* *Taphrina deformans* *Monilia fructigena* *Monilia fructicola* *Monilia laxa* *Apiognomonia erythrostoma*	Foliar spay	BBCH 00-55	a) 4 b) 4	14	a) 1.12 b) 4.48	a) 0.84 b) 3.36	800-1000	21	Concentration is 0,14-0,17% In apricote and peach appl. Till red/pink flower bud stage In plum, cherry, sour cherry appl. Till white flower bud stage.	
7	SI	Peach Nectarine	F	*Taphrina deformans*	Foliar spay	BBCH 00 - BBCH 53 & from BBCH 95	a) 2 b) 2	14	a) 2 b) 4	a) 1.5 b) 3.0	300-1000			

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks: e.g. safener/synergist per ha**[(f)]	**zRMS conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**			
8	SI	Olive	F	*Spilocea oleaginum*	Foliar spray	BBCH 00 - BBCH 53 BBCH 75 - BBCH 85 after harvest	a) 4 b) 4	21	a) 1.25 b) 5	a) 0.937 b) 3.75	800-1000	14		
9	HU	Vine	F	Downy mildew (*Plasmopara viticola*)	Foliar spray	BBCH 15 - BBCH 81 & BBCH 91	a) 5 b) 5	7-14	a) 2.00 b) 10.00	a) 1.50 b) 7.50	600-1000	21	Avoid max 28 kg/ha pure copper within 7 years Effective dose range 1.2-2.0 kg product / ha	
10	SI	Grape (Vine and Table)	F	Downy mildew (*Plasmopara viticola*)	Foliar spray	BBCH 15 - BBCH 81 & from BBCH 91	a) 3 b) 3	7-14	a) 1.6 b) 4.8	a) 1.2 b) 3.6	300-1200	21		
11	SI	Tomato Eggplant	F/G	*Phytophtora infestans*	Foliar spray	BBCH 15 - BBCH 89	a) 5 b) 5	7-14	a) 1 b) 5	a) 0.75 b) 3.75	300-1000	3/10	3 days fresh tomato, eggplant 10 days processed tomato	
12	HU	Potato	F	*Phytophthora infestans* *Alternaria solani* *Alternaria alternata*	Foliar spray	Based on disease forecast, before first symptoms appear on the leaf -/ until BBCH 81	a) 6 b) 6	8-12	a) 2.0 b) 12.0	a) 1.5 b) 9.0	400-600	7	Effective dose range 0.8-2.0 kg product / ha	
13	SI	Potato	F	*Phytophtora infestans*	Foliar spray	BBCH 15 - BBCH 85	a) 5 b) 5	7-14	a) 1 b) 5	a) 0.75 b) 3.75	200-1000	14		
14	HU	Sugarbeet Fodderbeet	F	*Cercospora betae* *Ramularia beticola* *Phoma betae*	Foliar spray	Preventively before first symptoms appear on the leaf. Until harvest BBCH 14 - BBCH 49	a) 6 b) 6	7-10	a) 2.0 b) 12.0	a) 1.5 b) 9.0	400-600	21	Effective dose range 0.8-2.0 kg product / ha	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks: e.g. safener/synergist per ha**[(f)]	**zRMS conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**			
Minor uses according to Article 51 (zonal uses)														
15	PL	Pear Quince	F	*Venturia pyrina* *Venturia inaequalis* Bacteriosis: *Pseudomonas syringae* *Ervinia amylovora* *Nectria galligena*	Foliar spray	From the beginning of dormancy period (autumn) – BBCH 99 and before BBCH 54(spring)	a) 2 b) 2	14	a) 1.67 b) 3.34	a) 1.25 b) 2.50	500-1000	144		
16	PL	Vine	F	Downy mildew (*Plasmopara viticola*)	Foliar spray	BBCH 15 - BBCH 81 & BBCH 91	a) 2 b) 2	7	a) 1.60 b) 3.20	a) 1.20 b) 2.40	200-400	21		
17	PL	Strawberry	F/G	*Marssonina fragariae,* *Zythia fragariae* *Mycosphaerella, bacterial disease,* *Colletotrichum sp.*	Foliar spray	BBCH 13 - BBCH 85	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1,0 b) 3.0	200 - 800	3		
18	PL	Tomato Eggplant Pepper	F/G	*Phytophtora spp., Alternaria, Colletotrichum, Bacterial disease (Pseudomonas spp., Xanthomonas spp.).*	Foliar spray	BBCH 15 - BBCH 51	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	10		
19	PL	Cucumber	F/G	*Alternaria,* *Antracnosis, Phytophtora spp.,*	Foliar spray	BBCH 15 - BBCH 89	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	3		
20	PL	Pumpkin, Courgettes Melon	F	*Alternaria,* *Antracnosis, Phytophtora spp.,*	Foliar spray	BBCH 15 - BBCH 89	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	3		
21	PL	Lettuce Scarole	F/G	*Alternaria,* *Bremia lactucae* *Bacterial disease:* *Erwinia spp., Pseudomonas spp.* *Xanthomonas spp.*	Foliar spray	BBCH12 - BBCH49	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	300-1000	3		
22	PL	Shallots Onion Garlic	F	*Alternaria,* *Antracnosis,* Bacterial disease, *Peronospora*	Foliar spray	BBCH 14 - BBCH 47	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	3		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks: e.g. safener/synergist per ha**[(f)]	**zRMS conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**			
				destructor, Stemphyllum										
23	PL	Ornamental plants	F	*Alternaria, Antracnosis, Phytophtora spp.,*	Foliar spray	Spring - until the beginning of flowering	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	-		
24	SI	Pome fruits (Apple, Pear)	F	*Erwinia amylovora*	Foliar spray	BBCH 00 - BBCH 53 & BBCH 57 - BBCH 69	a) 3 b) 3	7-12	a) 1-1.6 b) 3-4.8	a) 0.75-1.2 b) 2.25-3.6	500-1000	-	Minor use Application rate from BBCH 57 to 69 max 0.3 kg product/ha	
25	SI	Kiwi	F	*Pseudomonas syringae*	Foliar spray	BBCH 00 - BBCH 53 & from BBCH 93	a) 3 b) 3	14	a) 0.9-1.6 b) 2.7-4.8	a) 0.675-1.2 b) 2.025-3.6	500-1000	-	Minor use	
26	SI	Citrus	F	*Pseudomonas syringae*	Foliar spray	BBCH 00 - BBCH 51 & BBCH 71 - BBCH 78	a) 4 b) 4	14	a) 1.1-1.3 b) 4.4-5.2	a) 0.825-0.975 b) 3.3-3.9	1500-2000	-	Minor use	
27	SI	Olive	F	*Pseudomonas savastanoi*	Foliar spray	BBCH 00 - BBCH 53 & BBCH 75 - BBCH 85	a) 4 b) 4	21	a) 1.25 b) 5.0	a) 0.937 b) 3.75	800-1000	14	Minor use	
28	SI	Grape (Vine and Table)	F	*Xylophylus ampelinus*	Foliar spray	After cutting at bursting and after harvesting	a) 3 b) 3	7-14	a) 1.6 b) 4.8	a) 1.2 b) 3.6	300-1200	21	Minor use	
29	HU	Berries	F	Leaf and cane diseases (except powdery mildew)	Foliar spray	In the beginning of the vegetative growth, and after harvest	a) 4 b) 4	7-14	a) 0.8 b) 3.2	a) 0.6 b) 2.4	400-800	21 days Rapsberry 5 days	Max dose rate in concentration 0.17%-0.2%	
30	SI	Strawberry	F	*Xantomonas fragariae, Diplocarpon earlianum, Gnomonia fructicola*	Foliar spray	After season or during winter	a) 1 b) 1	-	a) 3.3 b) 3.3	a) 2.475 b) 2.475	400-800	-	Minor use	
31	HU	Tomato Pepper	F/G	*Phytophtora spp., Alternaria, Bacterial disease (Pseudomonas spp., Xanthomonas spp.).*	Foliar spray	BBCH 15 - BBCH 89	a) 4 b) 4	7-14	a) 0.8 b) 3.2	a) 0.6 b) 2.4	400-1500	7	Max dose rate in concentration is 0.14 %-0.2 %	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks: e.g. safener/synergist per ha**[f]	**zRMS conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**			
32	SI	Eggplant	F G	*Alternaria solani* *Colletotrichum spp.* *Pseudomonas spp.* *Xanthomonas spp.*	Foliar spray	BBCH 15 - BBCH 89	a) 3 b) 3	7-14	a) 0.7-1.6 b) 2.1-4.8	a) 0.525-1.2 b) 1.575-3.6	300-1000	3	Minor use	
33	HU	Cucurbits	F/G	Bacteriosis, Cucurbit downy mildew *(Pseudoperonosproa cubensis)*	Foliar spray	BBCH 16 - BBCH 89	a) 4 b) 4	7-14	a) 0.68 b) 2.72	a) 5.10 b) 2.04	400-1500	5	Max dose rate in concentration 0.14-0.17 %	
34	HU	Celery	F	Septoria on leaf	Foliar spray	BBCH 15 - BBCH 47	a) 4 b) 4	7-14	a) 1.0 b) 4.0	a) 0.75 b) 3.0	300-500	15	Max dose rate in concentration 0.14-0.2 %	
35	HU	Spinach	F	Downy mildew *Peronospore farinosa*	Foliar spray	BBCH 13 - BBCH 35	a) 4 b) 4	7-14	a) 0.68 b) 2.72	a) 0.51 b) 2.04	400-600	15	Max dose rate in concentration 0.14-0.17 %	
36	HU	Chicory	F	Downy mildew	Foliar spray	BBCH 13 - BBCH 35	a) 4 b) 4	7-14	a) 0.68 b) 2.72	a) 0.51 b) 2.04	400-600	15	Max dose rate in concentration 0.14-0.17 %	
37	HU	Brassicas (white cabbage, savoy cabbage, broccoli, cauliflower, broussel sprout)	F	Bacterial diseases *(Xanthomonas, Pseudomonas)* Cabbage downy mildew *Peronospora parasirica*	Foliar spray	BBCH 16 - BBCH 49	a) 4 b) 4	7-14	a) 0.68 b) 2.72	a) 0.51 b) 2.04	400-600	15	Max dose rate in concentration 0.14-0.17 %	
38	HU	Asparagus	F	Rust	Foliar spray	Before flowering	a) 4 b) 4	7-14	a) 0.8 b) 3.2	a) 0.6 b) 2.4	400-800	15	Max dose rate in concentration 0.14-0.2 %	
39	HU	Shallots Onion Garlic	F	Bacterial disease, *Peronospora destructor*	Foliar spray	BBCH 14 - BBCH 47	a) 5 b) 5	7-14	a) 0.6 b) 3.0	a) 0.45 b) 2.25	300-500	21	Max dose rate in concentration 0.14-0.2 %	
40	HU	Legumes	F	Bacteriosis Antracnosis Rust (*Uromyces pisi*) Ascohita (*Ascohyta pinodes, Acohyta pinodella, Ascohyta pisi)* Peronospora *(Peronospora viciae f.sp. pisi)*	Foliar spray	BBCH 12 - BBCH 69	a) 4 b) 4	7-14	a) 0.8 b) 3.2	a) 0.6 b) 2.4	400-600	5	Max dose rate in concentration 0.14-0.2 %	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks: e.g. safener/synergist per ha**[(f)]	**zRMS conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**			
41	HU	Walnut Hazelnut Almond Chestnut	F	Bacteriosis and other fungal diseases (except powdery mildew)	Foliar spray	BBCH 00 - BBCH 09 and autumn after leaf fall	a) 4 b) 4	14	a) 2.4 b) 9.6	a) 1.8 b) 7.2	800-1200	21	Dose rate maximum 0.3 % concentration	
42	HU	Ornamentals	F/G	Bacteriosis Fungal disease (except powdery mildew, and grey mold)	Foliar spray	Before flowering	a) 4 b) 4	7-14	a) 0.8 b) 3.2	a) 0.6 b) 2.4	400-2000	-	Max dose rate in concentration 0.14-0.2 %	
43	SI	Forest tree nurseries	F	*Dothistroma pini* *Lecanosticta acicola*	Foliar spray	Beginning of May, June, July	a) 3 b) 3		a) 1.6 b) 4.8	a) 1.2 b) 3.6	1000		Minor use	

Remarks table heading:
(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:
1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

Column 15: zRMS conclusion.

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

3.2 Efficacy data (KCP 6)

Introduction

This document reviews information related to data on application of the plant protection product Nordox 75 WG containing the active substance Copper (I) oxide.
This dossier is presented to support the approval of the product Nordox 75 WG under the Commission Regulation (EU) No 284/2013. The product Nordox 75 WG was the representative formulation in the EU evaluation.
The EFSA Report of Copper (EFSA Journal 2018;16(1):5152) is considered to provide the relevant review information or a reference to where such information can be found.

This document summarises the information related to the efficacy and crop safety of plant protection products containing Copper compounds (Copper oxide) which were included in Annex I of Directive 91/414 (2009/37/EC) on the 1st November 2009. The SANCO report for Copper compounds (SANCO/150/08 – 26th May 2009) is considered to provide the relevant review information or a reference to where such information can be found.
The Annex I of the Inclusion Directives for Copper compounds (2009/37/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 Copper compounds and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 May 2009 shall be taken into account. In this overall assessment:
Member States should pay particular attention to the:
- the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, are the minimum necessary to achieve the desired effects.

These concerns have been addressed within the current submission.

Important to mention, that evaluation using art. 43 is in the situation, when all the efficacy data evaluated by Member States using art. 33 and art. 51remain unchanged and the labels in the countries were not amended for several years. Chemical composition of the formulation since years remain unchanged, hence all the evaluations done by Member States in opinion of the applicant are valid. Previous evaluations were not refering to the resistance management, nevertheless efficacy data, conditions of use, list of crops remain unchanged

Table 3.2-1: List of intended uses.

Description of active substances

Copper oxide

Copper represents one of the oldest active ingredients developed to fight plant diseases. Some of the first fungicides developed contained copper and were used to combat diseases of vines and fruit.
In the 1800s copper sulfate pentahydrate was formulated with lime to produce Bordeaux mixture fungicide. Many other types of copper products followed, these include; basic copper carbonate and copper ammonium carbonate first used in 1887, copper oxychloride in about 1900 and cuprous oxide in 1932.
Copper is used in various forms as an algaecide, bactericide, fungicide and in water treatment.
Copper salts can be described as insoluble compounds, yet their action as fungicides and bactericides is due to the release of small quantities of copper (Cu^{2+}) ions when in contact with water. Copper gives

protectant control of a range of economically important diseases of agricultural and horticultural crops by preventing spore germination.
Copper is a naturally occurring element, occurring in various forms within the environment and present in the soil and in plant tissue, where it is essential for healthly growth and development with an important role in many metabolic processes within the plant. On copper deficient soils, the application of Copper fungicides can allieviate deficiencies and the need to apply Copper as a specific micro-nutrient.
Registered copper fungicides are therefore permitted for use on crops for certified organic production in EU countries and can be an essential part of disease control strategies in many crops grown for this market.

Mode of action
Copper has multi-site activity, involving non-specific disruption of cellular proteins. Following absorption into the fungus or bacterium, the copper ions will link to various chemical groups (imidazoles, phosphates, sulfhydryls, hydroxyls) present in many cellular proteins, thereby causing nonspecific denaturation and preventing germination of the spores.

Table 3.2-2 Details of the active substance in Nordox 75 WG

Active substance	**Copper oxide**
Concentration	750 g/kg
Chemical group	Inorganic
Mode of action	Multi-site activity
Biological action	Multi-site activity

Description of the plant protection product

NORDOX 75WG is solid formulation, presented as a Wettable Granule (WG). NORDOX 75WG is an original plant protection product at it is one of the most concentrated copper based product, containing 86.2% of copper oxide i.e 750 g/kg of copper (as metal).
Information on the detailed composition can be found in the confidential dossier of this submission (Registration Report - Part C).

The active substance of NORDOX 75WG, copper oxide, is a protectant fungicide/bactericide which prevents infection on plants, being active against a broad spectrum of plant pathogenic fungi including apple scab (*Venturia inaequalis*), apple canker (*Nectria galligena*), leaf curl (*Taphrina deformans*), downy mildew (*Plasmopara viticola, Bremia lactucae, Peronospora destructor, Pseudopernospora cubensis*), citrus brown rot gummosis (*Phytophthora spp.*), tomato and potato late blight (*Phytophthora infestans*) and olive leaf spot (*Spilocoea oleagina*). In addition to fungi, copper has demonstrated a great interest by its activity to limit bacteria diseases mainly caused by *Pseudomonas spp* (Citrus, olive, stone fruits, kiwi, tomato, leek...) and *Xanthomonas spp* (Stone fruits, walnut, grape, artichoke...).

Description of the target pests
NORDOX 75WG is a fungicide/bactericide preventatively acting on several pests. The most harmful pests are described below.

Grape downy mildew *Plasmopara viticola* (Berk. & M.A. Curtis) Berl. & de Toni
Plasmopara viticola, belonging to the Heterokontophyta phylum of fungi, is a widespread pathogen of grapevine crops worldwide where crops are grown under humid conditions. The pathogen is the causative agent of downy mildew on grapevine; it is native in North America and was inadvertently

introduced into Europe at the end of the 19th Century. *P. viticola* can cause serious losses on highly susceptible varieties. Whilst varieties vary in resistance to the disease, due to thickness and anatomy of the fruit skin and chemical composition, all European varieties of grapevine (*Vitis vinifera*) are susceptible to some extent. Downy mildew is the most destructive grapevine disease in Europe.

The Downy mildew fungus overwinters as oospores in fallen leaves. Sporangia then germinate in the spring after rainfall and a temperature of around 11°C. For primary infection to occur the sporangia liberate free swimming zoospores which are disseminated by rain splash onto grapevine tissue and make their way to the vicinity of stomata and encyst. Encysted zoospores infect grape tissue by forming germ tubes that enter stomata and from there invade inner tissues of the plant by growing between the cells.

The pathogen masses within the grape tissue and when the nights are cool and damp, sporangiophores structures form under leaf surfaces and on stems that are delicate. Single, lemon shaped sporangia (conidia) are formed at the tips of the secondary branches.
The sporangiophores, with their large number of terminally borne sporangia, make up the downy mildew growth. If water is present on grape plant tissue, the sporangia quickly germinate to produce large numbers of motile zoospores that can result in secondary infection throughout a vineyard and thus rapidly spreading the disease. Young lesions can be seen 7 to 12 days after infection. The sporangiophores and sporangia of the downy mildew pathogen are usually formed at night and are most visible in early morning while the leaves, fruit, and other infected parts are still damp. Toward the end of the growing season, oospores are formed in the old diseased leaves, overwintering when the leaves fall to the ground.
The disease affects the leaves and fruit of grapevine plants and causes losses in yield quantity due to destruction of leaf tissue and defoliation. Downy mildew infestation also reduces quality of the harvested produce due to blemished, diseased fruit and reductions in the size and number of grapes in bunches. The disease can also weaken, dwarf, and kill young shoots. When weather is favourable and no protection against disease is provided, downy mildew can destroy 50-70% of the crop in one season.

Disease development is favoured by high humidity, suitable temperatures of 18-25 °C and poor aeration. Rates of infection decline above 30°C due to the evaporation of water and decreased germination. Shaded and sheltered locations most favour mildew development. The longer the wet conditions persist, the greater the probability of infection. Transmission is via downy mildew spores, which are generally dispersed by the wind, rain and the handling of infected plants.

Cultural control includes the promotion of good air circulation and light penetration by removal of lateral shoots in dense canopies and where necessary the removal of leaves in the fruiting zone. Good management of irrigation is imperative, with excessive irrigation leading to excessive vigour and a higher disease potential. The location of vineyards in open situations with day long sunshine, where shade does not prevent plants and fruits from drying, is important for reducing the potential for disease development. Removal of leaves around clusters on cordon trained vines before bunch closure can reduce disease levels and improve fungicide spray coverage.

Grape varieties vary greatly in their susceptibility to downy mildew. In general, vinifera (*Vitis vinifera*) varieties are much more susceptible than American types and French hybrid varieties are somewhat intermediate in susceptibility, for which cultivars with large, juicy berries are in general the most susceptible.

Peach leaf curl *Taphrina deformans* (Berk.) (*T.deformans*)
<u>Biology</u>

Taphrinaceae belongs to the Ascomycota fungus. Characterized by their dicaryotic mycelium, they develop on ferns and few families of angiosperms, like *Aceraceae, Betulaceae, Fagaceae, Rosaceae, Salicaceae*... Its cycle counts two problematic phasis; the first one infects the host's tissues and induced symptoms. This one is constituted by long and partitioned hyphas. The second is the dicaryotic phase, morphologically near the yeasts. It reproduces and forms a white powder on infected leaves, this powder is propagate by wind and rain. In winter, the fungi can resist in this form, or it's ascosporous' form.

T.deformans is an endobiotrophic fungi, it develops in living tissues. Infections occur principally in winter when temperature reached 10°C. The much sensible timing is when buds swelling, but infections can occur even in summer if temperatures are low and the humidity important. High temperatures stopped the infections. Few weeks after infection, asci perforate the leaf's cuticle, and drops ascosporous. These ascosporous can germinate or reproduce by mitosis they'll become the yeast form that will show a white powder on leaves.
In winter, both ascosporous and secondary spores can wait in branch crevices and under buds scales to germinate at spring. So the best times to protect crops are at the leave's falling, and just before buds opening.

<u>Symptoms</u>

Taphrina deformans infect trees of the genre *Prunus*. In winter, fungi live in buds, in spring when the plant's tissues develop; it infects leaves, twigs, blossoms and finally, fruits. Infected organs distorted, and finally they die. So infected leaves fall, and new healthy ones appears that could be infected too if the weather conditions are propitious. Usually, infected fruits fall before maturity, but few fruits can dry on the tree and become "mummy fruits" that constituted a reserve of pathogens.
By destroying the leaves, the disease put trees in stress conditions and causes the loss of a high rate of production. Weak trees are more sensible to winter cold conditions, so trees can die if attacks occur during two or more seasons.

Peacock spot (*Spilocaea oleagina* (=*Cycloconium oleaginum*)) on olive trees.

<u>Biology</u>

Spilocaea oleagina (*S.oleagina*) is a fungus that develops under the leaves cuticle. Mycelium penetrates through leaves cuticle by perforating it with enzymatic secretions. Contaminations take place in a wide range of temperatures, with an optimum at 18-21°C. During minimum 12 days after infection, no visible symptom appears, but black spots could be revealed by dripping leaves in a KOH or NaOH at 5% solution. After incubation, black with yellow centre spots appears on leaves. Subcuticular colonies produce some conidiophores that ensure the disease propagation. Conidia formed on these spots may be viable for several months. They propagate when rain detach them from conidiophore, so dry periods slow down the disease development.

<u>Impact</u>

S.oleagina is present in each olive production areas. Infected leaves loose a part of their area for photosynthesis during some months, so disease weakens the trees and provokes a reduction of yield. In case of severe infections, young twigs and fruits pedicles could be attacked. Twigs could dieback and fruits could fall prematurely.

<u>Protection</u>

Preventive applications of contact fungicides is the best mean to control the disease. Three applications are recommended (at the end of winter, end of summer and late autumn) in regions where climatic conditions are dry.

Olive anthracnose (*Colletotrichum gloeosporioides*)

Observed the first time in Portugal in 1956, olive anthracnose is caused by the fungus *Colletotrichum gloeosporioides (C. gloeosporioides).* It affects a lot of crops, like lemon, orange fruits or strawberry.
On olive, *C. gloeosporioides* infects usually ripe fruits, and rarely the leaves, peduncles or shoots. On fruits, the disease causes soft circular rotted spots, on which slimy orange-colored masses of spores are produced under high humidity. The fungus affects oil quality by increasing fruit acidity. On leaves, small black spots appear, before the leave falls. Under favourable environmental conditions, the disease can devastate entire production fields.
The fungus biology is not well known. It seems that infections might occur in spring on flowers and on young fruits but symptoms develop in autumn with a secondary infection directly on fruits.

Apple scab (*Venturia inaequalis*, Cooke)
Venturia inaequalis is an Ascomycota fungus which infects trees from the rosacea family (apple tree, pear tree, quince tree, nashi) causing spots and deformations on leaves and fruits, infected fruits are unmarketable.
V. inaequalis is an endobiotrophic fungus that survives in leaves on soil during winter. At spring, spores are disseminated by wind and are responsible for the first infections and then conidia will cause the second infection. Fungus development needs humidity and cool temperatures (superior to 5°C). Leaves are very susceptible from appearing to 8 days after their expansion.

Apple canker (*Nectria galligena*, Bresad)
Apple canker is an economically important disease of apple and pear orchards. By destroying shoots, and eventually main stem or major branches, cankers can kill the trees, so infections can drastically shorten the lifetime of an orchard. Moreover, *N. galligena* can infect fruits, causing *Nectria* eye rot, *Nectria* stalk cavity or *Nectria* lenticel rot. Some fruit growers consider it to be the most damaging of all orchards diseases.

Nectria galligena infections occur mainly in the autumn through the leaf scars, even if visible symptoms appear only the following spring. Leaf scars remain susceptible to canker infection till 3 weeks after leaf drop. Disease propagation is due to ascosporous; that are propagated by rain projections or wind. Humid weather conditions favour spore germinations and infections.

The commonly used strategy to protect orchards against *N. galligena* is to apply copper based fungicides from the end of harvest to 2 weeks after the end of leaf falling. So about 5 applications may take place from the end of September to middle of December to protect the leaf scars.

Fruit brown rot (*Phytophthora spp.*) on Citrus
Described the first time in 1832 in the Azores, brown rot of Citrus fruits is due to different strains of *Phytophthora spp*. Heavy rains permit fungus development on the ground and the projection of spores on the lower parts of Citrus. Disease can provoke canker formation, defoliation and fruit fallen. Most common symptoms are brown spots on fruits, on which white mould develops if humid conditions. This disease is more common in orchards implanted on poorly drained soils, where 25-30% of the harvest can be lost.

Primarily infections occur on the bottom of the trees, and only a few number of *Phytophthora* strains can produce secondary inoculum and propagate to upper parts of canopy; so the crop protection needs to be concentrated on the lower branches. In case of wet conditions, preventative fungicide applications need to be realized when fruits are formed (in winter in Mediterranean regions).

Down mildew *(Bremia lactucae)* on artichoke and cardoon

Biology

B. lactucae is a fungus that develops on plants from the Asteraceae family. It is an endobiotrophic parasite which only develops on living tissues. Contamination needs a temperature between 10 to 20°C. Conidia need free water to germinate and create hypha, which penetrate through stomata to infect foliar tissues. Inoculum conserves in infected plant debris (artichoke or weed species)

Symptoms

Fungi cause discoloured spots on the upper face of leaves, that desiccate progressively. These spots are white felting on lower face of leaves. By reducing the photosynthetic area of leaves, fungus reduces the artichoke yield. *B. lactucae* infects lettuces too which finaly lose their marketable valour.

Anthracnose (*Ascochyta hortorum* (Speg.), Smith) on artichoke

A. hortorum develops preferentially on weak plants of artichoke situated in Mediterranean regions. By causing brown-black spots on leaves and bracts, it reduces the commercial value of artichokes. Under humid conditions and cool temperatures (15-20°C) symptoms may propagate through flower bulbs and flower peduncles. However, treatments are not usually applied to protect crops against this disease.

Downy mildew of cucurbits (*Pseudoperonospora cubensis* (Berk. & Curtis), Rostovstev

Firstly reported in Cuba in 1868, downy mildew of cucurbits is one the most destructive diseases of cucurbits, particularly in organic crops. It is yet widely distributed in all cucurbit production regions.
Disease characterized by oily angular spots on leaves that turned into grey-brown before leaves dessicate (equally named “wildfire”). The defoliation induced by this fungus exposed the fruits to sun, causing fruit sunscald.
The responsible fungus (*Pseudoperonospora cubensis*) needs living tissues to survive in winter. Plant debris and infected fruits constitute refuges for the pathogen. Spores are disseminated by rain splashes and wind current. In summer, when crops begin their growth, it develops in high humidity conditions at temperatures varying from 10 to 25°C. The first symptoms appear 3-4 days after infection and propagated very quickly if favourable conditions.

Downy mildew of allium (onion, shallots, garlic, leek) caused by *Peronospora destructor* (Berk.), Caspary

Peronospora destructor is widely distributed in onion production regions, causing the onion downy mildew, which is one of the most destructive diseases of allium crops. The destructive potential of the disease is due to the population dynamic as this fungus reproduces very quickly if favourable conditions. The rapidity of dissemination and infection by *P.destructor* allow it to potentially destroy the totality of a crop within 30-45 days.
Early season infections, characterized by plant dwarfism, chlorosis and lesions on leaves, as more late infected plants, showed elongated yellow spots on leaves. Infected leaves fade and falled on soil. In winter, fungus oospores survive in soil on plants debris (2-3 years) and mycelium in infected bulbs. In spring, under high humidity and adequate temperature, spores are liberated and infections may occur. Spores are disseminated by the wind and rain splash, 6-7 hours are needed for germination. First symptoms generally appear 10-16 days later.

Sunny and warm conditions (temperature >25°C) stop sporulation and kill the spores.
Some prophylactic measures can reduce disease pressure (crop rotations, warm water treatments of bulbs, etc). A fungicide protection is needed in regions where the disease is regularly present because of the low threshold (1%) for the disease explosive development.

Late blight of solanaceous crops (potato, tomato, eggplant) caused by *Phytophthora infestans* (Mont.), de Bary)
Late blight is one of the most destructive diseases on tomato and potato crops. Native from Mexico, the pathogen (*Phytophthora infestans* (Mont.) de Bary) is widely distributed since the beginning of the twentieth century.

This fungus needs alive tissues to survive during winter. The first symptoms appear 3 to 4 days after infection, a small necrotic lesion grows through the host tissues. In propitious conditions (high moisture for more than 10-12 hours and cool temperature (15-21°C)), sporulation can occur 6 days after infection, producing an abundant secondary inoculum. Sporangia are dispatched by rain splash and wind currents on several kilometres, so disease propagates very quickly and can destroy a field in a very short period of time. Infection causes severe defoliation, spots on tomato fruits and by the potato tuber infection a reduction of conservation time of tubers.

To protect tomatoes and potatoes against late blight, preventative applications of fungicides are needed since favourable conditions for disease development are reached.

Bacterial diseases
Diseases induced by bacteria are widely encountered in many crops and today copper based compounds are the only chemicals registered to control/limit such diseases. In France, NORDOX 75WG is registered for many years on several bacteria diseases on: artichoke, beans, chicory, celery, cabbages, dandelion, leek, lettuce, onion, tomato, kiwi, almond, hazelnut, walnut, apple, pear, , apricot, peach, cherry, olive and grape.

Some trials were laid down to evaluate the efficacy of NORDOX 75WG against some bacterial diseases caused by either *Xanthomonas spp* or *Pseudomonas spp*.

***Xanthomonas arboricola pv.juglandis* (*X. arboricola pv. juglandis*), responsible for walnut blight**
Described for the first time in 1890 in California, the bacteria responsible (*X. arboricola*) was isolated and described in 1896.Walnut blight is the main disease in walnut orchards; it is present in all production areas around the world. Although disease is not a danger for trees survival, the impact on yield can reach 70% lost. Infected trees present symptoms on leaves, twigs and fruits. All green infected parts (leaves and husks) present oily spots that turn into black oily necrosis during the season. Infected twigs turn into black and die.

Some environmental factors favor the development of the disease. In winter, bacteria refuge in buds and begin to infect young leaves when humidity is important and temperatures are between 16°C and 29°C. These conditions are frequently reached at spring when trees are flowering, at a high sensible crop stage. Disease propagation is principally assured by the contaminated pollen, when male catkins are infected. Frictions of infected organs are also reported to disseminate the bacteria.
Soil has been reported to play an important role on the disease occurrence. His depth and composition are apparently influencing the disease. Orchards implanted on deep clay soils are less suffering from walnut blight than the ones that grow on acidic and low profiled soils. Some prophylactic measures, like equilibrate pruning show an influence on disease development.

***Xanthomonas arboricola pv. pruni* (*X. arboricola pv. pruni*), responsible for bacterial leaf spot**
X. arboricola pv. *pruni* attacks only *Prunus* spp., particularly the fruit crops almonds, peaches, cherries, plums and apricots. Described the first time in North America, it is widespread in many production areas. On peach, *X. arboricola* pv. *pruni* overwinters primarily in the intercellular spaces of the cortex, phloem

and xylem parenchyma towards the tips of twigs produced during the preceeding season. On plum and apricot, summer cankers formed in one season continue developing the following spring, providing a source of inoculum at this time. Plum buds and fallen leaves have also been reported as overwintering sites.

In spring, before host division starts, bacteria multiply in the intercellular spaces and cause the epidermis to rupture, so initiating a visible lesion referred to as a spring canker. Inoculum from these cankers is disseminated in rain and wind and infects new leaf growth via stomata.

Infections are favored by hot (19-38°C) and wet conditions. Disease manifests by holes on leaves, brown spots on fruits and black tips on shoots. Wounds may exude gum, particularly after rain.
Serious attacks induce defoliation that weakens trees. In neglected peach orchards, 25-75% of fruit may be attacked. On plums, principal branches dead and yield reduce all years. No curative treatments are available yet. So all infected trees must be torn to avoid propagation.

***Xanthomonas cynarae (X. cynarae)*, responsible for bacterial bract spot of artichoke**
X. cynarae develops on plants since March-April without inducing symptoms. It needs an injury to penetrate in plant. Frequently, it passes through the epidermal detachment caused by climatic aggressions (freeze, hail, storm…). So, the most sensible period is spring, when bacteria develop and flower bulbs begin to form. Disease is mainly observed in the year following the plantation.

X. cynarae causes black oily spots on edible buds. These spots exude yellow mucus. Infected artichokes lost their market value. To protect crops, the only effective strategy is preventative applications of copper based products as soon as the first flower bulbs appear and eventually 7 to 10 days later.

***Pseudomonas spp*.**
Pseudomonas genus regroups some bacteria species (~60) that are widely encountered in several wet environments (soil, water, etc.). Some species are neutral or beneficial for crops (like *Pseudomonas fluorescens*, that is antagonistic from several pathogen fungi), and few species causes diseases on crops. *Pseudomonas syringae* is the most encountered pathogen species; it infects crops like bean, tomato, garlic, watermelon or kiwi.

P. syringae symptoms are generally brown spots on leaves or fruits, that causes defoliation and in sensible plants, sunscalds (cucurbits, tomato). *Pseudomonas* bacterium may reduce the yield of tomato fields up to 60%. On kiwi, two different strains of *P. syringae* could cause disease, one that provokes flower rot, and one that causes cankers that may destroy major branches of trees.
They develop in humid conditions, when temperatures reached 18-24°C. Propagation is ensured by rain splashes and contaminated plants issued from nurseries.

Plant protection is difficult because of the lack of efficient active substances. Only copper based formulations are allowed because of the risk of resistance apparition with antibiotic molecules.

Description of the target pests

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

Described in the point above

Table 3.2-4 Levels of control for fungicides

Claim level	Level of control
Control	*> 80 %*
Partial/moderate control	*60 - 80 %*
Some control	*40 - 60 %*

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

Crop and/or situation	Crop status	
	Major	minor
Apple	PL	-
Pear, quince	-	PL
Vine	-	PL
Strawberry	-	PL
Tomato, Eggplant, Pepper	-	PL
Cucumber	-	PL
Pumpkin, Courgettes, Melon	-	PL
Lettuce, Scarole	-	PL
Shallots, Onion, Garlic	-	PL
Ornamental plants	-	PL
Pome fruits (Apple, Pear, Quince tree, nashi)	HU	-
Stone fruits	HU	-
Vine	HU	-
Potato	HU	-
Sugarbeet, Fodderbeet	HU	-
Berries	-	HU
Tomato, pepper	-	HU
Cucurbits	-	HU
Celery	-	HU
Spinach	-	HU
Chicory	-	HU
Brassicas (white cabbage, savoy cabbage, broccoli, cauliflower, broussel sprout)	-	HU
Asparagus	-	HU
Shallots, Onion, Garlic	-	HU

Crop and/or situation	Crop status	
	Major	minor
Legumes	-	HU
Walnut, Hazelnut, Almond, Chestnut	-	HU
Ornamentals	-	HU
Pome fruits (Apple, Pear, Quince tree)	SI	-
Peach, Nectarine	SI	-
Olive	SI	-
Grape (Vine and Table)	SI	-
Tomato, Eggplant	SI	-
Potato	SI	-
Pome fruits (Apple, Pear)	-	SI
Kiwi	-	SI
Citrus	-	SI
Olive	-	SI
Grape (Vine and Table)	-	SI
Strawberry	-	SI
Eggplant	-	SI
Forest tree nurseries	-	SI

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)

Information on trials submitted in Poland

A total of seven trials have been carried out in 2001,2002, 2004 and 2011 to evaluate the efficacy of Copper oxide products applied at rates of 750g and1000g Cu/ha against Scab (*Venturia inaequalis*) in Apple.

Of these trials, one was carried out in Germany and within the Maritime climatic zone, three were carried out in Hungary and within the South-East climatic and three were carried out in Poland and within the North-East climatic zone (as defined in EPPO Guideline PP 1/241). Data generated in these trials is therefore considered to be fully supportive of label claims and relevant to countries within the EU Central zone with respect to zonal recognition.

Table 3.2-6.1 Presentation of trials (efficacy trials, preliminary trials...) –Poland

Crop(s)*	Target(s)	Country	Years	Type of trial*	Number of trials (number of valid trials)	GEP, non-GEP, official**	Comments (any other relevant information)
Apple	***Venturia inaequalis***	DE	2011	E	1	GEP	-
		HU	2011	E	1	GEP	-
		PL	2011	E	1	GEP	-
		PL	2004	E	1	GEP	-
		PL	2001	E	1	GEP	-
		HU	2002	E	2	GEP	-
TOTAL					7		

* P = preliminary trial, MED = minimum effective dose, E = efficacy trial.
** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Information on trials submitted in Southern Zone

Trials were conducted across a wide range of sites. The trials were therefore representative of a wide range of agricultural, plant health and environmental conditions (including climatic conditions) likely to be encountered in practice in the area of proposed uses.

Table 3.2-7.2 Presentation of trials (efficacy trials, preliminary trials...) – Southern Zone - Hungary, Slovenia

Crop(s)*	Target(s)	Country	Years	Type of trial*	Number of trials (number of valid trials)	GEP, non-GEP, official**	Comments (any other relevant information)
ONLY NORDOX 75WG APPLICATIONS DURING ALL SEASON							
Grapevine	***Plasmopara viticola***	FR	2001	E	2	GEP	-
		FR	2003	E	2	GEP	-
		FR	2005	E	5	GEP	-

		FR	2006	E	4	GEP	-
		FR	2007	E	4	GEP	-
		IT	2010	E	1	GEP	-
		ES	2010	E	1	GEP	-
		FR	2011	E	3	GEP	-
MANCOZEB APPLICATIONS BEFORE NORDOX 75WG APPLICATIONS							
Grapevine	***Plasmopara viticola***	FR	2009	E	4	GEP	-
		FR	2010	E	4	GEP	-
		FR	2011	E	3	GEP	-
		IT	2003	E	1	GEP	-
		FR	2005	E	1	GEP	-
Peach	***Taphrina deformans***	IT	2009	E	2	GEP	-
		FR	2010	E	2	GEP	-
		ES	2010	E	1	GEP	-
		FR	2011	E	4	GEP	-
Olive	***Spilocaea oleagina***	IT	2002	E	1	GEP	-
		ES	2003	E	3	GEP	-
		ES	2004	E	1	GEP	-
		ES	2009	E	2	GEP	-
		ES	2010	E	1	GEP	-
		IT	2011	E	1	GEP	-
Olive	***Colletotri-chum gloeosporio-ides***	PT	2006	E	1	GEP	-
Apple	***Venturia inaequalis***	FR	2010	E	1	GEP	
		IT	2010	E	1	GEP	-
		ES	2010	E	1	GEP	-
		FR	2003	E	2	GEP	-
Apple	***Nectria galligena***	FR	2004	E	1	GEP	-
		FR	2010	E	5	GEP	-
		IT	2010	E	1	GEP	-
		FR	2011	E	1	GEP	-
Citrus	**fruit brown rot (*Phytophthora* spp.)**	IT	2010	E	1	GEP	-
		ES	2011	E	1	GEP	-
		IT	2011	E	1	GEP	-

Artichoke	**Bacterial disease**	IT	2001	E	1	GEP	-
Walnut		FR	2008	E	1	GEP	-
		FR	2009	E	1	GEP	-
		FR	2010	E	1	GEP	-
		FR	2011	E	2	GEP	-
Kiwi		IT	2010	E	2	GEP	-
Peach		FR	2010	E	1	GEP	-
Artichoke	***Bremia lactucae* and *Ascochyta hortorum***	F	2011	E	2	GEP	-
		ES	2011	E	1	GEP	-
Cucurbits	***Pseudoperonospora cubensis***	ES	2010	E	1	GEP	-
		IT	2010	E	1	GEP	-
		FR	2010	E	1	GEP	-
Onion	***Peronospora destructor***	IT	2010	E	1	GEP	-
		ES	2011	E	1	GEP	-
Tomato	***Phytophthora infestans***	IT	2002	E	2	GEP	-
		IT	2009	E	1	GEP	-
		FR	2010	E	1	GEP	-
		IT	2011	E	1	GEP	-
		GR	2011	E	1	GEP	-
		PT	2011	E	1	GEP	-
		IT	2009	E	1	GEP	-
Tomato	***Alternaria solani***	IT	2009	E	1	GEP	-
Potato	***Phytophthora infestans***	IT	2010	E	1	GEP	-
		FR	2010	E	1	GEP	-
		ES	2010	E	1	GEP	-
		GR	2011	E	1	GEP	-
		PT	2011	E	1	GEP	-
				Total	102		

Table 3.2-8.3 List of crop safety trials carried out on top fruits

Year	Country (N/S)	Crop
2001	Italy	Pear
2001	Italy	Pear
2001	Italy	Pear

2001	Italy	Pear
2005	France (S)	Stone fruits
2005	France (S)	Pome fruits

The list of reference products used in trials submitted in Poland

The reference products used in the efficacy trials were: Funguran, Malvin WG, Champion 50 WP, Merpan 80 WDG, Captan 50 WP, Miedzian 50 WP as seen in the table below.

Table 3.2-9.1 Presentation of reference standards used in trials (efficacy trials, preliminary trials...) - Poland

Product	a.i.	Concentration of a.i.	Formulation type
Funguran	Copper (as copper oxychloride)	45%	WP
Malvin WG	Captan	80%	WG
Champion 50 WP	Copper (as copper hydroxide)	50%	WP
Merpan 80 WDG	Captan	80%	WDG
Champion 50 WP	Copper (as copper hydroxide)	50%	WP
Captan 50 WP	Captan	50%	WP
Miedzian 50WP	Copper (as copper oxychloride)	50%	WP

The list of reference products used in trials submitted in Hungary and Slovenia

Table 3.2-10.2 Presentation of reference standards used in trials (efficacy trials, preliminary trials...) – Southern Zone

Crop/Pest	Product	Active Substance(s)	Concentration Formulation	Approval status / notes
Grape/downy mildew	Bouillie Bordelaise RSR Disperss	Copper sulphate	20%	9500452 France
Peach/Leaf curl	Bouillie Bordelaise RSR Disperss	Copper sulphate	20%	9500452 France
	Caldo Bordeles RSR Disperss	Copper sulphate	20%	17223 Spain
	Poltiglia Disperss	Copper sulphate	20%	12096 Italy
Olive/Peacock spot	Kocide 2000	Copper hydroxide	35%	22002 Spain
	ZZ Cuprocol	Copper oxichloride	70%	14534 Spain
	Caldo bordeles	Copper sulphate	20%	12864 Spain
	Cuprocaffaro	Copper oxichloride	50%	21630 Spain
	CURENOX 50	Copper oxichloride	50%	13138 Spain
Olive/Anthracnose	ZZ Cuprocol	Copper oxichloridee	70%	14534 Spain
Apple/Apple scab	Merpan 80WG	Captan	80%	9300108 France
	NEORAM	Copper oxichloride	37.5%	002933 Italy
	Captan 50	Captan	50%	17589 Spain
Apple/Apple canker	Bouillie Bordelaise RSR Disperss	Copper sulphate	20%	9500452 France
Citrus/Downy mildew	NEORAM	Copper oxichloride	37.5%	13907 Spain
	Ossiclor 35WG	Copper oxichloride	35%	12759 Spain
	Cuprocaffaro	Copper oxichloride	50%	8800671 France
Artichoke/ Downy mildew	Rhodax	Fosethyl-aluminium	44%	8000144 France
		Mancozeb	26%	
Artichoke/Anthracnose	Caldo Bordelès	Copper sulphate	20%	12864 Spain
	Curenox 50	Copper oxichloride	50%	9400351 France

Crop/Pest	**Product**	**Active Substance(s)**	**Concentration Formulation**	**Approval status / notes**
Cucurbits/Downy mildew				13138 Spain
	Kocide 3000	Copper hydroxide	30%	012342 Italy
	Fungistop FL	Chlorothalonil	500g/L	8300270 France
Onion/Downy mildew	Curenox 50	Copper oxichloride	50%	13138 Spain
	Kocide 3000	Copper hydroxide	30%	012342 Italy
Tomato/Late blight	Kocide 2000	Copper hydroxide	35%	9700401 France
				010573 Italy
	Delan 70WG	Dithianion	66%	010040 Italy
	Dithane Neotec	Mancozeb		9900242 France
	Cuprocaffaro	Copper oxichloride	50%	003628 Italy
	Pasta caffaro	Copper oxichloride	37.5%	Greece
	Caldo Bordelès Vallès	Copper oxichloride	20%	Portugal
Potato/Late blight	Cuprocaffaro	Copper oxichloride	50%	003628 Italy
	Curenox 50	Copper oxichloride	50%	13138 Spain
	BM IQV 20WP	Copper sulphate	20%	Greece
	Iperion	Copper oxide	37.5%	Portugal
	Sekoya	Fluanizam SC	500g/L	9700467 France

3.2.1 Preliminary tests (KCP 6.1)

As copper oxide is a well-known substance, already registered in European countries, no preliminary trials were undertaken.

3.2.2 Minimum effective dose tests (KCP 6.2)

3.2.2-1 Minimum effective dose tests - Poland

Data was generated on the efficacy of Copper oxide products applied at 750g and 1000g Cu/ha up to crop growth stage BBCH 53-54, as part of a spray program followed by applications of another fungicide, against Scab of apple in three efficacy trials carried out in 2011.All trials included spray programs involving Copper oxide products applied at the first 2-4 timings, followed by applications of other fungicides.

Across all trials, intervals between applications were within the range of 3-9 days, which is typical of intervals between applications in multiple spray programs for the control of Scab in Apple in commercial practice. Intervals between applications on four trials were 7 or more days according to the minimum label interval with the exception of twos trial where intervals between applications were slightly shorter at 6 days. On all trials, treatments were applied in a water volume of 800l/ha and therefore representative of the 500-1000l/ha label range.

Overall rate related responses were evident with respect to the efficacy of Copper oxide products against Scab (*Venturia inaequalis*) on the leaves and fruits in the one trial in the North East climatic zone, where disease developed to moderate to very high levels. On this trial, the efficacy of spray program that included Copper oxide applied 1000g Cu/ha at the first four timings, was markedly higher that of the program that included the 750g Cu/ha rate. On the other trial, there were no pronounced differences in efficacy between spray programs involving the 1000g Cu/ha and the 750g Cu/ha rates whether on the leaves or fruit.

On the basis of the data generated in these trials, it is considered that the minimum effective dose rate starts at 750g Cu/ha and that higher rates are justified in terms of achieving effective control dependent on disease development and pressure.

3.2.2-2 Minimum effective dose tests - Southern Zone

Methodology and trial sites are the same as those detailed for the efficacy trials. Minimum effective dose will be discussed within efficacy tests section. Full information on location and methodology of the trials is provided in section 3.2.3 related to efficacy tests. As other copper active substances, minimum effective dose for copper oxide may be low if light pest pressure. At the opposite, under high pest pressure, mainly to control grape downy mildew, there is no minimum effective rate and targeted registration rate should be used in taking into account maximum rate authorized by year.

3.2.3 Efficacy tests (KCP 6.2)

3.2.3-1 Efficacy tests – Poland

Testing facilities

All trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC by the authorities in the relevant countries.

Summaries of trial site and application details for all trials used to demonstrate the efficacy of Copper oxide against Scab on Apple are given in Appendix 4.

Sites

All trials were conducted in areas representative of Apple growing areas in each region.

Efficacy trials presented in this Biological Assessment Dossier were located in Germany, within the Maritime climatic zone, Hungary within the South-East climatic zone and Poland within the North-East climatic zone (as defined by EPPO Standard PP1/241(1)).

The data is therefore considered to be fully supportive towards demonstrating the efficacy of Copper oxide on Scab (*Venturia inaequalis*) on Apple within the EU Central zone with respect to zonal recognition.

A total of three trials have been carried out in 2011 to evaluate the efficacy of Copper oxide products applied at rates of 750g and1000g Cu/ha against Scab (*Venturia inaequalis*) in Apple.

Of these trials, one was carried out in Germany and within the Maritime climatic zone, one was carried out in Hungary and within the South-East climatic and one was carried out in Poland and within the North-East climatic zone (as defined in EPPO Guideline PP 1/241). Data generated in these trials is therefore considered to be fully supportive of label claims and relevant to countries within the EU Central zone with respect to zonal recognition.

All trials used to demonstrate the efficacy of Copper oxide are listed in Table 3.2.3-1.1 below.

Table 3.2.3-1.1 List of all trials used to demonstrate the efficacy of Copper oxide

Crop	Trial number	Year trials conducted	Country	Zone
Apples	S11-00984-01	2011	Germany	Maritime
Apples	S11-00992-01	2011	Hungary	South-East
Apples	S11-00253-02	2011	Poland	North-East
Apples	NO-0017	2004	Poland	North-East
Apples	(no code)	2001	Poland	North-East
Apples	F-36/2002 (1)	2002	Hungary	South-East
Apples	F-36/2002 (2)	2002	Hungary	South-East

Details on trial methodology – Poland

The design, analysis of results and reporting of the efficacy trials were carried out in accordance with EPPO guidelines PP 1/152(3) Design and analysis of efficacy evaluation trials and PP 1/181(3) Conduct and reporting of efficacy evaluation trials. The conduct of the field work was a commensurate with 'Good Agricultural Practice' and accordance with EPPO guideline PP 1/135(3) Phytotoxicity assessment and PP 1/5(3) Venturia inaequalis and V. pyrina. There were no deviations from the EPPO guidelines.

Table 3.2.3-1.2 Description of applications in trials:

Crop	Target	Application timing	No. of appl'ns	Interval between appl'ns (min)	Appl'n volume	Dose rate
Apple	*Venturia inaequalis*	Crop growth stage 03-54 (BBCH)	2-4	3-9 days	800 l/ha	750-1000g and 1500g Cu/ha

Data has been generated on the efficacy of 2-4 applications of Copper oxide products applied at 750g, 1000g and 1500g Cu/ha, applied at the beginning of multiple spray programs with other fungicides, against Scab.

Of these trials, one was carried out Germany (within the Maritime climatic zone as defined in EPPO Guideline PP 1/241), three were carried out in Hungary (within the South-East climatic zone as defined in EPPO Guideline PP 1/241) and three were carried out in Poland (within the North-East climatic zone as defined in EPPO Guideline PP 1/241).

Across all trials, intervals between applications were within the range of 3-9 days, which is typical of intervals between applications in multiple spray programs for the control of Scab in Apple in commercial practice. Intervals between applications on four trials were 7 or more days according to the minimum label interval with the exception of twos trial where intervals between applications were slightly shorter at 6 days.

Applications of Copper oxide products and standard reference products were made when the crop was within the growth stage range 03-54 (BBCH). On two of the trials, final applications of copper products were applied very slightly beyond growth stage 53 but before flowering. Therefore, the efficacy of the copper product spray programmes can be considered to be representative of that of when applications are made within the 91-53 (BBCH) label range.

Across trials, treatments were applied in water volumes of 800l/ha and therefore representative of the 500-1000l/ha label range.

The Copper oxide product was included in all of the trials carried out. The Copper oxide product was applied at identical rates of the Copper active and subject to the same study protocol based directly on EPPO guidelines and therefore can be directly compared.

The efficacy of the Copper oxide products applied at the first 2-4 timings as part of a spray program when followed by applications of another fungicide, was compared to that of standard reference Copper products applied at the same timings and as part of the same spray programs, at national registered label rates, Funguran (Copper oxychloride, 45%, WP), Miedzian 50WP (Copper oxychloride,50%, WP) and Champion 50 WP (Copper hydroxide, 50%, WP).

Table 3.2.3-1.3 Treatments applied in the efficacy trials against Scab in Apple

Trial reference numbers		Product	Application timings –growth stage (BBCH)	Application rate g as/ha	Application rate Product/ha (L/Kg)
S11-00984-01		Untreated	-	-	-
		NORDOX 75 WG (Nordox)	A1: BBCH 03, A2: BBCH 10, A3: BBCH 11, A4: BBCH 54	750	1000
			A1: BBCH 03, A2: BBCH 10, A3: BBCH 11, A4: BBCH 54	1000	1330
		Funguran	A1: BBCH 03, A2: BBCH 10, A3: BBCH 11, A4: BBCH 54	675	1500
		Malvin WG	A5: BBCH 56, A6: BBCH 65, A7: BBCH 72, A8: BBCH 73, A9: BBCH 73, A10: BBCH 74, A11: BBCH 74, A12: BBCH 75, A13: BBCH 75, A14: BBCH 77, A15: BBCH 78, A16: BBCH 81	1200	1500
S11-00253-01		Untreated	-	-	-
		NORDOX 75 WG (Nordox)	A1: BBCH 03, A2: BBCH 53	750	1000
			A1: BBCH 03, A2: BBCH 53	1000	1330
		Champion 50 WP	A1: BBCH 03, A2: BBCH 53	1000	2000
		Merpan 80 WDG	A3: BBCH 60, A4: BBCH 64, A5: BBCH 67, A6: BBCH 69, A7: BBCH 71, A8: BBCH 71, A9: BBCH 72, A10: BBCH 73, A11: BBCH 73, A12: BBCH 78	960	1200
S11-00992-01		Untreated			
		NORDOX 75 WG (Nordox)	A1: BBCH 03, A2: BBCH 07, A3: BBCH 53, A4: BBCH 54	750	1000
			A1: BBCH 03, A2: BBCH 07, A3: BBCH 53, A4: BBCH 54	1000	1330
		Champion 50 WP	A1: BBCH 03, A2: BBCH 07, A3: BBCH 53, A4: BBCH 54	375	750
		Captan 50 WP	A5: BBCH 56, A6: BBCH 59, A7: BBCH 60, A8: BBCH 65, A9: BBCH 69, A10: BBCH 71	1500	3000
NO-0017		Untreated	-	-	-
		NORDOX 75 WG (Nordox)	A1: BBCH 03, A2: BBCH 10, A3: BBCH 54	526,5	750
				750	1000
				1125	1500
-		Untreated	-		
		NORDOX 75 WG (Nordox)	Before BBCH 57(before pink bud stage)	1125	1500
		Miedzian 50 WP	Before BBCH 57(before pink bud stage)	750	1500

Application details

Applications to all trials were made using a mistblower to represent or simulate commercial application. Applications were made in a spray volume of 800l water/ha, to achieve good coverage and are therefore representative of the 500-1200l water/ha label recommended range.

Across the three trials, crop growth stages at the time of application were within the range of 03-54 (BBCH). On two of the trials, final applications of copper products were applied very slightly beyond growth stage 53 but before flowering. Therefore, the efficacy of the copper product spray programmes can be considered to be representative of that of when applications are made within the 91-53 (BBCH) label range.

Across all trials, intervals between applications were within the range of 3-9 days, which is typical of intervals between applications in multiple spray programs for the control of Scab in Apple in commercial practice. Intervals between applications on four trials were 7 or more days according to the minimum label interval with the exception of twos trial where intervals between applications were slightly shorter at 6 days. Full details on application, including crop growth stage and application intervals, for all three trials are given in Appendix 4.

Assessments

Observations were made for the ease of mixing of the formulations and for any conspicuous problems associated with nozzle blockages or uneven spray pattern during mixing and application in all trials.

Phytotoxicity was assessed as the percentage of total leaf area affected by chlorosis and necrosis and any other symptom or plot differences were observed using a scale appropriate to symptom.

Differences in crop vigour were assessed on an overall plot basis using a 0-10 scale where 0 = no crop and 10 = most vigorous plot within the trial area.

Disease control on the leaves was determined by visual assessment of the percentage of spotted leaves (visual plot assessment) based on all trees of the net plot and also assessment of the number of infected leaves and non-infected leaves on at least 200 leaves of long shoots and rosettes per plot.

Disease control on the fruit was assessed using the number of attacked fruits on at least 100 fruits per plot (a similar number of fruit from each tree of the plot was picked and was picked from the central part of the tree top and all around the tree). The fruit was also assessed for fruit affected according to the following EPPO scale:

1 = No attack
2 = 1-3 spots per fruit
3 = > 3 spots per fruit

The quality of fruits were assessed on fruit russeting on at least 75 fruits per plot and assessed according to the following scale:

1 = no russeting
2 = < 10 %
3 = 10 – 30 %
4 = > 30 %

Details of assessment dates, assessment timings and crop growth stages at assessment on all trials are given in Table 3.2.3-1.4:

Table 3.2.3-1.4: Details of assessments carried out on efficacy trials against Scab in Apple

Trial no	Assessment date	Timing	Crop growth stage (BBCH)	Untreated crop ground cover (%)	Assessment type
S11-00984-01	04/04/2011	0 DAA2	11	n/a	Phytotoxicity, Crop vigour (No disease symptoms or russeting)
	11/04/2011	0 DAA3	11	n/a	
	18/04/2011	0 DAA4	54	n/a	
	26/04/2011	8 DAA4	56	n/a	
	05/05/2011	17 DAA4	69	n/a	
	13/05/2011	25 DAA4	72	n/a	
	21/09/2011	156 DAA4	87	n/a	
S11-00253-01	18/04/2011	11 DAA2	60	n/a	Pytotoxicity, Crop vigour
	13/05/2011	36 DAA2	69	n/a	
	10/06/2011	72 DAA2	72	n/a	
	23/09/2011	89 DAA2	89	n/a	
	07/04/2011	0 DAA2	3	n/a	Disease Control
	18/04/2011	11 DAA2	60	n/a	
	13/05/2011	36 DAA2	69	n/a	
	10/06/2011	64 DAA2	72	n/a	
	23/09/2011	169 DAA2	89	n/a	
S11-00992-01	16/04/2011	0 DAA3	83	n/a	Pytotoxicity, Crop vigour, Disease control
	21/04/2011	0 DAA4	54	n/a	
	27/04/2011	6 DAA4	56	n/a	
	16/05/2011	25 DAA4	69	n/a	
	09/06/2011	49 DAA4	72	n/a	
	04/10/2011	166 DAA4	85	n/a	
NO-0017 Skierniewice	20/05/2004				Disease Control
NO-0017 Sójki	11/06/2004				
NO-0017Pęchecin	26/05/2004				
	18/06/2004				
-,Dąbrowice	1/06/2001				Disease Control
	4/07/2001				
	24/07/2001				
	31/08/2001				
-, Miłobądz	16/07/2001				Disease Control

[a] No plot differences were recorded

[b] Growth stage after

[c] DA-A = Days after treatment application

Summary and evaluation of trial results

Data has been generated on the efficacy of 2-4 applications of Copper oxide products applied at 750g ,1000g Cu/ha, applied at the beginning of multiple spray programs with other fungicides, against Scab in seven efficacy trials carried out on Apple in 2001,2002,2004 and 2011.

Of these trials, one was carried out Germany (within the Maritime climatic zone as defined in EPPO Guideline PP 1/241), three were carried out in Hungary (within the South-East climatic zone as defined in EPPO Guideline PP 1/241) and three were carried out in Poland (within the North-East climatic zone as defined in EPPO Guideline PP 1/241).

Copper oxide products were applied at the first four timings, followed by twelve applications of another fungicide product (Malvin WG – Captan 80% WG), for on one trial (S11-00984-01), Copper oxide products were applied at the first two timings, followed by ten applications of another fungicide product (Merpan 80 WG – Captan 80% WG), on one trial (S11-00253-01) and Copper oxide products were applied at the first four timings, followed by six applications of another fungicide product (Captan 50 WP – Captan 50% WP) on one trial (S11-00992-01).

Across all trials, intervals between applications were within the range of 3-9 days, which is typical of intervals between applications in multiple spray programs for the control of Scab in Apple in commercial practice. Intervals between applications on four trials were 7 or more days according to the minimum label interval with the exception of twos trial where intervals between applications were slightly shorter at 6 days.

Applications of Copper oxide products and standard reference products were made when the crop was within the growth stage range 03-54 (BBCH). On two of the trials, final applications of copper products were applied very slightly beyond growth stage 53 but before flowering. Therefore, the efficacy of the copper product spray programmes can be considered to be representative of that of when applications are made within the 91-53 (BBCH) label range.

Across trials, treatments were applied in water volumes of 800l/ha and therefore representative of the 500-1000l/ha label range.

The Copper oxide product was included in all of the trials carried out. The Copper oxide product was and subject to the same study protocol based directly on EPPO guidelines and therefore can be compared.

The efficacy of the Copper oxide products applied at the first 2-4 timings as part of a spray program when followed by applications of another fungicide, was compared to that of standard reference Copper products applied at the same timings and as part of the same spray programs, at national registered label rates, Funguran (Copper oxychloride, 45%, WP), Miedzian 50WP (Copper oxychloride,50%, WP) and Champion 50 WP (Copper hydroxide, 50%, WP).

Efficacy against Scab (VENTIN) on Apple leaves

Assessments of scab were made in reference to the application timings of the Copper oxide products. Scab was first recorded on the leaves 25 days after the fourth application timing on one trial (S11-00992-01) and 169 days after the second application timing on one trial (S11-00253-01). In one trial, (S1100984), disease did not develop throughout the trial period. Disease severity reached low to moderate levels on one trial (S11-00253-01) and developed to very high levels on the other trial (S11-0000992-01) in the untreated plots by last assessment timing.

In trial S11-00253-01, where disease pressure reached low to moderate levels, spray programmes involving the Copper oxide product applied at rates of 750g and 1000g Cu/ha at the first two timings achieved total control at all rates. In trial S11-00992-01, where disease pressure reached high levels at early assessment timing, spray programmes involving the Copper oxide product applied at rates of 750g and 1000g Cu/ha achieved moderate levels of control. As disease pressure reached very high levels at final assessment timing the copper oxide product achieved low levels of control at all rates.

The overall efficacy of the spray programs involving the Copper oxide product applied at 750g and 1000g Cu/ha at the first 2-4 timings were consistently comparable to those achieved by the equivalent programs involving standard reference Copper products applied at the same timings at nationally approved label rates. The overall efficacy of the programs involving Copper oxide products applied at the first four timings on trial S11-00992-01 was higher than that of the equivalent spray programme that was left untreated at the first four application timings at early assessment timing. However, by finial assessment timing in both trials, the overall efficacy of the programs involving Copper oxide products applied at the first two or four timings was not markedly higher than that of the equivalent spray program that was left untreated at the first two or four application timings on two of the trials. The data generated on these trials demonstrates that early applications of Copper oxide at the start of a spray program for the control of Scab, contributes to the overall good levels of control achieved by the program, when disease first develops relatively early in the season.

Table 3.2.3-1.5: Overall summary of combined mean % efficacy (based on disease severity) of spray programs involving Copper oxide applied at the first 2-4 timings against Scab (*Venturia inaequalis*) on Apple, disease on leaves

Climatic zone	Treatment	Application Timing	Mean % control, (No. of trials) (Min- Max control)	
			Assessment Timing	
			Early Assessment	Final Assessment
			Crop Stage (BBCH 69)	Crop Stage (BBCH 85-89)
North-East	Untreated (% disease severity)	-	34,1 (4) (29,4 - 38.8)	75,7(4) (72,6-78.8)
	Untreated/Captan 50 WP	A1-A4/A5-A10	0.5 (1) (0.5-0.5)	17.5 (1) (17.5-17.5)
	COX (750g Cu/ha)/Captan 50 WP	A1-A4/A5-A10	67.7 (1) (67.7-67.7)	0.5 (1) (0.5-0.5)
	COX (1000g Cu/ha)/Captan 50 WP	A1-A4/A5-A10	74.2 (1) (74.2-74.2)	12.7 (1) (12.7-12.7)
	Champion (375g Cu/ha)/Captan 50 WP	A1-A4/A5-A10	71 (1) (71-71)	12.7 (1) (12.7-12.7)
	COX 750	A1-A3	92,25	100
	COX 1125		94,6	100
South-East	Untreated (% disease severity)	-	0, (1), (0-0)	19,3 (3) (12.5-45,1)
	Untreated/Merpan 80 WG	A1-A2/A3-A12	-	100 (1) (100-100)
	COX (750g Cu/ha)/Merpan 80 WG	A1-A2/A3-A12	-	100 (1) (100-100)
	COX (1000g Cu/ha)/Merpan 80 WG	A1-A2/A3-A12	-	100 (1) (100-100)
	Champion (375g Cu/ha)/Merpan 80 WG	A1-A2/A3-A12	-	100 (1) (100-100)
	COX (800gCu/ha)			60,86 (2)
	COX (1200gCu/ha)			64,12 (2)
Combined	Untreated (% disease severity)	-	38.8 (1) (38.8-38.8)	45.6 (2) (12.5-78.8)
	Untreated/Standard Fungicide	A1 to A2-A4/A3-A5 to A10-A12	0.5 (1) (0.5-0.5)	58.8 (2) (17.5-100)
	COX (750g Cu/ha)/Standard Fungicide	A1 to A2-A4/A3-A5 to A10-A12	67.7 (1) (67.7-67.7)	50.3 (2) (0.5-100)
	COX (1000g Cu/ha)/Standard Fungicide	A1 to A2-A4/A3-A5 to A10-A12	74.2 (1) (74.2-74.2)	56.4 (2) (12.7-100)
	Standard reference product/Standard Fungicide	A1 to A2-A4/A3-A5 to A10-A12	71 (1) (71-71)	56.4 (2) (12.7-100)

Table 3.2.3-1.6: Overall summary of combined mean % reduction in the incidence of Scab (*Venturia inaequalis*) on Apple by spray programs involving Copper oxide products applied at the first 2-3 timings, disease on leaves

Climatic zone	Treatment	Application Timing	Mean % control, (No. of trials) (Min- Max control)	
			Assessment Timing	
			Early Assessment	Final Assessment
			Crop Stage (BBCH 69)	Crop Stage (BBCH 85-89)
North-East	Untreated (% disease severity)	-	43 (1) (43-43)	97 (1) (97-97)
	Untreated/Captan 50 WP	A1-A4/A5-A10	49.1 (1) (49.1-49.1)	21.4 (1) (21.4-21.4)
	COX (750g Cu/ha)/Captan 50 WP	A1-A4/A5-A10	69.8 (1) (69.8-69.8)	13.5 (1) (13.5-13.5)
	COX (1000g Cu/ha)/Captan 50 WP	A1-A4/A5-A10	73 (1) (73-73)	23.6 (1) (23.6-23.6)
	Champion (375g Cu/ha)/Captan 50 WP	A1-A4/A5-A10	70.3 (1) (70.3-70.3)	21.9 (1) (21.9-21.9)
	COX 750	A1-A3	92,25	100
	COX 1125		94,6	100
South-East	Untreated (% disease severity)	-	0, (1), (0-0)	27,7 (3) (11.4-54,43)
	Untreated/Merpan 80 WG	A1-A2/A3-A12	-	100 (1) (100-100)
	COX (750g Cu/ha)/Merpan 80 WG	A1-A2/A3-A12	-	100 (1) (100-100)
	COX (1000g Cu/ha)/Merpan 80 WG	A1-A2/A3-A12	-	100 (1) (100-100)
	Champion (375g Cu/ha)/Merpan 80 WG	A1-A2/A3-A12	-	100 (1) (100-100)
	COX (800gCu/ha)		-	51,87
	COX (1200gCu/ha)		-	49,715
Combined	Untreated (% disease severity)	-	21.5 (2) (0-43)	54.2 (2) (11.4-97)
	Untreated/Standard Fungicide	A1 to A2-A4/A3-A5 to A10-A12	49.1 (1) (49.1-49.1)	60.7 (2) (21.4-100)
	COX (750g Cu/ha)/Standard Fungicide	A1 to A2-A4/A3-A5 to A10-A12	69.8 (1) (69.8-69.8)	56.8 (2) (13.5-100)
	COX (1000g Cu/ha)/Standard Fungicide	A1 to A2-A4/A3-A5 to A10-A12	73 (1) (73-73)	61.8 (2) (23.6-100)
	Standard reference product/Standard Fungicide	A1 to A2-A4/A3-A5 to A10-A12	70.3 (1) (70.3-70.3)	61 (2) (21.9-100)

Summary of data on effectiveness trials per use (crop/harmful organism); (EPPO code)

Table 3.2.3-1.7 Mean % control of Scab (*Venturia inaequalis*) on leaves, based on disease severity, following multiple applications of Copper oxide products in Apple

			Trial Number	S11-00253-01						
			Testing facility	EAS GmbH, Germany						
			Country	Hungary						
			Pest code	VENTIN						
			Crop	Apple						
			Cultivar	Idared						
			Application date	A1: 29/03/11, A2: 07/04/2011, A3: 18/04/11, A4: 27/04/11, A5: 06/05/11, A6: 13/05/11, A7: 26/05/11, A8: 01/06/11, A9: 10/06/11, A10: 17/06/11, A11: 24/06/11, A12: 01/07/11						
			Crop stage at appl'n. (BBCH)	A1: 03, A2: 53, A3: 60, A4: 64, A5: 67, A6: 69, A7: 71, A8: 71, A9: 72, A10: 73, A11: 73, A12: 78						
			Assessment	% of leaves affected by scab of apples						
			Part Rated	Leaves						
			Assessment date	07/04/2011	18/04/2011	13/04/2011	10/04/2011		23/09/2011	
			Crop stage at assessm't (BBCH)	3	60	69	72		89	
			Days after appl'n.	0 DAA2	11 DAA2	36 DAA2	64 DAA2		169 DAA2	
Treatment	Rate	Unit	Code						(%)	
Untreated	---	---	---	0.00	0.00	0.00	0.00		12.50	a(-)
Untreated / Merpan 80 WG	- / 960	g ai/ha	A1-A2 / A3-A12						100.00	b
NOROX 75 WG / Merpan 80 WG	750 / 960	g ai/ha	A1-A2 / A3-A12						100.00	b
	1000 / 960	g ai/ha	A1-A2 / A3-A12						100.00	b
Champion / Merpan 80 WG	1000 / 960	g ai/ha	A1-A2 / A3-A12						100.00	b
			LSD (P=.05)	0	0	0	0		2.432	
			Standard Deviation	0	0	0	0		1.667	
			CV	0	0	0	0		120	
			Treatment Prob(F)	1	1	1	1		0.0001	
			Transformation	none	none	none	none		none	

Table 3.2.3-1.8: Mean % control of Scab (*Venturia inaequalis*) on leaves, based on disease severity, following multiple applications of Copper oxide products in Apple

<table>
<tr><td colspan="4">Trial Number</td><td colspan="6">S11-00992-01</td></tr>
<tr><td colspan="4">Testing facility</td><td colspan="6">EAS GmbH, Germany</td></tr>
<tr><td colspan="4">Country</td><td colspan="6">Poland</td></tr>
<tr><td colspan="4">Pest code</td><td colspan="6">VENTIN</td></tr>
<tr><td colspan="4">Crop</td><td colspan="6">Apple</td></tr>
<tr><td colspan="4">Cultivar</td><td colspan="6">Jonagored</td></tr>
<tr><td colspan="4">Application date</td><td colspan="6">A1: 04/04/11, A2: 11/04/11, A3: 16/04/11, A4: 21/04/11, A5: 27/04/11, A6: 02/05/11, A7: 07/05/11, A8: 12/05/11, A9: 17/05/11, A10: 24/05/11</td></tr>
<tr><td colspan="4">Crop stage at appl'n. (BBCH)</td><td colspan="6">A1: 03, A2: 07, A3: 53, A4: 54, A5: 56, A6: 59, A7: 60, A8: 65, A9: 69, A10</td></tr>
<tr><td colspan="4">Assessment</td><td colspan="6">% of leaves affected by scab of apples</td></tr>
<tr><td colspan="4">Part Rated</td><td colspan="6">Leaves</td></tr>
<tr><td colspan="4">Assessment date</td><td>16/04/2011</td><td>21/04/2011</td><td>27/04/2011</td><td>16/05/2011</td><td>09/06/2011</td><td>04/10/2011</td></tr>
<tr><td colspan="4">Crop stage at assessm't (BBCH)</td><td>83</td><td>54</td><td>56</td><td>69</td><td>72</td><td>85</td></tr>
<tr><td colspan="4">Days after appl'n.</td><td>0 DAA3</td><td>0 DAA4</td><td>6 DAA</td><td>25 DAA4</td><td>49 DAA4</td><td>166 DAA4</td></tr>
<tr><td>Treatment</td><td>Rate</td><td>Unit</td><td>Code</td><td></td><td></td><td></td><td>(%)</td><td>(%)</td><td>(%)</td></tr>
<tr><td>*Untreated*</td><td>---</td><td>---</td><td>---</td><td>0.00</td><td>0.00</td><td>0.00</td><td>38.75 a (-)</td><td>60.00 a (-)</td><td>78.75 a (-)</td></tr>
<tr><td>*Untreated / Captan 50 WP*</td><td>- / 960</td><td>g ai/ha</td><td>A1-A4 / A5-A10</td><td></td><td></td><td></td><td>0.52 b</td><td>54.20 b</td><td>17.50 b</td></tr>
<tr><td rowspan="2">NOROX 75 WG / Captan 50 WP</td><td>750 / 960</td><td>g ai/ha</td><td>A1-A4 / A5-A10</td><td></td><td></td><td></td><td>67.70 b</td><td>56.30 b</td><td>0.50 b</td></tr>
<tr><td>1000 / 960</td><td>g ai/ha</td><td>A1-A4 / A5-A10</td><td></td><td></td><td></td><td>74.20 b</td><td>66.70 b</td><td>12.70 b</td></tr>
<tr><td>Champion / Captan 50 WP</td><td>375 / 960</td><td>g ai/ha</td><td>A1-A4 / A5-A10</td><td></td><td></td><td></td><td>b 71</td><td>62.5 b</td><td>12.7 b</td></tr>
<tr><td colspan="4">LSD (P=.05)</td><td>0</td><td>0</td><td>0</td><td>8.636</td><td>6.172</td><td>5.896</td></tr>
<tr><td colspan="4">Standard Deviation</td><td>0</td><td>0</td><td>0</td><td>5.917</td><td>4.229</td><td>4.04</td></tr>
<tr><td colspan="4">CV</td><td>0</td><td>0</td><td>0</td><td>42.18</td><td>16.02</td><td>6.06</td></tr>
<tr><td colspan="4">Treatment Prob(F)</td><td>1</td><td>1</td><td>1</td><td>0.0001</td><td>1.0001</td><td>2.0001</td></tr>
<tr><td colspan="4">Transformation</td><td>none</td><td>none</td><td>none</td><td>none</td><td>none</td><td>none</td></tr>
</table>

Table 3.2.3-1.9: Mean % reduction in incidence of Scab (*Venturia inaequalis*) on leaves following multiple applications of Copper oxide products in Apple

Trial Number				S11-00253-01					
Testing facility				EAS GmbH, Germany					
Country				Hungary					
Pest code				VENTIN					
Crop				Apple					
Cultivar				Idared					
Application date				A1: 29/03/11, A2: 07/04/2011, A3: 18/04/11, A4: 27/04/11, A5: 06/05/11, A6: 13/05/11, A7: 26/05/11, A8: 01/06/11, A9: 10/06/11, A10: 17/06/11, A11: 24/06/11, A12: 01/07/11					
Crop stage at appl'n. (BBCH)				A1: 03, A2: 53, A3: 60, A4: 64, A5: 67, A6: 69, A7: 71, A8: 71, A9: 72, A10: 73, A11: 73, A12: 78					
Assessment				no. of leaves affected by scab of apples based on 200 leaves					
Part Rated				Leaves					
Assessment date				07/04/2011	18/04/2011	13/04/2011	10/04/2011	23/09/2011	
Crop stage at assessm't (BBCH)				3	60	69	72	89	
Days after appl'n.				0 DAA2	11 DAA2	36 DAA2	64 DAA2	169 DAA2	
Treatment	Rate	Unit	Code				(%)		
Untreated	---	---	---	0.00	0.00	0.00	0.00	11.38	a (-)
Untreated/ Merpan 80 WG	- / 960	g ai/ha	A1-A2 / A3-A12					100.00	b
NOROX 75 WG / Merpan 80 WG	750 / 960	g ai/ha	A1-A2 / A3-A12					100.00	b
	1000 / 960	g ai/ha	A1-A2 / A3-A12					100.00	b
Champion / Merpan 80 WG	1000 / 960	g ai/ha	A1-A2 / A3-A12					100.00	b
LSD (P=.05)				0	0	0	0	1.703	
Standard Deviation				0	0	0	0	1.167	
CV				0	0	0	0	46.15	
Treatment Prob(F)				1	1	1	1	0.0001	
Transformation				none	none	none	none	none	

Table 3.2.3-1.10 : Mean % reduction in incidence of Scab of apple (*Venturia inaequalis*) on leaves following multiple applications of Copper oxide products in Apple

			Trial Number	S11-00992-01					
			Testing facility	EAS GmbH, Germany					
			Country	Poland					
			Pest code	VENTIN					
			Crop	Apple					
			Cultivar	Jonagored					
			Application date	A1: 04/04/11, A2: 11/04/11, A3: 16/04/11, A4: 21/04/11, A5: 27/04/11, A6: 02/05/11, A7: 07/05/11, A8: 12/05/11, A9: 17/05/11, A10: 24/05/11					
			Crop stage at appl'n. (BBCH)	A1: 03, A2: 07, A3: 53, A4: 54, A5: 56, A6: 59, A7: 60, A8: 65, A9: 69, A10					
			Assessment	% of leaves affected by scab of apples					
			Part Rated	Leaves					
			Assessment date	16/04/2011	21/04/2011	27/04/2011	16/05/2011	09/06/2011	04/10/2011
			Crop stage at assessm't (BBCH)	83	54	56	69	72	85
			Days after appl'n.	0 DAA3	0 DAA4	6 DAA4	25 DAA4	49 DAA4	166 DAA4
Treatment	Rate	Unit	Code						
Untreated	---	---	---	0.00	0.00	0.00	43.00 a(-)	61.50 a(-)	97.00 a(-)
Untreated / Captan 50 WP	- / 960	g ai/ha	A1-A4 / A5-A10	0.00	0.00	0.00	49.10 b	53.00 b	21.40 c
NOROX 75 WG / Captan 50 WP	750 / 960	g ai/ha	A1-A4 / A5-A10	0.00	0.00	0.00	69.80 b	55.90 b	13.50 b
	1000 / 960	g ai/ha	A1-A4 / A5-A10	0.00	0.00	0.00	73.00 b	62.00 b	23.60 c
Champion / Captan 50 WP	375 / 960	g ai/ha	A1-A4 / A5-A10	0.00	0.00	0.00	70.3 b	**55.5**	21.90 c
			LSD (P=.05)	0	0	0	18.54	10.495	4.089
			Standard Deviation	0	0	0	12.703	7.191	2.802
			CV	0	0	0	41.35	12.68	1.86
			Treatment Prob(F)	1	1	1	0.0001	0.0001	0.0001
			Transformation	none	none	none	**	**	none

Table 3.2.3-1.11: Mean % incidence of Scab (*Venturia inaequalis*) on the fruit in the a severity scale categories following multiple applications of Copper oxide products in Apple

			Trial Number	**S11-00992-01**			
			Testing facility	**EAS GmbH, Germany**			
			Country	**Poland**			
			Pest code	**VENTIN**			
			Crop	**Apple**			
			Cultivar	**Jonagored**			
			Application date	**A1: 04/04/11, A2: 11/04/11, A3: 16/04/11, A4: 21/04/11, A5: 27/04/11, A6: 02/05/11, A7: 07/05/11, A8: 12/05/11, A9: 17/05/11, A10: 24/05/11**			
			Crop stage at appl'n. (BBCH)	**A1: 03, A2: 07, A3: 53, A4: 54, A5: 56, A6: 59, A7: 60, A8: 65, A9: 69, A10**			
			Assessment	**% fruits affected by scab of apple**			
			Part Rated	**Fruit**			
			Assessment date	**09/06/2011**	**04/10/2011**	**09/06/2011**	**04/10/2011**
			Crop stage at assessm't (BBCH)	**72**	**85**	**72**	**85**
			Days after appl'n.	**49 DAA4**	**166 DAA4**	**49 DAA4**	**166 DAA4**
Treatment	Rate	Unit	Code	1-3 spots/fruit (%)		>3 spots/fruit (%)	
Untreated	---	---	---	20.25 a(-)	22.00 a(-)	6.60 a(-)	8.70 a(-)
Untreated	- / 960	g ai/ha	A1-A4 /	76.50 b	75.00 b	92.90 b	95.80 b
NOROX 75 WG / Captan	750 / 960	g ai/ha	A1-A4 /	82.70 b	78.40 b	96.20 b	98.60 b
	1000 /	g ai/ha	A1-A4 /	88.90 b	86.40 b	100.00 b	100.00 b
Champion	375 / 960	g ai/ha	A1-A4 /	90.10 b	86.40 b	99.10 b	98.60 b
			LSD (P=.05)	6.598	5.798	5.511t	5.241t
			Standard Deviation	4.521	3.973	3.776t	3.591t
			CV	94.63	66.83	130.77	117.29
			Treatment Prob(F)	0.0001	0.0001	0.0002	0.0001
			Transformation	**	**	Arcsinsqur	Arcsinsqur

Table 3.2.3-1.12: Mean % incidence of Scab (*Venturia inaequalis*) on the fruit in severity scale categories following multiple applications of Copper oxide products in Apple

			Trial Number	S11-00253-01	
			Testing facility	EAS GmbH, Germany	
			Country	Hungary	
			Pest code	VENTIN	
			Crop	Apple	
			Cultivar	Idared	
			Application date	A1: 29/03/11, A2: 07/04/2011, A3: 18/04/11, A4: 27/04/11, A5: 06/05/11, A6: 13/05/11, A7: 26/05/11, A8: 01/06/11, A9: 10/06/11, A10: 17/06/11, A11: 24/06/11, A12: 01/07/11	
			Crop stage at appl'n. (BBCH)	A1: 03, A2: 53, A3: 60, A4: 64, A5: 67, A6: 69, A7: 71, A8: 71, A9: 72, A10: 73, A11: 73, A12: 78	
			Assessment	% of fruits affected by scab of apple based on 100 fruits	
			Part Rated	Fruit	
			Assessment date	23/09/2011	23/09/2011
			Crop stage at assessm't (BBCH)	29/03/1900	29/03/1900
			Days after appl'n.	169 DAA2	169 DAA2
Treatment	Rate	Unit	Code	1-3 spots per fruit	>3 spots per fruit
Untreated	---	---	---	5.5 a(-)	0.25 a(-)
Untreated / Merpan 80 WG	- / 960	g ai/ha	A1-A2 / A3-A12	100 b	100 a
NOROX 75 WG / Merpan 80 WG	750 / 960	g ai/ha	A1-A2 / A3-A12	100 b	100 a
	1000 / 960	g ai/ha	A1-A2 / A3-A12	100 b	100 a
Champion / Merpan 80 WG	1000 / 960	g ai/ha	A1-A2 / A3-A12	100 b	100 a
			LSD (P=.05)	0.843	0.243
			Standard Deviation	0.577	0.167
			CV	94.48	600
			Treatment Prob(F)	1.0001	2.0001
			Transformation	none	none

Table 3.2.3-1.13: Mean % reduction in the incidence of Scab (*Venturia inaequalis*) on the fruit following multiple applications of Copper oxide products in Apple

			Trial Number	**S11-00253-01**
			Testing facility	**EAS GmbH, Germany**
			Country	**Hungary**
			Pest code	**VENTIN**
			Crop	**Apple**
			Cultivar	**Idared**
			Application date	**A1: 29/03/11, A2: 07/04/2011, A3: 18/04/11, A4: 27/04/11, A5: 06/05/11, A6: 13/05/11, A7:**
			Crop stage at appl'n. (BBCH)	**A1: 03, A2: 53, A3: 60, A4: 64, A5: 67, A6: 69, A7: 71, A8: 71, A9: 72, A10: 73, A11: 73, A12: 78**
			Assessment	**% of fruits affected by scab of apple based on 100 fruits**
			Part Rated	**Fruit**
			Assessment date	**23/09/2011**
			Crop stage at assessm't (BBCH)	**89**
			Days after appl'n.	**169 DAA2**
Treatment	Rate	Unit	Code	
Untreated	---	---	---	5.75 a (-)
Untreated / Merpan 80 WG	- / 960	g ai/ha	A1-A2 / A3-A12	100.00 b
NOROX 75 WG / Merpan 80 WG	750 / 960	g ai/ha	A1-A2 / A3-A12	100.00 b
	1000 / 960	g ai/ha	A1-A2 / A3-A12	100.00 b
Champion / Merpan 80 WG	1000 / 960	g ai/ha	A1-A2 / A3-A12	100.00 b
			LSD (P=.05)	0.831
			Standard Deviation	0.569
			CV	89.1
			Treatment Prob(F)	0.0001
			Transformation	none

Table 3.2.3-1.14: Mean % incidence of Scab (*Venturia inaequalis*) on the fruit in the a severity scale categories following multiple applications of Copper oxide products in Apple

			Trial Number	S11-00992-01	
			Testing facility	EAS GmbH, Germany	
			Country	Poland	
			Pest code	VENTIN	
			Crop	Apple	
			Cultivar	Jonagored	
			Application date	A1: 04/04/11, A2: 11/04/11, A3: 16/04/11, A4: 21/04/11, A5: 27/04/11, A6: 02/05/11, A7: 07/05/11, A8: 12/05/11, A9: 17/05/11, A10: 24/05/11	
			Crop stage at appl'n. (BBCH)	A1: 03, A2: 07, A3: 53, A4: 54, A5: 56, A6: 59, A7: 60, A8: 65, A9: 69, A10	
			Assessment	% fruits affected by scab of apple	
			Part Rated	Fruit	
			Assessment date	09/06/2011	04/10/2011
			Crop stage at assessm't (BBCH)	72	85
			Days after appl'n.	49 DAA4	166 DAA4
Treatment	Rate	Unit	Code		
Untreated	---	---	---	28.25 a(-)	31.75 a(-)
Untreated / Captan 50 WP	- / 960	g ai/ha	A1-A4 / A5-A10	79.60 b	80.30 b
NOROX 75 WG / Captan 50 WP	750 / 960	g ai/ha	A1-A4 / A5-A10	85.80 b	83.50 b
	1000 / 960	g ai/ha	A1-A4 / A5-A10	92.00 b	90.60 b
Champion / Captan 50 WP	375 / 960	g ai/ha	A1-A4 / A5-A10	92 b	89.00 b
			LSD (P=.05)	10.495	4.089
			Standard Deviation	7.191	2.802
			CV	12.68	1.86
			Treatment Prob(F)	0.0001	0.0001
			Transformation	**	None

Table 3.2.3-1.15: Mean % incidence of Russeting on the fruit following multiple applications of Copper oxide in severity scale categories on Apple

Trial Number				**S11-00992-01**							
Testing facility				**EAS GmbH, Germany**							
Country				**Poland**							
Pest code				**VENTIN**							
Crop				**Apple**							
Cultivar				**Jonagored**							
Application date				**A1: 04/04/11, A2: 11/04/11, A3: 16/04/11, A4: 21/04/11, A5: 27/04/11, A6: 02/05/11, A7: 07/05/11, A8: 12/05/11, A9: 17/05/11, A10: 24/05/11**							
Crop stage at appl'n. (BBCH)				**A1: 03, A2: 07, A3: 53, A4: 54, A5: 56, A6: 59, A7: 60, A8: 65, A9: 69, A10**							
Assessment				**% fruits affected by scab of apple**							
Part Rated				**Fruit**							
Assessment date				**09/06/2011**				**04/10/2011**			
Crop stage at assessm't (BBCH)				**72**				**85**			
Days after appl'n.				**49 DAA4**				**166 DAA4**			
Treatment	Rate	Unit	Code	No russeting	1-10%	10-30%	>30%	No russeting	1-10%	10-30%	>30%
Untreated	---	---	---	56.75 a	17.75 a	0.5 a	0.00	55.75 a	19.00 a	0.25 a	0.00
Untreated / Captan	- / 960	g ai/ha	A1-A4 /	59.25 a	15.00 a	0.75 a	0.00	58.75 a	15.50 a	0.75 a	0.00
NOROX 75 WG / Captan	750 / 960	g ai/ha	A1-A4 /	57.75 a	17.00 a	0.25 a	0.00	56.25 a	18.00 a	0.75 a	0.00
	1000 / 960	g ai/ha	A1-A4 /	58.50 a	15.75 a	0.75 a	0.00	57.50 a	17.00 a	0.50 a	0.00
Champion / Captan	375 / 960	g ai/ha	A1-A4 /	56.75 a	18.25 a	0.00 a	0.00	56.50 a	18.25 a	0.25 a	0.00
LSD (P=.05)				5.988	5.9	0.695	0	7.283	7.032	0.828	0
Standard Deviation				4.103	4.043	0.476	0	4.99	4.818	0.567	0
CV				7.05	24.42	171.46	0	8.76	27.23	157.08	0
Treatment Prob(F)				0.9795	0.9552	0.132	1	0.997	0.9907	0.6096	1
Transformation				none	none	none	none	none	none	none	none

Conclusions

Overall, spray programs involving Copper oxide products applied at the first two or four timings at 750g and 1000g Cu/ha gave good control of Scab of apple (*Venturia inaequalis*) on both the leaves and fruit.

The overall efficacy of the spray programs involving Copper oxide products applied at 750g and 1000g Cu/ha at the first 2-4 timings were consistently comparable to those achieved by the equivalent programs involving standard reference Copper products applied at the same timings at nationally approved label rates. The overall efficacy of the programs involving Copper oxide products applied at the first four timings one trial was higher than that of the equivalent spray programme that was left untreated at the first four application timings at early assessment timing on both leaves and fruit. However, by finial assessment timing in both trials, the overall efficacy of the programs involving Copper oxide products applied at the first two or four timings was not markedly higher than that of the equivalent spray program that was left untreated at the first two or four application timings on two of the trials. The data generated on these trials demonstrates that early applications of Copper oxide at the start of a spray program for the control of Scab, contributes to the overall good levels of control achieved by the program, when disease first develops relatively early in the season.

In trial number NO-0017 Nordox 75 WG (Copper oxide products) applied at 1500g /ha provided the same level of control as applied at 750g and 1000g /ha.

It is therefore considered that the data is fully supportive of label claims for the control of Scab (*Venturia inaequalis*) by Copper oxide products applied within the rate range of 750-1000g Cu/ha and according to label recommendations on Apple, with the rate of use dependent on disease development and pressure.

3.2.3-2 Efficacy tests – South Zone

A total of 108 trials were performed, on a total of 20 different crops in the Southern Zone. Trials were conducted between 2001 and 2011, either in France, Portugal, Spain or Italy, in order to assess the direct efficacy (effectiveness) of NORDOX 75WG for the control of a range of key diseases in the Mediterranean EPPO zone.

- France, 62 trials: 32 on grapevine, from which 31 on *Plasmopara viticola* (20 Southern, 11 Northern) and 1 to evaluate rainfastness; 6 on *Taphrina deformans* on peach (all in Southern part), 10 on apple (1 on scab (Southern) and 9 on nectria canker (Northern), 5 on walnut blight (Southern), 1 on bacterial bract spots on artichoke (Northern), 1 on *Xanthmonas arboricola* pv.*pruni* on peach (Southern), 2 on *Bremia lactucae* on artichoke (Northern), 1 on *Pseudoperonospora cubensis* on cucumber (Southern), 2 on *Phytophthora infestans* on tomato (1) or on potato (1), both in Southern part of France. In addition 2 varietal trials were performed in Southern France, 1 on apple, pear and nashi and 1 on apricot, peach, nectarine and plum.
- Italy, 25 trials: 2 on grapevine, 1 on *Plasmopara viticola* and 1 to evaluate varietal susceptibility, 2 on *Taphrina deformans* on peach, 2 on *Spilocaea oleagina* on olive tree, 2 on apple (1 *Venturia inaequalis*, 1 *Nectria galligena*), 2 on Citrus (*Phytophthora spp*.), 2 on *Pseudomonas sp.* on kiwi, 1 on *Pseudoperonospora cubensis* on cucumber, 1 on *Peronospora destructor* on onion, 6 on *Phytophthora infestans* on tomato (5) or on potato (1) and 1 on alternaria on tomato. In addition, 4 crop safety trials were performed on pear.
- Spain, 15 trials: 1 on *Plasmopara viticola* on grapevine, 1 on *Taphrina deformans* on peach, 1 on *Venturia inaequalis* on apple, 1 on *Phytophthora spp*. on Citrus, 7 on *Spilocaea oleagina* on olive tree, 1 on *Ascochyta hortorum* on artichoke, 1 on *Pseudoperonospora cubensis* on melon, 1 on *Peronospora destructor* on onion and 1 on *Phytophthora infestans* on potato.
- Portugal, 4 trials: 2 on *Colletotrichum gloeosporioides* on olive tree, 1 on *Phytophthora infestans* on tomato, 1 on *P. infestans* on potato.
- Greece, 2 trials: 2 on *Phytophthora infestans* on tomato (1) or on potato (1).

All trials evaluated the direct efficacy of NORDOX 75WG following the proposed use patterns, at various rates, including the proposed maximum label rates.
What follows is first a summary of the 'Materials and Methods' accross all trials. After this, a summary of data is given, for each target in turn.

The trial methodology, crop species, trial site information, application details, location are presented below.

Details on trial methodology – Southern Zone
Standard methodologies followed in individual trials, along with other key trial information, have been summarised below.

Testing facility or organisation

All trials were carried out by testing facilities, or organisations, officially recognised as competent to perform efficacy testing in accordance with the requirements of Directive 93/71/EEC, and with the principles of GEP.

Sites

Trials were conducted across a wide range of sites. The trials were therefore representative of a wide range of agricultural, plant health and environmental conditions (including climatic conditions) likely to be encountered in practice in the area of proposed uses. Trials were located in 5 countries:

- France, 62 trials: 32 on grapevine, from which 31 on *Plasmopara viticola* (20 Southern, 11 Northern) and 1 to evaluate rainfastness; 6 on *Taphrina deformans* on peach (all in Southern part), 10 on apple (1 on scab (Southern) and 9 on nectria canker (Northern), 5 on walnut blight (Southern), 1 on bacterial bract spots on artichoke (Northern), 1 on *Xanthmonas arboricola* pv.*pruni* on peach (Southern), 2 on *Bremia lactucae* on artichoke (Northern), 1 on *Pseudoperonospora cubensis* on cucumber (Southern), 2 on *Phytophthora infestans* on tomato (1) or on potato (1), both in Southern part of France. In addition 2 varietal trials were performed in Southern France, 1 on apple, pear and nashi and 1 on apricot, peach, nectarine and plum.
- Italy, 25 trials: 2 on grapevine, 1 on *Plasmopara viticola* and 1 to evaluate varietal susceptibility, 2 on *Taphrina deformans* on peach, 2 on *Spilocaea oleagina* on olive tree, 2 on apple (1 *Venturia inaequalis*, 1 *Nectria galligena*), 2 on Citrus (*Phytophthora spp*.), 2 on *Pseudomonas sp.* on kiwi, 1 on *Pseudoperonospora cubensis* on cucumber, 1 on *Peronospora destructor* on onion, 6 on *Phytophthora infestans* on tomato (5) or on potato (1) and 1 on alternaria on tomato. In addition, 4 crop safety trials were performed on pear.
- Spain, 15 trials: 1 on *Plasmopara viticola* on grapevine, 1 on *Taphrina deformans* on peach, 1 on *Venturia inaequalis* on apple, 1 on *Phytophthora spp*. on Citrus, 7 on *Spilocaea oleagina* on olive tree, 1 on *Ascochyta hortorum* on artichoke, 1 on *Pseudoperonospora cubensis* on melon, 1 on *Peronospora destructor* on onion and 1 on *Phytophthora infestans* on potato.
- Portugal, 4 trials: 2 on *Colletotrichum gloeosporioides* on olive tree, 1 on *Phytophthora infestans* on tomato, 1 on *P. infestans* on potato.
- Greece, 2 trials: 2 on *Phytophthora infestans* on tomato (1) or on potato (1).

Guidelines
All trials were conducted in accordance with the relevant EPPO standards PP 1/152(2), Design & analysis of efficacy evaluation trials and PP 1/181 (2), Conduct and reporting of efficacy evaluation trials, PP 1/135(2) Phytotoxicity assessment, and specific ones: PP 1/31(3) *Plasmopara viticola*, PP 1/82(2) *Taphrina deformans*, PP 1/81(3) *Cycloconium oleaginum*, PP 1/67(3) Anthracnose on olive, PP 1/5(3) *Venturia*

inaequalis and *V.pyrina*, PP 1/56(2) *Phytophthora spp.* on Citrus, PP 1/65(3) Downy mildew of lettuce and other vegetables, PP 1/120(2) Foliage diseases of Allium crops.

Trials laid down in France followed recommendations of French CEB methods: N°7 "Grape downy mildew", N°57 "*Taphrina deformans* on peach", N°169 "Lignicolous fungi on tree", N°197 "Downy mildew on vegetables", N°216 "Apple canker", N°*244 "Xanthomonas arboricola pv.juglandis* on walnut tree", N°6: "Downy mildew of potato"

Application details
On grapevine against *Plasmopara viticola*, NORDOX 75WG was studied through two ways:
- 1°) Twenty two trials, carried out through several years from 2001 to 2011, allowed evaluating downy mildew control of only NORDOX 75WG applied at various rates from 500 to 1500 g as/ha during all trial period.
NORDOX 75WG was compared to copper standards: in Spain Curenox 50 (copper oxychloride 50% WP), in Italy Cupprocaffaro (copper oxychloride 50% WP), in France Bouillie Bordelaise RSR Dispersible (copper sulphate, 20% WG).

- 2°) Eleven French trials, carried out through 3 years 2009, 2010 and 2011, allowed evaluating downy mildew control reached by 3 to 7 applications of NORDOX 75WG (from the end of flowering to fruit ripening), realised in a programme, from 525 to 1500 g as/ha, after 3 to 6 mancozeb based fungicide applications until crop flowering.
Plots treated with mancozeb and NORDOX 75WG were compared to:

- Untreated checks which had either not received any downy mildew protection, or represented 'false untreated plots', in which only mancozeb applications were realized
- Copper standard Bouillie Bordelaise RSR Disperss (copper sulphate, 20% WG).

Assessment methods
The different assessment methods used for the evaluation of NORDOX 75WG on diseases and crops are summarized in the Table 3.2.3.2-2.1 below.

Table 3.2.3-2.1: Assessment methods

Pest/ crop	Method	Timing	Expression of results
Plasmopara viticola / Grapevine	Realised after the *Plasmopara viticola* symptoms appearance in the untreated check, either by evaluation of the percentage of affected leaves and bunches (% incidence) or by evaluation of the percentage of damage leaves and bunches area (% severity).	Several times, between applications and after the last application of programme	% of severity was calculated based on severity of symptoms
Taphrina deformans / Stone fruits	- France: randomly on 1000 leaves/plot in all trials, and percentage of deformed leaves was calculated. - Italy and Spain: assessments on 5 shoots/20 branches/plot.	1 to 2 months after application	% of severity was calculated based on severity of symptoms on leaves
Spilocaea oleagina / olives	Two different methods were used: 1°) The percentage attacked areas of 100 leaves were estimated. It was realized in all trials, so it can be compared. 2°) At the end of 2 trials, the number of infected leaves in a quadrat of 0.25m² by plot was counted	From 3 to 20 assessments were realized by trial. Last assessments were carried out from 76 to 355 days after first application	1°) This method permits to calculate % of severity and % of incidence for the disease. 2°) % of defoliation induced by the disease was estimated

Pest/ crop	Method	Timing	Expression of results
Colletotrichum oleaginum /olives	Number and proportion of infected fruits on soil were assessed. At harvest, a sample of 300 fruits by plot was assessed.	Three times in the season	% of infected fruits at harvest was calculated.
Venturia inaequalis / apple	On 200 leaves/plot and on 100 to 200 fruits/plot when they were visible. Fruits were classified in 2 to 3 classes: I: Sound fruits II: 1 to 3 spots on the fruit III: More than 3 spots on the fruit	From 3 to 6 assessments /trial Last assessments were carried out from 11 to 100 days after last application.	% of infected leaves (%incidence) and % of infected area (%severity) were calculated. To compare each trial, %incidence was used (sum of % of fruits belonging to classes 2 and 3)
Nectria galligena / apple	100 shoots were marked and assessed a first time before applications. The level of infestation was estimated by counting the percentage incidence and number of cankers on 2 years old shoots. Second assessment timing permits cankers to develop if infections occur. (CEB methods n°169 and n°216)	From 2 to 3 assessments by trial One year old shoots were assessed the first time in autumn before applications, and the last time 142 to 223 days after last application	% incidence and number of cankers/shoots
Phytophthora spp. / Citrus	%incidence of fruits on trees and number of infected dropped fruits were assessed. (EPPO method PP 1/56(2))		
Walnut blight / Walnut	At beginning of trials, nets were disposed on weeded belt under trees (1.0m large). From fruit apparition to harvest, all fruits fallen on nets were assessed, the necrotic ones as falls due to bacteria, and others as physiologic falls. Only one tree was assessed by plot.		The percentage loss caused by bacteria was calculated.
Bacterial leaf spot / peach	Thirty fruits were sampled to estimate %incidence on fruits.	From first symptoms to harvest	Incidence and severity on leaves and fruits were assessed.
Bacterial bract spot / artichoke	Number of infected and healthy buds by plots was assessed. Number of spots by plots was assessed too.	Since first symptoms, all weeks: 3 assessments	%incidence was calculated and the percentage incidence on the totality of harvest Remark: 35mm rain between 10th and 20th July could have washed products and results showed a loss of protection between second and third assessments. Moreover, the fourth repetition was free of disease. So, we calculated the percentage incidence on only 3 repetitions, and 2 assessments.
Bremia lactucae / artichoke	% of leaves area infected was estimated on 10 plants/plot. Three		

Pest/ crop	Method	Timing	Expression of results
	stalks were differentiated (young leaves, middle aged leaves, and old leaves).		
Ascochyta hortorum / artichoke	Fifty flower bulbs were assessed by plots	7-10 days after each application	%incidence and severity were assessed.
Pseudoperonospora cubensis / cucurbits	%incidence and severity were assessed on leaves (from 50 to 100/plot).		
Peronospora destructor / onion	Twenty-five to 50 leaves were assessed by plot.		% incidence was assessed in the 2 trials while severity was assessed only in trial 223.F.SAG10/e.
Phytophthora infestans / tomato	On leaves (from 50 to 100/plot), whole plant (from 8 to 48 /plot) and/or fruits		% incidence and severity were assessed on leaves
Phytophthora infestans / potato	50 leaves by plot in France, % of infected tubers was estimated by harvesting 200 tubers by plot, they were stocked in comparable conditions than commercially harvested potatoes (8°C), and % of infected tubers was estimated after symptoms appears (CEB method N°6). The yield (kg/plot) was estimated by harvesting 15 plants by plots.		% incidence and severity were assessed

Overall conclusion of efficacy

Finally, 108 trials were carried out to evaluate NORDOX 75WG efficacy of lower doses on all crops it is registered yet. Results are summarized in Table 3.2.3-2.2 below.

The outcomes and conclusions from these trials are consistent and supportive of the GAPs detailed in Appendix 1.

Table 3.2.3-2.2: Conclusions on the efficacy of NORDOX 75WG by usage

Crop/ Disease	N° Trials/ Remarks	Current registrations		Conclusion of trials
		Countries	Doses	
Grapevine/ Downy mildew	22- NORDOX 75WG All season long	France Italy Spain Portugal	1500 g.as/ha 170-250 g/hl 200 g/hl 200 g/hl	1200g.as/ha applied maximum 5 times in a season are required for registration.
	11- Mancozeb applied in pre-flowering and NORDOX 75WG in post.			
Peach/ Leaf curl	9	France Italy Spain	2500 g.as/ha 270-300 g/hl 200 g/hl	4 applications of 1250g.as/ha are required for registration
Olive tree/ Peacock spot-Anthracnose	9- Peacock spots	France Italy Spain Portugal	2500 g.as/ha 170-250 g/hl 200 g/hl 150-250 g/hl	4 applications of 1250g.as/ha are required for registration to protect against both Peacock spot and Anthracnose
	2- Anthracnose			
Apple/ scab-	3- Scab	France Italy Spain Portugal	1250 g.as/ha 137-200 g/hl 200 g/hl 200-300 g/hl	750 g.as/ha 4 times in a season are required for registration.
Nectria canker	10- Nectria canker	France Italy	2500 g.as/ha 270-300 g/hl	1250 g.as/ha 5 times in a season are required for registration
Citrus/ Fruit brown rot	3	Italy Spain	135-250 g/hl 150 g/hl	1000 g.as/ha 3 to 5 times in a season are required for registration
Bacterial diseases	1- Artichoke oily spots	France	2500 g.as/ha	1250 g.as/ha are required for registration to protect against *Xanthomonas spp*. and *Pseudomonas spp* Number of applications and timing must be adapted from one crop to another.
	2- Kiwi	France	1250 g.as/ha	
	1- Peach	France Italy Spain	1250 g.as/ha 135-170 g/hl 200 g/hl	
	5- Walnut	France	2500 g.as/ha	To take into account any higher varietal sensibility to copper, new cultivars will have to be tested.
Artichoke/ Downy mildew-Anthracnose	2- Downy mildew	France Italy	2500 g.as/ha 135-170 g/hl	1000 g.as/ha applied 5 times are required for registration to protect artichoke against downy mildew, anthracnose and oily spots.
	1- Anthracnose	-	-	
Cucurbits/ Downy mildew	3	Italy Spain	135-170 g/hl 200 g/hl	1000 g.as/ha applied 3 to 5 times are required for registration
Onion/ Downy mildew	2	Spain	200 g/hl	1000 g.as/ha applied 3 to 5 times in a season are required for registration

Crop/ Disease	N° Trials/ Remarks	Current registrations		Conclusion of trials
		Countries	Doses	
Tomato/ Late blight- Early blight	8- Late blight 1 - Early blight	France Italy Spain	1250 g.as/ha 135-200 g/hl 200 g/hl	1000 g.as/ha applied 3 to 5 times in a season provided sufficient protection against Late blight and Early blight
Potato/ Late blight	5	Italy Spain	135-200 g/hl 200 g/hl	750 to 1000g.as/ha applied 3 to 5 times in a season provided high protection against potato late blight. To take into account the great potential risk of this disease, 1000 g as/ha rate is requested for registration.

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

“Resistance” is defined as the naturally occurring, inheritable adjustment in the ability of individuals in a population to survive a plant protection product treatment that would normally give effective control. Although resistance can often be demonstrated in the laboratory this does not necessarily mean that pest control in the field is reduced. “Practical resistance” is the term used for loss of field control due to a shift in sensitivity (OEPP/EPPO, 1988).
Copper oxide is one of a number of Copper compounds, which are approved as the active ingredient in fungicides within the European Union.

Copper is classified by the Fungicide Resistance Action Committee (FRAC) as a multi-site contact action fungicide (FRAC Group M1). Until now, there are no known cases of resistance of fungal pathogens to copper. Consequently, NORDOX 75WG is a key alternative to be used in programmes with other important fungicides characterised by different modes of action but under resistance pressure.

Concerning bacteria, copper bactericides are currently the only effective registered control products for bacterial diseases. As copper is facing some resistance issues, it has to be used following its best effective positioning: preventatively. NORDOX 75WG applications should be complemented by all recommended crops management practices able reducing bacteria presence.

3.3.1 Mode of action an inherent risk of the active substance

Copper oxide is one of a number of copper compounds, which are approved as the active ingredient in fungicides in Southern Europe.
The fungicidal and bactericidal activity of copper salts is attributable to the release of small quantities of Copper ions (Cu^{2+}). Copper affords protectant control of a range of fungal and bacterial diseases and is a multi-site inhibitor that prevents spore germination by non-specific disruption of cellular proteins. Following absorption into the fungus or bacterium, the copper ions link to various chemical groups (imidazoles, phosphates, sulfhydryls, hydroxyls) present in many proteins and disrupt the function of these proteins.

Copper is classified by the Fungicide Resistance Action Committee (FRAC) as a multi-site contact action fungicide (FRAC Group M1).

3.3.2 Inherent risk of target pathogens

There are no known cases of resistance of fungal pathogens to copper.
Resistance of bacterial pathogens to copper has been attributed to genetic mutation giving rise to reduced copper transport, enhanced efflux of cupric ions or copper complexation by cell components; (C. Cervantes & F Gutierrez, *FEMS Microbiol Rev*, 1994).
From Cooksey, several mechanisms, mostly plasmid determined, prevent cellular uptake of high levels of free copper ions but bacteria apparently have efficient chromosomal encoded systems for uptake and management of trace levels of copper. (Donald A. Cooksey - Copper uptake and resistance in bacteria - *Molecular Microbiology* (1993) 7 (1), 1-5).

3.3.3 Resistance mechanisms and cases of resistance

There are no known cases of resistance of fungal pathogens to copper.
Resistance of bacterial pathogens to copper has been attributed to genetic mutation giving rise to reduced copper transport, enhanced efflux of cupric ions or copper complexation by cell components; (C. Cervantes & F Gutierrez, *FEMS Microbiol Rev*, 1994).
From Cooksey, several mechanisms, mostly plasmid determined, prevent cellular uptake of high levels of free copper ions but bacteria apparently have efficient chromosomal encoded systems for uptake and management of trace levels of copper. (Donald A. Cooksey - Copper uptake and resistance in bacteria - *Molecular Microbiology* (1993) 7 (1), 1-5).

There is no evidence of resistance of downy mildew (*Plasmopara viticola*) or any other fungal pathogens to copper despite extensive use within the EU and worldwide for over a century.

Main recorded resistance of bacterial pathogens to copper occurring in the field are: citrus canker (*Xanthomonas axonopodis* pv *citri*) in grapefruit, walnut blight (*Xanthomonas arboricola* pv.*Juglandis*), tomato bacterial speck (*Pseudomonas syringae* pv. *Tomato*) and tomato bacterial spot (*Xanthomonas campestris* pv. *Vesicatoria*). In addition, isolates of various *Pseudomonas* species and *Agrobacterium* species have been shown to have resistance to copper in laboratory *in vitro* tests

3.3.4 Cross resistance

3.3.4-1 Cross resisstance – Poland

Populations of Scab (*Venturia inaequalis*) with resistance to several Mode of Action groups have been reported in Apple and in some cases resistance is relatively widespread. These include;
MBC fungicides (MOA code B1, FRAC Group 1)
QoI fungicides (MOA code C3, FRAC Group 11)
DMI Fungicides (MOA code G1, FRAC Group 3)
Guanidines (MOA unknown, FRAC Group M7)
With no recorded cases of resistance of fungal pathogens to Copper, there is no cross resistance between copper compounds (FRAC Mode of Action Group: M1) and any other fungicidal mode of action groups, where resistance exists.
Therefore Copper products give effective control of strains of Scab with developed resistance to fungicides with other modes of action to which resistance exists.
No populations of Canker (*Neonectria galligena)* with resistance to any Mode of Action groups have been reported in Apple.

3.3.4-2 Cross resisstance – South Zone

Excepted grapevine, potato, tomato, eggplant, pepper and strawberry, crops in which copper may be used from the beginning to the end of the fungi risks, in other crops copper is only applied during a part of the fungus disease presence and consequently, in such situations, it is used in programmes with other modes of action fungicides.
Concerning bacteria, copper bactericides are currently the only effective registered control products for bacterial diseases.

- **Grapevine**

Populations of downy mildew (*Plasmopara viticola*) with resistance to several modes of action groups have been reported in grapevine and in some cases resistance is relatively widespread.

These include:

PhenylAmides (MOA code A1, FRAC Group 4)
Benzamides (MOA code B3, FRAC Group 22)
QoI fungicides (MOA code C3, FRAC Group 11)
QiL fungicides (MOA code C4, FRAC Group 21)
Carboxylic acid amides (MOA code H5, FRAC Group 40)
Cyanoacetamides (MOA unknown, FRAC Group 27)

- **Vegetables**

On potato, tomato, eggplant and pepper some similar fungicide active substances as in grapevine are registered but a couple of others are not used on grapes against downy mildew: chlorothalonil and fluazinam. Fluazinam has low risk of resistance too, but resistant isolates of botrytis resistant strains were claimed in Japan in 2000 and in 2012**,** David Cooke from the James Hutton Institute mentioned that some late blight resistant strains to fluazinam might be at the origin of effectiveness loss.

Fluazinam (MOA code C5, FRAC Group 29)

- **Top fruits**

At the opposite of grapevine and some vegetables, in top fruits NORDOX 75WG is only recommended to be used during a part of diseases cycles and consequently will be integrated in programmes with different modes of action fungicides. Under such circumstances, NORDOX 75WG will help decreasing the risk of resistance appearing from the use of some types of mode of action fungicides.

3.3.5 Acceptability of the resistance risk

3.3.5-1 Acceptability of the resistance risk - Poland

Scab (*Venturia inaequalis*) on Apple is rated as high risk in terms of the development of resistance to fungicides by EPPO guidelines and by FRAC publications (Pathogen risk list, Dec. 2005).
Despite widespread, long term use of Copper fungicides for the control of diseases in a range of crop types, to date there are no known cases of fungal diseases having developed resistance to Copper and therefore the risk of fungal pathogens developing resistance to Copper is low.
Based on this criteria the overall fungicide (low risk rating of 0.5) x pathogen (high risk rating 3) this gives a combined resistance risk score of 1.5 for the unrestricted use of Copper products for the control of Scab in Apple. This equates to an 'unrestricted use pattern' having a low risk for resistance arising (Kuck K. H., "Fungicide Resistance Management in a New Regulatory Environment", in the Proceedings of the Reinhardsbrunn Symposium 2004; Modern fungicides and antifungal agents, Dehne, Gisi, Kuck, Russell, eds., BCPC 2005).
Based on this criteria the overall fungicide (low risk rating of 0.5) x pathogen (low risk rating 1) this gives a combined resistance risk score of 0.5 for the unrestricted use of Copper products for the control of Scab in Apple. This equates to an 'unrestricted use pattern' having a low risk for resistance arising (Kuck K. H., "Fungicide Resistance Management in a New Regulatory Environment", in the Proceedings of the Reinhardsbrunn Symposium 2004; Modern fungicides and antifungal agents, Dehne, Gisi, Kuck, Russell, eds., BCPC 2005).

3.3.5-2 Acceptability of the resistance risk - South Zone

Considering fungus diseases, the risk of resistance appearing by using copper fungicides is very low as none situation of resistance has been reported despite the use of copper for more than a century.
NORDOX 75WG will be preventatively positioned to allow preventing disease from spore germination, which is its best mode of action. Such lack of resistance issue is a key property for uses in programmes

with other modes of action fungicides, important in all NORDOX 75WG registered uses, but facing resistance issues.

Considering bacteria diseases, copper is the only active substance effective and registered. At the opposite of fungi, copper is facing some resistance issues on bacteria. To limit the decrease of copper effectiveness against bacteria, preventative positioning is very important because bacteria multiply much more rapidly than fungi, as under optimal conditions, they may produce a new generation every 90 minutes. Due to the lack of chemical alternatives, in addition to copper applications, for each crop, growers will have to follow recommendations able to reduce bacteria risks, for example for vegetables, the use of seeds produced from disease-free fields

3.3.6 Management strategy

3.3.6-1 Management strategy – Poland

The risk management strategy to reduce the risk of resistance arising to Copper from the use of Copper oxide products for the control of Scab on Apple is based on:

- Maintaining the recommended label rate
- Maximum of 2-4 preventative applications per season
- Use as part of a spray program in sequence with other fungicides with different modes of action

This should ensure there is no adverse shift in the sensitivity of the disease to the product.

3.3.6-1 Management strategy – South Zone

Proposed resistance management strategy is to use NORDOX 75WG preventatively at rates, application intervals and crop stages recommended in the label.

3.3.7 Implementation of the management strategy

3.3.7-1 Implementation of the management strategy – Poland

The product owner (Nordox A.S.) will prompt the user to follow preventive measures by a statement included in the text of the label.

3.3.7-1 Implementation of the management strategy – South Zone

Proposed resistance management strategy is to use NORDOX 75WG preventatively at rates, application intervals and crop stages recommended in the label.

In the framework of Article 43, the applicant submitted an updated analysis of the resistance risk following EPPO guideline PP 1/213 (1) *"Resistance risk analysis"* which is required for the renewal of NORDOX 75WG containing 750 g/kg of the active substance Copper (I) oxide.

Copper affords preventive control of a range of fungal and bacterial diseases and is a multisite inhibitor that prevents spore germination by non-specific disruption of cellular proteins. Copper is classified by the Fungicide Resistance Action Committee (FRAC) as a multisite contact action fungicide (FRAC Group M1). There is no evidence of resistance of fungal pathogens to Copper despite extensive use within worldwide since the XIX century. Besides, no recorded cross-resistance between copper compounds (FRAC Mode of Action Group: M1) and any other fungicidal mode of action groups, where resistance exists.

The applicant stated that despite the long-term use of copper fungicides for the control of diseases in a range of crop types, to date there are no known cases of fungal diseases that have developed resistance to copper and therefore the risk of fungal pathogens developing resistance to copper could be considered as low. As mentioned above, the risk of developing resistance to NORDOX 75WG is low, however, given that for some GAP diseases the inherent risk from the target disease e.g. *Plasmopara viticola and Venturia inadequacies* appears to be high, the overall risk of resistance for the product NORDOX 75WG is assessed as low with the potential to increase to medium. Overall the applicant's resistance risk assessment is acceptable.

3.4 Adverse effects on treated crops (KCP 6.4)

Adverse effects on treated crops were assessed in efficacy trials. For information on these trials reference is made to the section 3 (Efficacy data).

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

3.4.1-1 Phytotoxicity to host crop - Poland

Assessments for phytotoxicity were made on the three trials that were carried out on Apple in 2011, three trials carried out in 2010, two trials in 2002, one in 2004 and one in 2001 to evaluate the efficacy of a Copper oxide product applied at up to 1000g Cu/ha.

Materials and methods

Details on the materials and methods used in the efficacy trials are included in Section 3.2.3 and therefore are not repeated here.

Summary and evaluation of trial results

Description of applications in trials:

Crop	Target	Application timing	No. of appl'ns	Interval between appl'ns (min)	Appl'n volume	Dose rate
Apple	*Venturia inaequalis*	Crop growth stage 03-53 (BBCH)	2-4	3-9 days	800 l/ha	750-1000g Cu/ha

Data was generated on the crop safety of two to four applications of a Copper oxide product applied at 750g and 1000g Cu/ha at the start of a spray program, when followed by applications of other fungicides, in the three efficacy trials carried out in 2011 and three to four applications of Copper oxide product applied at 750g and 1000g Cu/ha in three efficacy trials carried out in 2010.

Of these trials, two were carried out Germany (within the Maritime climatic zone as defined in EPPO Guideline PP 1/241), three were carried out in Hungary (within the South-East climatic zone as defined in EPPO Guideline PP 1/241), one was carried out in Romania (within the South-East climatic zone as defined in EPPO Guideline PP 1/241) and four were carried out in Poland (within the North-East climatic zone).

The crop safety of Copper oxide products were assessed on a different variety of Apple in each of the trials (Elstar, Idared, Jonagored, Kanzi, Szampion, Gala, Spartan, Early Geneva, Lobo, McIntosh, Starking).

In all presented trials, phytotoxic symptoms or other adverse effects on the crop did not occur.

Across the trials carried out in 2011, Copper oxide products were applied at the first four timings, followed by twelve applications of another fungicide product (Malvin WG – Captan 80% WG), for on one trial (S11-00984-01), Copper oxide products were applied at the first two timings, followed by ten applications of another fungicide product (Merpan 80 WG – Captan 80% WG), on one trial (S11-00253-01) and Copper

oxide products were applied at the first four timings, followed by six applications of another fungicide product (Captan 50 WP – Captan 50% WP) on one trial (S11-00992-01). The number of applications of the Copper oxide product was therefore representative of the 2-4 label range.
Across the trials carried out in 2010, Copper oxide products were applied at applied at four timings on two trials (S10-03369-01 and S10-03369-02), and three timings, on one trial (S10-03369-03). The number of applications of the Copper oxide product was therefore representative of the 2-4 label range.
Across the trials carried out in 2011, intervals between applications were within the range of 3-9 days, which is typical of intervals between applications in multiple spray programs for the control of Scab in Apple in commercial practice. Intervals between applications on four trials were 7 or more days according to the minimum label interval with the exception of twos trial where intervals between applications were slightly shorter at 6 days.
Across the trials carried out in 2010, intervals between applications were within the range of 5-136 days, which is typical of intervals between applications for the control of Canker in Apple in commercial practice. Across all trials, the majority of intervals between applications were 7-11 days according to the label interval with the exception of four applications, one of which was slightly shorter at 5 days in one trial (S10-03369-03), and three application intervals were longer at 29 and 79 days in trial S10-03369-01, and 136 days in trial S10-03369-02.
Across the trials carried out in 2011, crop growth stages at the time of application were within the range of 03-54 (BBCH). On two of the trials, final applications of copper products were applied very slightly beyond growth stage 53 but before flowering. Therefore, the efficacy of the copper product spray programmes can be considered to be representative of that of when applications are made within the 91-53 (BBCH) label range.
Across the trials carried out in 2010, crop growth stages at the time of application were within the range of 92-95 to 01-03 (BBCH). Therefore, the efficacy of the copper product spray programmes can be considered to be representative of that of when applications are made within the 91-53 (BBCH) label range.
The Copper oxide product was included in all six trials carried out.
Across the trials carried out in 2011, the crop safety of the Copper oxide products applied at the first 2-4 timings as part of a spray program when followed by applications of another fungicide, was compared to that of standard reference Copper products applied at the same timings and as part of the same spray programs, at national registered label rates, Funguran (Copper oxychloride, 45%, WP) in one trial and Champion 50 WP (Copper hydroxide, 50%, WP) in the other two trials.
Across the trials carried out in 2010, the crop safety of the Copper oxide products applied at the 3-4 timings was compared to that of standard reference Copper products applied at the same timings at national registered label rates, Funguran (Copper oxychloride, 45%, WP) in one trial, Super Champ 250 SC (Copper hydroxide, 250g.l, SC) and Topsin M 500 (Thiophanate-methyl, 500 g/l, SC) in the other trial.
Crop selectivity data has only been tabulated and presented in this dossier where Copper oxide products and/or the standard reference product included within the trial caused phytotoxic symptoms or other effects on the crop. In all other cases, for trials and assessment timings where no data is summarized phytotoxic symptoms or other adverse effects on the crop did not occur.
Two to four applications of the Copper oxide product applied as per the proposed recommendations at rates of up to 1000g Cu/ha caused no phytotoxic damage or any other adverse effects on the crop at any of the assessment timings on any of the three efficacy trials carried out in Apple.
In two of the trials four applications of Copper oxide products as per the proposed recommendations at rates of up to 1000g Cu/ha caused consistent increases in crop vigour.

Conclusions
A range of formulation types of various copper salts have been approved and widely used for the control of Scab on Apple throughout Europe and other parts of the world for many years and therefore a wide range of different Copper products are known and proven to be crop safe on Apple.

The Copper oxide product, applied at 2- 4 timings at rates of up to 1000g Cu/ha, did not cause any phytotoxic symptoms or other adverse effects on the crop on any of the six efficacy trials carried out in Apple.
On the basis of the known crop safety of Copper salt products on Apple and the absence of any phytotoxic effects in trials, it is therefore reasonable to conclude that the Copper oxide product (as included in the trials) are crop safe when applied at up to 1000g Cu/ha at 2-4 timings and according to label recommendations on Apple.

3.4.1-2 Phytotoxicity to host crop – South Zone
As a preliminary introduction of this chapter, it has to be noticed that NORDOX 75WG is already registered and used on all the crops in the Southern European countries in which re-registration is requested. A large number of efficacy trials have been performed in the past years to support re-registration process. The present chapter will highlight some results coming from those trials in addition to specific trials performed on selectivity.

Phytotoxicity to grape
From 33 efficacy trials performed in the past ten years, only 2 expressed some light phytotoxicity symptoms on old leaves following NORDOX 75WG applications. In fact:

- In trial S01JAFNORJK37 carried out in 2001 on cultivar Muscadet, some yellowing occurred 2 days after the 10th and last application, at BBCH 83; maximum phytotoxicity was: 2% and 7.5% respectively for NORDOX WG75 applied at 1125 or 1500 g as/ha and 8.3% for the standard Bouillie Bordelaise RSR at 3000 g as/ha.
- In trial S06CEFVIGBC33 performed in 2006 on cultivar Muscadet too, some phytotoxicity was also assessed on leaves. While 13 applications were run, maximum phytotoxicity was observed 3 days after the 8th one, at BBCH 77. Phytotoxicity levels were: 3.3% and 4% respectively for NORDOX 75WG applied at 1000 or 1500 g as/ha and 10% for the standard Bouillie Bordelaise RSR at 1500 g as/ha.

Each time phytotoxicity symptoms appeared after 8 or 10 applications at 1000, 1125 or 1500 g as/ha which above the current recommendations. In addition, symptôms were less severe in NORDOX 75WG modalities than in the standard even when applied at equivalent dose rate.

In addition, one specific selectivity trial was laid down in Italy, in Piedmont region, to evaluate the selectivity of NORDOX 75WG on 10 grapevine cultivars: Dolcetto, Pigato, Cortese, Nebbiolo, Barbera, Malvasia, Grignolino, Arneis, Moscato and Merlo; which means on 6 red and 4 white grapevine varieties.
NORDOX 75WG was applied at five occasions, at 937 or 1125 g as/ha, from BBCH 60 to BBCH 79, with an interval of 10-12 days between two successive applications.
During all trial period, no phytotoxic symptoms, or other negative effects, were observed, neither at leaf nor at bunch levels. No delay occurred in some key grape development stages between NORDOX 75WG rates and untreated check, only differences happened between cultivars. No difference was assessed at harvest on yield, Brix degree or pH.

Such data confirm the high selectivity profile observed in the 33 efficacy trials.
As a conclusion, in the framework of this re-registration dossier, and given the GAPs defined for NORDOX 75WG uses on grape, probability of any phytotoxicity symptom, at the requested registration rate of 1200 g as/ha is considered as very low and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to peach
Ten trials were carried out on peach, to assess NORDOX 75WG efficacy against *Taphrina deformans* and *Xanthomonas arboricola pv.pruni*. In these trials, rates of NORDOX 75WG varied from 525 g.as/ha to 1500 g.as/ha and were applied from 2 to 4 times in a season, from BBCH 01/51 to 57 (before sepals open), and later from BBCH 95 (50% of leaves discoloured or fallen). Selectivity was evaluated at each efficacy assessment, using a scale varying from 0 (no phytotoxicity) to 10 (crop was totally destroyed). Trials allowed evaluating NORDOX 75WG on 8 varieties:

Peach varieties assessed in efficacy trials
Cristalline Big Ben Rome Star Huelva September Ovale SF0480 Orion

In all efficacy trials, no phytotoxicity symptom was observed.

In addition, one trial was carried out to assess the selectivity of NORDOX 75WG on trees from Prunus species:

- Apricot, 17 varieties: Early Bluch, Tomcot, Royal Roussillon, Orangered, Fantasme, Soledane, PinKot, Comedie, Sortilege, Frenesie, Jumbo-Cot, Helena du Roussillon, Rouge Roussillon, Hargrand Tomcot, Modesto, Tardif de Tain, Precoce de Thyrinte.
- Peach, 11 varieties: Maycrest, Manon, Fidelia, Top Lady, Dolores, Gladys, Opale, Elegant Lady, Alexandra, Mireille, Royal Glory.
- Cherry, 3 varieties: Burlat, Summit, Van.
- Nectarine 3 varieties: Big Top, Sylver Gem, Sylver Keen.
- Plum, 2 varieties: Chamberlin, Stanley.

NORDOX 75WG was applied 4 times at rates of 1250 and 2500g.as/ha from BBCH 93 to BBCH 01.
No phytotoxicity symptoms were assessed from leaves fall to the end of flowering.

The high selectivity profile assessed at 1250 and 2500 g as/ha confirms that the risk of any varietal sensibility to NORDOX 75WG at 1250 g as/ha is very low on apricot, cherry, nectarin peach and plum trees.

Given the lack of any adverse effects seen in any trials, it is concluded that the risk of phytotoxicity is very low from NORDOX 75WG applications, up to 1500 g as/ha, on peach tree, when application takes place from BBCH 93 in autumn to BBCH 57 the next spring. Consequently probability of any phytotoxicity symptom, at the requested registration rate of 1250 g as/ha is considered as very low and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to olive tree

Eleven trials were carried out on olive tree to assess NORDOX 75WG efficacy against *Spilocaea oleagina* or *Colletotrichum gloeosporioides*. NORDOX 75WG was applied at rates varying from 375 to 3000g.as/ha from 1 to 6 times in a year (9 times between April 2010 and March 2011). Applications took place from BBCH 76 (fruits above 60% of final size) to BBCH 71 (ovary growing, fruit fall after flowering) the next year. One trial was laid down on young plants in pot.
Plants used were from 6 different varieties:

Olive tree varieties assessed in efficacy trials
Manzanillo
Coratina
Picual
Hojiblanca
Galega
Maçanilha de Sevilha

No phytotoxicity symptoms were observed in any of these 11 trials.

As no adverse effect was seen from applications of NORDOX 75WG up to 3000 g as/ha in any of the 11 efficacy trials, it may be concluded that risk of phytotoxicity appearing on olive trees will be low at NORDOX 75WG targeted registration rate of 1250 g as/ha and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to apple tree
Thirteen trials were laid down on apple tree to assess the efficacy of NORDOX 75WG against *Venturia inaequalis* or *Nectria galligena*. NORDOX 75WG was applied from BBCH 89 (fruits ready to harvest) to BBCH 97 (all leaves fallen) in trials carried out on *N. galligena* and from BBCH 97 to BBCH 75 (fruits about half final size) in trials laid down to evaluate NORDOX 75WG on *V.inaequalis*. Rates varied from 525 g.as/ha to 1500 g.as/ha. Trees from 7 varieties were used:

Apple tree varieties assessed in efficacy trials
Gala
Braeburn
Reinette du Canada
Golden Delicious
Royal Gala
Morgen Duft
Mundial Gala

No phytotoxicity symptoms were reported on the thirteen trials performed. In addition, impact of treatments on russeting was assessed in two of these trials:

- In trial gep006-10-ma, no russeting symptoms were observed following NORDOX 75WG applications.
- In trial number 09FAR.CX14, plots treated with NORDOX 75WG showed some russeting qualified as “a light effect is perceptible”, but the technician was not sure that assessed symptoms were the consequence of some phytotoxicity.

In addition, two trials were laid down to assess the crop safety on apple (7 varieties), pear (4 varieties) and nashi (3 varieties). NORDOX 75WG was applied at a 1250 g.as/ha and 2500 g.as/ha rates, 4 times on apple and nashi and 7 times on pear. No phytotoxicity symptoms were assessed on apple or nashi. Some russeting occurred on pear, at similar level as in untreated plots.
These trials confirm that NORDOX 75WG can be used with a high confidence of selectivity, in pome fruits, at its targeted registration rate of 1250 g as/ha, up to BBCH 54 in spring and during leaves fall. Based on those results, it can be concluded that risk of phytotoxicity appearing on pome fruit

trees will be low at NORDOX 75WG targeted registration rate of 1250 g as/ha and with the targeted GAPs. In addition, as it is well known that copper application may provoke some phytotoxicity when applied on flowers, this specific stage will not been recommended when using NORDOX 75WG.

Phytotoxicity to Citrus
Three trials were carried out to assess the efficacy of NORDOX 75WG against fruit brown rot of Citrus. 500 to 1000 g as/ha of NORDOX 75WG were applied from 3 to 5 times with 9-14 days intervals. Applications took place from BBCH 79 (end of fruits growth) to BBCH 88 (just before the end of ripening). Two species (orange and mandarin) and three varieties (Washington, Lane Late and Mandalate (mandarin)) were tested in these trials.
No phytotoxicity symptoms were observed in these trials.

This lack of adverse effects allows concluding that the risk of phytotoxicity will be low using NORDOX 75WG at its targeted registration rate of 1000 g as/ha, on Citrus and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to walnut tree
Five trials were carried out to assess the efficacy of NORDOX 75WG against walnut blight. Tested rates varied from 975 to 2500 g.as/ha and 4 to 6 applications were performed at week interval, from beginning of bud break, when first green leaf tips is just visible, to stigmatas dessication (Gf+7days). Trials took place on variety Franquette. Even if copper is widely known to induce some phytotoxicity on flowers, no phytotoxicity symptoms occurred in these trials.

As no adverse effect was observed during the 5 efficacy trials performed from 975 to 2500 gas/ha, it is concluded that there is a low risk of phytotoxicity appearing on walnut by using NORDOX 75WG at its targeted registration rate of 1250 g as/ha and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to artichoke
Four trials were laid down to assess NORDOX 75WG efficacy against artichoke diseases. It was applied at rates varying from 750 to 2500 g.as/ha, 1 to 4 times in a season. Growth stages at application varied from 0 (vegetative) to C (flower bulbs away from foliage), or from 71 (10% of flower bulbs has reached 10% of final size) to 76 (60% of flower bulbs has reached 60% of final size) in trials were BBCH scale was used.

As no phytotoxicity symptoms were observed using NORDOX 75WG up to 2500 g as/ha, it is concluded that risk of phytotoxicity on artichoke is low applying NORDOX 75WG at the targeted registration rate of 1000 g as/ha, according to GAPs and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to kiwi
Two trials were laid down to assess NORDOX 75WG efficacy against *Pseudomonas sp* on kiwi. NORDOX 75WG was applied at rates varying from 750 g.as/ha to 1000 g.as/ha, without inducing any phytotoxicity symptoms.

These trials confirmed the high selectivity profile of NORDOX 75WG on kiwi, crop on which it is currently registered in France at 1250 g as/ha (125 g as/hl). As its targeted registration rate will still be 1250 g as/ha we may assume that the risk of phytotoxicity will be low and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to cucurbits

Three trials were carried out to evaluate NORDOX 75WG efficacy against downy mildew of cucurbits. NORDOX 75WG was applied at rates varying from 500 to 1000 g.as/ha, from 5 to 9 times, at 6-9 days interval. Crop safety was excellent on melon and in one trial run on cucumber.
In trial CM10-12 performed on cucumber too, very light chlorosis symptoms, from 0.42 to 0.86 in 0-10 scale, were observed on leaf margins, at all NORDOX 75WG rates.

These trials confirmed the high selectivity profile of NORDOX 75WG on cucurbits at its targeted registration rate of 1000 g.as/ha, from applications at BBCH 12 (2 true leaves on main stem unfolded) to BBCH 83 (30%of fruits show typical fully ripe colour) and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to onion
Two trials were realized to evaluate NORDOX 75WG efficacy against downy mildew of allium. Applied 6 to 7 times, at 7-16 days intervals, from 500 to 1000 g.as/ha of NORDOX 75WG selectivity was complete.

Given the lack of adverse effects of NORDOX application on onion, and the fact that it is currently registered in France at 2500 g as/ha on shallots, we may conclude that the risk of any phytotoxicity is low at its targeted registration rate of 1000 g as/ha and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to tomato
Eight trials were laid down to evaluate 500 to 1500 g.as/ha doses of NORDOX 75WG efficacy against *Phytophthora infestans*. NORDOX 75WG applied from 6 to 9 times from BBCH 61 (beginning of flowering) to BBCH 83 (30% of fruits show typical ripe fruits colour) provided a high protection level without inducing any phytotoxicity symptoms.

As no phytotoxicity symptoms were observed in the 8 trials, and based on the fact that NORDOX 75WG is currently registered at 1250 g as/ha, we must assume that the risk of phytotoxicity at its targeted registration rate of 1000 g as/ha is very low and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to potato
Five trials were carried out to evaluate NORDOX 75WG efficacy against late blight of potato. After 5-6 applications at 500-1000 g.as/ha rates, NORDOX 75WG crop safety was complete.

Given the lack of adverse effects of NORDOX 75WG applied at 1000 g.as/ha, we may conclude that the risk of phytotoxicity on potato is very low and by consequence no restriction is proposed on such a parameter.

Phytotoxicity to ornementals
Information related to uses on ornamentals is presented in specific BAD in the Zonal BAD, prepared by the French Technical Institute in charge of Ornementals, ASTREDHOR. No phytotoxicity symptoms have been observed in trials, nevertheless some marks could sometimes be observed on foliage following NORDOX 75WG applications at dedicaded GAPs. As such aspects can be critical on Ornementals and based on the large variety of cultivated species, **it will always be recommended to perfom a test with Nordox 75WG on small sample prior to treatment generalization on the whole surface.**

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

3.4.2-1 Effect on yield of treated plants or plant protection product - Poland

Yield evaluations were not carried on any of the efficacy trials. Due to typically non-homogenous nature of yield across Orchards, assessments of yield do not usually produce meaningful data.
Various Copper fungicides have been approved and extensively used on a wide range of different crops, including Apple, for many years and it is well established that their use does not result in an adverse effect on yield. Therefore it is reasonable to conclude that multiple applications of Copper oxide products have no adverse effects on crop yield when applied according to label recommendations.

3.4.2-2 Effect on yield of treated plants or plant protection product – South Zone

NORDOX 75WG is a fungicide and as such the risk of phytotoxic effects of the test product to the host crops is neither predicted nor been investigated in specific crop safety trials. However, throughout all efficacy trials, regular, detailed observations were made of the presence or absence of phytotoxic effects/symptoms.

A total of 108 efficacy trials were conducted between 2001 and 2011, in either of France, Portugal, Spain or Italy, in order to permit an evaluation to be made of the effect of NORDOX 75WG on crops.

No significant effects of any kind were observed following treatment of crops with NORDOX 75WG. This is fully in line with the very long-term use of this product and others like it, in all of the crops listed.

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

3.4.3-1 Effects on the quality of plants and plant products - Poland

Observations for any effects the quality of plant and plant products were made on all six trials that were carried out to evaluate the efficacy of Copper oxide products applied at 2-4 timings at rates of up to 1000g Cu/ha, at the start of spray programs to control Scab.

Materials and methods

Details on the materials and methods used in the efficacy trials are included in Section **Błąd! Nie można odnaleźć źródła odwołania.** and therefore are not repeated here.

Summary and evaluation of trial results

Description of applications in trials:

Crop	Target	Application timing	No. of appl'ns	Interval between appl'ns (min)	Appl'n volume	Dose rate
Apple	*Venturia inaequalis*	Crop growth stage 03-54 (BBCH)	2-4	3-9 days	800 l/ha	750-1000g Cu/ha

Data on the quality of the fruit has been generated following 2-4 applications of the Copper oxide product applied at rates of up to 1000g Cu/ha, at the start of spray programs, when followed by applications of other fungicides, in the three efficacy trials carried out in 2011 on Apple.
Of these trials, two were carried out Germany (within the Maritime climatic zone as defined in EPPO Guideline PP 1/241), one was carried out in Hungary (within the South-East climatic zone as defined in EPPO Guideline PP 1/241), one were carried out in Poland (within the North-East climatic zone).
Each of the three efficacy trials were carried out on a different variety of Apple (Elstar, Idared, Jonagored, Gala, Szampion, Kanzi).
Across the trials carried out in 2011, Copper oxide products were applied at the first four timings, followed by twelve applications of another fungicide product (Malvin WG – Captan 80% WG), for on one trial (S11-00984-01), Copper oxide products were applied at the first two timings, followed by ten applications of

another fungicide product (Merpan 80 WG – Captan 80% WG), on one trial (S11-00253-01) and Copper oxide products were applied at the first four timings, followed by six applications of another fungicide product (Captan 50 WP – Captan 50% WP) on one trial (S11-00992-01). The number of applications of the Copper oxide product was therefore representative of the 2-4 label range.

Across the trials carried out in 2011, intervals between applications were within the range of 3-9 days, which is typical of intervals between applications in multiple spray programs for the control of Scab in Apple in commercial practice. Intervals between applications on four trials were 7 or more days according to the minimum label interval with the exception of twos trial where intervals between applications were slightly shorter at 6 days.

Across the trials carried out in 2011, the crop safety of the Copper oxide products applied at the first 2-4 timings as part of a spray program when followed by applications of another fungicide, was compared to that of standard reference Copper products applied at the same timings and as part of the same spray programs, at national registered label rates, Funguran (Copper oxychloride, 45%, WP) in one trial and Champion 50 WP (Copper hydroxide, 50%, WP) in the other two trials.

Russeting is a naturally occurring blemishing effect that develops on the skin of Pome fruit, including Apple, causing a superficial difference in the colour and texture of the skin. Differences exist between the occurrence and extent of symptoms between different varieties of Apple. Russeting always occurs on some varieties, on which it is considered to be acceptable, but on the majority of varieties it is considered to be an adverse effect on the quality of the fruit. The occurrence and severity of russeting is influenced by environmental conditions, the presence of disease and the application of plant protection products.

Russeting developed on the fruit and was assessed on one efficacy trial (S11-00992-01).

All spray programs, involving four applications of Copper oxide products or standard reference products, followed by applications of another fungicide, had similar levels of russeting to the untreated control. Therefore, spray programmes involving applications of Copper oxide did not increase russeting in the fruit compared to untreated plots.

An overall summary of mean numbers of fruit (out of 75 assessed) in each of the severity score categories at early assessment timing and at the final assessment timing, following spray programs involving applications of Copper oxide products at the first four timings, on one trial is given in table 3.4.3-1

1: Overall summary of mean numbers of fruit (out of 75 assessed) in each Russeting severity score category following spray programs involving four applications of Copper oxide at the first two timings

Climatic zone	Treatment	Application Timing	Mean % control, (No. of trials) (Min- Max control)					
			% reduction of russeting on a severity scale					
			Crop growth stage BBCH 72			Crop growth stage BBCH 85		
			No russeting	1- 10 %	10-30%	No russeting	1- 10 %	10-30%
North-East	Untreated (% disease severity)	-	56.8 (1) (56.8-56.8)	17.8 (1) (17.8-17.8)	0.5 (1) (0.5-0.5)	55.8 (1) (55.8-55.8)	19 (1) (19-19)	0.3 (1) (0.3-0.3)
	Untreated/Captan 50 WP	A1-A4/A5-A10	59.3 (1) (59.3-59.3)	15 (1) (15-15)	0.8 (1) (0.8-0.8)	58.8 (1) (58.8-58.8)	15.5 (1) (15.5-15.5)	0.8 (1) (0.8-0.8)
	COX (750g Cu/ha)/Captan 50 WP	A1-A4/A5-A10	57.8 (1) (57.8-57.8)	17 (1) (17-17)	0.3 (1) (0.3-0.3)	56.3 (1) (56.3-56.3)	18 (1) (18-18)	0.8 (1) (0.8-0.8)
	COX (1000g Cu/ha)/Captan 50 WP	A1-A4/A5-A10	58.5 (1) (58.5-58.5)	15.8 (1) (15.8-15.8)	0.8 (1) (0.8-0.8)	57.5 (1) (57.5-57.5)	17 (1) (17-17)	0.5 (1) (0.5-0.5)
	Champion (375g Cu/ha)/Captan 50 WP	A1-A4/A5-A10	56.8 (1) (56.8-56.8)	18.3 (1) (18.3-18.3)	0 (1) (0-0)	56.5 (1) (56.5-56.5)	18.3 (1) (18.3-18.3)	0.3 (1) (0.3-0.3)

It is likely that the similar levels of russeting in all spray programs, including those involving the Copper oxide products, and in the untreated plots are likely to be due to the susceptibility of the Apple varieties to russeting. Therefore, spray programmes involving Copper oxide had no significant effect on russeting and the quality of the fruit.

Conclusions

The Copper oxide product applied at 2-4 timings at the rate range of 750 and 1000g Cu/ha, was not observed to have any adverse effects on the quality of the fruit on any of the six efficacy trials carried out on Apple. Copper salt products have been approved and widely used for the control of disease on Apple for many years and therefore a wide range of different Copper products are known and proven to have no adverse effects on the quality of the harvested produce.

On the basis of the known crop safety of Copper salt products on Apple and the absence of any effects in trials, it is therefore reasonable to conclude that the Copper oxide product (as included in the trials) has no adverse effects on the quality of the fruit when applied within the rate range of 750-1000g Cu/ha at 2-4 timings and according to label recommendations on Apple.

3.4.3-2 Effects on the quality of plants and plant products – South Zone

NORDOX 75WG is a fungicide and as such the risk of phytotoxic effects of the test product to the host crops is neither predicted nor been investigated in specific crop safety trials. However, throughout all efficacy trials, regular, detailed observations were made of the presence or absence of phytotoxic effects/symptoms.

A total of 108 efficacy trials were conducted between 2001 and 2011, in either of France, Portugal, Spain or Italy, in order to permit an evaluation to be made of the effect of NORDOX 75WG on crops.

No significant effects of any kind were observed following treatment of crops with NORDOX 75WG. This is fully in line with the very long-term use of this product and others like it, in all of the crops listed.

3.4.4 Effects on transformation processes (KCP 6.4.4)

EPPO standard PP 1/243 ('Effects of plant protection products on transformation processes') defines a processing procedure as being, any process used for the transformation of the harvested crop into the final product, dependent in whole or in part on biological activity. This is distinguished from processing that is purely physical and/or chemical in nature, which may impact on the quality of the processed product but does not affect the process itself. The potential effect of NORDOX 75WG on the quality of plant or plant products has been assessed separately (see Point 6.1.4.1).

Given the long, problem-free history of safe use of NORDOX 75WG and similar products across Europe, effects on any processing procedures are not expected, and as such specific studies were not considered necessary.

To date there have been no reports of any phytotoxicity of any kind. Therefore, in addition to the excellent crop selectivity discussed under Points 3.4.1 (Phytotoxicity), 6.1.4.1 (Quality) and 3.4.2 (Yield), these reinforce an excellent crop safety profile for NORDOX 75WG towards all crops listed.

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

3.4.5-1 Impact on treated plants or plant products to be used for propagation - Poland

Copper is a naturally occurring element, occurring in various forms within the environment and present in the soil and in plant tissue, where it is essential for healthly growth and development with an important role in many metabolic processes within the plant.

Various Copper salt fungicides have been approved and widely used on a wide and varied range of different crops for many years and are known and proven to have no adverse effects on plant parts for plant propagation.

Therefore it is reasonable to conclude that the Copper oxide product (as included in the trials) has no adverse effects on plant parts for propagation when applied according to label recommendations on Apple

3.4.5-2 Impact on treated plants or plant products to be used for propagation – South Zone

NORDOX 75WG is a fungicide and as such the risk of effects of the test product to the host crops for propagating purposes is neither predicted nor been investigated in specific crop safety trials. However, throughout all efficacy trials, regular, detailed observations were made of the presence or absence of phytotoxic effects/symptoms.

A total of 108 efficacy trials were conducted between 2001 and 2011, in either of France, Portugal, Spain or Italy, in order to permit an evaluation to be made of the effect of NORDOX 75WG on crops.

No significant effects of any kind were observed following treatment of crops with NORDOX 75WG.

This is fully in line with the very long-term use of this product and others like it, in all of the crops listed

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

3.5.1-1 Impact on succeeding crops - Poland

Copper is a naturally occurring element, occurring in various forms within the environment and present in the soil and in plant tissue, where it is essential for healthly growth and development with an important role in many metabolic processes within the plant. On copper deficient soils, the application of Copper fungicides can alleviate deficiencies and the need to apply Copper as a specific micro-nutrient.

Various Copper fungicides have been approved and extensively used on a wide range of different crops and it is well established that their use does not result in the build-up of copper in the soil to sufficiently high levels to cause phytotoxicity to crops sown or planted following application to previous crops.
Based on this, it is reasonable to conclude that the Copper oxide product has no adverse effects on replacement or succeeding crops sown or planted following the application of Copper oxide products applied as per label recommendations. Therefore, no label restrictions on the sowing or planting of succeeding or replacement crops following the application of Copper oxide products are necessary.

3.5.1-2 Impact on succeeding crops – South Zone
Requested NORDOX 75WG uses refer to several perennial crops for which this point does not apply. Considering annual crops, the targeted registration rates are inferior or similar to the currently registered ones. Until now, none negative issue on succeeding crops was raised and by consequence, no restriction is proposed on such parameter in the framework of this re-registration dossier.

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

3.5.2-1 Impact on other plants including adjacent crops - Poland
Copper is a naturally occurring element, occurring in various forms within the environment and present in the soil and in plant tissue, where it is essential for healthly growth and development with an important role in many metabolic processes within the plant. On copper deficient soils, the application of Copper fungicides can allieviate deficiencies and the need to apply Copper as a specific micro-nutrient.
Various Copper fungicides have been approved and extensively applied in many crops using a wide variety of application methods and equipment and are therefore widely proven in commercial practice to have no adverse effects on other plants, including adjacent crops, resulting from spray drift away from the area of application.
It is therefore reasonable to conclude that the application of Copper oxide products have no adverse effects on other plants, including adjacent crops.

3.5.2-2 Impact on other plants including adjacent crops – South Zone
In view of the long, problem-free history of use of this and similar products in Europe, the risk of effects on other plants including adjacent crops is considered to be low. Based on this, further investigation of the effects of treatments with NORDOX 75WG were considered unnecessary.

At application, principals of good agricultural practices should be followed in order to avoid drift to sensitive crops.

3.6 Other/special studies

No additional studies were performed.

List of test facilities including the corresponding certificates

Refer to individual trial reports..

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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	Owner

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

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

The following tables are to be completed by MS

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner