

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 0**

Product Background, Regulatory Context and  
GAP information

Product code: SHA 7273 A

Product name(s): CASINO ROYALE

Chemical active substances:

Boscalid, 267 g/kg

Pyraclostrobin, 67 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2020

MS Finalisation date: 08/2021; 01/2022

## Version history

When	What
April 2021	Applicant update
August 2021	Draft assessment by zRMS
January 2022	Final Registration Report after the commenting period

## Table of Contents

<b>0</b>	<b>Product background, regulatory context and GAP information .....</b>	<b>4</b>
0.1	Introduction.....	4
0.1.1	Reason for application .....	4
0.1.2	Details of zRMS(s) and concerned MS .....	4
0.1.3	Regulatory history of the active(s).....	4
0.1.3.1	Pyraclostrobin .....	4
0.1.3.2	Boscalid.....	5
0.1.4	Regulatory history of the product (if relevant) .....	6
0.2	zRMS conclusion .....	6
<b>Appendix 1</b>	<b>ALL intended uses .....</b>	<b>9</b>

## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

#### 0.1.1 Reason for application

This application is submitted by SHARDA CROPChem ESPAÑA S.L. for approval of CASINO ROYALE, a water dispersible granule formulation containing 267 g/kg boscalid and 67 g/kg pyraclostrobin for use as a fungicide in Central Europe.

This application follows the data requirements for the active substances laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

#### 0.1.2 Details of zRMS(s) and concerned MS

**Table 0.1-1: Overview of zRMS and cMS**

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland CASINO ROYALE	None
Southern zone	Malta CASINO ROYALE (2019-08-29 P01 (SZ))	

#### 0.1.3 Regulatory history of the active(s)

##### 0.1.3.1 Pyraclostrobin

**Table 0.1-2: Summary of regulatory history of CAS No: 175013-18-0**

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2004/30/EC and Commission Directive 2009/25/EC (extension of the use)  Commission Implementing Regulation (EU) No 540/2011 Reg. (EU) <del>2019/2094</del> 2021/52
RMS	Germany
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.06.2004

<b>Status</b>	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.11.2004
Date of final Commission (re-registration) deadline (Step 2)	30.11.2005
Current expiration of approval	<del>31.01.2021</del> 31.01.2022
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

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

- the protection of aquatic organisms, especially fish.
- the protection of terrestrial arthropods and earthworms

The SANCO report for pyraclostrobin (SANCO/1420/2001-Final – 8 September 2004) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is not available.

**Table 0.1-3: Information on minimum purity of Pyraclostrobin**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
975 g/Kg	<del>minimum purity of active substance: 985 g/Kg</del> <del>Equivalence report available: N</del> <del>RMS: UK</del> minimum purity of active substance: 975 g/Kg Equivalence report available: Y RMS: MT

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\*. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The endpoints used in the evaluation are in line with EU endpoints.

### 0.1.3.2 Boscalid

**Table 0.1-4: Summary of regulatory history of CAS No: 188425-85-6**

<b>Status</b>	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/44/EC Commission Implementing Regulation (EU) No 540/2011 Reg. (EU) 2020/869
RMS	Slovakia (the original MS was Germany)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.08.2008

<b>Status</b>	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.01.2009
Date of final Commission (re-registration) deadline (Step 2)	31.01.2010
Current expiration of approval	31.07.2021
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

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

- the operator safety
- the long-term risk of birds and soil organisms
- the risk of accumulation in soil if the substance is used in perennial crops or in succeeding crops in crop rotation.

The SANCO report for boscalid (SANCO/3919 /2007-rev. 5 – 21 January 2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is not available.

**Table 0.1-5: Information on minimum purity of Boscalid**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
960 g/kg	minimum purity of active substance: 970 g/Kg Equivalence report available: Y RMS: UK

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\* If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The endpoints used in the evaluation are in line with EU endpoints.

#### 0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised

#### 0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

Efficacy section: 1-30  
Mammalian toxicology section: 1-30.  
Residues section: 1-2, 4-5, 12-22, 24, 26-28, 30  
Environmental fate and behavior section: 1-30  
Ecotoxicology section: 1-30

Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: none  
Mammalian toxicology section: none  
Residues section: 3, 6-11, 23, 25, 29  
Environmental fate and behavior section: none  
Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

The refined risk for birds, mammals, aquatic organism should be considered at MSs level.  
The combined long-term toxicity assessment for mammals should be considered at MSs level.

Residues section: All accepted uses/ GAPs are covered by established MRLs

Physical and chemical properties:

Data gaps: the shelf-life study is on-going and the report shall be submitted when finished.

Efficacy section:

Poland: Use on sugar beet, tomato against ALTESP and carrot can be accepted according to Article 33.

Following minor uses: beetroot, celery root, parsnip, parsley, radish, radish Horseradish, swedes/rutabagas, turnip, chicory roots, shallot, onion, aubergines/eggplants, ornamentals in field and greenhouses, redcurrant, white currant and salsifies can be accepted in line to Article 51. Alco, onion and tomato against PHYTIN can be accepted with Art. 51. In Poland, on the basis on SIG-NUM 33 WG, which was registered in Poland (R-33/2010, dated 19.04.2010), uses claimed in the GAP table (cabbage, tomato in greenhouses, strawberry, cherry, raspberry, blackcurrant) and Polish label project can be accepted on the basis on unprotected data. cMS: decision about acceptance or rejection each use was left to cMS.

Mammalian toxicology:

Classification: Eye Irrit.2, H319

Operator: protective gloves, eye/face protection and work wear (coverall) during mixing/loading and work wear during application, cherry: protective gloves, eye/face protection and work wear (coverall) during mixing/loading and protective gloves and work wear during application. **Additional respiratory protection (minimum FFP2 mask) when spraying tomatoes in greenhouses.**

Worker: protective gloves, work wear (covered arms, body and legs) no entry to the area treated with SHA 7273A/ Casino Royale:

- until spray deposit on plant surfaces has dried: sugarbeet, carrot, beetroot, celery root, parsnip, parsley, radish, horseradish, swedes/rutabagas, turnip, chicory roots, shallot, Jerusalem artichokes, salsifies, tomato, onion, cabbage, aubergines/eggplants;
- for 2 days: raspberry, blackcurrant, redcurrant, white currant;
- **for 2 days in tomato (indoor);**
- for 6 days in ornamentals;
- for 7 days in cherries.

Bystander/resident: The incidental short-time exposure of bystander and resident (children and adult) to pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table

Residues section:

Noticed data gaps are:

Residue trials according to uses No 3, No 6-11, 23, 25 and 29

Environmental fate and behavior section: No risk to ground water is expected following application

Casino Royale according proposed GAP.

Ecotoxicology section: The refined risk for aquatic organism is acceptable, when relevant restriction will applied to surface water bodies ( e.g. buffer zone).

In addition, refined risk for birds and mammals should be decided at MSs level.



## Appendix 1 ALL intended uses

**PPP (product name/code):** CASINO ROYALE / SHA 7273 A  
**Active substance 1:** Boscalid  
**Active substance 2:** Pyraclostrobin  
**Safener:** -  
**Synergist:** -  
**Applicant:** Sharda Cropchem España S.L.  
**Zone(s):** Central  
**Verified by MS:** yes/no

Formulation type: GAP rev. 0, date: 2017-Septemeber-12th  
WG (Water Dispersible granules)

Conc. of as 1: 267 g/Kg  
Conc. of as 2: 67 g/Kg  
Conc. of safener: -  
Conc. of synergist: -  
Professional use: ☒  
Non professional use: ☐

**Field of use:** Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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 con- trolled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between appli- cations (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	Sugarbeet	F	<i>Cercospora beticola</i>	Foliar Spray	BBCH 31-39	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	
2	CEU	Tomato	F	<i>Phytophthora infestans</i> ,	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	Efficacy section: in PL only in line to Art. 51 can be accepted.
3	CEU	Tomato	F	<i>Alternaria sp.</i>	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-3 b) 1-3	8-10	a) 1.5 b) 4.5	a) 0.4 boscalid + 0.1 pyraclostrobin b) 1.2 boscalid + 0.3 pyraclostrobin	300-600	-	Metabolism and Residues: not accepted
4	CEU	Carrot	F	<i>Septoria apiicola</i> , <i>Cercospora sp.</i> , <i>Alternaria sp.</i>	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	
5	CEU	Onion	F	<i>Puccinia allii</i>	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 1-2 b) 1-2	14	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	Efficacy section: in PL only in line to Art. 51 can be accepted.
Unprotected use in SIGNUM													
6	PL	Cabbage	F	<i>Alternaria</i> , <i>Botrytis cinerea</i>	Spray	BBCH 41-49	a) 1-3 b) 1-3	7	a) 1.0 b) 3.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	600-800	14	Unprotected use in SIGNUM Metabolism and Residues: not accepted
7	PL	Tomatoe in greenhouses	G	<i>Botrytis cinerea</i> ,	Spray	BBCH 51-85	a) 1-2	7	a) 2.0	a) 0.534	4000	3	Unprotected use in SIG-

				<i>Phytophthora infestans</i>			b) 1-2		b) 4.0	boscalid + 0.134 pyra- elostrobin b) 1.068 + 0.268 pyra- elostrobin			NUM Metabolism and Residues: not accepted
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8	PL	Strawberry	F	<i>Botrytis cinerea</i> , <i>Ramularia grevilleana</i> <i>Spaerotheca macularis</i> ,	Spray	BBCH 60-81	a) 1-2 b) 1-2	5	a) 1.8 b) 3.6	a) 0.481 boscalid + 0.121 pyraclostrobin b) 0.961 boscalid + 0.241 pyraclostrobin	500-700	3	Unprotected use in SIG- NUM Metabolism and Residues: not accepted
9	PL	Cherry	F	<i>Monilinia sp.</i>	Spray	BBCH 60-67	a) 1-2 b) 1-2	5	a) 1.0 b) 2.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.534 boscalid + 0.134 pyraclostrobin	500-750	7	Unprotected use in SIG- NUM Metabolism and Residues: not accepted
10	PL	Raspberry	F	<i>Botrytis cinerea</i> , <i>Didymella applanata</i>	Spray	BBCH 51-90	a) 1-2 b) 1-2	7	a) 1.8 b) 3.6	a) 0.481 boscalid + 0.121 pyraclostrobin b) 0.961 boscalid + 0.241 pyraclostrobin	600-700	3	Unprotected use in SIG- NUM Metabolism and Residues: not accepted
11	PL	Blackcurrant	F	<i>Drepanopeziza ribis</i> <i>Cronartium ribicola</i>	Spray	BBCH 55-90	a) 1-2 b) 1-2	7-10	a) 1.8 b) 3.6	a) 0.481 boscalid + 0.121 pyraclostrobin b) 0.961 boscalid + 0.241 pyraclostrobin	600-800	3	Unprotected use in SIG- NUM Metabolism and Residues: not accepted

**Minor uses according to Article 51 (zonal uses)**

12	PL	Beetroot	F	<i>Erysiphe betae</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	10-14	a) 1.0 b) 2.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.534 boscalid + 0.134 pyraclostrobin	300-600	14	
13	PL	Celery root	F	<i>Sclerotinia sclerotiorum</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	10-14	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin	300-600	14	

										b) 0.8 bos- calid + 0.2 pyraclostrobin			
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14	PL	Parsnip, Parsley	F	<i>Alternaria sp.</i> <i>alternata</i> , <i>Erysiphe heraclei</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	21-28	a) 0.75 b) 1.5	a) 0.200 boscalid + 0.050 pyra- clostrobin b) 0.400 boscalid + 0.100 pyra- clostrobin	600- 800	14	
15	PL	Radish	F	<i>Botrytis cinerea</i> ,	Spray	BBCH 11-49	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	
16	PL	Radish	F	<i>Rhizoctonia solani</i>	Spray	BBCH 11-12	a) 1 b) 1	NR	a) 1.5 b) 1.5	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.4 bos- calid + 0.1 pyraclostrobin	300- 600	14	
17	PL	Horseradish	F	<i>Peronospora sp.</i> <i>Alternaria</i> <i>Erysiphe sp.</i>		BBCH 15-49	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	
18	PL	Swedes/rutabagas	F	<i>Peronospora sp.</i> <i>Cercospora</i> <i>beticola</i> <i>Erysiphe sp.</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	10-14	a) 1.0 b) 2.0	a) 0.267 boscalid + 0.067 pyra- clostrobin b) 0.534 boscalid + 0.134 pyra- clostrobin	300- 600	14	
19	PL	Turnip	F	<i>Botrytis cinerea</i> , <i>Thanatephorus</i> <i>cucumeris</i>	Spray	BBCH 11-49	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	
20	PL	Chicory roots	F	<i>Chicory Alterna- ria</i> , <i>Chicory Puccinia</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos-	300- 600	14	

										calid + 0.2 pyraclostrobin			
21	PL	Shallot	F	<i>Peronospora destructor</i> <i>Alternaria</i> , <i>Stemphylium</i>	Spray	BBCH 13-48	a) 1-2 b) 1-2	14	a) 1.0 b) 3.0	a) 0.267 boscalid + 0.067 pyra- clostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	
22	PL	Onion "seven years old"	F	<i>Puccinia porri</i> <i>Phytophthora porri</i> <i>Alternaria</i> ,	Spray	BBCH 13-47	a) 1-2 b) 1-2	21-28	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	
23	PL	Aubergines/eggplants	G	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Leveillula taurica</i>	Spray	BBCH 12-89	a) 1-2 b) 1-2	7-10	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	4000	14	Metabolism and Residues: not accepted
24	PL	aubergines/eggplants	F	<i>Phytophthora infestans</i> ,	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	-	
25	PL	aubergines/eggplants	F	<i>Alternaria sp.</i>	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-3 b) 1-3	8-10	a) 1.5 b) 4.5	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 1.2 bos- calid + 0.3 pyraclostrobin	300- 600	-	Metabolism and Residues: not accepted
26	PL	Ornamentals in field and greenhouses	F/G	<i>Alternaria</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	7-14	a) 0.1 b) 0.2	a) 0.0267 boscalid + 0.0067 pyra- clostrobin b) 0.0534 boscalid + 0.00134 pyraclostrobin	100	-	
27	PL	Ornamentals in field and greenhouses	F/G	<i>Erysiphales</i>	Spray	BBCH 13-47	a) 1-2	7-14	a) 0.18	a) 0.0481	100	-	

							b) 1-2		b) 0.36	boscalid + 0.0121 pyraclostrobin b) 0.0962 boscalid + 0.0242 pyraclostrobin			
28	PL	Ornamentals in field and greenhouses	F/G	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Thanatephorus cucumeris</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	7-14	a) 0.15 b) 0.3	a) 0.04 boscalid + 0.01 pyraclostrobin b) 0.08 boscalid + 0.02 pyraclostrobin	100	-	
29	PL	Redcurrant, White currant	F	<i>Drepanopeziza ribis</i> , <i>Drepanopeziza rubric</i> , <i>Botrytis cinerea</i> ,	Spray	BBCH 55-90	a) 1-2 b) 1-2	7-10	a) 1.8 b) 3.6	a) 0.4806 boscalid + 0.1206 pyraclostrobin b) 0.9612 boscalid + 0.2412 pyraclostrobin	600-800	3	Metabolism and Residues: not accepted
30	PL	Salsifies	F	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Rhizoctonia</i>	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	
<b>Minor uses according to Article 51 (zonal uses)</b>													
<b>Minor uses according to Article 51 (interzonal uses)</b>													

**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.



<b>Remarks columns:</b>	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	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.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	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	