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Outcome of the consultation with Member States and EFSA on the additional information submitted in relation to the basic substance application for talc E553B for use in plant protection as repellent on fruit trees and grapevines

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the additional information submitted in relation to the basic substance application for talc E553B are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of talc E553B as a basic substance for use in plant protection as repellent on fruit trees and grapevines. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

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Keywords: talc E553B, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2017-00249

Correspondence: pesticides.peerreview@efsa.europa.eu

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Summary

Talc E553B is an active substance for which, in accordance with Article 23(3) of Regulation (EC) No 1107/2009, the European Commission received an application from Compo Expert France SAS for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in March 2016, EFSA was asked to organise a consultation on the basic substance application for talc E553B, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table. The Technical report containing the finalised reporting table was issued by EFSA on 1 June 2016. As a follow up, the applicant was requested by the European Commission to provide comments on the Technical Report of EFSA. As a response, in September 2016, the applicant submitted new information in relation to the risk assessment to groundwater and the operator exposure assessment. In March 2017, EFSA received a follow-up mandate by European Commission requesting to organise a second consultation process on the new information provided and to update as appropriate the Technical Report on Talc E553B.

A consultation on the additional information concerning the basic substance application for talc E553B, organised by EFSA, was conducted with Member States via a written procedure in March-May 2017. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the second consultation process organised by EFSA on the additional information for talc E553B and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

The hazard characterisation of talc by inhalation to workers was based on the REACH registration dossier where a Derived No Effect Level (DNEL) of 2.16 mg/m³ was established based on a NOAEC of 10.8 mg/m³ and overall assessment factor (AF) of 5. Estimated operator inhalation exposure, without the use of personal protective respiratory equipment (PPR) when applying talc to pome fruits or grapes, does not exceed the derived DNEL corrected for 6h exposure and average breathing rate of 1.25 m³/h.

An appropriate realistic worst case assessment of water soluble elements (magnesium, silicon, calcium, potassium and aluminium) originating from talc E553B mined in Europe and their potential to leach to groundwater has been presented.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1107/2009¹ (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Talc E553B is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Compo Expert France SAS for approval as a 'basic substance' for use in plant protection as repellent on fruit trees and grapevines. In March 2016, EFSA was asked to organise a consultation on the basic substance application for talc E553B, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months from acceptance of the specific request. EFSA issued a Technical report containing the finalised reporting table on 1 June 2016 (EFSA, 2016). As a follow up, the applicant was requested by European Commission to provide comments on the Technical Report of EFSA. In September 2016, new information was submitted by the applicant in relation to the risk assessment to groundwater and the operator exposure assessment. On 29 March 2017 EFSA was requested by European Commission to organise a second consultation process on the new information provided and to update as appropriate the Technical Report on Talc E553B.

The European Food Safety Authority (EFSA) organised a consultation with Member States on new information as regards the basic substance application for Talc E553B, which was conducted via a written procedure in March-May 2017. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on new information in relation to the risk assessment to groundwater and the operator exposure assessment as regards the basic substance application for talc E553B and to present EFSA's scientific views on the individual comments received in the format of a reporting table. For the sections where no new information was submitted, reference is made to the conclusions of the previous Technical report (EFSA, 2016).

The application and, where relevant, any update thereof submitted by the applicant for approval of Talc E553B as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (Compo Expert, 2017a,b).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 29 March 2017, EFSA was asked to organise a second consultation on the additional information submitted by the applicant concerning the basic substance application for talc E553B, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 2 August 2017.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

2. Assessment

The comments received on the additional information as regards the basic substance application for talc E553B and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix B and C, respectively.

Documentation provided to EFSA

1. Compo Expert France SAS, 2017a. Basic substance application on talc E553B submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2017. Documentation made available to EFSA by the European Commission.
2. Compo Expert France SAS, 2017b. Basic substance application update on talc E553B submitted in the context of Article 23 of Regulation (EC) No 1107/2009. June 2017. Documentation made available to EFSA by the applicant.

References

- EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for talc E553B for use in plant protection as repellent on fruit trees and grapevines. EFSA Supporting Publication 2016; 13(7):EN-1044. 39 pp. doi:10.2903/sp.efsa.2016.EN-1044

Abbreviations

a.s.	active substance
ACGIH	American Conference of Governmental Industrial Hygienists
AOEM	Agricultural Operator Exposure Model
AF	Assessment factor
DAR	draft assessment report
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
EU	European Union
GAP	good agricultural practice
IARC	International Agency for Research on Cancer
MPPCF	millions of particles per cubic foot
MS	Member State
NIOSH	National Institute of Occupational Safety and Health
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
PEC	predicted environmental concentration
PEC _{gw}	predicted environmental concentration in ground water
PPR	personal protective respiratory equipment
REACH	Registration, Evaluation, Authorisation of Chemicals
RMS	rappporteur Member State
RPE	Respiratory protective equipment
TER	Toxicity Exposure Ratio
TLV	Threshold Limit Value
TWA	time -weighted average

Appendix A – Collation of comments from Member States and EFSA on the additional information concerning the basic substance application for Talc E553B and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General					
No.	Column 1 Reference to Document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)		DE: No comment			Noted
1(2)		NL: no comments			Noted
1(3)	8. Effects on non-target species	<p>DK: Roughly page 41: Please exclude this text:</p> <p>'However, small herbivorous mammals are no longer considered as relevant for the risk assessment because of their population dynamics and their reproduction high capability allowing for rapid recolonisation. On the other hand, the TER for frugivorous mammals in orchards is actually > 4.1 (a value not very far from the trigger) because the NOAEL is > 1600 mg/kg bw/day and no higher dose was assayed. Therefore, the TER for frugivorous mammals is most probably higher than the calculated value of 4.1 and</p>	<p>Please change the GAP to canopy spray (not foliar spray), as well as lowering the number of applications pr. season if relevant.</p> <p>For the foliar application spray please lower the GAP e.g. the number of applications.</p>	<p>Text has been removed and replaced by new risk assessment. Spray restriction to canopy will be difficult to perform in field under realistic conditions; therefore GAPs were reviewed considering foliar application. The acute and long-term risks are now acceptable for all mammal categories considering the following GAPs:</p> <ul style="list-style-type: none"> - <u>Orchards/insectifuge</u>: first application at 25 kg product/ha (<i>i.e.</i>, 21.25 kg a.s/ha) from BBCH 41, followed by 4 applications at 20 kg product/ha (<i>i.e.</i>, 17 kg a.s/ha), spaced 21 days minimum - <u>Orchards/fungifuge</u>: 5 	Noted. See EFSA, 2016.

General					
No.	Column 1 Reference to Document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>therefore above the trigger of 5. As a consequence, the use of talc E 553B poses a low acute risk to mammals when used at the recommended rates'</p> <p>DK objects to a vertebrate risk assessment that involves the re-colonisation potential of the organisms. This argument may be acceptable for non-target arthropods, but not for vertebrates.</p> <p>DK proposes that the risk assessment should only include the application scenarios relevant for the GAP. If talc is intended to use on the fruit only (canopy spray, not foliar spray) then some of the higher tier application scenarios currently included (and indicating an unacceptable risk) are no longer relevant. Thus, please change the GAP to canopy spray, including relevant BBCH intervals, and the risk to small herbivorous mammals living on the ground</p>		<p>applications at 15 kg product/ha (<i>i.e.</i>, 12.75 kg a.s/ha) from BBCH 41, spaced 14 days minimum</p> <ul style="list-style-type: none"> - <u>Vines/fungifuge</u>: 5 applications at 15 kg product/ha (<i>i.e.</i>, 12.75 kg a.s/ha) from BBCH 20, spaced 21 days minimum <p>Application dossier has been updated accordingly and presents detailed calculations.</p>	

General					
No.	Column 1 Reference to Document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>will no longer be at unacceptable risk. Furthermore, the TER value of 4.1 is not close to 5. It is noted, that the endpoint is a '>' value, however this argument alone is not enough to show safe use in grapevine. In this case a lowering of the GAP is in order (e.g. fewer applications pr. season). Thus, please lower the GAP for foliar application spraying.</p>			

2. Operator exposure through inhalation and risk assessment

No.	Column 1 Reference to Document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1, Operator exposure through inhalation to talc and risk assessment parameters	DE: A DNEL of 2.16 mg/m ³ was derived for workers in the REACH registration report ² available on the ECHA website. This value is lower than the TWA _{corrected} of 3.3 mg/m ³ . Nevertheless, estimated operator exposure is also below this value without RPE.			See comment 2(3)
2(2)		NL: no comments			Noted.
2(3)	2.1, Operator exposure through inhalation to talc and risk assessment parameters, p. 6	EFSA: A TLV value of 2 mg/m ³ is reported, but we miss the basis for the setting of this value, such as toxicological data, and as such it cannot be independently assessed.	The toxicological information that is the basis for setting the TLV or TWA should be submitted.	1) TLV value of 2 mg/m ³ applies to non-asbestiform talc such as talc E 553B and is presented in several documents such as NIOSH, ACGIH and IARC and is cited in the document 'Safety assessment of talc as used in cosmetics' released in 2012 ³ . The current American	The hazard characterisation of talc by inhalation to workers in the REACH registration dossier was defined by a Derived No Effect Level (DNEL) of 2.16 mg/m ³ based on a NOAEC of 10.8 mg/m ³ and overall assessment factor (AF) of 5. Operator exposure through inhalation is below the derived DNEL corrected (6h exposure, average breathing

² ECHA (European Chemicals Agency). REACH Registration dossier of talc, available on www.echa.europa.eu

³ CIR (Cosmetic Ingredient Review), 2012. Safety assessment of talc as used in cosmetics released. Tentative Report for Public Comment, December 2012.

No.	Column 1 Reference to Document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>Conference of Governmental Industrial Hygienists⁴ TLV-TWA is 2 mg/m³ (15 MPPCF), which also is the proposed Occupational Safety and Health Administration limit. These values were derived for dry talc. The product Invelop® is moistened talc (85% talc and 15% water). Using a TLV of 2 mg/m³ can be considered as a worst case scenario regarding inhalation exposure and as a worst case approach, operator risk was assessed considering that Invelop® contained 100% of talc E 553B, instead 85% of talc E 553B.</p> <p>2) As precised by German</p>	<p>rate of 1.25 m³/h) without the use of personal protective respiratory equipment (PPR) when applying talc to pome fruits or grapes.</p>

⁴ ACGIH (American Conference of Governmental Industrial Hygienists), 2005. Documentation of the TLVs and BEIs with Other Worldwide Occupational Exposure Values, 2005.

No.	Column 1 Reference to Document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>Authorities (see above in section 2(1)), a DNEL of 2.16 mg/m³ was derived for workers in the REACH registration report. This value is lower than the TWA_{corrected} of 3.3 mg/m³. The talc DNEL is 2.16 mg/m³ and when using respiratory volume for one working day (7.5 m³), the talc DNEL_{corrected} is 16.2 mg/working day.</p> <p>Fruit trees: The estimated exposure by inhalation to talc with AOEM model is 12.7 mg/day (without any RPE during mixing loading and application).</p> <p>Grapes: The estimated exposure by inhalation to talc with AOEM model is 9.7 mg/day (without any RPE during mixing loading and application).</p>	

No.	Column 1 Reference to Document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>These assessments confirm that estimated operator exposure is also below the DNEL without RPE according to the GAPs, using worst-case application rates.</p> <p>The application dossier has been updated accordingly.</p>	

3. Risk assessment to groundwater

No.	Column 1 Reference to Document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		DE: No comment			Noted
3(2)		NL: No comments			Noted
3(3)		EFSA: Though a publication was now provided (De Parseval P., Martin. F. and Hoffler P., 2001) indicating the water soluble fraction of talc, this relates to talc sourced from only a single geographical location (Trimouns, Pyrenees, France). Reliable evidence for the water solubility of talc with a specification relevant for E553b is necessary to support your argumentation and not just information on Le gisement de talc de Trimouns.	Provision of information on the water soluble fraction constituents of talc for a range of mine locations across the EU that confirms the nature of exactly what might leach to groundwater from talc of different origins.	Mineralogical data of mines over the world was provided in updated application dossier. Data show that European talc usually constitutes of mineral talc (associated quantifiable soluble elements: Mg and Si), chlorite (associated quantifiable soluble elements: Mg, Si, Al), dolomite (associated quantifiable soluble elements: Ca and Mg), phlogopite (associated quantifiable soluble elements: K, Mg, Si, Al) and magnesite (associated quantifiable soluble elements: Mg). Mg and Si are the major ones. Groundwater risk assessment was updated and showed that worst-case PEC _{gw} of any of the potential constituents of the water-soluble fraction of talc does not exceed the	The issue regarding the identity of the water soluble fraction of talc E553B from mine sources across the EU has been adequately addressed. Satisfactory estimates of leached minerals from talc leaving the top 1m soil layer expressed as an annual average recharge concentration, considered a surrogate for groundwater are available in the application.

Outcome of the consultation on the basic substance application for talc E553B

No.	Column 1 Reference to Document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				parametric or nutritional values. The application dossier has been updated accordingly.	

4. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

Overall conclusions with respect of eligibility of the substance to be approved as basic substance

No.	Column 1 Reference to document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)		DE: No comment			Noted
4(2)		NL: No comments.			Noted

5. Other comments

Other comments

No.	Column 1 Reference to document	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the documentation should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)		DE: No comment			Noted
5(2)		NL: No comments			Noted

Appendix B – Identity and biological properties

Common name (ISO)	There is no ISO common name for this substance
Chemical name (IUPAC)	Magnesium hydrogen metasilicate silicate mineral
Chemical name (CA)	Magnesium hydrogen metasilicate silicate mineral
Common names	Talc, talcum
CAS No	14807-96-6
CIPAC No and EEC No	Not available
FAO specification	Not available
Minimum purity	Commission Regulation (EU) No 231/2012 ⁵ of 9 March 2012
Relevant impurities	Free of asbestos As: max 10 mg/kg Pb: max 2 mg/kg
Molecular mass and structural formula	Molecular formula: Mg ₃ Si ₄ O ₁₀ (OH) ₂ Molar mass: 379.26 g/mol
Mode of Use	Spray applications
Preparation to be used	Invelop (Wettable Powder, WP). (min. 85% in natural water)
Function of plant protection	insectifuge, fungifuge

⁵ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

Appendix C – List of uses

Active ingredient, talc E 553b represents 85% of the final product Invelop®

Crop and/or situation (a)	Member State for use	Example product name as available	FI (b)	Target (c)	Product**		Application			Application rate per treatment			Total rate kg a.i./ha min max (kg/h)	PHI (days) (m)	Remarks		
					Type (d-f)	Conc of a.i. g/kg	Method kind (f-h)	Growth stage and season *	Number min max	Interval between applic	kg a.i./hl min max (kg/hl)	Water l/ha min max				kg a.i./ha min max (kg/ha)	
Fruit trees Ex: Apple fruit <i>Malus domestica</i> , Pear tree <i>Pyrus sp</i> , Olive tree <i>Olea europea</i> , <i>etc.</i>	FR France All Member State	Invelop®	F	Physical barrier Insectifuge: Insects and acarions like <i>Cacopsylla pyri</i> , <i>Cacopsylla fulguralis</i> , <i>Drosophila suzukii</i> , <i>Panonychus ulmi</i> , <i>Bactrocera oleae</i> ,	Wettable Powder (WP)*	850	Foliar application spraying	From BBCH 41 to end of summer	2-5	3 to 4 weeks	1 st application: 2.13 to 3.54 Succeeding applications : 1.7 to 2.83	600 to 1000	1 st application: 21.25 Succeeding applications: 17	38.25 to 89.25	Not relevant	Water solution prepared just before application and maintained stirred	
Fruit trees Ex: Apple fruit <i>Malus domestica</i> , Pear tree <i>Pyrus sp</i> ,				Physical barrier Fungifuge : Foliar fungi like mildews: <i>Venturia inaequalis</i> , <i>Erysiphe necator</i>			Foliar application spraying	From BBCH 41	3-5	2 to 3 weeks	1.28 to 2.13	600 to 1000	12.75				38.25 to 63.75
Grapevine <i>Vitis vinifera</i>				Foliar application spraying			From BBCH 20	2-5	3 to 4 weeks	4.25 to 8.5	150 to 300	12.75	25.5 to 63.75				

* The product should be applied early in the morning or late in the evening for a maximum of efficiency. It should not be used on wet plants or in case of rainy weather. It should be applied again after a heavy rain. Although no effects have been observed on bees, we recommend the application of Invelop® apart from the periods of bees' activity specially during the flowering of the crop. This is for a maximum efficacy related to the critical stages observed during the experimental trials and in order not to disturb pollinator insects.

** The product is a mineral dispersed in water (dispersion). Water dispersion prepared just before application and maintained stirred.

- (a): For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b): Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c): e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor
- (d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
- (e): GCPF Codes – GIFAP Technical Monograph N° 2, 1989
- (f): All abbreviations used must be explained
- (g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
- (i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
- (j): Growth stage at 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
- (k): Indicate the minimum and maximum number of application possible under practical conditions of use
- (l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m): PHI - minimum pre-harvest interval