Trusted science for safe food

TG IUCLID PESTICIDES meeting

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Section 3
GAP Table for IUCLID

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Summary

- Introduction
- Different GAP tables
- Pilot project in MRL applications
- Next steps under IUCLID
- Discussion

Introduction

Definition of GAP in Art. 3(2)(a) of Regulation 396/2005

'Good Agricultural Practice' (**GAP**) means the nationally **recommended**, authorized or registered **safe use** of **plant protection products** under actual conditions at **any stage of production, storage, transport, distribution and processing** of **food** and **feed**.
It implies the application of the principles of integrated pest control in a given **climate zone**, as well as using the minimum **quantity of pesticides** (…) which allows the desired effect to be obtained.

To demonstrate the safe use, the applicants have to submit a dossier including studies representative for the intended use ("valid studies").

Introduction

The GAP should describe in an unambiguous way how the pesticide shall be used… but experience has shown that if we do not use a **common language** to describe the GAP, we face difficulties in assessing the intended uses (e.g. for MRL applications).

Consequences

Often we need to requests **clarifications** or **clock-stops** (for MRL applications)

- If GAP table is not clear or
- If studies submitted in the dossier are not representative for the intended GAP

→ Delays in the assessment.

OECD GAP table

GAP table template -OECD

Crop and/ or situation (a)	Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		

Remarks: (a) For crops, Codex (or other, *e.g.* EU) classifications should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 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 plants - type of equipment used must be indicated
(i) g/kg or g/l
(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) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Excel GAP table (for MRL assessments)

We tried to improve the clarity of the GAP table

- Translate parameters into Excel-spreadsheet
- Identify which parameters are relevant for MRL setting
- Use codes and develop standard terminology for the most important parameters (work still ongoing)
  - Crops, a.s., countries….
- Standard terminology shall allow validation of data required to support MRL application (“crop characteristics database”)
- Develop functionalities that facilitate the completion of the GAP table (work still ongoing)

Structure of GAP table (for MRL assessments)

Parameter	Mandatory	Pick-lists
Crop code	(linked to crop name)	
Crop name	Y	Y
Region	Y	Y
Country full name	Y	
Country ISO code	(linked to country full name)	
Outdoor / Indoor	Y	Y
Pests controlled		
Active substance (a.s.)	Y	Y
Variant of a.s.	depends on a.s.	
Formulation type	Y	Y
a.s.concentration in formulation	Y	
Unit (concentration of a.s. in formulation)	Y	Y
Method	Y	Y
Growth stage from BBCH	Y	Y
Growth stage until BBCH	Y	Y
Min. number		
Max. number	Y	
Interval (days) Min.	Y	
Interval (days) Max.		
Min. water amount		
Max. water amount		
Unit for water amount		Y
Min. application rate (expressed as a.s.)		
Max. application rate (expressed as a.s.)	Y	
Unit for application rate	Y	Y
PHI or wiaiting period (days)	Y	Y
Comments (max. 250 charachters)		

Pilot project

Since **December 2018**

- EFSA transferred the GAPs from Evaluation Report into Excel table
- We asked MS to confirm the correctness of the GAP
- The confirmed GAP replaced the GAP from ER/application form
- The exercise was useful to identify what works/does not work in practice for the real intended uses on a wide range of commodities
- Identify need for improvements of the GAP table
- We realized that due to diversity of GAPs, the GAP table will not cover all cases.
- Need to allow some 'freedom' to complete certain data elements.

Structure of a comprehensive GAP table 1/3

Comprehensive GAP table is developed for national authorization purposes (**PPPAMS**)

Discussions to develop a comprehensive GAP table to describe the use parameters are a good starting point for the development of the GAP table format used under IUCLID

Field	Ex…	Controlled terminology available
Reference (Application)		free text
Authorised/intended/representative/use authorised		Y, to be furthr developed
Use number		numerical field
Crop EPPO code		Y, to be furthr developed
Crop common name (EN)		Y
Crop scientific name		Y
Food code (Reg. 396/2005)		Y
Commondity name (MRL request)		Y
Country full name	…eral	Y
Country ISO code		Y
Regulatory zone under 1107/2009		Y
Region for MRL setting	…n residue zone	Y
Regions for efficacy assessment	EP…	Y, to be furthr developed
Growing crops	This is a …base, In PPPAMS the field 'growing crops' covers: Gl… …oor and Outdoor or field use. To be furter elaborated	to be discussed
Outdoor / Indoor	Probably overlap with "growing crops"; to be further elaborated.	Y, to be furthr developed
Pest/harmful organism/disease- EPPO codes	Drop-down list to be developed; needs to contain also "others" which have to be specified in a separate field.	Y
Pest/harmful organism/disease scientific name	linked to "Pest/harmful organism/diseases- EPPO codes	Y
Pests/harmful organism/disease common name (EN)	linked to "Pest/harmful organism/diseases- EPPO codes	Y
Development stage of pest/harmful organism/disease	pre-emergence of weed, post emergence of weed etc.	Y, to be furthr developed
Comments pest/harmful organism/diseases	allows to specify "others"; any further explanation beyound the codes	free text
Professional/non-professional use		only Y or N allowed
Formulation identifier	Unique identifier for each formulation composition.	free text
Formulation type	Drop-down list with GIFAP codes	Y
Formulation type- full name	linked to "formulation type"	Y
Number of a.s. present in the formulation	To specify how many different active substances are in the formulation. The following 3 cells will be multiplied, depending on the number inserted.	numerical field

Structure of a comprehensive GAP table 2/3

Cont.

Field	Explanation	Controlled terminology available
active substance 1 (a.s. 1)	Drop-down list with list of a.s. from COM database. If necessary, additional active substance can be added to the list.	Y
variant of a.s. 1	If an active substance is used in the formulation as a variant, the type of variant needs to be specified.	Y, to be furthr developed
a.s. 1- conc. in formulation	The concentration of the active substance needs to be expressed for the basic substance (not fo the variant)	numerical field
Unit (concentration of a.s. 1 in formulation)		Y
active substance 2 (a.s. 2)		see a.s. 1
variant of a.s. 2		see a.s. 1
a.s. 2- conc. in formulation		see a.s. 1
Unit (concentration of a.s. 2 in formulation)		see a.s. 1
active substance 3 (a.s. 3)		see a.s. 1
variant of a.s. 3		see a.s. 1
a.s. 3- conc. in formulation		see a.s. 1
Unit (concentration of a.s. 3 in formulation)	Unit how the concentration is expressed, drop down list. Is it enough to have one field on the unit of the concentration of a.s. in formulation?	see a.s. 1
Safener in formulation or added to formulation		Y, to be furthr developed
Safener - conc. in formulation		Y, to be furthr developed
Unit (concentration of safener in formulation)		Y
Adjuvant added to the formlation		Y, to be furthr developed
Adjuvant - conc. to be added to formulation		Y
Unit (concentration of adjuvant in formulation)		Y
Method / kind of application	Drop-down list to be further developed.	Y
Growth stage from BBCH	Drop-down list	Y
Description of growth stage	To be completed automatically, depending on BBCH code and crop	Y
Growth stage until BBCH	Drop-down list	Y
Description of growth stage	To be completed automatically, depending on BBCH code and crop	Y
Season		Y
Min. number of applications	numerical field, number of applications	numerical field
Max. number of applications	numerical field, to be used to identify critical GAP	numerical field
Min. application rate formulation		numerical field
Max application rate formulation		numerical field
Interval (days) Min.	numerical field, to be used to identify critical GAP; shall we split the unit (days) to be reported in a separate field?	numerical field
Interval (days) Max.	numerical field	numerical field

Structure of a comprehensive GAP table 3/3

Cont.

Field	Explanation	Controlled terminology available
Min. water amount		numerical field
Max. water amount		numerical field
Unit for water amount		Y
concentration formuation/hL min.	in tank mix	numerical field
concentration formulation/hL max.	in tank mix	numerical field
Min. application rate (expressed as a.s. 1)	The following two fields are repeated, depending on the entry in field "Number of a.s present in the formulation". Can be linked to concentration of a.s. 1 in formulation and minimum application rate formulation.	numerical field
Max. application rate per application (expressed as a.s. 1)	used to identify critical GAP; applciation rate needs to be expressed for the basic substance (not the variant). Can be linked to concentration of a.s. 1 in formulation and minimum application rate formulation.	numerical field
Unit for application rate for a.s. 1		Y
Min. application rate (expressed as a.s. 2)		see a.s. 1
Max. application rate per application (expressed as a.s. 2)		see a.s. 1
Unit for application rate for a.s. 2		see a.s. 1
Min. application rate (expressed as a.s. 3)		see a.s. 1
Max. application rate per application (expressed as a.s. 3)		see a.s. 1
Unit for application rate for a.s. 3		see a.s. 1
Maximum seasonal application rate a.s. 1		see a.s. 1
Unit for application rate (seasonal application) for a.s. 1		Y
Maximum seasonal application rate a.s. 2		see a.s. 1
Unit for application rate (seasonal application) for a.s. 2		see a.s. 1
Maximum seasonal application rate a.s. 3		see a.s. 1
Unit for application rate (seasonal application) for a.s. 3	drop down list	see a.s. 1
PHI or wiaiting period		numerical field
Unit for PHI		Y
Reentry period	for workers re-entering treated fields/structures…	numerical field
Unit for re-entry period		Y
Seed/sowing rate		Y, to be furthr developed
Use restrictions		free text
Comments (max. 250 charachters)		free text
Duration of tretament window	For dispensers	free text
Ventilation practices	for greenhouses, storage rooms,	free text

Next steps under IUCLID

- Develop GAP table format to be used under IUCLID
- Identify the parameters needed to describe the use of plant protection products
- Identify for which parameters harmonized terminology exists/needs to be developed (compatibility with OHT templates for studies required to be submitted in support of an application)
- Define the repeatable blocks of parameters
- Identify mandatory / conditional mandatory / non-mandatory information
- Develop validation rules for the GAP table
- Prepare a guidance document to explain how to code GAPs (to ensure harmonized use)

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