EUROPEAN COMMISSION
HEALTH & FOOD SAFETY DIRECTORATE-GENERAL

Safety of the food chain
Chemicals, contaminants, pesticides

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DRAFT

Template to notify intended zonal applications under Article 33 and Article 43 of Regulation (EC) No 1107/2009

Background

At least six months before the application is due to be made it is recommended that the applicant should submit to all zonal contact points in MSs in the zone a summary of the products for which authorisation will be sought, detailing in which MSs the authorisation is envisaged. In the case of application according to Article 43 this summary should preferably submitted 1 year before the indicative/estimated application of the renewal of the PPP.

A common format ("notification form") has been developed which should be used by applicants (see Appendix). This will help to organise the allocation of work to MSs and speed up the process. In future, the applicant shall also feed this information into the authorisation database.

Implementation schedule

This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014. This template is already in use for zonal applications as it is similar to the appendix 3 of the Guidance document on zonal evaluation and mutual recognition (SANCO/13169/2010).

Form to notify intended zonal applications under Article 33 and Article 43 of Regulation (EC) No 1107/2009

Send to contact points of zonal Rapporteur(s) (zRMS) and concerned MS (cMS) [1] preferably via e-mail

Please use one sheet for every product

1. Product name(s)

2. Product code(s):

3. Type of formulation:

4. Name and content of the active substance(s) (name all active substances); if applicable, date of application for renewal of each substance:

5a. EU countries, in which authorisation is granted (authorisation status):

5b. EU countries, in which renewal of the product is envisaged

[1] For list of contact points see European Commission Website http://ec.europa.eu/food/plant/protection/evaluation/contact_points_en.xls

6. Applicant/authorisation holder:

Company name: Company address: Name contact: Tel.no. contact: Email contact:

The applicant is the notifier for renewal of the active?

☐ **yes**

☐ **no**

If NO, please indicate data access to studies necessary for renewal of the active:

☐ **Letter of access**

☐ **Alternative and equivalent studies**

☐ **Other (indicate, what)**

7. Intended zones, proposal for zRMS of each zone (for possible work sharing of zonal independent assessments) and indicative date for submission of the application to zRMS and cMS (in case of renewal 3 months after indicative renewal decision of the active substance):

Northern zone:	indicative/estimated submission date:

Central zone:	indicative/estimated submission date:

Southern zone:	indicative/estimated submission date:

EU-wide zone: izRMS: cMS:	indicative/estimated submission date:

Planned MR (mutual recognition) MS:	submission date:

8. **If interzonal worksharing is possible, please indicate proposal for zRMS** of section 1 (i.e. phys-chem properties), section 2 (i.e. analytical methods), section 3 (i.e. study evaluation without risk assessment) and part C (confidential information)

9. Studies to be provided reflecting new data requirements and/or possible change of endpoints (indicative statement):

The applicant intends to provide all studies required (reflecting new data requirements and/or possible change of end points)?

☐ **yes**

☐ **no**

If NO, please indicate which studies to be provided later (***if possible***) including a reasoned statement why the studies may not be provided in time and a binding date for completion of the studies:

Study	**Reasoned statement for not providing in time**	**Date for completion**

10. Summary of uses

a. For general overview of products within the zone, please complete table in appendix A.

b. For details of all national GAPs within the zone, please complete table in appendix B.

c. For the zone, which MS authorized use represents the critical GAP – and thus can be used to establish the risk envelope. Please complete table in appendix C.

11. Is the source of the active substance(s) identical with the one(s) evaluated for the (renewal of the) approval?

If the source has been assessed previously please, provide information which MS carried out an equivalence assessment and when.

If not, an equivalence assessment has to be carried out according to Article 38 of Regulation 1107/2009 (in line with Article 43 of 1107/2009). In that case appendix E would need to be completed and should be sent separately or provided at the pre-submission meeting[2].

Please note:
A short but sufficiently descriptive summary should be provided together with this form highlighting critical aspects and potential areas of concern.

Detailed technical questions should be submitted separately in time prior to pre-submission meetings with zRMS (or cMS, if relevant).

[2] In cases that the applicant has no access to these data, the specification could be sent directly from the respective applicant/manufacturer to the zRMS/cMS with a clear reference.

PPP (product name/code):
Active substance(s) (name and content, g/L or g/kg):
Formulation type:
Field of use:
Zone(s):

Appendix A - General overview of products or existing authorisations within the zone

MS	Product name	Product code	Active substance(s) and content (g/L or g/kg)	Crop(s)	Applicant or authorisation holder	Authorisation number of authorised product[3]	Comments

[3] For new products not yet authorised this field is not applicable.

PPP (product name/code):
Active substance(s) (name and content, g/L or g/kg):
Formulation type:
Field of use:
Zone(s):

Appendix B - details of all intended national GAPs within the zone (to be sorted by crop); for existing authorisations this should be based on the existing uses in the zone
(For further information regarding filling the table see appendix D)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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		
1													
2													
3													
4													
Field uses													
1													
2													
EU-wide uses (use on sowing seed, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to article 51													
5													
6													

PPP (product name/code):
Active substance(s) (name and content, g/L or g/kg):
Formulation type:
Field of use:
Zone(s):

Appendix C – critical intended uses within each zone; for existing authorisations this should be based on the based on the existing uses in the zone

Table A: Operator/worker/bystander/resident exposure risk assessment (copy of relevant use(s) from appendix B)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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		
1													
2													
3													

Table B: Dietary risk assessment (copy of relevant use(s) from appendix B)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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		
1													
2													
3													

PPP (product name/code):
Active substance(s) (name and content, g/L or g/kg):
Formulation type:
Field of use:
Zone(s):

Table C: Environmental risk assessment (copy of relevant use(s) from appendix B)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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		
1													
2													
3													

Table D: Ecotoxicological risk assessment* (copy of relevant use(s) from appendix B)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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		
1													
2													
3													

*) For the ecotoxicological risk assessment the critical organism should be indicated under remarks.

Appendix D – guidance for filling the GAP table

General remarks/explanations:

The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data) – not relevant for the notification form.
The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops).

All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.
Make use of existing standards like EPPO and BBCH.

Product:

Please indicate the specific variant of the active substance if relevant.

If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks.

As the product usually will be determined either for professional or non-professional use, this information should be given here. Otherwise it should be indicated in column 4 of the GAP-sheet (conditions/location of use).

Formulation:

Type:

e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1)].

Conc. of as:

g/kg or g/L
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Safener/Synergist:

Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.

Zone(s):
All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.

Explanations to the particular columns:

No.:

Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.

Member State(s):

For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the

[1)] http://www.croplife.org/files/documentspublished/1/en-us/PUB-TM/4147_PUB-TM_2008_05_01_Technical_Monograph_2_-_Revised_May_2008.pdf

zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order according to the zone they belong.

Crop and/or situation:

The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote).
If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones.

Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated.

This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).

Conditions / location of use:

Outdoor or field use (F), glasshouse application (G) or indoor application (I)
"Glasshouse" indicates that the respective trials are acceptable for all zones.

As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is authorised], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated.

[Remark: Greenhouse definitions are at the moment under evaluation].

Conditions include also information concerning the substrate (natural soil, artificial substrate).

Pests or Group of pests controlled:

Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling 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.
If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated.
In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually).

If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:

Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).

Growth stage of crop (BBCH-code, …) – period, first and last treatment.
Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition.

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column "pest or group of Pests controlled".

In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications

a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.

It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.

Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:

A (Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.

Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.

For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.
Information concerning the sowing method (precision drilling, …) would be advantageous.

See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:

a) (Maximum) as rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.

The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:

It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations.
In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials.
If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".

PHI (days) – minimum pre harvest interval

PHI - minimum pre-harvest interval

For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks:

Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product.

Additional recommendations:

For the description of uses of a PPP the following EPPO Standards should be considered:

- EPPO Standard PP 1/240 "Harmonized basic information for databases on plant protection products"
- EPPO Standard PP1/ 248 "Harmonized classification and coding of the uses of plant protection products"

Whereas EPPO Standard PP1/ 248 gives more general information on possible description of uses, EPPO Standard PP 1/240 especially gives an overview of all points necessary to fully understand a use.

For EPPO-Guidelines, see: http://archives.eppo.org/EPPOStandards/efficacy.htm

Use EPPO extrapolation tables, see http://www.eppo.org/PPPRODUCTS/extrapolation/tables.htm

For EPPO Plant Protection Thesaurus, see: http://eppt.eppo.org/

Appendix E – Specification of the used technical material
(Document should be sent separately or provided at the pre-submission meeting)

Name of the active substance or variant:
Manufacturer:
Location of the manufacturing site:

Chemical name/code	CAS number, if available	Structural formula	Specified levels Minimum purity (as) Maximum content (impurities) [g/kg]