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HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E - Safety of the food chain
E3 - Chemicals, contaminants, pesticides

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WORKING DOCUMENT

on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009

COMMISSION STAFF WORKING DOCUMENT – DOES NOT NECESSARILY REPRESENT THE VIEW OF THE COMMISION SERVICES

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Background

This document aims to provide guidance for the submission of applications concerning active substances which could be approved as "basic substances" according to provisions laid down by Regulation 1107/2009[1] on placing plant protection products on the market. In addition, it aims to clarify the procedural steps for approval.

Regulation 1107/2009 introduces the new category of "basic substances" which are defined by recital 18 as "certain substances which are not predominantly used as plant protection products may be of value for plant protection, but the economic interest of applying for approval may be limited. Therefore, specific provisions should ensure that such substances, as far as their risks are acceptable, may also be approved for plant protection use".

On this basis, specific provisions are set to ensure that such active substances, as far as they do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment, can be legally used in the EU after having been approved as "basic" under Regulation 1107/2009.

In particular, in its Article 23, the Regulation lays down specific criteria to identify an active substance as eligible as basic:

(a) is not a substance of concern as defined in Article 3(4) of Regulation 1107/2009; and

(b) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

(c) is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and

(d) is not placed on the market as a plant protection product.

In addition, Article 23 states that "*an active substance which fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002*[2] *shall be considered as a basic substance*".

The definition of "foodstuff" given in Article 2 of Regulation (EC) No 178/2002 : 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

"Food" does not include: (a) feed; (b) live animals unless they are prepared for placing on the market for human consumption; (c) plants prior to harvesting; (d) medicinal products within

[1] OJ L 309, 24.11.2009,p. 1
[2] OJ L 31, 1.2.2002,p. 1

the meaning of Council Directives 65/65/EEC (1) and 92/73/EEC (2); (e) cosmetics within the meaning of Council Directive 76/768/EEC (3); (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (4); (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971; (h) residues and contaminants.

Therefore, ingredients such as food additives or flavourings are considered food and benefit from the provisions of Article 23 paragraph 1.

A basic substance should comply with approval condition of Article 23(2). In particular the substance should benefit from a previous evaluation under EU law and have no harmful effect on human or animal health and no unacceptable effect on the environment.

The basic substance will be then approved by the Commission and listed in a separate list in Regulation 540/2011, before its use is legal for plant protection purposes.

Finally, the Regulation establishes that when a substance is approved as a basic substance, it is approved for an unlimited period of time and no authorisations will be required for sale and use of products consisting exclusively of basic substances.

1. Compliance with established criteria on basic substances and their products

Information to be provided with the application must demonstrate the compliance of the substance with criteria of Article 23. The applicant will have to demonstrate that the substance is not a substance of concern; that it is not known to have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects and any immediate or delayed harmful effect on human or animal health nor any unacceptable effect on the environment, deriving from the use of the substance, either directly or in a mixture consisting of the substance and a simple diluent. Finally, the basic substance is not be placed on the market as plant protection product.

The applicant must substantiate that the substance complies with all criteria of Article 23 by means of information included in the application.

In order to be approved as a basic substance, it should comply with provisions of Article 23(2) which means that the substance should have already been evaluated in view of other uses. The applicant will provide within the application all information on the assessments carried out under other legislative frameworks and a detailed description of the intended use pattern to exclude unacceptable risks. The substance must fulfil the specifications set under the other Community legislative frameworks. Those assessments should be collated, summarised and analysed to support the approval of the substance as "basic substance". The referenced studies will be submitted when available, at least an electronic reference should be provided.

1.1. Food or foodstuffs as defined in Regulation (EC) No 178/2002

In case of food or foodstuffs as defined in Regulation (EC) No 178/2002, the applicant should include all available assessments. When food grade specifications have been set, as in the case of additives, and such assessment is used to support the basic substance identification, again evidence has to be provided to demonstrate compliance with those specifications (see Chapter 3 below). Nevertheless, in the case no specific assessment nor authorisation is required under EU food law, assessments may not be available. In this case, it is considered that the assessments are not necessary for the purpose of the Article 23, as the principle is that food does not present a risk for human health and does not require an assessment before being marketed, hence the qualification as food under Regulation 178/2002 stands for a relevant evaluation (with respect to human health).

On the other hand, for all basic substances, it means that all evaluations carried out for example in the context of approval of food additives, pharmaceuticals and veterinary drugs, cosmetic, novel foods should be provided to support the identification and evaluation of the substance as basic substance under Regulation No (EC) 1107/2009. However, additional risk assessment may be needed due to the specific use in plant protection. Risks can result from the manner of application, including possible outdoor uses of the substances, so that human and animal health, the environment and non-target organisms can be affected.

To substantiate the judgement that a substance has no immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment, justifications can be included instead of studies and information, wherever appropriate. For example: it would be not necessary to supply an assessment of a specific risk, when the exposure by the plant protection use would only add a little to an existing exposure not subject to any limit. In that case the use for plant protection would not pose any specific risk.In case of foodstuff the applicant will compile the application for the parts concerning description of the substance, the preparation of the substance (e.g. plant extracts) and of the product to be applied, the details of envisaged uses for plant protection, including information on the absence of any potential harmful effect on human and animal health or unacceptable effect on the environment and legal references to substantiate the claim that the substance is foodstuff.

For any application, the applicant is requested to submit all available information which might have also an influence on the setting of conditions for use according to Article 6.

Compliance with criteria of Article 23 (1) (c) and (d) will have to be explained under point 2 of the Application (see Application template in Annex I). Chapter 3, below, will provide further clarification on these issues.

1.2. Products on the market containing exclusively one or more "basic substances" Article 28(2)(a)

Since products falling under Article 28(2)(a) of the Regulation (products containing exclusively one or more basic substances) do not require any authorisation for use as they are on the market not as plant protection products, hence they do not profit from data protection under the Regulation, it can be anticipated that many dossiers will be mainly based on information which is already available, such as:

- unprotected studies

- scientific literature or

- a bibliographic review of safety data collated, for example in compliance with other Community regulatory frameworks together with an expert analyses complemented or supplemented by any data considered necessary to fulfil criteria.

Considering that no authorisation under Reg.1107/2009 will be necessary for placing a product on the market containing exclusively one or more basic substances (Art. 28(2)(a)) as they are not plant protection products, it is the producer's responsibility to ensure that its product is safe in accordance to provisions of Product safety Directive 2001/95/EC[3] and its respective national implementations.

The product shall not be placed on the market as a plant protection product, but the label on the product may indicate that the basic substances it contains are approved under Article 23 of Regulation 1107/2009.

Whenever, the producer will add a reference on the label of the product to Article 23 of Regulation 1107/2009, it is recommended to add also any information related to conditions of approval of the basic substances of which the product consists of. However, it must be borne in mind that the product cannot be sold as plant protection product.

It is recognised that the producer of such product may choose not to add such reference to the label. This may particularly be the case where the producer (under the other Community regulatory framework) is not the applicant for the approval as a basic substance. Hence, the Commission as well as member states will have to put measures into place to inform the public of basic substance approvals and their respective conditions.

1.3. Products made of "basic substances" and other substances

Any other products deviating from the definition of Article 28(2)(a) containing for example an already approved "basic substance" and a co-formulant shall have to be considered as plant protection product. Therefore, in compliance with Article 2 in that case the substance will constitute the "active substance". In such case, the substance need to be approved as active substance. An application accompanied by a dossier in compliance with Article 8 of the Regulation will have to be submitted.

In the hypothetical case of a substance already listed as "basic" where an applicant would submit an application for an approval as "active", the applicant will provide evidence in conformity with data requirements for the"active"substance, including efficacy data. Moreover, for example in the case of a basic substance being a plant extract the "active" can often be linked to a specific component, hence related to a purified extract not yet available on the market and having own specifications different from the basic substance already approved. In this last case, the two compounds having different specifications will potentially be listed separately.

[3] OJ L 11, 15.1.2002,p. 4

On the contrary, a basic substance may be used in a formulation of plant protection product together with one or more active substances, as it has already been clarified in the document Questions and Answers on Regulation (EC) No 1107/2009 available at the SANCO webpage http://ec.europa.eu/food/plant/plant_protection_products/legislation/docs/qanda_regulation_1107-2009_en.pdf

Therein is stated: " ..If a basic substance is mixed with an active substance and it is intended to be used for one of the purposes listed in Article 2(1) paragraphs a) to e) of Regulation (EC) No 1107/2009, the mixture will be considered as a plant protection product. This plant protection product may not be placed on the market or used unless it has been authorised in the Member State concerned.
The active substance contained in the plant protection product needs to be approved as described in Articles 4 to 13 of Regulation (EC) No 1107/2009. The basic substance which is contained in the plant protection product does not need to be approved as an active substance following the procedure described in Articles 7 to 12, nor according to the procedure described in Article 23. In fact, in case of a product containing at least one active substance, it is irrelevant if the other components are basic substances or not.
When a Member State receives an application for the authorisation of a plant protection product consisting of a mixture of a basic substance with an active substance, it will evaluate the plant protection product containing the basic substance in the same way as in the case of a plant protection product containing a co-formulant."

For sake of clarity, with respect to plant protection products assessment, any substance has to be evaluated for its specific function in the formulation as being in the scope of Regulation 1107/2009 laid down in its Article 2(3). On the basis of its function, it is added to the formulation itself and such function must be duly sustantiated with scientific evidence.

2. Application for approval of a basic substance

The application for the approval of a basic substance may be submitted by a Member State or by any interested party to the Commission following the template attached in this Guidance as Annex I.

The application will be made available to the public, therefore the applicant may include a request for certain information to be treated as confidential as foreseen in Article 63 of Regulation (EC) 1107/2009. In that case, the applicant shall keep that information separate and write also, in the same separate document, the reasons why such information shall be treated as confidential. In addition, in compliance with Article 63(1) of that same Regulation, he/she shall provide "*verifiable evidence to show that the disclosure of the information might undermine his/her commercial interests, or in the protection of privacy and the integrity of the individual*". It is recommended to consult Article 63 to verify which type of information is considered to be relevant to the protection of commercial interests or privacy or integrity of the individual.

The application template is based on the structure of the EU assessment report compiled for active substances to be used in plant protection products. It refers to all areas of the risk assessment usually evaluated in regulating uses of plant protection products and has to be considered as a structured template to elaborate a file collating and assessing all possible information to demonstrate that basic substances criteria are fulfilled.

Due to the variability of combinations among substances and possible uses under examination, a wide approach is taken. Therefore, in many cases, not all the items included in the template will be relevant or require supporting data. In cases where an item is considered not applicable or not appropriate by the applicant, the applicant will restrict his contribution under this item to "Not applicable" together with a justification why he deems this item not to be applicable/appropriate for the substance in question.

Article 23(3) requires that:

"The application shall be accompanied by the following information:

(a) any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Community legislation regulating the use of the substance; and

(b) other relevant information on its possible effects on human or animal health or the environment. "

The users will be responsible for using only approved basic substances for plant protection purposes, having in mind that the substance is placed on the market for other purpose(s) than plant protection.

However, this does not relieve the applicant of its responsibility to provide only trustworthy information and to include in the application any relevant information on any foreseeable negative effects (see also reference to Directive 2001/95/EC under chapter 2).

In case an application is referring to a substance for which an application for approval as active substance is pending, this substance will be evaluated as an active substance in accordance of Regulation 1107/2009. No application for approval as basic substance for the same substance will be accepted.

However, in the case an active substance approval is expired, no plant protection products containing the active substance are authorised in EU and the active substance itself complies with the other criteria for approval as a basic substance, than an applicant could apply for approval as basic substance for this previously approved active substance.

3. Content of the Application (see also template in Annex I of this Guidance)

3.1. General

For basic substances representing only foodstuffs, the risks are supposed to be inherently low for human health. However, human and animal health, the environment and non-target organisms can be affected as risks can result from the manner of application and given the possible outdoor uses of the substances. Therefore, it is important to provide a detailed description of the intended use pattern and results of any assessment carried out on the substances to exclude unacceptable risks.

The amount of information to be provided will depend on the properties of the substance and its intended uses. The application template which is included as Annex I to this Guidance is therefore quite comprehensive, but the application should be completed in a proportionate manner and matters which are not relevant need not to be addressed. However, the applicant must justify why a certain type of information/documentation is not needed in the particular case which means that the applicant should give an appropriate justification for each section why it might be acceptable to waive information or studies.

As far as practically possible, coherence must be ensured in terms of specifications as the substance should respect the same specifications assessed and, as appropriate, set under other Community legislation. A case should be made that the assessed specification covers the sources of the substance.

All relevant available information submitted with the application (studies, scientific publications, regulatory evaluations finalised in the context of authorisation for other uses e.g. food additive assessments, as well as evaluations available in OECD or other countries) should be submitted physically in the Appendix to the Application template and always listed in the Annex I as reference relied upon.

To include peer-reviewed open literature the applicant should follow the recommendations of the specific European Food Safety Authority (EFSA) Guidance on submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009[4].

For EU assessments, such as opinions of the European Food Safety Authority (EFSA), and others widely available in electronic format, a list of references with links is sufficient. Copy of the results publication or electronic reference to the original studies can be sufficient when studies themselves are not available and an evaluation under other Community regulatory frameworks has been performed.

The information provided should be sufficient to allow the identification of the basic substance. When the substance is not to be used directly, sufficient information should be provided for at least one mixture which is expected to be prepared by users.

In case of plants and plant extracts, the substance can be used as such, it is therefore not always possible to differentiate between the substance and the product. At least, the extraction

[4] EFSA Journal 2011; 9(2):2092.doi:10.2903/j.efsa.2011.2092 available on line: www.efsa.europa.eu

process (which may include heating and other steps) has to be thoroughly explained, as a sort of recipe for the preparation and/or the use. The extraction method shall become part of the specification of the basic substance.

3.2 Clarifications on the structure of the application template

Purpose of the application (Point 1 of the Template) : The Applicant should describe the reasons why he/she supports the substance as basic substance and the envisaged uses in plant protection adding, when possible, information on its traditional use in agriculture e.g. interest for organic agriculture. The applicant should also provide his/her contact details.

Identity of the substance and product as available on the market and their predominant uses (Point 2)

The Applicant should provide information demonstrating that criteria of Article 23 (1) (c) and (d) are fulfilled: information on the substance, the type and specification of product, whether it is directly used or in a simple diluent preparation, information on how it is normally used, feedback justifying harmlessness and information on how it is put on the market and finally information on the use for plant protection. This final information should be detailed under point 3. See below.

Specific points from 2.1. to 2.1.7.

Applicant should provide specifications data related to the substance and where appropriate to the product. Where relevant, this information should address the issue of the relation with the specifications already assessed and as appropriate set under other Community legislation[5] e.g. food additives.

When specifications are not yet set under other legislative frameworks, enough information should be provided to characterise the substance and its product in terms of purity and impurities, identity of significant impurities must have been assessed and their toxicity verified to establish a chemical profile with e.g. for plant extracts description of the major components concentration range and any possible contaminants. To fulfil these requirements, please consult the specific data requirements on active substances included in Regulation 544/2011.

If possible, the applicant should provide reference to a validated method for analysing the substance and in case of plant extracts if not all components can be identified, a validated method of analysis of the markers of the extract should be available.

Methods of manufacturing of the substance and product should be provided where relevant and applicable to exclude existence of any possible sources of contamination.

[5] Reference to specifications set by other relevant international institutions such as FAO could also be included.

When applicable, reference[6] to validated methods for analysing the substance in water, soil and air should be provided if exposure of the respective compartment is likely and if the additional contribution compared to natural exposure levels is relevant and detectable.

If any toxic impurity, relevant for human or animal health and the environment could be present a validated methods of analysis must be available.

Current, former and in case proposed trade names of substances/ products as put on the market (Point 2.2.)

Applicant should indicate some of the trade names under which the substance and products are normally marketed.

Manufacturer of the substance/products (Point 2.3.)

Applicant should indicate the names of manufacturers when appropriate.

Type of preparation of the substance/product (Point 2.4.): The substance/product should be described as well as how it is presented when placed on the market.

Description of the preparation for the product to be used (Point 2.5.) The preparation for the use must be thoroughly described: indeed both ingredients and the process itself must be described, to be thoroughly detailed the recipe of the product as it will have to be applied.

Uses of the substance and its product for plant protection (Point 3)

From Points 3.1. to 3.3. Function on plant protection: Applicant should indicate which is the mechanism of action against pests, weeds and diseases or if it has any eliciting mechanism, etc...Where there is uncertainty, a putative mechanism should be suggested.

Applicant should provide detailed information on the uses of the basic substance for plant protection completing the table provided: the description of typical practices of applying the products, method of mixing/loading and way of application on plants. Applicant should indicate if post application exposure may occur.

Applicant shall also provide any information available on the usefulness for plant protection deriving from the supported uses, preferably studies or literature. Such information can also be provided in the form of a statement from growers associations or/and extension services.

Classification and labelling of the substance (Point 4)

In case the substance is classified, information should be given as well as if it has been identified a necessity for classification. Indeed, whenever applicable, proposals for the classification and labelling are mandatory in compliance with Regulation (EC) No

[6]In case new validated methods are considered necessary, the applicant will be informed to provide them.

1272/2008[7] of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

Impact on human and animal health (Point 5)

The substance must comply with the criteria in Article 23(1) (a) and (b):

- It is is not a substance of concern; and

- It does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects.

As required in Article 23(2) the substance must have already been evaluated in view of other uses, except for certain foodstuffs for which no specific assessment nor authorisation is required under EU food law.

Finally, a basic substance can be approved "as far as it does not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment".

If for foodstuffs the criteria are already proved, for other substances regulated under other legislative frames, it may still need to be demonstrated or it may need to be proven that the exposure due to the intended use(s) as a basic substance for plant protection purposes does not lead to higher exposures than already resulting from the uses regulated. Relevant dermal and inhalation exposure must be considered, too.

Therefore, all toxicological information available should be examined and summarised including studies, scientific publications, relevant evaluations carried out in accordance with other Community legislation regulating the use of that substance for purposes other than for a plant protection product, but also evaluations done under regulatory reviews performed in OECD or other countries.
When applicable, information on acceptable daily intake, acute reference dose and acceptable operator exposure level should be compiled and provided in the application.
For a more detailed explanation of points from 5.1. to 5.14 please consult the data requirements included in Regulation 544/2011[8]. It should be noted that not all points necessarily need to be addressed, justification needs to be given why certain points do not apply.

Residues (Point 6)

The extent of exposure due to the pesticide use must be compared to the natural exposure or to the exposure arising from other uses and to the exposure via food if the substance itself is part of the normal human diet. No need for setting Maximum Residues Levels (MRLs) should arise, as this would not allow for approval of the substance as basic.

[7] OJ L , 31.12.2008,p. 1
[8] OJ L 155, 11.6.2011,p. 1

If applicable, information on the residue behaviour of the substance should be provided (e.g. metabolism in/on plants, behaviour during processing operations; depending on the properties of the substance, also further data might be required). For a more detailed explanation of point 6 please consult the data requirements included in Regulation 544/2011 or in Regulation 2013/283 respectively. Based on ADI and ARfD values and the expected exposure both from pesticide uses and other sources, the applicant shall conduct a consumer risk assessment to demonstrate that no unacceptable effects on humans have to be anticipated.

However, in case of foodstuffs a simple comparison with possible background range of exposure could be sufficient.

Fate and behaviour in the environment (Point 7)

Based on the description of the intended uses, the potential consequences of increased exposure with respect to natural exposure levels of water, soil or air or to exposure due to other uses should be considered and substantiate that the substance will not have "an unacceptable effect on the environment".

Therefore, all information available should be examined and summarised including studies, scientific publications, relevant evaluations carried out in accordance with other Community legislation regulating the use of that substance for purposes other than for plant protection, but also evaluations done under regulatory reviews performed in OECD or other countries.

More information will be submitted based on expert judgement, as the conclusions on exclusion of any unacceptable effects on environment must be justified.

Effects on non-target species (Point 8)

Based on the description of the intended uses, the potential consequences of increased exposure with respect to natural exposure levels or to exposure due to other uses should be considered and substantiated that the substance has " neither an immediate or delayed harmful effect on animal health nor unacceptable effects on environment".

Therefore, all eco-toxicological information available should be examined and summarised including studies, publications, relevant evaluations carried out in accordance with other Community legislation regulating the use of that substance for purposes other than for plant protection, including evaluations done in OECD or other countries.

More information will be submitted based on expert judgement, as the conclusions on absence of any immediate or delayed harmful effect on animal health and of any unacceptable effects on environment must be justified.

Overall conclusion with respect to eligibility of the substance for approval as basic substance (Point 9)

A synthesis concerning the compliance of the substance with criteria of Article 23, including the properties of the substance, and where appropriate its products, and of the intended manner of use should be included.

Annex I

The Annex I should list all references relied upon. A template table is included.

Appendix

In attachment to the application template, as appendix all evaluations reports, studies, publications and evaluations referred to in the Annex I (list of references) should be collated and submitted (e.g. CD ROM) to complete the file for the basic substance. The studies should be submitted whenever possible (see section 3.1.1.).

4. Procedure for approval of Basic substances

The complete application including all appendices shall be submitted to the Commission (DGSANCO), who will perform a first mainly administrative check on admissibility related to the definition of basic substances, acceptable level of compilation of application, references to studies/documentation and submission of Appendix.

In this first phase, the applicant will be given the possibility to complete its application.

Whenever judged admissible, the Commission will make all documentation received available to all Member States and EFSA via CIRCA BC electronic Forum following an advertising e-mail.

At the receipt of such e-mail, the EFSA's Pesticides Unit will as soon as possible start the consultation process on the complete application allowing a period of two months for Member States and EFSA experts to comment.

At the end of that period, on the basis of a specific mandate from the Commission, EFSA will provide its technical assistance to finalise the commenting round. EFSA Pesticides Unit will collate comments in a structured reporting table and forward it to the applicant.

The applicant will be required to address the comments received within a period of 30 days. After that period, EFSA Pesticides Unit shall collate all comments received including responses from applicant in the structured reporting table finalised on each specific point with its scientific opinion taking into account the discussion in the commenting phase and the applicant responses. In accordance with Article 23, the deadline for technical assistance from EFSA will be three months, therefore, the reporting table will be finalised and submitted to the Commission within 3 months from the reception of the specific mandate from the Commission. In addition to the completed reporting table, EFSA shall deliver its assessment (including consideration of comments) in the form of a technical report with brief discussion of main findings and properties for each section as a summary.

On the basis of the reporting table, the Commission may decide to consult further EFSA to organise a complete or focused peer review, or to deliver its conclusion on certain specific open points.

Finally, EFSA will make all information available to the public excluding Appendix of the application, which includes full text of studies and other background information, and any information for which confidential treatment has been requested and justified pursuant to Article 63 of Regulation 1107/2009.

The Commission, within 6 months from the finalisation of the assessment by EFSA, will submit a review report on the substance stating if the criteria for the approval of the basic substance are met. The applicants will be given the possibility to comment the report.

The Commission will submit the review report and a draft Regulation for approval of the substance as basic to the SCoFCAH.

A Regulation shall be adopted to approve and include basic substances in a separate list in Annex to Regulation 540/2011, conditions and restrictions of approval can be applied as appropriate in accordance with Article 6 of Regulation 1107/2009 and included as appropriate in the approval regulation.

Basic substances are approved for an unlimited period.

Review clause

According to Article 23(6) the Commission may review (withdrawal of approval or revision of conditions of approval) the approval of a basic substance at any time. Article 23(6) describes the procedure for the review of the approval as basic substance.

Member States may require to review the approval. Where the Commission decides not to follow such request it should provide a justification. If the Commission considers that there are indications that the substance no longer satisfies the criteria on basic substances, it will inform Member States, EFSA and the interested parties, setting a period for their comments to be submitted.

The Commission shall ask EFSA for an opinion, or for scientific or technical assistance. EFSA will provide its opinion or the results of its work to the Commission within three months of the date of the request.

The interested parties will have the possibility to comment during a period for the submission of comments set by the Commission.

After that, if the Commission concludes that the criteria are no longer satisfied, a regulation to withdraw or amend the approval is adopted in accordance with the regulatory procedure referred to in Article 79(3) of Regulation 1107/2009.

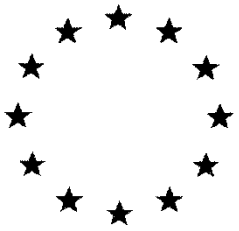
Communication to users

The Commission will keep an updated list of approved basic substances electronically available to the public.

Considering basic substances are not subject to any further authorisation assessment, the approval of a basic substance and its conditions of use will have to be communicated by the competent authorities to the general public and professionals, by means of their national websites and/or by any other form of communication appropriate to ensure information will reach potential users.

ANNEX I – Application Template

European Commission



Pilot project: Proposal for approval of basic substances, in the context of Regulation (EC) N°1107/2009

NAME of substance

BASIC SUBSTANCE APPLICATION TEMPLATE

Date : March 2014

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"Name of substance"

1. PURPOSE OF THE APPLICATION

This report is submitted to support the application for the approval of XXXXXXX as a substance according to Article 23 of Regulation (EC) No 1107/2009 of the European Parliament and Council.

Include reasons to support the substance as basic, its possible use in plant protection and when possible, information on its traditional use in agriculture e.g. interest for organic agriculture.

Name and address of applicants

Name	
Contact person :	
Telephone :	
Fax :	
Email :	
Address :	
Contact person :	
Telephone :	
Fax :	
Email :	
Address :	

2. IDENTITY OF THE SUBSTANCE/PRODUCT AS AVAILABLE ON THE MARKET AND PREDOMINANT USE

Predominant uses of the substance outside plant protection

CITE USE FIELDS AND PROVIDE ARGUMENTS WHY THEY SHALL BE CONSIDERED AS PREDOMINANT REGARDING THE INTENDED USE IN PLANT PROTECTION

2.1. Identity and physical chemical properties of the substance and product to be used

It can be the substance itself or a simple diluent preparation.

Description of the final product and method of preparation to be detailed under 2.5.

2.1.1. Common name of the substance and product and their synonyms/plant nomenclature

Proposed name: *xxxxxxxxxx*

ISO common name (approved or proposed): Not relevant

Synonyms: xxxxxxxxxx

2.1.2. Chemical name with CAS, EEC and CIPAC numbers

2.1.3. Molecular and structural formula, molecular mass

2.1.4. Method or methods of manufacture of the substance and of the product

2.1.5. Description and specification of purity of the substance and product

2.1.6. Identity of inactive isomers, impurities and additives

2.1.7. Methods of analysis

2.1.7.1.Methods of analysis for determination of the substance as manufactured

2.1.7.2.Analytical methods for determination of relevant impurities

2.1.7.3.Analytical methods for determination of residues

2.2. Current, former and in case proposed trade names of substances/ products as put on the market

Indicate some of the trade names under which the substance and products are normally marketed

2.3. Manufacturer of the substance/products

Indicate the names of manufacturers when appropriate.

2.4. Type of preparation of the substance/product

The substance/product should be described as well as how it is presented when placed on the market.

e.g. Dispersible concentrate (decoction).

2.5. Description of the preparation for the product to be used

Describe the recipe/dilution process in details.

3. USES OF THE SUBSTANCE AND ITS PRODUCT

3.1. Field of use

3.2. Effects on harmful organisms or on plants (including mode of action)

3.3 Usefulness in the framework of plant protection

Indicate the mechanism of action against pests or any eliciting or barrier mechanism

3.3. Summary of intended uses

Crop and/ or situation (a)	Member State or Country	Example product name as available on the market	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days) (m)	Remarks*
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l)		

*** e.g. The product can be used only for post harvest application**

* For uses where the column „Remarks. As above or other conditions to take into account	(i) g/kg or g/L. Normally the rate should be given for the substance (according to ISO)
(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)	(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
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)	(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(c) *e.g.* pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor	(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
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..	(m) PHI - minimum pre-harvest interval
(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	

4. CLASSIFICATION AND LABELLING OF THE SUBSTANCE

When not applicable as justified by …….

5. IMPACT ON HUMAN AND ANIMAL HEALTH

Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities contained in the substance/product or their transformation products

5.1. Toxicokinetics and metabolism in humans

5.2. Acute toxicity

5.3. Short-term toxicity

5.4. Genotoxicity

5.5. Long-term toxicity

5.6. Reproductive toxicity

5.7. Neurotoxicity

5.8. Toxicity studies on metabolites

5.9. Medical data: adverse effects reported in humans

5.10. Additional information related to therapeutic properties or health claims

5.11. Additional information related to use as food

5.12. Acceptable Daily Intake, Acute reference Dose, Acceptable Operator Exposure Level

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it

6. RESIDUES

7. FATE AND BEHAVIOUR IN THE ENVIRONMENT-

(EFFECTS ON THE ENVIRONMENT AS DEGRADATION/DISSIPATION IN SOIL; RISK TO GROUNDWATER AND RISK TO SURFACE WATER)

7.1 Fate and behaviour in the environment

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water)

8. EFFECTS ON NON TARGET SPECIES

Effects having relevance to non-target organisms arising from exposure to the substance/its products or to impurities contained in the substance/product or their transformation products

8.1. Effects on terrestrial vertebrates

8.2. Effects on aquatic organisms

8.3. Effects on bees and other arthropods species

8.4. Effects on earthworms and other soil macro-organisms

8.5. Effects on soil micro-organisms

8.6. Effects on other non-target organisms (flora and fauna)

8.7. Effects on biological methods of sewage treatment

9. OVERALL CONCLUSIONS WITH RESPECT OF ELIGIBILITY OF THE SUBSTANCE TO BE APPROVED AS BASIC SUBSTANCE

It has to be described in synthesis the fulfilment of the following criteria to allow for the identification as basic substance

(a) is not a substance of concern; and

(b) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

(c) is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and

(d) is not placed on the market as a plant protection product.

It should be also included a synthesis of the conclusions of the evaluation demonstrating that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment and therefore could be approved as "basic substance".

ANNEX I - LIST OF REFERENCES RELIED ON

Include here all references studies and assessment reports cited in the various chapter of application model.

Author(s)	**Year**	**Title** **Source** **Company, report N°** **GLP or GEP status** **Published or not**
SECTION 1: Identity of the substance and products, uses and preparation process, Physical chemical properties and methods of analyses		
European Pharmacopoeia		N

Author(s)	**Year**	**Title** **Source** **Company, report N°** **GLP or GEP status** **Published or not**
SECTION 2: Classification and labelling		

Author(s)	**Year**	**Title** **Source** **Company, report N°** **GLP or GEP status** **Published or not**
SECTION 3 : Impact on human and animal health		

Author(s)	**Year**	**Title** **Source**

		Company, report N° **GLP or GEP status** **Published or not**
SECTION 4: Residues		

Author(s)	**Year**	**Title** **Source** **Company, report N°** **GLP or GEP status** **Published or not**
SECTION 5 : Fate and Behaviour in the environment		

Author(s)	**Year**	**Title** **Source** **Company, report N°** **GLP or GEP status** **Published or not**
SECTION 6 : Effects on non target species		