

Guidance document on the comparative assessment of plant protection products in France

Version 1 of 27 July 2015
Available on the ANSES website

I. Purpose and regulatory context

Marketing authorisation applications for plant protection products submitted by applicants are assessed in accordance with the uniform principles for evaluation mentioned in Article 29(6) of Regulation (EC) No 1107/2009¹, validated European guidance documents and, where applicable, national regulations.

For plant protection products (PPPs) containing an active substance identified as a candidate for substitution, the assessment prior to the marketing authorisation decision shall also include a comparative assessment for each use, in accordance with the requirements of Article 50 and Annexes II (Point 4) and IV of Regulation (EC) No 1107/2009, within the time limits set out in this regulation.

An active substance approved as a candidate for substitution² is a substance that fulfils one or more of the criteria listed in Annex II Point 4 of Regulation (EC) No 1107/2009.

In accordance with Article 50(1) of this same regulation, Member States shall not authorise or shall restrict the use of a plant protection product containing a candidate for substitution on a particular crop where the comparative assessment weighing up the risks and benefits demonstrates that:

- for the specified uses, other solutions (other authorised plant protection products or non-chemical control or prevention methods) already exist which are significantly safer for human or animal health or the environment; and
- substitution by these other solutions does not present significant economic or practical disadvantages; and
- the chemical diversity of the active substances or practices of crop management and pest prevention are adequate to minimise the occurrence of resistance; and
- the consequences on minor use authorisations are taken into account.

In exceptional cases, if a non-chemical control or prevention method exists for the same use and it is in general use in France, a comparative assessment can also be carried out when assessing an application for authorisation of a plant protection product not containing a candidate for substitution or a low-risk active substance, in accordance with Article 50(2) of Regulation (EC) No 1107/2009.

The purpose of this guidance document is to explain and specify the process implemented in France by ANSES, which is responsible for issuing marketing authorisations (MAs) for plant protection products, pursuant to Article L. 1313-1 of the French Public Health Code.

This guidance document was written on the basis of the following European guidance documents:

- the referenced guidance document SANCO/11507/2013 rev.12 "Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009" published by the European Commission on 10 October 2014;

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

² Pursuant to Article 80(7), the European Commission shall establish a list of substances approved as candidates for substitution. As of the date of this document, the list of active substances approved as candidates for substitution appears in the Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution.

- the EPPO guidance document PP 1/271(1) "Guidance on comparative assessment", published in 2011 by the European and Mediterranean Plant Protection Organization.

Guidance documents prepared by other Member States were also consulted.

This guidance document is meant to be revised, particularly in light of acquired experience with the implementation of comparative assessment.

II. Comparative assessment: conditions of implementation

II.1. Which applications does it concern?

In accordance with the Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 establishing a list of candidates for substitution, comparative assessment shall be implemented by every Member State in the European Union for all applications for the authorisation of products containing a candidate for substitution submitted as from 1 August 2015.

The submission date for each application that will be taken into account shall be the filing date for the application in France, whether or not it is the rapporteur Member State.

For a plant protection product containing a candidate for substitution, the following applications are covered by the comparative assessment procedure:

- new MA applications,
- MA renewals,
- extensions of use (only the uses in the extension will be covered by a comparative assessment),
- mutual recognition.

Comparative assessment shall be undertaken for every use³ in the application.

II.2. Which documents and information have to be submitted?

The applicant shall submit the information defined by the French Ministry of Agriculture's Order⁴ on a proposal from the Director General of ANSES.

This information, written in English (see Annex 2), should be included in the dedicated section of Part A of the dossier submitted by the applicant if France is the zonal Rapporteur Member State (zRMS), or in a national addendum to Part A if France is not the zRMS.

II.3. On what basis is comparative assessment undertaken?

Comparative assessment is undertaken by ANSES based on the information submitted by applicants. This information should refer to relevant publications, which can be written in French, or any other reliable sources of information that have been identified. The Agency's analysis will also take into account additional information at its disposal.

³ A use generally corresponds to the combination of a plant species or an agricultural group of plants with a method of treatment and a function or a pest or an agricultural group of pests. Refer to the general instructions in the catalogue of uses pursuant to Section II of Article D253-8 of the French Rural and Maritime Fishing Code (as of the date of this document, refer to Guidance Note DGAL/SDQP/2015-253 of 10 March 2015, published in the Official Bulletin of the French Ministry of Health, Contents No 12 from 12-03-2015 to 19-03-2015).

⁴ Order of 23 July 2015 relating to information to be submitted to the French Agency for Food, Environmental and Occupational Health & Safety when implementing the comparative assessment of plant protection products pursuant to Article 50 of Regulation (EC) No 1107/2009 (NOR: AGRG1517028A).

II.4. How long does comparative assessment take?

No additional time period relating to the assessment procedure for products is set out in the regulations for the implementation of comparative assessment by Member States.

II.5. What are the consequences of comparative assessment?

Conclusions on comparative assessment shall be included in an annex to the assessment's conclusions. These conclusions shall also be presented in Part A of the Registration Report⁵ if France is the zonal rapporteur Member State, or in a national addendum to Part A if France is the Member State of application.

In the event that the principle of substitution is approved for one or more uses pursuant to Article 50(1) of Regulation (EC) No 1107/2009, the Agency shall not authorise or shall restrict the use of a PPP for the specified uses.

In the event that the principle of substitution is approved pursuant to Article 50(5) of Regulation (EC) No 1107/2009, the Agency shall withdraw or amend the authorisation of a PPP for the specified uses. Withdrawal or amendment shall take effect three years after the decision or at the end of the approval period for the candidate for substitution where that period ends earlier.

III. The steps of the process

Also refer to the flowchart in Annex 1.

III.A. Preliminary step

For products for which the applicant has justified that it is necessary to acquire prior experience, comparative assessment will not be implemented, if the proposed justification is accepted by the Agency, pursuant to Article 50(3) of Regulation (EC) No 1107/2009.

Such situations involve the following in particular:

- new plant protection products containing a new active substance approved under Regulation (EC) No 1107/2009 and a candidate for substitution,
- a new active substance/use combination,
- a significant advance enabling exposure to be reduced (e.g. formulation type),
- a new combination of active substances having real agricultural advantages or enabling the authorised doses to be lowered.

In this case, the authorisation will be granted once for a period not exceeding five years.

III.B. Implementation of comparative assessment

For applications not falling within the framework of Article 50(3) mentioned above, a comparative assessment shall be carried out for every use in the application. The various points described in steps 1 and 2 will be examined by ANSES in light of the information submitted by the applicant in the dossier and relevant information already available, particularly additional industry information or information from the French Ministry of Agriculture, on the basis of the work of the Commission des usages orphelins (French Commission for Orphan Uses⁶) in particular.

⁵ The Registration Report is the assessment report.

⁶ The Commission for Orphan Uses (CUO) was established on 26 June 2008. It is chaired by the Directorate General for Food of the French Ministry of Agriculture, and brings together representatives from business sectors, the plant protection industry, technical institutes, ANSES and the government. It is in charge of approving and monitoring the national action plan and, in the context of the work undertaken by the 'sector technical groups' and the Comité Technique Opérationnel (CTOP) inter-filières (inter-sector Operational Technical Committee) placed under its supervision, identifying minor uses for which there are no reasonable means for controlling crop pest risks.

Step no. 1: Taking into account minor uses, the management of resistance and regulatory control measures

In the event that the use corresponds to at least one of the situations below, the applicant shall submit the necessary justification.

- ✓ Taking into account minor uses

It is considered that comparative assessment for minor uses has little relevance, in reference to Articles 50(1d) and 51 of Regulation (EC) No 1107/2009. In this case, substitution of the product will not be considered.

The information provided by the applicant should enable assessment of the potential consequences of substitution for the major uses covered by the comparative assessment on the minor uses of the product.

If the withdrawal of a major use leads to an unsustainable control on a minor use, substitution will not be considered for the major use in question.

- ✓ Taking into account the management of resistance

For each use, the number of available modes of action⁷ should be indicated. The information provided by the applicant should enable assessment of the potential significance of the active substance in the resistance management strategy.

If the number of available modes of action for a use is insufficient⁸ or if the candidate substance is a significant component of the resistance management strategy, substitution will not be considered for the use in question.

- ✓ Uses related to regulated pest control measures

In the event that the PPP is a significant component of the strategy for controlling a regulated quarantine pest or a pest subject to mandatory control measures, pursuant to the Ministerial Order of 31 July 2000 establishing a list of organisms harmful to plants, plant products and other items subject to mandatory control measures, and pursuant to the Ministerial Order of 15 December 2014 relating to a list of Category 1 and 2 health hazards for plant species, substitution will not be considered for the use in question.

Step no. 2: Comparison with other available solutions

- ✓ Identification of other available solutions for the specified use

Identification of available non-chemical prevention or control methods

Non-chemical prevention or control methods available in France for the specified use should be identified on the basis of scientific and technical publications. These publications should enable assessment of the ability of the identified non-chemical methods, where applicable, to replace the PPP in question.

Identification of authorised plant protection products

Available PPPs should be identified for the specified use. If the number of available PPPs for the specified use is high, one or two PPPs representative of each available active substance should be selected.

⁷ For the classification of modes of action, refer in particular to the information published by the following committees: Fungicide Resistance Action Committee (FRAC), Herbicide Resistance Action Committee (HRAC) and Insecticide Resistance Action Committee (IRAC).

⁸ For information, the EPPO guidance document PP 1/271(1) recommends at least two modes of action in situations of low resistance risk, at least three modes of action in situations of medium risk, and at least four modes of action in situations of high risk. Moreover, the United Kingdom's guidance document indicates that if there are fewer than four available modes of action for a use, substitution will not be appropriate.

- ✓ Taking into account the practical and economic disadvantages of other available solutions

The information submitted should enable assessment of the potential practical and economic disadvantages of the other available solutions.

Substitution will not be considered when:

- there are no other available solutions for the specified use,
- the other available solutions for the specified use have practical and economic disadvantages for users.

- ✓ Taking into account the efficacy of other available solutions

The available information should enable assessment of the efficacy, in the broad sense, of the other solutions (efficacy, spectrum of action, adverse effects on crops, impact on integrated control systems, etc.).

Substitution will not be considered when the other available solutions for the specified use have markedly lower efficacy.

Step no. 3: Comparison of risks to human or animal health or the environment

The comparison of the risks to health and the environment will be undertaken by the Agency for the solutions identified at the end of step 2.

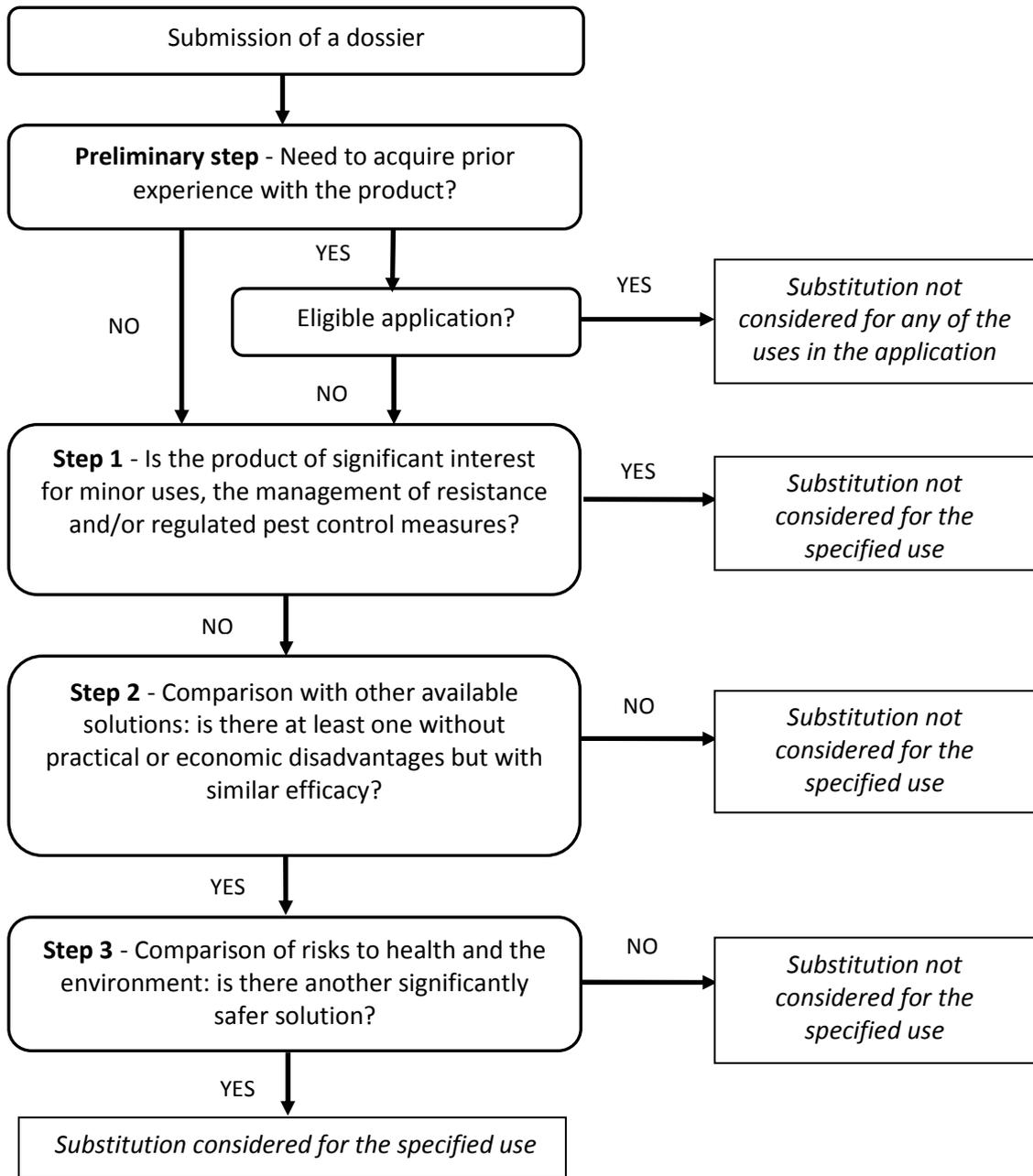
Initially, this assessment will examine the criteria that led to the status of candidate for substitution, on the basis of the available assessments. Then, if necessary, it may take into account the complete risk profiles and risk management measures identified in the assessment of the candidate product and the potential alternative product(s). These two steps are described in detail in the SANCO/11507/2013 rev.12 document.

Comparative assessment conclusion

Substitution will be considered for the specified use if there is a non-chemical prevention or control method or an authorised plant protection product, identified at the end of step 3, that is significantly safer for human or animal health or the environment.

Annex 1

The steps of the comparative assessment process



Annexe 2

Version en français

Informations à soumettre à l'Anses dans le cadre de la mise en œuvre de l'évaluation comparative des produits phytopharmaceutiques en application de l'article 50 du règlement (CE) n°1107/2009

Information sur le produit et sur la substance active

Produit concerné	
Substance(s) active(s) composant le produit	
Substance active candidate à la substitution	
Raison(s) du statut de candidate à la substitution de la substance active	

Etape préliminaire

Une justification doit être fournie dans les cas où il est nécessaire d'acquérir une expérience préalable grâce à l'utilisation de ce produit dans la pratique, en application du paragraphe 3 de l'article 50 du règlement (CE) n°1107/2009.

Etape 1 : prise en compte des usages mineurs, de la gestion des résistances et des mesures de lutte réglementée

Lister dans le tableau ci-dessous les usages concernés par la demande et identifier, pour chaque usage et en fonction des cultures couvertes par l'usage, son caractère mineur ou majeur en France. Le statut de l'usage doit être conforme au catalogue national des usages phytopharmaceutiques mentionné à l'article D. 253-8 du code rural et de la pêche maritime.

Référence de l'usage	Libellé de l'usage	Cultures couvertes par la revendication ⁹	Statut de l'usage (majeur ou mineur)

✓ **Usages mineurs**

Les conséquences sur les usages mineurs doivent être précisées si le produit concerné est substitué sur l'(les) usage(s) majeur(s) concerné(s).

Exemples d'informations qui peuvent être pertinentes :

- importance du bio-agresseur sur les cultures mineures en France,
- données économiques relatives au produit sur les usages mineurs concernés.

⁹ Lister les cultures concernées en se référant à la portée des usages définies par l'arrêté du 26 mars 2014 (arrêté relatif à la mise en œuvre du catalogue national des usages phytopharmaceutiques visés dans les décisions d'autorisation de mise sur le marché et de permis de commerce parallèle des produits phytopharmaceutiques et des adjuvants) et par la notice générale du catalogue des usages pris en application du II de l'article D253-8 du code rural et de la pêche maritime (à la date du présent arrêté, se référer à la note de service DGAL/SDQP/2015-253 du 10 mars 2015 publiée au bulletin officiel du ministère chargé de l'agriculture, sommaire n° 12 du 12-03-2015 au 19-03-2015), en précisant pour chacune le caractère mineur ou majeur de l'usage.

✓ **Gestion des résistances**

Compléter le tableau ci-dessous.

Référence de l'usage	Libellé de l'usage	Mode d'action	Code du mode d'action	Substance active	Nombre de modes d'action par usage

Fournir des informations en particulier si le produit concerné est un composant important de la stratégie de gestion de la résistance du bio-agresseur cible et d'autres bio-agresseurs de la même culture non sujets à l'évaluation comparative.

Exemples d'informations qui peuvent être pertinentes :

- le produit concerné fournit le seul mode d'action disponible sur l'usage concerné ;
- information sur le statut du bio-agresseur relatif à la résistance ;
- le produit concerné ne présente pas de résistance croisée pour le bio-agresseur ;
- le produit concerné a un rôle spécifique dans la stratégie nationale de gestion des résistances.

✓ **Mesures de lutte réglementée**

Fournir des informations si le produit est un composant important de la stratégie de lutte contre un organisme nuisible réglementé de quarantaine ou soumis à des mesures obligatoires de lutte.

Etape 2 : comparaison avec les autres solutions disponibles

✓ **Identification des autres solutions disponibles**

Méthodes non chimiques de prévention ou de lutte

Fournir des informations sur les méthodes non chimiques de prévention ou de lutte existantes pour chacun des usages majeurs concernés dans le tableau suivant.

Référence de l'usage	Libellé de l'usage	Méthodes non chimiques de lutte	Méthodes non chimiques de prévention

Produits phytopharmaceutiques autorisés

Fournir les informations dans le tableau suivant. S'il existe beaucoup d'autres produits, sélectionner un ou deux produits par substance active pour exemple.

Référence de l'usage	Libellé de l'usage	Substance active	Produits représentatifs

✓ **Prise en compte des inconvénients pratiques et économiques des autres solutions pour l'utilisateur**

Fournir des informations référencées afin d'apprécier les inconvénients pratiques et économiques éventuels des autres solutions disponibles.

Exemples d'informations qui peuvent être pertinentes :

- l'utilisation de ces solutions repose sur la disponibilité d'un équipement spécialisé,
- présence des bâtiments ou structures nécessaires pour la mise en œuvre de ces solutions,
-

- les autres produits sont appliqués à des stades spécifiques de la culture ou du bio-agresseur (par exemple, les traitements de semences ou les traitements avec des délais avant récolte courts),
- autres inconvénients résultant de l'utilisation d'une autre solution si le produit concerné n'est plus disponible.

✓ **Prise en compte de l'efficacité des autres solutions**

Fournir des informations référencées afin d'apprécier l'efficacité au sens large des autres solutions par rapport à celui du produit concerné (efficacité, spectre d'action, effets indésirables sur la culture traitée, impact sur les systèmes de lutte intégrée, etc.).

Etape 3 : comparaison des risques pour la santé et pour l'environnement

L'étude comparative des risques pour la santé humaine et animale et pour l'environnement sera entreprise par l'Agence sur les solutions identifiées à l'étape 2.

Proposition de conclusion de l'évaluation comparative

Utiliser le format prévu dans le modèle de « draft Registration Report » pour la partie A disponible sur le site internet de la Commission européenne.

Version en anglais

Information to be submitted to Anses for the implementation of comparative assessment of plant protection products in application of the article 50 of regulation (EC) No 1107/2009

Information on the product and the active substance

Product under evaluation	
Active substance(s) in the product	
Candidate for Substitution (active substance name)	
Reason(s) for approval as candidate for substitution	

Preliminary step

A justification should be provided in cases where it is necessary to acquire experience first through using that product in practice, as described in Article 50, paragraph 3, of regulation (EC) No 1107/2009.

Step 1: Consideration of minor uses, resistance management and regulated pest control measures

The uses of the application should be listed in the table below and it should be identified for each use and depending on the crops covered by the use whether the use is a major or a minor use. The status of the use should be based on the French document "Catalogue des usages, Notice générale" referred to in article D. 253-8 of the French rural code.

French use code	French use	Crops covered by the intended use ¹⁰	Statut of the use (major or minor)

✓ **Minor uses**

The consequences for the minor uses should be explained if the product in question is substituted for the major use(s) subject(s) to the comparative assessment.

Examples of information that may be useful to consider here include:

- Importance of the pest in minor crops in France ;
- Economic data related to the product for the minor uses in question.

✓ **Resistance management**

Please fill in the table below.

¹⁰ The crops in question should be listed with reference to the scope of uses defined by the order of 26 March 2014 (arrêté relatif à la mise en œuvre du catalogue national des usages phytopharmaceutiques visés dans les décisions d'autorisation de mise sur le marché et de permis de commerce parallèle des produits phytopharmaceutiques et des adjuvants) and to the French document "Catalogue des usages, Notice générale" adopted pursuant to the article D253-8 of the French rural code (on the date of the present document refer to the memo DGAL/SDQPV/2015-253 published on 10 March 2015 by the French Ministry in charge of agriculture), specifying for each crop whether the use is a major or a minor use.

French use code	French use	Mode of action	Mode of action code	Active Substances	Number of modes of action per use

Information should be provided especially if the candidate is an important component of the resistance management strategy for the target pest and for other pests in the crop not themselves subject to the comparative assessment.

Examples of information that may be relevant here include:

- whether the candidate provides the only mode of action available for the use in question;
- information on current resistance status for the crop/pest;
- whether the candidate does not exhibit cross-resistance in the target pest;
- whether the candidate has a specific role in national resistance management strategies.

✓ **Regulated pest control measures**

Information should be provided if the product is an important component of the control strategy for a quarantine-regulated pest or for a pest subject to mandatory control measures.

Step 2 : Comparison with available alternatives

✓ **Identification of available alternatives**

Non-chemical control or prevention methods

Details should be provided in the table below on existing non-chemical control or prevention methods for each major use in question.

French use code	French use	Non chemical control methods	Non chemical prevention method

Authorised plant protection products

Details should be provided in the table below. If there are many alternatives products, one or two products containing each of the possible alternative active substances should be selected as examples.

French use code	French use	Active substance	Representative products

✓ **Consideration of economic and practical disadvantages of alternatives for the user**

Referenced information should be provided in order to evaluate the possible economic and practical disadvantages of the available alternatives

Examples of information that may be relevant here:

- the use of alternative controls relies upon the availability of specialist equipment;
- buildings or structures required for implementing these alternatives are available;
- the alternative products are applied at specific life stages of the crops or pests – for example, seed treatments or treatments with short pre-harvest intervals;

- other disadvantages resulting from use of an alternative if the candidate is no longer available.

✓ **Consideration of the efficacy of alternatives**

Referenced information should be provided in order to evaluate the efficacy (in the broad sense) of these alternatives as compared with that of the product in question (efficacy, spectrum of activity, adverse effects on the treated crops, impact on integrated pest management systems, etc.).

Step 3 : Comparison of risks for health and environment

The comparative assessment of risks for human or animal health and the environment will be performed by Anses on alternatives identified at the step 2.

Proposal for conclusion of the comparative assessment

The format found in the template of the Part A of the “draft Registration Report” available on the website of the European Commission should be used.