No. 52173#01

EXPLANATORY NOTE FOR FILLING OUT THE FORM RELATING TO A MARKETING AUTHORISATION FOR A PLANT PROTECTION PRODUCT, ADJUVANT OR MIXED PRODUCT AND FOR PREPARING A DOSSIER

*This note sets out general rules for preparing a dossier relating to a marketing authorisation for a plant protection product, adjuvant or mixed product and provides additional information about the sections of the form CERFA 15722*01*

This translation into English is provided for information only. The form Cerfa 15722*01 must be completed in French and only that version is officially valid".

Reference texts

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;

Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market;

Articles L. 253-1 *et seq.* and R. 253-5 *et seq.* of the *Code rural et de la pêche maritime* ("French Rural and Maritime Fishing Code");

Ministerial Order of 26 March 2014 on the implementation of the national catalogue of plant protection uses referred to in marketing authorisations and parallel trade permits for plant protection products and adjuvants[1];

Ministerial Order of 30 December 2010 on packaging conditions for plant protection products able to be used by non-professional users[2].

Definitions and terms used in the note and form

Adjuvants: substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market, to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties. **Composition:** (according to context) the formulation of the active substance(s) and all associated co-formulants; the full formulation details.

Data matching active substance dossier: dossier submitted to justify access to protected data on active substances. It includes a data matching table and may contain:

- a letter of access to protected data,
- study reports,
- a rationale for derogation from the supply of data.

Reference Member State: Member State that granted the authorisation for the product (PPP) covered by the application for mutual recognition.

Rapporteur Member State, all zones: Member State that assesses the application for the zone when it refers to all zones (North, Centre and South) (inter-zonal RMS).

Rapporteur Member State, Southern zone: Member State that assesses the application for the Southern zone (Southern zRMS).

Concerned Member State (cMS): Member State in the zone in which the application is submitted, when the assessment is performed by another Member State in the zone (i.e., the zRMS).

Amateur" range: The "amateur" range of uses includes all uses for which placing on the market is authorised for non-professional users. For the "amateur" range of uses, the only products that can be authorised are those whose proposed formulation, method of application, packaging and label are likely to guarantee a limited risk of exposure for the user.

Professional" range: The "professional" range of uses includes all uses reserved for professional users as defined in Article R. 254-1 of the French Rural and Maritime Fishing Code.

CAS number: The CAS number (or CAS registry number) of a chemical is its unique registration number from the Chemical Abstracts Service (CAS) database.

Origin (active substance): The origin of the active substance is determined by the name of the applicant of the origin, the name of the manufacturer, and the name and address of the manufacturing site.

Biocontrol products: according to Article L. 253-6 of the French Rural and Maritime Fishing Code, these are agents and products using natural mechanisms for the integrated control of crop pests. They include, in particular, macro-organisms and plant protection products containing micro-organisms, chemical mediators such as pheromones and kairomones, and natural substances of plant, animal or mineral origin.

Low-risk product: a product fulfilling the criteria of Article 47 of Regulation (EC) No 1107/2009.

Identical product: a product administratively related to another product and having exactly the same composition.

Resale product: a product having exactly the same composition as another product already authorised in France, known as the "reference product". It is called a "resale product" when the application involving it is presented by an applicant other than the holder of the marketing authorisation for the reference product, after the authorisation holder's agreement. The range of uses may be the same as or different from that of the reference product.

Second-range product: a product having exactly the same composition as another product already authorised in France, known as the "reference product". It is called a "second-range product" when the application involving it is presented by the holder of the marketing authorisation for the reference product and refers to a range of uses different from that of the reference product. (For example, amateur range when the reference product is authorised for the professional range);

Generic product: a plant protection product that has the same qualitative and quantitative composition of active substances and the same type of formulation as a related plant protection product and whose effects are similar to those of this related product.

Mixed product: a product either composed of a fertiliser or growing medium and a plant protection product or liable to have a dual effect as a plant protection product and a fertiliser or growing medium.

Plant protection products: "products, in the form in which they are supplied to the user, consisting of or containing active substances (…) and intended for (…) protecting plants or plant products against all harmful organisms or preventing the action of such organisms (...), influencing the life processes of plants (...), preserving plant products (...), destroying undesired plants or parts of plants (…), checking or preventing undesired growth of plants" [3].

BBCH stage: Growth stage for mono- and dicotyledonous plants.

Substance: a chemical element and its compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.

Active substance: a substance, including micro-organisms, having general or specific action against harmful organisms or on plants, parts of plants or plant products.

Use and scope: A marketing authorisation (MA) for a plant protection product is granted for one or more plant protection uses. These uses are listed in a national catalogue published by the French Ministry of Agriculture. 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. The names of uses are simplified. Thus, a specific term may cover several plant species: this is the **scope of use**.

Acronyms used in the note and form

ANSES: French Agency for Food, Environmental and Occupational Health & Safety

MA: Marketing Authorisation

PMA: provisional marketing authorisation

BBCH: Biologische Bundesanstalt, Bundessortenamt und CHemische Industrie.

SDS: Safety Data Sheet

dRR: draft Registration Report

RR: Registration Report

zRMS: zonal Rapporteur Member State

cMS: concerned Member State

PPE: Personal Protective Equipment

GAP: Good Agricultural Practice

I, F and G: I = Indoor; F = Field; G = Greenhouse

EX, FL or EX/FL: EX = Application authorised during exudate-production periods; FL = Application authorised during flowering; EX/FL = Application authorised during exudate-production periods and Application authorised during flowering

Information by section

A section is a set of information to be completed; it is characterised by a number. The form contains thirteen sections. A "paragraph" is a category of information linked to a section.

All fields must be filled in using upper-case letters.

[3] Art. 2 of Regulation (EC) No 1107/2009

1. IDENTIFICATION OF THE APPLICATION:

In this section, the numbers given in *italics* refer to the numbers appearing in the first column of the summary tables of applications in Annexes I and II of this Explanatory Note. For each application, they help to identify the sections of the form to be completed and the documents required to prepare the dossiers.

PARAGRAPH 1.1. PRODUCT TYPE:

Specify the type of product covered by the application. If necessary, refer to the definitions above. Tick only one box. In the rest of the form, regardless of the box that is ticked, the word "product" will be used.

PARAGRAPH 1.2. RANGE OF USES:

Specify the requested range of uses: professional or amateur. Tick only one box.

PARAGRAPH 1.3. APPLICATION TYPE:

1.3.1. Marketing authorisation (MA) application:

Tick one of these boxes for a new marketing authorisation. The product covered by this new MA application cannot already be authorised or pending authorisation when the application is submitted.

A marketing authorisation application, when France is the concerned Member State, falls in the framework of an application for a "New authorisation *(1)*". In this case, fill out Sections 10.1 to 10.3 to enable ANSES to obtain information from the Rapporteur Member State.

For an authorisation application under the mutual recognition procedure according to Article 40 of Regulation (EC) No 1107/2009 *(2)*, the applicant must specify in which Member State and for which product the authorisation was granted. Fill out Sections 10.1 to 10.4 to enable ANSES to obtain information from the Rapporteur Member State.

For an authorisation application for a generic product *(3)*, resale product *(4)* or second-range product *(5)*, fill out Section 2.3, specifying the reference product authorised in France and its authorisation number.

1.3.2. Authorisation renewal application:

The case of ten-year renewal *(6)* applies only to adjuvant products specified as such in Paragraph 1.1.

Case *(7)* of MA renewal follows the renewal of the approval of an active substance.

For an application involving the conversion of a PMA into an MA, tick the "Renewal following the re-approval or approval of an active substance *(7)*" box.

In cases *(6)* and *(7)*, fill in points 2.1 and 2.2.1.

1.3.3. Application to totally or partially withdraw an MA:

Tick the MA withdrawal box *(8)* for an application to totally withdraw an authorisation.

For an application to withdraw one or more uses from an authorisation, tick box *(9)* and in section "8. USES", specify only the use(s) covered by the withdrawal application.

In the two cases *(8)* and *(9)*, fill in points 2.1 and 2.2.1.

1.3.4. Request for:

1.3.4.1. bee notation *(10)*

Specify the type of requested bee notation: FL or EX (both boxes can be ticked) – refer to the list of acronyms above.

1.3.4.2. product type:

Specify the requested product type.

1.3.5. Other application *(15)*

Tick the "Post-authorisation monitoring" box if submitting data required for the product described in Section 2.

1.3.6. Application to amend an authorisation with scientific assessment:

These applications require a specific assessment undertaken in accordance with the uniform principles for evaluation and authorisation mentioned in Article 29(6) of Regulation (EC) No 1107/2009 and in Articles R. 253-13 and 14 of the French Rural and Maritime Fishing Code. They involve currently authorised products.

The extension of use *(11a)* corresponds to an extension of major or minor use for which France is the Rapporteur Member State or concerned Member State.

The extension of use *(11b)* corresponds to an extension of use pursuant to Article 51 of Regulation (EC) No 1107/2009.

The extension of use *(11c)* corresponds to an extension of use by mutual recognition according to Article 40 of Regulation (EC) No 1107/2009. The applicant must specify in which Member State and for which product the authorisation was granted. Fill out Sections 10.1 to 10.4 to enable ANSES to obtain information from the Rapporteur Member State.

The minor change of composition *(12)* corresponds to a non-significant (i.e., minor) change of composition according to the European "Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC" (current

version).

Tick only one box except for the application *(13)* for a change of classification for which it is necessary to specify if the requested change of classification relies on a calculation or on studies.

When the "Another MA amendment case *(14)*" box is ticked, specify the requested amendment type: change or addition of packaging, amendment of conditions of use, etc.

In cases *(11), (12), (13)* and *(14)*, fill out Sections 2.1 and 2.2.1 of the form.

1.3.7. Application to amend an authorisation with administrative assessment:

These applications require an administrative assessment and not an assessment in accordance with the terms defined in Article R. 253-13 of the French Rural and Maritime Fishing Code. They involve products currently authorised.

An application to transfer an MA to another holder *(18)* must be submitted by the company wanting to benefit from the MA transfer.

Tick the "Classification amendment notification *(19)*" box when the notification is submitted in accordance with Article R. 253-42 of the French Rural and Maritime Fishing Code. All other classification amendments must be submitted in the framework of an application for a change of classification, Paragraph 1.3.6, application *(13)*.

When the "Another MA amendment case *(20)*" box is ticked, specify the requested amendment type not requiring a scientific assessment. The possible choices are: addition of a manufacturing site for the active substance, amendment of a manufacturing site for the active substance, change of commercial type for the product, or addition of packaging.

In cases *(18), (19),* and *(20)*, fill out Sections 2.1 and 2.2.1 of the form.

1.3.8. Amendment of an application currently being assessed:

Tick the "Amendment of information declared in an application being processed *(21)*" box if amending an application in progress and specify the reference number of the application being processed in the free-text field. This application is compatible with all applications in progress and no other application boxes in Paragraph 1.3 must be ticked. These applications can only be taken into account at an early stage of assessing an application and are limited to the subject of the application being processed.

PARAGRAPH 1.4. CHARACTERISATION OF THE APPLICATION:

1.4.1.: Characterisation of the assessment of the application:

Tick one or two boxes depending on the desired type of assessment for the application.

The possible choices are:

- Southern zone
- All zones
- Southern zone and all zones (e.g. application involving greenhouse and field uses)
- National

For an adjuvant, tick the "National" box.

1.4.2.: Member State status for France:

Specify the status that must be taken into consideration.

When France is the concerned or Co-Rapporteur Member State, specify the Rapporteur or Co-Rapporteur Member State for the Southern zone and all-zone assessment.

When France is the concerned Member State, the application must be submitted at the same time as in the zonal Rapporteur Member State.

Complete the section if the choices "Southern zone", "all zones" or "Southern zone and all zones" were ticked in Section 1.4.1, for the following applications only:

- New authorisation *(1)*
- New authorisation for a second-range product *(5)*
- Renewal following the re-approval of an active substance *(7)*
- Extension of major uses *(11a)*
- Extension of minor uses *(11a)* (other than Article 51): application for an extension of minor use not covered by Article 51 of Regulation (EC) No 1007/2009.

1.4.3.: Clarification relating to the application:

Tick the box "The application has been notified" for an application that has been notified to France in the framework of the zonal procedure, for example, for an application for a new MA. The notification procedure is described in the European "Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorization under Regulation (EC) No 1107/2009" (current version). When the notification involves an application for which France is asked to be the zRMS, ANSES assigns a notification number if it accepts. This notification number must be specified in the free-text field when submitting the notified application.

If the product concerned by the application can be considered identical to a product covered by the same application,

the applicant must tick box *(22) (Application already submitted for a product with an identical composition)*, specify the type of application in Section 1.3, and in Section 2.3, specify the reference product covered by the same application. The two applications must be jointly submitted (one form per application).

2. PRODUCT IDENTIFICATION:

Paragraph 2.1. Trade name: enter the product's name in upper-case letters as desired or mentioned in the authorisation decision.

Paragraph 2.2.1. Authorisation number: if the product has previously been covered by an MA, enter the number appearing in the authorisation decision.

Paragraph 2.3.1. Name of the reference product: if the product is administratively related to a reference product (addition of new trade name, resale, etc.), enter the trade name of the reference product.

Paragraph 2.3.2. Authorisation number of the reference product: enter the MA number of the reference product to which the product covered by the application is related.

3. APPLICANT IDENTIFICATION:

Complete the section with information enabling the identification of the company that holds the marketing authorisation or is applying for an MA. The holder is the company responsible for placing the product on the market. SIRET and intra-Community VAT numbers are to be provided only for companies having their head office in France. The e-mail address given in this section will be used to send the applicant "Part A" of the Registration Report.

4. DETAILS OF THE CONTACT PERSON (FOR MONITORING THE DOSSIER):

Complete the section with the details of the person to be contacted if in case of additional data are needed. When the applicant or its representative has its head office or domicile in a country other than France, it is necessary to provide the specific country codes to obtain complete phone numbers from France.

The e-mail address given in this section will be used to monitor the dossier.

Decisions and other final documents related to the application will be sent to the person and address indicated in this section.

5. ACTIVE SUBSTANCE(S) / SAFENER(S) / SYNERGIST(S) IN THE PRODUCT:

Complete only with the names of the active substances in French and their level of pure active substance.

In cases where the active substance can be expressed in various forms, fill in Sections a) and b) for each substance contained in the product as follows:

a) The name of the active substance in French as mentioned in the approval regulation

b) If applicable, provide the name of the active substance in French, expressed in its acid, salt, ester form, etc.

Add lines if necessary.

Do not complete this section for an adjuvant.

6. PRODUCT DESCRIPTION:

6.1. PRODUCT FUNCTIONS:

Specify the product's function(s) according to the list appearing in 1.6 in the Annex of Regulation (EU) No 284/2013. Use the "other" box to add a function not appearing in the proposed list (e.g. bactericide, nematicide, pheromone, growth regulator, repellent, rodenticide, chemical mediator, talpicide, viricide). The **Adjuvant** box is reserved for adjuvant products.

6.2. PHYSICAL STATE/FORMULATION TYPE:

Formulation type (CropLife International code): Enter the acronym and name in French of the code from the CropLife International Catalogue of pesticide formulation types and international coding system [CropLife International Technical Monograph No. 2[4]].

6.3. PRODUCT PACKAGING:

Points 6.3.1., 6.3.2., 6.3.3., 6.3.4., 6.3.5. and 6.3.6. cannot be filled out simultaneously. The applicant can, for a given packaging, propose several volumes and several packaging materials, as one column can contain several values. In this case, the applicant must duplicate the packaging line as many times as needed so that each requested packaging type/size is listed.

For example:

6.3.1. Case of a liquid product	Requested volume (L):	Nature of the packaging material
☐ Bottle (0 to 2 L)	0.5 L	high-density polyethylene – HDPE
☐ Bottle (0 to 2 L)	1 L	high-density polyethylene/polyamide – HDPE/PA
☐ Can (from > 2 L to < 20 L)	10 L	low-density polyethylene/aluminium/low-density polyethylene – LDPE/Al/LDPE

Section 6.3.7 may be completed to provide additional technical information required for Sections 6.3.4, 6.3.5 and 6.3.6.

1/ Volume or mass of the requested packaging

The gross volume or gross mass of the packaging must be precisely indicated for all of the requested packaging.

A range of volumes or masses is not sufficiently precise.

The packaging type must be indicated as follows in the case of liquid products:

Bottle: for volumes of 0 to 2 L

Can: for volumes of above 2 L to 20 L

Barrel: for volumes of above 20 L to 200 L

Tank: for volumes above 200 L

In the case of solid products, the packaging type must also be specified: bag, box, cardboard box, tube.

When the product is in tablet form, the number of tablets per package must be specified in addition to the mass of one tablet.

2/ Description of the packaging material

The packaging material must be specified in full together with its abbreviation in English and French.

Monolayer packaging

For example, high-density polyethylene – HDPE, specifying for polyethylene if it is high-density and/or low-density polyethylene and not simply polyethylene.

Multilayer packaging

All of the layers of the packaging must be described. Case of coextruded packaging: specify the two materials that are coextruded, e.g. high-density polyethylene/polyamide – HDPE/PA. Similarly, for rolled aluminium packaging, specify the materials that are rolled with the sheet of aluminium, e.g. low-density polyethylene/aluminium/low-density polyethylene – LDPE/Al/LDPE.

Metallic packaging

Specify the nature of the metallic part and whether a varnish is applied inside the packaging.

Packaging made of several types of materials

In the case of packaging containing a system such as a gun, all the components of the gun must be described.

In the case of a cardboard box with a plastic bag inside, the plastic bag must be described.

Soluble packaging

The soluble packaging material must be specified in addition to the primary packaging that contains the soluble pouches.

Preparation on a medium (e.g. passive diffuser)

The material acting as medium for the product must be specified in addition to the primary packaging containing the product.

3/ Packaging for non-professional use

In the case of a product for non-professional use, indicate if the packaging contains a system for limiting exposure.

4/ System limiting exposure

All systems put into place to limit user exposure must be described, such as self-dispensing cans and automated transfer systems from tanks to cans.

7. PRODUCT MANUFACTURING SITE: ☐ *CONFIDENTIAL*

Tick the confidential box for the confidential processing of the information in the section.

This concerns the exact address where the product is manufactured. If the information is available in "dRR Part C", this section does not need to be completed. In this case, tick the "Information given in Part C of the draft Registration Report" box. This section must be completed for every manufacturing site for the product. Note that there is no need to include repackaging sites in this section.

Tick " confidential "in the section heading if the applicant wants this information to be confidentially processed.

8. USES:

If, for the same use (number and name), different application doses are requested, depending on the crop, number of applications, stage of application, pre-harvest interval, etc., the line for this use must be duplicated accordingly.

Add as many lines as necessary.

Enter only the uses covered by the application.

If one of the sections cannot be completed because it is not applicable for the corresponding use, enter "NA".

8.1. Use number: refer to the national category of plant protection uses, current version, of the French Ministry of Agriculture.

8.2. Use name: refer to the national category of plant protection uses, current version, of the French Ministry of Agriculture.

8.3. Scope of use: the applicant can limit the scope of the requested use. If no clarification is provided, the total scope of the use will be considered as requested. If the scope of the use is limited, the applicant must justify this limitation in the submitted dossier.

8.4. Maximum application dose: specify the maximum application dose. Specify the unit (e.g. kilograms / hectare, or litres / hectare). The expression of the application dose must be adapted to use by a professional or amateur (e.g. for a product intended for amateurs, the applicant can use a unit such as grams / m²) (refer to the Ministerial Order of 30 December 2010 on packaging conditions for plant protection products able to be used by non-professional users[5]).

8.5. Number of applications per year: specify the number of applications.

8.6. Interval between applications (Min): specify the minimum number of days between each application, where applicable.

8.7. Application period: specify the minimum and maximum seasons of application, where applicable. This value can be expressed in months.

8.8. BBCH application stage: specify the application stage, which must correspond to a growth stage in keeping with the crop in question.

8.9. Pre-harvest interval (day(s) or BBCH stage): indicate, where applicable, the proposed minimum interval between the last treatment and the harvesting of a crop. If the pre-harvest interval is entered as F, the maximum BBCH stage will be considered.

If the maximum BBCH stage is not specified, the pre-harvest interval (F) will be considered as being longer than 120 days.

8.10. Bee notation: specify if application is requested during flowering or during exudate-production periods or both, without the presence of bees.

8.11. Use: specify if use of the product is requested in the field (F), indoors (I) or in the greenhouse (G).

8.12. Recommendations / Restrictions / Other requirements: to be used to provide clarifications about the information entered above.

8.13. GAP number: in this column, enter the serial number of the use given in the table in European GAP format provided in the application in "Appendix 1 All intended uses of the dRR B0".

9. PROPOSED CLASSIFICATION/LABELLING ACCORDING TO REGULATION (EC) NO 1272/2008:

PARAGRAPH 9.1. HAZARD SYMBOLS:

Specify the requested hazard symbols.

PARAGRAPH 9.2. WARNING STATEMENT:

Specify the requested warning statement.

PARAGRAPH 9.3. HAZARD CLASSES:

Specify the requested hazard classes.

PARAGRAPH 9.4. ADDITIONAL HAZARD STATEMENTS/PHRASES:

Specify the requested risk phrases.

10. IN THE EVENT OF MUTUAL RECOGNITION OR IF FRANCE IS THE CONCERNED MEMBER STATE:

Complete this section for an application (MA or extension of use) by mutual recognition (Art. 40 of Regulation (EC) No 1107/2009) or for an application (MA or extension of use) for which France is the concerned Member State.

10.1. Trade name of the product: Specify the name of the authorised product or the product pending authorisation in the Reference Member State.

10.2. Member State: Specify the Member State in which the assessment of the reference product is undertaken.

10.3. Code name of the product: Specify the "firm" or trade/commercial code name of the product, to allow easier identification of products between Member States.

10.4. Authorisation number: Specify the authorisation number of the reference product in the context of an MA

[5] Cf. page 1

application under the mutual recognition procedure (Art. 40 of Regulation (EC) No 1107/2009). Point 10.4 is non-applicable in the framework of an application when France is the concerned Member State.

11. IN CASE OF A CHANGE OF HOLDER:

Indicate the company or business name of the current holder of the MA to be transferred. SIRET and intra-Community VAT numbers are to be provided only for companies having their head office in France.

12. IN CASE OF A CHANGE OF TRADE NAME FOR THE PRODUCT:

Indicate the new proposed name for the product. This new name cannot be that of a product already having a marketing authorisation or permit.

13. CONFIRMATION OF THE APPLICATION:

The form must be dated and signed by hand by the applicant's legal representative.

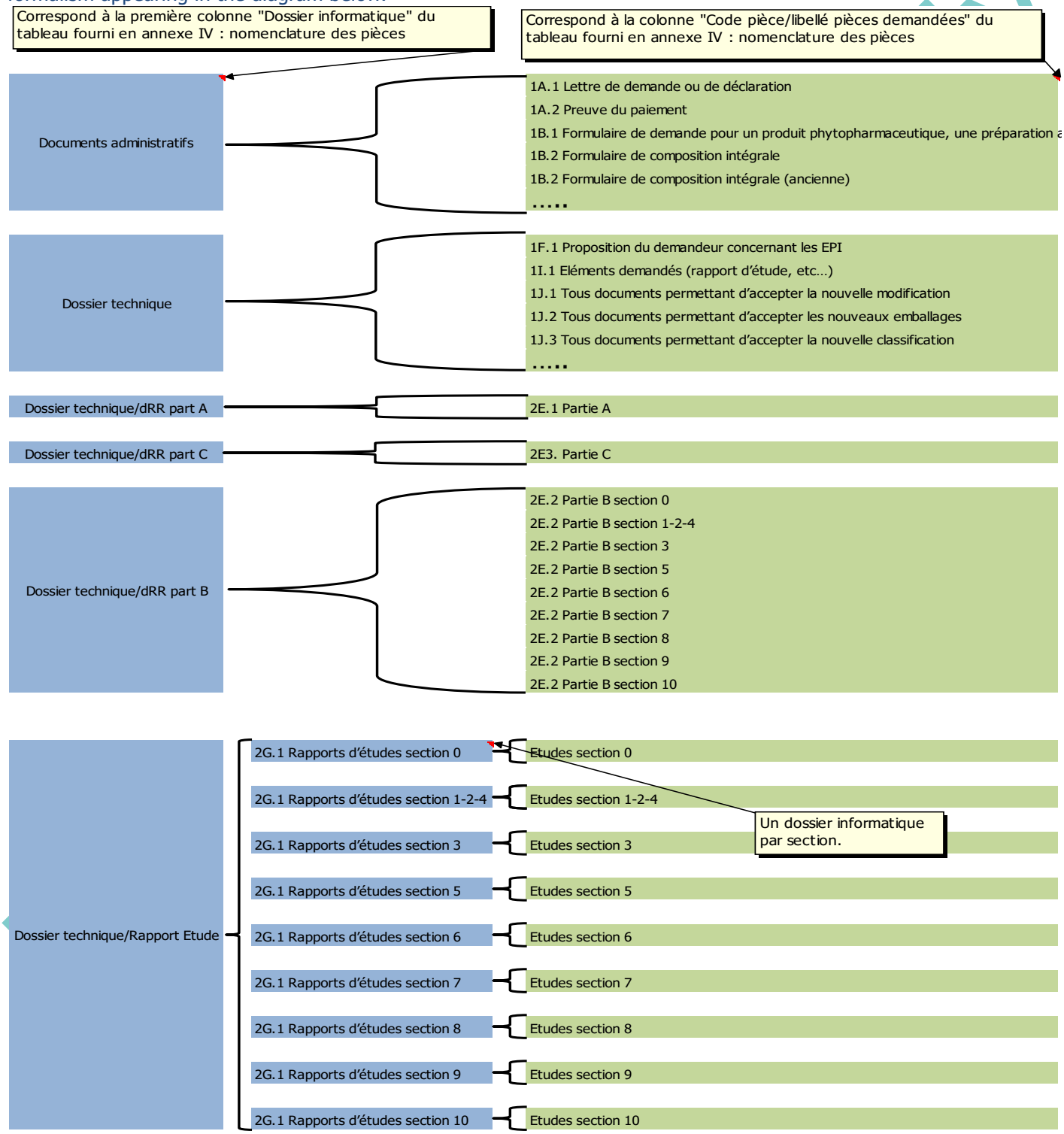
Preparation of dossiers

A dossier comprises:

- one copy in electronic format (CD, DVD);
- two copies for submission in paper format. In the case of mutual recognition or when France is the concerned Member State: only one copy of dRR Part B and the study reports is necessary.

Presentation of dossiers:

Documents in electronic format and in paper format must be named and organised according to the nomenclature appearing in Annex IV.
The numbering of documents comes from this reference system and is not alphanumeric.
Computerised filing by document, provided in Annex IV, enables the electronic dossier to be presented with the formalism appearing in the diagram below.



The document code (1A.1, 2B.2, etc.) must be included in the name of the submitted electronic file.

Electronic format:

Computer directories correspond to the blue blocks shown in the above diagram. The name of the directory is that of the block. The green blocks refer to files; the document code (1A.1, 2B.2, etc.) must appear at the beginning of the

name of each electronic file.

Paper format:
The sections of the paper dossier (binders, dividers, folders) correspond to the blue blocks shown in the above diagram. The name of the block must be included at the beginning of the section. The green blocks refer to documents; the document's code (1A.1, 2B.2, etc.) and name must be included on the first page of the submitted document. Documents must be presented in the same order as electronic documents.

Clarification regarding the submission of dRRs:
For applications involving products that can be used in a greenhouse or indoors and in the field, submit two separate dRRs:

- an intra-zonal dRR, which will be submitted for comments to all EU Member States;
- a zonal dRR, which will be submitted for comments to Member States in the Southern zone.

ANNEX I. PREPARATION OF DOSSIERS FOR PLANT PROTECTION AND MIXED PRODUCTS

Sections of the application form to be completed

Sections 3, 4 and 13 must be completed for all applications

Number in the form	Application label related to the preparation of dossiers ***(with examples of ANSES application codes)***	Page	Section to be completed for each paragraph/application									
			1	2	5	6	7	8	9	10	11	12
1.	Marketing authorisation application *(PAMM, PAMN, PMUS)*	**12**	1, 2, 3, 4	1	x	x	x	x	x	PMUS		
2.	Marketing authorisation application under the mutual recognition procedure *(PMUT, PMTS)*	**13**	1, 2, 3, 4	1	x	x	x	x	x	x		
3.	Marketing authorisation application for a generic product *(PBIS)*	**14**	1, 2, 3, 4	1, 3	x	x	x	x	x			
4.	Marketing authorisation application for a resale product *(PVEN)*	**15**	1, 2, 3, 4	1, 3	x	x	x	x	x			
5.	Marketing authorisation application for a second-range product *(PIDG, PGAM)*	**15**	1, 2, 3, 4	1, 3	x	x	x	x	x			
7.a.	Authorisation renewal application following the approval of an active substance: with No Category 4 study in progress *(PREX)*	**16**	1, 2, 3, 4	1, 2	x	x	x	x	x	x[6]		
7.b.	Authorisation renewal application following the approval of an active substance for which Category 4 studies are in progress *(PREX)*	**18**	1, 2, 3, 4	1, 2	x	x	x	x	x	x[6]		
7.c.	Authorisation renewal application following the approval of an active substance containing two active substances whose renewal dates are within one year of one another *(PREX)*	**20**	1, 2, 3, 4	1, 2	x	x	x	x	x	x[6]		
8.	Application to withdraw an authorisation for a product *(PRET)*	**22**	1, 2, 3	1, 2								
9.	Application to withdraw a use of a product *(PRTU)*	**22**	1, 2, 3	1, 2				x				
10.	Bee notation application *(PABE)*	**22**	1, 2, 3	1, 2	x			x				
11.	Application for an extension of use *(PMAJ, PMIN)*	**23**	1, 2, 3, 4	1, 2	x			x				
12.	Application for a minor change of composition *(PCC)*	**25**	1, 2, 3	1, 2	x							
13.	Application for a change of classification *(PMCC, PMCT)*	**26**	1, 2, 3	1, 2	x				x			
14.	Application to amend an authorisation requiring an assessment *(PMEM, PTAE, PMOD)*	**26**	1, 2, 3	1, 2	x	PMEM		PMOD PTAE				
15.	Post-authorisation monitoring application *(PSPA)*	**26**	1, 2, 3	1, 2	x							
16.	Application for a change of trade name *(PNOM)*	**27**	1, 2, 3	1, 2	x							x
17.	Application to add a new trade name for a product already authorised *(PIDQ)*	**27**	1, 2, 3	1, 2	x							
18.	Application to transfer an authorisation to another holder *(PTRS)*	**27**	1, 2, 3	1, 2	x						x	
19.	Classification amendment notification *(PCLP)*	**27**	1, 2, 3	1, 2	x				x			
20.	Application to amend an authorisation with administrative assessment *(PMOI)*	**28**	1, 2, 3	1, 2	x	x	x[7]	x				
21.	Application to amend information declared in an ongoing application *(PMOI)*	**28**	1, 2, 3	1	x	x	x[7]	x	x[7]			
22.	Application for a product with an identical composition *(PDPI1, PDPI2, PDPI3)*	**29**	1, 2, 3, 4	1, 2, 3	x	x	x[7]	x	x[7]			

[6] When France is the concerned Member State.
[7] To be completed on a case-by-case basis

Preparation of dossiers

The numbering of documents comes from a document reference system and is not alphanumeric.

1. Marketing authorisation application

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Certificate dated and signed by hand mentioning the product's name as well as the name of the holder of the source, the address(es) of the manufacturers, and the manufacturing sites in question. Certificates must be provided by active substance and by origin.
1E. Comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution. Information related to the comparative assessment must be written in English and included in the dedicated section of Part A of the dossier submitted by the applicant if France is the zRMS or in a national addendum if France is not the zRMS.
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	To be provided in Part A or in a national addendum.
1G. Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1G. Proposed label	**1G.2 Sample or description of the packaging**	To be provided, where applicable when the product requests an "Amateur" range of uses.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including active substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the ".xls" format appearing in Annex V. This list is the Excel version of the compilation of lists appearing in Annex IV of dRR Part A.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	For each GAP, the concerned Member States must be included in a list in the format presented in the table of the dRR, current version.
2D. Access to data	**2D.1 Justification of access to protected data on the active substances**	The supporting documents may be: - A declaration confirming access for the data owner (specify the applicants in the event of a task force), - A letter of total access to protected data, - "Permission to refer", For the permission to refer, indicate if it has already been assessed or is currently being assessed in a Member State, specifying which one. If the permission to refer has been submitted or is being assessed by a Member State, provide proof of its submission in this Member State. If the permission to refer has been assessed by a Member State, provide justification (letter, e-mail from the Member State, etc.) stating that the results of this assessment have been placed on CIRCABC.
2E. dRR	**2E.1 Part A**	
	2E.2 Part B	Each dRR must involve a specific product and be "self-sufficient", not calling on or referring to dRRs involving other products. Present the sections separately, except for Sections B1, B2 and B4 which must be grouped together. Provide a document for each section. If a section is deemed irrelevant, include a rationale in the corresponding document.
	2E.3 Part C	
2G. Study reports	**2G.1 Study reports**	If study reports have already been submitted to ANSES, in the context of another application, they do not need to be submitted again in paper format provided that the previously assessed application is clearly referred to (NumDoc and application type) in the list of studies.

2. Marketing authorisation application under the mutual recognition procedure

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application An MA application under the mutual recognition procedure can only be based on a reference product authorised in another Member State, according to the approval conditions for the active substance(s) it contains, when its MA is not pending renewal. Therefore, the application must be submitted within a time period enabling it to be assessed before the approval renewal date of the active substance(s) it contains. As a guideline, submission six months before the approval renewal date is advisable as a minimum period.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Original certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.
	1C.7 Identification certificate for the dossier submitted in the Member State that issued the MA and the dossier submitted in France	Certificate dated and signed by hand
	1C.10 Identification certificate	Original certificate stating that the plant protection product is identical to that authorised by the Reference Member State.
1E. Comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution.
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	To be provided in the national addendum.
1G. Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1G. Proposed label	**1G.2 Sample or description of the packaging**	To be provided, where applicable when the product requests an "Amateur" range of uses.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including active substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
1L. Member State decision	**1L.1 French translation of the MA decision issued by the Reference Member State**	
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the ".xls" format appearing in Annex V. This list is the Excel version of the compilation of lists appearing in Annex IV of dRR Part A.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	For each GAP, the concerned Member States must be included in a list in the format presented in the table of the dRR, current version.

2D. Access to data	**2D.1 Justification of access to protected data on the active substances**	The supporting documents may be: - A declaration confirming access for the data owner (specify the applicants in the event of a task force), - A letter of total access to protected data, - "Permission to refer", For the permission to refer, indicate if it has already been assessed or is currently being assessed in a Member State, specifying which one. If the permission to refer has been submitted or is being assessed by a Member State, provide proof of its submission in this Member State. If the permission to refer has been assessed by a Member State, provide justification (letter, e-mail from the Member State, etc.) stating that the results of this assessment have been placed on CIRCABC.
2E. dRR	**2E.1 Part A** **2E.2 Part B** **2E.3 Part C**	Provide only the copy of the dRR submitted to the Reference Member State.
2F. RR	**2F.1 Parts A, B and C**	Provide justification (letter, e-mail from the Member State, etc.) stating that the final registration report of the Member State that issued the authorisation has been placed on CIRCABC. or Provide the RR if this document is not available on CIRCABC.
2G. Study reports	**2G.1 Study reports**	Provide only copies of the reports submitted to the Reference Member State. It is not possible to submit additional reports in the framework of this type of application.

3. Marketing authorisation application for a generic product ("bis product" or "me-too"))

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application. An MA application for a generic product can only be based on an authorised reference product, according to the approval conditions for the active substance(s) it contains, when its MA is not pending renewal. Therefore, the application must be submitted within a time period enabling it to be examined before the approval renewal date of the active substance(s) it contains. As a guideline, submission eight months before the approval renewal date seems to be the minimum period.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	The level of pure active substance in the generic product must be identical to that in the reference product. The type of product must be indicated and must also be identical to that of the reference product. Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.
1E. Comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution.
1F The applicant's proposal regarding PPE	**1F.1 The applicant's proposal regarding PPE**	
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1G. Proposed label	**1G.2 Sample or description of the packaging**	To be provided, where applicable when the product requests an "Amateur" range of uses.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including active substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
2D. Access to data	**2D.1 Justification of access to protected data on the active substances**	The supporting documents may be: - A declaration confirming access for the data owner (specify the applicants in the event of a task force), - A letter of total access to protected data, - "Permission to refer", For the permission to refer, indicate if it has already been assessed or is currently being assessed in a Member State, specifying which one. If the permission to refer has been submitted or is being assessed by a Member State, provide proof of its submission in this Member State. If the permission to refer has been assessed by a Member State, provide

		the results of this assessment.
	2D.2 Justification of access to applicable data on the product	The supporting documents may be: - A rationale for derogation from the supply of data, e.g. the absence of protected data. - Letter of total or partial access to protected data on the product for the uses authorised for the reference product.
	2G.1 Study reports	It is not possible to submit study reports in the framework of this application, with the exception of those mentioned in the "Comments" section below.

COMMENTS

It is the applicant's responsibility to demonstrate similarity between the generic product and the related product (called the reference product).
In the framework of Article 253-9 of the French Rural Code and for demonstration purposes, the applicant can rely, for example, on an accelerated stability study for the requested commercial packaging and/or on measurements of physico-chemical properties, which must be undertaken in accordance with Good Laboratory Practice (GLP).
In the event that an accelerated stability study is submitted, the measurement of the level of active substance(s) and the technical properties (according to the product type and GLP) before and after storage must be submitted. The sample used for the initial pre-storage measurements cannot be a sample stored in parallel at 0°C. Moreover, the validation data on the analytical method for the active substance(s) used in the accelerated storage study must also be provided.

4. Marketing authorisation application for a resale product

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application. An MA application for a resale product must be based on an authorised reference product, according to the approval conditions for the active substance(s) it contains, when its MA is not pending renewal. Therefore, the application must be submitted within a time period enabling it to be assessed before the approval renewal date of the active substance(s) it contains. As a guideline, submission four months before the approval renewal date seems to be the minimum period.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	Form dated and signed by hand. This form can be submitted by the company holding the MA for the reference product.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates (supply and procurement) for the product	Certificate dated and signed by hand mentioning the product's name. In case of absence, provide the agreement of the holder of the MA for the reference product for this application.
	1C.10 Identification certificate for the products	Original certificate (with the names of both products mentioned).
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1G. Proposed label	**1G.2 Sample or description of the packaging**	To be provided, where applicable when the product requests an "Amateur" range of uses.

5. Marketing authorisation application for a second-range product

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.
1E. Comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution. Information related to the comparative assessment must be written in English and included in the dedicated section of Part A of the dossier submitted by the applicant if France is the zRMS or in a national addendum to Part A if France is not the zRMS.
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	To be provided in Part A or in a national addendum.
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1G. Proposed label	**1G.2 Sample or description of the packaging**	To be provided, where applicable when the product requests an "Amateur" range of uses.
1H. SDS according to	**1H.1 SDS for the product**	

Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.2 SDSs for the co-formulants (including active substances)**	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	For each GAP, the concerned Member States must be included in a list in the format presented in the table of the dRR (new format).
2E. dRR	**2E.1 Part A**	
	2E.2 Part B	All items not yet assessed must be highlighted in yellow. Each dRR must involve a specific product and be "self-sufficient", not calling on or referring to dRRs involving other products. Present the sections separately, except for Sections B1, B2 and B4 which must be grouped together. Provide a document for each section. If a section is deemed irrelevant, include a rationale in the corresponding document.
	2E.3 Part C	
2G. Study reports	**2G.1 Study reports**	If study reports have already been submitted to ANSES, in the context of another application, they do not need to be submitted again in paper format provided that the previously assessed application is clearly referred to (NumDoc and application type) in the list of studies.

7.a. Marketing authorisation renewal application for a plant protection product: with no Category 4 study[8] in progress

All documents must be submitted three months after the renewal of the approval of the active substance.

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.
1D. Authorisation of the product in France	**1D.1 Copies of the authorisation decisions in France**	
1E. Comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution. Information related to the comparative assessment must be written in English and included in the dedicated section of Part A of the dossier submitted by the applicant if France is the zRMS or in a national addendum to Part A if France is not the zRMS.
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	To be provided in Part A or in a national addendum.
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1G. Proposed label	**1G.2 Sample or description of the packaging**	To be provided, where applicable when the product requests an "Amateur" range of uses.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including active substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V.

8 Category 4 studies are defined in the European "Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009".

2A. European completeness form	**2A.1 European completeness form**	"Template CoCh Art 43" document available on ANSES's website[9], completed by the applicant.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	For each GAP, the concerned Member States must be included in a list in the format presented in the table of the dRR, current version.
	2B.2 Certificate stating that there are no amendments to the requested GAP or justification of amendments	Amendments can be justified by new endpoints, risk assessment results, or the harmonisation of GAP in the zone. At least one certificate, dated and signed by hand.
2C. Certificate of absence of change of composition for the authorised product, or justification of the need for a minor change of composition due to the renewal of the active substance	**2C.1 Certificate of absence of change of composition for the authorised product, or justification of the need for a minor change of composition due to the renewal of the active substance**	Certificate dated and signed by hand.
2D. Access to data	**2D.1 Justification of access to protected data on the active substances**	The supporting documents may be: - A declaration confirming access for the data owner (specify the applicants in the event of a task force), - A letter of total access to protected data, - "Permission to refer", For the permission to refer, indicate if it is currently being assessed by the Rapporteur Member State for the active substance[10] or by another Member State, specifying which one. If the permission to refer has been submitted or is being assessed by a Member State, provide proof of its submission in this Member State and justification of its processing by this Member State (letter, e-mail from the Member State, etc.).
2E. dRR[11]	**2E.1 Part A**	
	2E.2 Part B	All new information not yet assessed in the zone must be highlighted in yellow. New information will be required as a result of amendments in data requirements or criteria, pursuant to Article 43(2) of Regulation (EC) No 1107/2009. Each dRR must involve a specific product and be "self-sufficient", not calling on or referring to dRRs involving other products. Present the sections separately, except for Sections B1, B2 and B4 which must be grouped together. Provide a document for each section. If a section is deemed irrelevant, include a rationale in the corresponding document.
	2E.3 Part C	All new information not yet assessed in the zone must be highlighted in yellow.
2N.1 Justification if details are lacking for required information	**2N.1 Justification if details are lacking for required information**	Provide justification for the absence of details for the points of the dRR that cannot be completed.
2G. Study reports	**2G.1 Study reports**	Only new study reports must be provided in paper format. If study reports have already been submitted to ANSES, in the context of another application, they do not need to be submitted again in paper format provided that the previously assessed application is clearly referred to (NumDoc and application type) in the list of studies.
2H. Report on monitoring data	**2H.1 Report on monitoring data**	This is a report on the information resulting from monitoring, if the authorisation was subject to monitoring.

7.b. Marketing authorisation renewal application for a plant protection product for which Category 4 studies are in progress

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application. To be submitted three months after the renewal of the approval of the active substance.
	1A.2 Proof of payment	To be submitted three months after the renewal of the approval of the active substance.

[10] In application of the European "Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009", the permission to refer shall be assessed by the Rapporteur Member State for the active substance.

[11] For AIR II substances for which the new requirements of Commission Regulations (EU) Nos 283/2013 and 284/2013 are not necessary, the corresponding parts of the dRR do not have to be completed. The new dRR format is not mandatory for the review of products containing substances from the AIR II programme but its use is highly recommended by the French authorities.

1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses. To be submitted three months after the renewal of the approval of the active substance.
	1B.2 Full composition form	Form dated and signed by hand. To be submitted three months after the renewal of the approval of the active substance.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III). To be submitted three months after the renewal of the approval of the active substance.
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin. To be submitted three months after the renewal of the approval of the active substance.
1D. Authorisation of the product in France	**1D.1 Copies of the authorisation decisions in France**	To be submitted three months after the renewal of the approval of the active substance.
1E. Comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution. Information related to the comparative assessment must be written in English and included in the dedicated section of Part A of the dossier submitted by the applicant if France is the zRMS or in a national addendum to Part A if France is not the zRMS. To be submitted when submitting Category 4 studies.
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	To be provided in Part A or in a national addendum. To be submitted when submitting Category 4 studies.
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name. A new copy can be submitted when submitting Category 4 studies in the event of a change of GAP.
1G. Proposed label	**1G.2 Sample or description of the packaging**	To be provided, where applicable when the product requests an "Amateur" range of uses.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	To be submitted three months after the renewal of the approval of the active substance.
	1H.2 SDSs for the co-formulants (including active substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.). To be submitted three months after the renewal of the approval of the active substance.
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V. To be submitted when submitting Category 4 studies.
2A. European completeness form	**2A.1 European completeness form**	"Template CoCh Art 43" document available on ANSES's website, completed by the applicant. To be submitted three months after the renewal of the approval of the active substance and updated when submitting Category 4 studies.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	For each GAP, the concerned Member States must be included in a list in the format presented in the table of the dRR, current version. To be submitted three months after the renewal of the approval of the active substance.
	2B.2 Certificate stating that there are no amendments to the requested GAP or justification of amendments	Amendments can be justified by new endpoints, risk assessment results, or the harmonisation of GAP in the zone. Certificate dated and signed by hand. To be submitted three months after the renewal of the approval of the active substance.
2C. Certificate of absence of change of composition for the authorised product, or justification of the need for a minor change of composition due to the renewal of the active substance	**2C.1 Certificate of absence of change of composition for the authorised product, or justification of the need for a minor change of composition due to the renewal of the active substance**	Certificate dated and signed by hand. To be submitted three months after the renewal of the approval of the active substance.
2D. Access to data	**2D.1 Justification of access to protected data on the active substances**	The supporting documents may be: - A declaration confirming access for the data owner (specify the applicants in the event of a task force), - A letter of total access to protected data, - "Permission to refer", For the permission to refer, indicate if it is currently being assessed by the Rapporteur Member State for the active substance[12] or by another Member

[12] In application of the European "Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009",

		State, specifying which one. If the permission to refer has been submitted or is being assessed by a Member State, provide proof of its submission in this Member State and justification of its processing by this Member State (letter, e-mail from the Member State, etc.). To be submitted three months after the renewal of the approval of the active substance.
2E. dRR	**2E.1 Part A**	To be submitted when submitting Category 4 studies.
	2E.2 Part B	All new information not yet assessed in the zone must be highlighted in yellow. New information will be required as a result of amendments in data requirements or criteria, pursuant to Article 43(2) of Regulation (EC) No 1107/2009. Each dRR must involve a specific product and be "self-sufficient", not calling on or referring to dRRs involving other products. Present the sections separately, except for Sections B1, B2 and B4 which must be grouped together. Provide a document for each section. If a section is deemed irrelevant, include a rationale in the corresponding document. To be submitted when submitting Category 4 studies.
	2E.3 Part C	All new information not yet assessed in the zone must be highlighted in yellow. To be submitted when submitting Category 4 studies.
2N. Justification if details are lacking for required information	**2N.1 Justification if details are lacking for required information**	Provide justification for the absence of details for the points of the dRR that cannot be completed. To be submitted when submitting Category 4 studies.
2G. Study reports	**2G.1 Study reports**	Only new study reports must be provided in paper format. If study reports have already been submitted to ANSES, in the context of another application, they do not need to be submitted again in paper format provided that the previously assessed application is clearly referred to (NumDoc and application type) in the list of studies. Category 4 study reports must be submitted when submitting Category 4 studies.
2H. Report on monitoring data	**2H.1 Report on monitoring data**	This is a report on the information resulting from monitoring, if the authorisation was subject to monitoring. To be submitted three months after the renewal of the approval of the active substance.
2I. List of Category 4 studies and their submission dates	**2I.1 List of Category 4 studies and their submission dates**	The format used must be that appearing in the Annexes of the European "Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009", current version. It is necessary to: - justify why the mentioned studies fall in Category 4. - justify that the studies have been initiated (e.g. through a certificate from the laboratory undertaking the study) or commissioned and indicate the submission dates for the studies. To be submitted three months after the renewal of the approval of the active substance.
2J. Signed declaration confirming that the authorised product and its uses are compliant with the conditions and restrictions for the renewal of the approval of the active substance	**2J.1 Signed declaration confirming that the authorised product and its uses are compliant with the conditions and restrictions for the renewal of the approval of the active substance**	To be submitted three months after the renewal of the approval of the active substance.

7.c. Marketing authorisation renewal application for a plant protection product containing two active substances whose renewal dates are within one year of one another (with or without Category 4 studies in progress)

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	To be submitted three months after the renewal of the approval of the first active substance.
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses. To be submitted three months after the renewal of the approval of the first active substance.
	1B.2 Full composition form	Form dated and signed by hand. To be submitted three months after the renewal of the approval of the first

the permission to refer shall be assessed by the Rapporteur Member State for the active substance.

		active substance.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III). To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these Category 4 studies are submitted.
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin. To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these Category 4 studies are submitted.
1D. Copies of previous authorisation decisions for the product in France	**1D.1 Copies of the authorisation decisions in France**	To be submitted three months after the renewal of the approval of the first active substance.
1E. Information related to the comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution. Information related to the comparative assessment must be written in English and included in the dedicated section of Part A of the dossier submitted by the applicant if France is the zRMS or in a national addendum to Part A if France is not the zRMS. To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these Category 4 studies are submitted.
1F. The applicant's proposal regarding PPE	**1F.1 The applicant's proposal regarding PPE**	To be provided in Part A or in a national addendum. To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these Category 4 studies are submitted.
1G Proposed label	**1G.1 Proposed label**	To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these Category 4 studies are submitted.
1G. Proposed label	**1G.2 Sample or description of the packaging**	To be provided, where applicable when the product requests an "Amateur" range of uses.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these Category 4 studies are submitted.
	1H.2 SDSs for the co-formulants (including active substances)	To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these Category 4 studies are submitted. If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V. To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these Category 4 studies are submitted.
2A. European completeness form	**2A.1 European completeness form**	"Template CoCh Art 43" document available on ANSES's website, completed by the applicant. To be submitted three months after the renewal of the approval of the first and second active substances and updated when submitting Category 4 studies.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	For each GAP, the concerned Member States must be included in a list in D1 format. To be submitted three months after the renewal of the approval of the second active substance.
	2B.2 Certificate stating that there are no amendments to the requested GAP or justification of amendments	Amendments can be justified by new endpoints, risk assessment results, or the harmonisation of GAP in the zone. Certificate dated and signed by hand. To be submitted three months after the renewal of the approval of the second active substance.
2C. Certificate of absence of change of composition for the authorised product, or justification of the need for a minor change of composition due to the renewal of the active substance	**2C.1 Certificate of absence of change of composition for the authorised product, or justification of the need for a minor change of composition due to the renewal of the active substance**	Certificate dated and signed by hand. To be submitted three months after the renewal of the approval of the second active substance.
2D. Access to data	**2D.1 Justification of access to protected data on the active substances**	The supporting documents may be: - A declaration confirming access for the data owner (specify the applicants in the event of a task force), - A letter of total access to protected data, - "Permission to refer",

		For the permission to refer, indicate if it is currently being assessed by the Rapporteur Member State for the active substance[13] or by another Member State, specifying which one. If the permission to refer has been submitted or is being assessed by a Member State, provide proof of its submission in this Member State and justification of its processing by this Member State (letter, e-mail from the Member State, etc.). To be submitted three months after the renewal of the approval of the first active substance for access to data on the first active substance and three months after the renewal of the approval of the second active substance for access to data on the second active substance.
2E. dRR	**2E.1 Part A**	To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these studies are submitted.
	2E.2 Part B	All new information not yet assessed in the zone must be highlighted in yellow. New information will be required as a result of amendments in data requirements or criteria, pursuant to Article 43(2) of Regulation (EC) No 1107/2009. Each dRR must involve a specific product and be "self-sufficient", not calling on or referring to dRRs involving other products. Present the sections separately, except for Sections B1, B2 and B4 which must be grouped together. Provide a document for each section. If a section is deemed irrelevant, include a rationale in the corresponding document. To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these studies are submitted.
	2E.3 Part C	All new information not yet assessed in the zone must be highlighted in yellow. To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these studies are submitted.
2N. Justification if details are lacking for required information	**2N.1 Justification if details are lacking for required information**	Provide justification for the absence of details for the points of the dRR that cannot be completed. To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these studies are submitted.
2G. Study reports	**2G.1 Study reports**	Only new study reports must be provided in paper format. If a study report has already been submitted in paper form to ANSES, there is No need to submit it again. Simply submit the electronic version and refer to the dossier (NumDoc and application type) for which the paper report was submitted. To be submitted three months after the renewal of the approval of the second active substance, or if Category 4 studies are in progress, when these studies are submitted.
2H. Report on monitoring data	**2H.1 Report on monitoring data**	This is a report on the information resulting from monitoring, if the authorisation was subject to monitoring. To be submitted three months after the renewal of the approval of the first and second active substances.
2I. List of Category 4 studies and their submission dates	**2I.1 List of Category 4 studies and their submission dates**	The format used must be that appearing in the Annexes of the European "Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009", current version. It is necessary to: - justify why the mentioned studies fall in Category 4. - justify that the studies have been initiated (e.g. through a certificate from the laboratory undertaking the study) or commissioned and indicate the submission dates for the studies. To be submitted three months after the renewal of the approval of the first active substance for Category 4 studies on the first active substance and three months after the renewal of the approval of the second active substance for Category 4 studies on the second active substance.
2J. Signed declaration confirming that the authorised product and its uses are compliant with the conditions and restrictions for the renewal of the approval of the active substance	**2J.1 Signed declaration confirming that the authorised product and its uses are compliant with the conditions and restrictions for the renewal of the approval of the active substance**	To be submitted three months after the renewal of the approval of the first and second active substances.

8. Application to withdraw an authorisation for a product

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.

[13] In application of the European "Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009", the permission to refer shall be assessed by the Rapporteur Member State for the active substance.

1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.

9. Application to withdraw a use of a product

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses to be withdrawn in France expressed according to the national catalogue of plant protection uses.

10. Bee notation application

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1N. Notation Registration Report	**1N.1 Notation Registration Report**	In the application dossier for the "bee" notation, provide only justification of the agronomic relevance of this notation for each use, referring to the appropriate dRR Part B data. When a "bee" notation application is submitted in parallel with an MA or extension application, the risk assessment for bees must be included in dRR Part B accompanying the MA application.
2G. Study reports	**2G.1 Study reports**	

11a. Application for the extension of major uses

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1E. Information related to the comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution. Information related to the comparative assessment must be written in English and included in the dedicated section of Part A of the dossier submitted by the applicant if France is the zRMS or in a national addendum to Part A if France is not the zRMS.
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	To be provided in Part A or in a national addendum.
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	For each GAP, the concerned Member States must be included in a list in the format presented in the table of the dRR, current version.
2D. Access to data	**2D.1 Justification of access to protected data on the active substances**	To be provided only for the uses covered by the application, if necessary. The supporting documents may include: ○ A letter of access to protected data, ○ Study reports, ○ A rationale for derogation from the supply of data.
2E. dRR	**2E.1. Part A**	

	2E.2. Part B	Provide an additional dRR taking into account the data and assessments on the new uses. If similar assessments have already been undertaken, do not refer to other RRs: the submitted dRR must be "self-sufficient". All items not yet assessed must be highlighted in yellow.
2G. Study reports	**2G.1 Study reports**	Only new study reports must be provided in paper format. If a study report has already been submitted in paper form to ANSES, there is no need to submit it again. Simply submit the electronic version and refer to the dossier (NumDoc and application type) for which the paper report was submitted.

11b. Application for the extension of minor uses

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1E. Information related to the comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution. Information related to the comparative assessment must be written in English and included in the dedicated section of Part A of the dossier submitted by the applicant if France is the zRMS or in a national addendum to Part A if France is not the zRMS.
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	To be provided in Part A or in a national addendum.
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V.
1U. Justification of the application under Article 51	**1V.1 Annex VI**	Provide Annex VI, completed.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	For each GAP, the concerned Member States must be included in a list in the format presented in the table of the dRR, current version.
2D. Access to data	**2D.1 Justification of access to protected data on the active substances**	To be provided only for the uses covered by the application, if necessary. The supporting documents may include: ○ A letter of access to protected data, ○ Study reports, ○ A rationale for derogation from the supply of data.
2E. dRR	**2E.1. Part A**	Provide the draft Registration Report (dRR) Part A written in English adapted to applications for the extension of an authorisation for minor uses. It must include, among other things, information extrapolated from the risk assessments available for major uses already authorised in France.
	2E.2. Part B	Provide a dRR Part B for the relevant sections if new assessments are necessary based on the uses already authorised, possible extrapolations, and their validity. All items not yet assessed must be highlighted in yellow.
2G. Study reports	**2G.1 Study reports**	If necessary. In this case, only new study reports must be provided in paper format.

11c. Application for the extension of major and minor uses under the mutual recognition procedure

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	

1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Original certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.
	1C.10 Identification certificate	Original certificate stating that the plant protection product is identical to that authorised by the Reference Member State.
1E. Information related to the comparative assessment	**1E.1 Information related to the comparative assessment**	Where applicable, when the product contains an active substance approved as a candidate for substitution. Information related to the comparative assessment must be written in English and included in the dedicated section of Part A of the dossier submitted by the applicant if France is the zRMS or in a national addendum to Part A if France is not the zRMS.
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	To be provided in Part A or in a national addendum.
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1L. Member State decision	**1L.1 French translation of the MA decision issued by the Reference Member State**	
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	For each GAP, the concerned Member States must be included in a list in the format presented in the table of the dRR, current version.
2D. Access to data	**2D.1 Justification of access to protected data on the active substances**	To be provided only for the uses covered by the application, if necessary. The supporting documents may include: ○ A letter of access to protected data, ○ Study reports, ○ A rationale for derogation from the supply of data.
2E. dRR	**2E.1 Part A**	Provide only the copy of the dRR submitted to the Reference Member State.
	2E.2 Part B	
2F. RR	**2F.1 Parts A, B**	Provide justification (letter, e-mail from the Member State, etc.) stating that the final registration report of the Member State that issued the authorisation has been placed on CIRCABC. or Provide the RR if this document is not available on CIRCABC.
2G. Study reports	**2G.1 Study reports**	Provide only copies of the reports submitted to the Reference Member State. It is not possible to submit additional reports in the framework of this application.

12. Application for a minor change of composition

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description and justification of the application in accordance with the "Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC".
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form (authorised)	Form dated and signed by hand.
	1B.2 Full composition form (requested)	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.

1R. Dossier for the comparison of toxicological, ecotoxicological and physico-chemical properties	**1R.1 Dossier for the comparison of toxicological, ecotoxicological and physico-chemical properties**	All information demonstrating similarity between the current composition and the new requested composition.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1. SDS for the product**	
	1H.2. SDSs for the co-formulants (including active substances)	To be submitted for the old and new co-formulants. If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
COMMENTS It is the applicant's responsibility to demonstrate similarity between the old and new compositions of the product. To do so, the applicant can rely, for example, on an accelerated stability study for the requested commercial packaging and/or on measurements of physico-chemical properties, which must be undertaken in accordance with Good Laboratory Practice (GLP). In the event that an accelerated stability study is submitted, the measurement of the level of active substance(s) and the technical properties (according to the product type and GLP) before and after storage must be submitted. The sample used for the initial pre-storage measurements cannot be a sample stored in parallel at 0°C. Moreover, the validation data on the analytical method for the active substance(s) used in the accelerated storage study must also be provided. Similarly, in case of a change or addition of suppliers for a co-formulant, the applicant is responsible for demonstrating similarity between the co-formulants. To do so, the applicant can rely on the composition of the co-formulant or on measurements of physico-chemical properties, which must be undertaken in accordance with Good Laboratory Practice (GLP).		

13. Application for a change of classification

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the requested classification.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1J. Any information justifying the amendment application	**1J.1 Any information justifying the amendment application**	Well-founded proposal for the new classification, study report, access letter, EFSA report, etc.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including active substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).

14. Application to amend an authorisation requiring an assessment

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1G. Proposed label	**1G.2 Sample or description of the packaging**	To be provided, where applicable when the product requests an "Amateur" range of uses.

2E. dRR	**2E.2 Part B**	Provide an additional dRR taking into account the data and assessments on the requested amendments. If similar assessments have already been undertaken, do not refer to other RRs: the submitted dRR must be "self-sufficient". All items not yet assessed must be highlighted in yellow.
2G. Study reports	**2G.1 Study reports**	

15. Post-authorisation monitoring

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the submitted dossier.
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1D. Authorisation of the product in France	**1D.1 Copies of the authorisation decisions in France**	Provide copies of the decisions mentioning the post-authorisation applications. Not applicable in the framework of an application according to Article 56.
1I Requested items (study report, etc.)	**1I.1 Requested items (study report, etc.)**	

16. Application for a change of trade name

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	Form dated and signed by hand. To be completed with the new requested name.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).

17. Application to add a new trade name

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
1C. Certificate	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.10 Identification certificate for the reference product and its second name	Original certificate dated and signed (with the names of the two products mentioned).

18. Application to transfer an authorisation to another holder

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application by the company wanting to benefit from the MA transfer.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand by the applicant.
	1B.2 Full composition form	Form dated and signed by hand by the applicant.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.

	1C.4 Certificate of acceptance of the transfer by the initial holder	Certificate dated and signed by hand by the MA holder before the transfer application is processed.
1D. Authorisation of the product in France	**1D.2 Original of the authorisation decision(s) for the product in France**	All decisions amending the MA must be submitted.

19. Classification amendment notification

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C1. Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1J. Any information justifying the amendment application	**1J.3 Any information justifying the classification amendment notification**	Well-founded proposal for the new classification, study report, access letter, EFSA report, etc.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including active substances)	Provide the SDS for the active substance or the co-formulant covered by the regulation amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008.

20. Application to amend an authorisation with administrative assessment

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	The letter must mention the type of requested amendment: addition of a manufacturing site for the active substance, amendment of a manufacturing site for the active substance, change of commercial type for the product, or addition of packaging.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	Submit the form dated and signed by hand for the following applications: addition of a manufacturing site for the active substance, amendment of a manufacturing site for the active substance.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Submit the form dated and signed by hand for the following applications: addition of a manufacturing site for the active substance or amendment of a manufacturing site for the active substance. Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.
1G Proposed label	**1G.1 Proposed label**	Submit the form dated and signed by hand for the following applications: change of commercial type for the product or addition of packaging. To be provided in French, in the product's name.
1J. Any information justifying the amendment application	**1J.1 Any information justifying the amendment application**	

21. Application to amend information declared in an ongoing application

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application. The provision of the required documents does not prejudge acceptance of the application, which depends on the stage of assessment of the ongoing application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	To be provided depending on the application type. Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and**	Certificate dated and signed by hand, where applicable (see Annex III).

	electronic documents	
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	To be provided depending on the application type. Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.
1J. Any information justifying the amendment application	**1J.1 Any information justifying the amendment application**	

22. Application for a product with an identical composition

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin	Certificate dated and signed by hand mentioning the product's name. Certificates must be provided by active substance and by origin.
1S. All documents submitted for the application for the reference product	**1S.1 All documents submitted for the application for the reference product**	Provide the documents submitted in the application for the reference product or demonstrate access to these documents.

ANNEX II. PREPARATION OF DOSSIERS FOR ADJUVANT PRODUCTS

Sections of the application form to be completed

Sections 3, 4 and 13 must be completed for all applications

Number in the form	Application label related to the preparation of dossiers *(application code, for example)*	Page	Section to be completed for each paragraph/application								
			1	2	6	7	8	9	10	11	12
1.	Marketing authorisation application *(AAMM)*	**31**	1, 2, 3, 4	1	x	x	x	x			
2.	Marketing authorisation application under the mutual recognition procedure *(AMUT)*	**31**	1, 2, 3, 4	1	x	x	x	x	x		
3.	Marketing authorisation application for a generic product *(ABIS)*	**32**	1, 2, 3, 4	1	x	x	x	x			
4.	Marketing authorisation application for a resale product *(AVEN)*	**33**	1, 2, 3, 4	1, 3	x	x	x	x			
6.	Application to renew an authorisation for an adjuvant product *(ARNV)*	**33**	1, 2, 3, 4	1	x	x	x	x			
8.	Application to withdraw an authorisation for a product *(ARET)*	**34**	1, 2, 3	1, 2							
11.	Application for an extension of use *(AUSA)*	**34**	1, 2, 3, 4	1, 2			x				
12.	Application for a minor change of composition *(ACC)*	**35**	1, 2, 3	1, 2							
13.	Application for a change of classification *(AMCC)*	**37**	1, 2, 3	1, 2				x			
14.	Application to amend an authorisation requiring an assessment *(AMOD)*	**37**	1, 2, 3	1, 2	x		x				
15.	Post-authorisation monitoring application *(ASPA)*	**37**	1, 2, 3	1, 2							
16.	Application for a change of trade name *(ANOM)*	**38**	1, 2, 3	1, 2							x
17.	Application to add a new trade name for a product already authorised *(AIDQ)*	**38**	1, 2, 3	1, 2							
18.	Application to transfer an authorisation to another holder *(ATRS)*	**37**	1, 2, 3	1, 2						x	
19.	Classification amendment notification *(ACLP)*	**37**	1, 2, 3	1, 2				x			
20.	Application to amend an authorisation with administrative assessment *(AMOI)*	**38**	1, 2, 3	1, 2		x	x				
21.	Application to amend information declared in an ongoing application *(AMOI)*	**38**	1, 2, 3	1		x	x	x			
22.	Application for a product with an identical composition *(ADPI1, ADPI2, ADPI3)*	**38**	1, 2, 3, 4	1, 2, 3	x						

Preparation of dossiers

The numbering of documents comes from a document reference system and is not alphanumeric.

1. Marketing authorisation application

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including adjuvant substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V.
2B. GAP	**2B.1 List of uses with their conditions of application compliant with Good Agricultural Practice**	For each GAP, the concerned Member States must be included in a list in the format presented in the table of the dRR, current version.
2E. RR	**2E.4 Registration Report**	It is advisable to submit a Registration Report in the "dRR" format used for plant protection products.
2G. Study reports	**2G.1 Study reports**	If study reports have already been submitted to ANSES, in the context of another application, they do not need to be submitted again in paper format provided that the previously assessed application is clearly referred to (NumDoc and application type) in the list of studies.

2. Marketing authorisation application under the mutual recognition procedure

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.7 Identification certificate for the dossier submitted in the Member State that issued the MA and the dossier submitted in France	
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including adjuvant substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).

(EC) No 1272/2008		
1L. Member State decision	**1L.1 English translation of the MA decision issued by the Member State**	
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	
2F. RR	**2F.2 MS Registration Report**	Provide a certified English translation of the Registration Report of the Member State that authorised the adjuvant Or Provide justification (letter, e-mail from the Member State, etc.) stating that the final Registration Report of the Member State that issued the authorisation is available.
	2G.1 Study reports	Provide a copy of the dossier submitted to the Member State that issued the authorisation.

3. Marketing authorisation application for a generic product ("bis product" or "me-too"))

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	The level of adjuvant substance in the generic product must be identical to that in the reference product. The type of product must be indicated and must also be identical to that of the reference product. Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1F. The applicant's proposal regarding PPE	**1F.1 The applicant's proposal regarding PPE**	
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including adjuvant substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
2D. Access to data	**2D.2 Declaration confirming access to applicable data on the product and supporting evidence of this access**	The supporting evidence may be: - A rationale for derogation from the supply of data, e.g. the absence of protected data. - A letter of total or partial access to protected data on the product for the uses authorised for the reference product.
2E. RR	**2E.4 Registration Report**	It is advisable to submit a Registration Report in the "dRR" format used for plant protection products.
2G. Study reports	**2G. Study reports**	It is not possible to submit study reports in the framework of this application, with the exception of those mentioned in the "Comments" section below.

COMMENTS

It is the applicant's responsibility to demonstrate similarity between the generic product and the related product (called the reference product).
In the framework of Article 253-9 of the French Rural Code and for demonstration purposes, the applicant can rely, for example, on an accelerated stability study for the requested commercial packaging and/or on measurements of physico-chemical properties, which must be undertaken in accordance with Good Laboratory Practice (GLP).
In the event that an accelerated stability study is submitted, the measurement of the level of adjuvant substance(s) and the technical properties (according to the product type and GLP) before and after storage must be submitted. The sample used for the initial pre-storage measurements cannot be a sample stored in parallel at 0°C. Moreover, the validation data on the analytical method for the adjuvant substance(s) used in the accelerated storage study must also be provided.

4. Marketing authorisation application for a resale product

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	Form dated and signed by hand. This form can be submitted by the company holding the MA for the reference product.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.2 Cross-certificates (supply and procurement) for the product	Certificate dated and signed by hand mentioning the product's name.
	1C.10 Identification certificate for the products	Original certificate (with the names of the two products mentioned).
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.

6. Application to renew an authorisation for an adjuvant product

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1D. Authorisation of the product in France	**1D.1 Copies of the authorisation decisions in France**	
1F. PPE	**1F.1 The applicant's proposal regarding PPE**	
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including adjuvant substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).
1P. List of studies for data protection in France	**1P.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V.
2E. RR	**2E.4 Registration Report**	It is advisable to submit a Registration Report in the "dRR" format used for plant protection products.
2G. Study reports	**2G.1 Study reports**	Only new study reports must be provided in paper format. If study reports have already been submitted to ANSES, in the context of another application, they do not need to be submitted again in paper format provided that the previously assessed application is clearly referred to (NumDoc and application type) in the list of studies.

8. Application to withdraw an authorisation for a product

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses to be withdrawn in France expressed according to the national catalogue of plant protection uses.

11. Application for the extension of uses

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the uses requested in France expressed according to the national catalogue of plant protection uses.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1F. PPE	**1F. The applicant's proposal regarding PPE**	
1G. Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
1O. List of studies for data protection in France	**1O.1 List of studies for data protection in France**	Provide the list in the Excel format appearing in Annex V.
2B. GAP	**2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)**	
2E. RR	**2E.4 Registration Report**	It is advisable to submit a Registration Report in the "dRR" format used for plant protection products.
2G. Study reports	**2G.1 Study reports**	Only new study reports must be provided in paper format. If a study report has already been submitted in paper form to ANSES, there is no need to submit it again. Simply submit the electronic version and refer to the dossier (NumDoc and application type) for which the paper report was submitted.

12. Application for a minor change of composition

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application or justification of the application
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form (Old composition)	Form dated and signed by hand.
	1B.2 Full composition form (New composition)	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1R. Comparison dossier	**1R.1 Dossier for the comparison of toxicological, ecotoxicological and physico-chemical properties**	
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including adjuvant substances)	To be submitted for the old and new co-formulants. If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).

COMMENTS

It is the applicant's responsibility to demonstrate similarity between the old composition of the product and the new composition of the product.

To do so, the applicant can rely, for example, on an accelerated stability study for the requested commercial packaging and/or on measurements of physico-chemical properties, which must be undertaken in accordance with Good Laboratory Practice (GLP).
In the event that an accelerated stability study is submitted, the measurement of the level of active substance(s) and the technical properties (according to the product type and GLP) before and after storage must be submitted. The sample used for the initial pre-storage measurements cannot be a sample stored in parallel at 0°C. Moreover, the validation data on the analytical method for the adjuvant substance(s) used in the accelerated storage study must also be provided.

Similarly, in case of a change or addition of suppliers for a co-formulant, the applicant is responsible for demonstrating similarity between the co-formulants. To do so, the applicant can rely on the composition of the co-formulant or on measurements of physico-chemical properties, which must be undertaken in accordance with Good Laboratory Practice (GLP).

13. Application for a change of classification

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand. This form must be completed with the requested classification.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1J. Any information justifying the amendment application	**1J.3 Any information justifying the amendment application**	Well-founded proposal for the new classification, study report, access letter, EFSA report, etc.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including adjuvant substances)	If several suppliers are listed for the same co-formulant, they must be specified in the full composition form and all the SDSs must be provided. The information contained in the SDSs must be consistent with the information given in the full composition form (CAS No of the substance(s), etc.).

14. Application to amend an authorisation requiring an assessment

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1G Proposed label	**1G.1 Proposed label**	To be provided in French, in the product's name.
2E. RR	**2E.4 Registration Report**	It is advisable to submit a Registration Report in the "dRR" format used for plant protection products.
2G Study reports	**2G.1 Study reports**	

15. Post-authorisation monitoring

	Documents	Observations
1A. Cover letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
1D. Authorisation of the product in France	**1D.1 Copies of the authorisation decisions in France**	Mentioning the post-authorisation applications.
1I. Requested items (study report, etc.)	**1I.1 Requested items (study report, etc.)**	

16. Application for a change of trade name

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	Form dated and signed by hand.

		To be completed with the new requested name.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).

17. Application to add a name for an authorised product

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).

18. Application to transfer an authorisation to another holder

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application by the company wanting to benefit from the MA transfer.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
	1C.4 Certificate of acceptance of the transfer by the initial holder	Certificate dated and signed by hand by the holder before the transfer application is processed.
1D. Authorisation of the product in France	**1D.2 Original of the authorisation decision(s) for the product in France**	

19. Classification amendment notification

	Documents	Observations
1A. Application letter	**1A. Application letter**	Description of the application.
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1J. Any information justifying the amendment application	**1J.3 Any information justifying the classification amendment notification**	Well-founded proposal for the new classification, study report, access letter, EFSA report, etc.
1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	**1H.1 SDS for the product**	
	1H.2 SDSs for the co-formulants (including adjuvant substances)	Provide the SDS for the adjuvant substance or the co-formulant covered by the regulation amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008.

20. Application to amend an authorisation with administrative assessment

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	The letter must mention the type of requested amendment: addition of a manufacturing site for the adjuvant substance, amendment of a manufacturing site for the adjuvant substance, change of commercial type for the product, or addition of packaging.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B2. Full composition form	To be provided depending on the application type. Form dated and signed by hand.

1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1G Proposed label	**1G.1 Proposed label**	To be provided depending on the application type. To be provided in French, in the product's name.
1J. Any information justifying the amendment application	**1J.1 Any information justifying the amendment application**	

21. Application to amend information declared in an ongoing application

	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	To be provided depending on the application type. Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1J. Any information justifying the amendment application	**1J.3 Any information justifying the amendment application**	

22. Application already submitted for a product with an identical composition

Document class	Documents	Observations
1A. Application letter	**1A.1 Application letter**	Description of the application.
	1A.2 Proof of payment	
1B. Forms	**1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product**	Form dated and signed by hand.
	1B.2 Full composition form	Form dated and signed by hand.
1C. Certificates	**1C.1 Identification certificate for paper documents and electronic documents**	Certificate dated and signed by hand, where applicable (see Annex III).
1S. All documents submitted for the application for the reference product	**1S.1 All documents submitted for the application for the reference product**	Provide the documents submitted in the application for the reference product or demonstrate access to these documents.

ANNEX III. MODEL CERTIFICATES

MODEL IDENTIFICATION CERTIFICATE (1C.1)

Certificate to be written on letterhead paper from the company submitting the marketing application or any other application relating to an active substance, safener, synergist, plant protection product or adjuvant and to be signed by the person who is responsible for marketing the product mentioned on the application form and who signed that form.

We, the undersigned, …(1)…, certify that the content of the copies of the paper or electronic (CD-ROM) dossiers submitted in the framework of our application dated …(2)…, involving …(3)…, is identical.

dated and signed *(the signatory's surname, first name and function written legibly)*

(1): name and address of the company submitting the application

(2): date mentioned on the application form

(3): trade name of the product, name of the substance (and possibly an identification number: MA, input, registration, etc.) covered by the application

Note in case of differences between the copies, the signed documents will be deemed authoritative

MODEL CERTIFICATE FOR THE PROCUREMENT OF AN ACTIVE SUBSTANCE (1C.2)

Certificate to be written on letterhead paper from the company submitting the marketing application or any other application relating to an active substance, safener, synergist, plant protection product or adjuvant and to be signed by the person who is responsible for marketing the product mentioned on the application form and who signed that form.

We, the undersigned, …(1)…, certify that we use the company …(2)… as our supplier for the active substance …(3)…, for the …(4)… application involving the …(5)... product

dated and signed *(the signatory's surname, first name and function written legibly)*

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(1): name and address of the company submitting the application

(2): name and address of the company originally holding the active substance

(3): name of the active substance

(4): name of the application

(5): trade name of the product, name of the substance (and possibly an identification number: MA, input, registration, etc.) covered by the application

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MODEL SUPPLY CERTIFICATE (1C.2)

Certificate to be written on letterhead paper from the company supplying the active substance

We, the undersigned, …(1)…, certify that we supply the company …(2)… with the active substance…(3)…, for the …(4)… application involving the …(5)… product

The addresses of the manufacturing sites for this active substance are as follows:

- …
- … (6)

dated and signed *(the signatory's surname, first name and function written legibly)*

(1): name and address of the company supplying the active substance

(2): name and address of the company submitting the application

(3): name of the active substance

(4): name of the application

(5): trade name of the product, name of the substance (and possibly an identification number: MA, input, registration, etc.) covered by the application

(6) exact addresses of the manufacturing sites to be provided only if they are not specified in dRR Part C (in this case, refer to dRR Part C in the certificate).

MODEL CERTIFICATE OF ORIGIN (1C.2)

Certificate to be written on letterhead paper from the company submitting the marketing application or any other application relating to an active substance, safener, synergist, plant protection product or adjuvant and to be signed by the person who is responsible for marketing the product mentioned on the application form and who signed that form.

We, the undersigned, …(1)…, certify that we produce the active substance …(2)…, for the …(3)… application involving the …(4)… product

The addresses of the manufacturing sites for this active substance are as follows:

- …(5)
- …

dated and signed *(the signatory's surname, first name and function written legibly)*

---

(1): name and address of the company submitting the application

(2): name of the active substance

(3): name of the application

(4): trade name of the product, name of the substance (and possibly an identification number: MA, input, registration, etc.) covered by the application

(5) exact addresses of the manufacturing sites to be provided only if they are not specified in dRR Part C (in this case, refer to dRR Part C in the certificate).

MODEL TRANSFER ACCEPTANCE CERTIFICATE (1C.4)

Certificate to be written on letterhead paper from the company that currently holds the marketing authorisation covered by the application (before the transfer application is processed)

We, the undersigned, …(1)…, certify that we accept the transfer of the marketing authorisation [number …(2)…] for the …(3)… product to the company …(4)…

dated and signed *(the signatory's surname, first name and function written legibly)*

(1): name and address of the company that currently holds the marketing authorisation

(2): authorisation number in France

(3): trade name of the product (and possibly an identification number: MA, input, registration, etc.) covered by the application

(4) name and address of the company that will hold the marketing authorisation in the future

MODEL CERTIFICATE FOR THE IDENTIFICATION OF DOSSIERS IN THE CONTEXT OF A MARKETING AUTHORISATION APPLICATION UNDER THE MUTUAL RECOGNITION PROCEDURE (1C.7)

Certificate to be written on letterhead paper from the company submitting the marketing application or any other application relating to an active substance, safener, synergist, plant protection product or adjuvant and to be signed by the person who is responsible for marketing the product mentioned on the application form and who signed that form.

We, the undersigned, …(1)…, certify that the content of the dossier submitted in France in the context of our application dated …(2)…, involving …(3)…, is identical to the content of the dossier submitted in the Member State (…(4)…) that issued the marketing authorisation.

dated and signed *(the signatory's surname, first name and function written legibly)*

---

(1): name and address of the company submitting the application

(2): date mentioned on the application form

(3): trade name of the product, name of the substance (and possibly an identification number: MA, input, registration, etc.) covered by the application

(4): name of the Member State

MODEL PRODUCT IDENTIFICATION DECLARATION (1C.10)

Certificate to be written on letterhead paper from the company submitting the marketing application or any other application relating to an active substance, safener, synergist, plant protection product or adjuvant and to be signed by the person who is responsible for marketing the product mentioned on the application form and who signed that form.

Identification with a product authorised in another Member State (mutual recognition):

We, the undersigned, …(1)…, certify that the plant protection product …(2)… covered by the marketing authorisation application in France under the mutual recognition procedure dated …(3)… is identical to the ….(4)… product authorised by the Reference Member State …(5)… ,

Identification with a product authorised in France:

We, the undersigned, …(1)…, certify that the plant protection product …(2)… covered by the marketing authorisation application in France dated …(3)… is identical to the …(4)… product authorised in France,

dated and signed *(the signatory's surname, first name and function written legibly)*

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(1): name and address of the company submitting the application

(2): trade name of the product, name of the substance (and possibly an identification number: MA, input, registration, etc.) covered by the application

(3): date mentioned on the application form

(4): trade name of the product in the Reference Member State

(5): Reference Member State (Member State that issued the marketing authorisation on which the application is based)

ANNEX IV. DOCUMENT NOMENCLATURE

Computer folder	Document class	Document code	Document code/Requested document name
Administrative documents	1A. Application letter	1A.1	1A.1 Application or declaration letter
Administrative documents	1A. Application letter	1A.2	1A.2 Proof of payment
Administrative documents	1B. Forms	1B.1	1B.1 Form relating to a marketing authorisation for a plant protection project, adjuvant or mixed product (Cerfa 15722#01)
Administrative documents	1B. Forms	1B.2	1B.2 Full composition form (full formulation details)
Administrative documents	1B. Forms	1B.2	1B.2 Full composition (old) form (full formulation details of the old formulation)
Administrative documents	1B. Forms	1B.3	1B.3 Minor use form
Administrative documents	1B. Forms	1B.4	1B.4 Experimentation form
Administrative documents	1B. Forms	1B.5	1B.5 Active substance form
Administrative documents	1B. Forms	1B.6	1B.6 Reporting form
Administrative documents	1C. Certificates	1C.1	1C.1 Identification certificate for paper documents and electronic documents
Administrative documents	1C. Certificates	1C.2	1C.2 Cross-certificates for the active substance (supply and procurement) or certificate of origin
Administrative documents	1C. Certificates	1C.3	1C.3 Certificate of acceptance of the transfer by the former holder
Administrative documents	1C. Certificates	1C.4	11C.4 Certificate of acceptance of the transfer by the initial holder
Administrative documents	1C. Certificates	1C.5	1C.5 Certificate of acceptance of the transfer by the holder of the reference product
Administrative documents	1C. Certificates	1C.6	1C.6 Cross-certificate for the supply and procurement of the product
Administrative documents	1C. Certificates	1C.7	1C.7 Identification certificate for the dossier submitted in the Member State that issued the MA and the dossier submitted in France
Administrative documents	1C. Certificates	1C.8	1C.8 Certificate relating to the full composition
Administrative documents	1C. Certificates	1C.9	1C.9 Certificate relating to the co-formulants

Administrative documents	1C. Certificates	1C.10	1C.10. Identification certificate
Administrative documents	1D. Authorisation of the product in France	1D.1	1D.1 Copies of the authorisation decisions in France
Administrative documents	1D. Authorisation of the product in France	1D.2	1D.2 Original of the authorisation decision(s) for the product in France
Administrative documents	1D. Authorisation of the product in France	1D.3	1D.3 Document mentioning the change in holder name (e.g. extract from the Commercial Register)
Administrative documents	1E. Comparative assessment	1E.1	1E.1 Information related to the comparative assessment
Technical dossier	1F. PPE	1F.1	1F.1 The applicant's proposal regarding PPE
Administrative documents	1G. Proposed label (or product information sheet)	1G.1	1G.1 Proposed label (or product information sheet)
Administrative documents	1G. Proposed label (or product information sheet)	1G.2	1G.2 Sample or description of the packaging
Administrative documents	1G. Proposed label (or product information sheet)	1G.3	1G.3 Original label(s) of the product in the Member State of origin
Administrative documents	1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2008	1H.1	1H1. Safety Data Sheet for the product
Administrative documents	1H. SDS according to Regulation (EC) No 1907/2006 including the classification according to Regulation (EC) No 1272/2009	1H.2	1H.2 Safety Data Sheets for the co-formulants
Technical dossier	1I. Requested items (study report, etc.)	1I.1	1I.1 Requested items (study report, etc.)
Technical dossier	1J. All documents enabling the new amendment to be accepted	1J.1	1J.1 Any information justifying the amendment application
Technical dossier	1J. All documents enabling the new amendment to be accepted	1J.2	1J.2 All documents enabling the new packaging to be accepted
Technical dossier	1J. All documents enabling the new amendment to be accepted	1J.3	1J.3 Any information justifying the classification amendment notification
Technical dossier	1K. Letter of access to protected data on the product (ANNEX III)	1K.1	1K.1 Letter of access to protected data on the product (ANNEX III)
Administrative documents	1L. Member State decision	1L.1	1L.1 French translation of the MA decision issued by the Member State
Administrative documents	1L. Member State decision	1L.2	1L.2 Copy of the MA decision issued in the Member State
Technical dossier	1M. Identification certificate for the dossier submitted in the other Member State and the one provided.	1M.1	1M.1 Identification certificate for the dossier submitted in the other Member State and the one provided.

Technical dossier	1N. Registration Report to obtain a notation	1N.1	1N.1 Registration Report to obtain a notation
Administrative documents	1P. List of studies for data protection in France	1P.1	1P.1 List of studies for data protection in France
Technical dossier	1R. Comparison dossier	1R.1	1R.1 Dossier for the comparison of toxicological, ecotoxicological and physico-chemical properties
Technical dossier	1S. All documents submitted for the application for the reference product	1S.1	1S.1 All documents submitted for the application for the reference product
Technical dossier	1U. Justification of the application under Article 51	1U.1	1U.1 Annex VI
Technical dossier	2A. European completeness form	2A.1	2A.1 European completeness form
Technical dossier	2B. GAP	2B.1	2B.1 List of uses with their conditions of use compliant with Good Agricultural Practice (GAP required in the zone)
Technical dossier	2B. GAP	2B.2	2B.2 Certificate stating that there are no amendments to the requested GAP or justification of amendments
Technical dossier	2C. Certificate of absence of change of composition for the authorised product, or justification of the need for a minor change of composition due to the renewal of the active substance	2C.1	2C.1 Certificate stating that the formulation of the authorised product is unchanged, or justification of the need for a minor change of composition due to the renewal of the active substance
Technical dossier	2D. Access to data	2D.1	2D.1 Declaration confirming access to applicable data on the active substances and supporting evidence of this access
Technical dossier	2D. 2D.2 Declaration confirming access to data and supporting evidence of this access	2D.2	2D.2 Declaration confirming access to applicable data on the product and supporting evidence of this access
Technical dossier/dRR Part A	2E. dRR	2E.1	2E.1 Part A
Technical dossier/dRR Part B	2E. dRR	2E.2	2E.2 Part B
Technical dossier/dRR Part C	2E. dRR	2E.3	2E3. Part C including the list of manufacturing sites for the product
Technical dossier	2E. RR	2E.4	2E.4 Registration Report
Technical dossier	2F. RR	2F.1	2F.1 Parts A, B and C
Technical dossier	2F. RR	2F.2	2F.2 MS Registration Report
Technical dossier	2N. Justification if details are lacking for required information	2N.1	2N.1 Justification if details are lacking for required information
Technical dossier/Study Report	2G. Study reports	2G.1	2G.1 Study reports

Technical dossier	2H. Report on monitoring data	2H.1	2H.1 Report on monitoring data
Technical dossier	2I. List of Category 4 studies and their submission dates	2I.1	2I.1 List of Category 4 studies and their submission dates
Technical dossier	2J. A signed declaration confirming that the authorised product and its uses are compliant with the conditions and restrictions for the renewal of the approval of the active substance	2J.1	2J.1 A signed declaration confirming that the authorised product and its uses are compliant with the conditions and restrictions for the renewal of the approval of the active substance
Technical dossier	1R. Dossier for the comparison of toxicological, ecotoxicological and physico-chemical properties	1R.1	1R.1 Dossier for the comparison of toxicological, ecotoxicological and physico-chemical properties
Technical dossier	2M. Copy of the dossier submitted in the other Member State (dRR Parts A, B and C, K documents)	2M.1	2M.1 Copy of the dossier submitted in the other Member State (dRR Parts A, B and C, K documents)
Technical dossier	2M. Copy of the dossier submitted in the other Member State (dRR Parts A, B and C, K documents)	2M.2	2M.2 Final Registration Report of the Rapporteur Member State (RMS)
Technical dossier	2M. Copy of the dossier submitted in the other Member State (dRR Parts A, B and C, K documents)	2M.3	2M.3 Certified (French or English) translation of the MA decision obtained in the Rapporteur Member State
Technical dossier	1S. All documents submitted for the application for the reference product	1S.1	1S.1 All documents submitted for the application for the reference product

ANNEX V. List format for studies on data protection in France

Data_protection_List of studies (2).xlsx

List of data submitted by the applicant

Data point	Author(s)	Year	Title Company report No Source (Where different from company) GLP or GEP status	~~Company Report No.~~	~~Source (where~~	~~GLP or G~~	~~Published~~	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Relied on (Y/N)	Starting date of data protection	Period of data protection (months or years)
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Y/N					Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of	Owner	Y/N	mm/AAAA	x months y months

ANNEX VI.
Justification of the public interest of the extension of minor use under Article 51

1 Information specific to product types:

1.1 ☐ The product is intended to respond to a need that is currently unmet or inadequately met

1.2. ☐ The product aims to control Category 1 and 2 health hazards (see *Note* below)

1.3. ☐ The product contains one or more low-risk active substance(s)

1.4. ☐ The product is for biological control

1.5. ☐ The product is intended to minimise the emergence of a risk of resistance in the target organism or provide a solution in the event of established resistance *(to be justified in the box below).*

Note

Please tick the box corresponding to the product type.

Category 1 and 2 health hazards according to Article L. 201-1 of the French Rural and Maritime Fishing Code[14] are hazards that require (or that may require), in the general (or collective) interest, prevention, monitoring or control measures that are considered mandatory (or defined or approved) by the administrative Authority.

Please use the box to provide justification, when the product is intended to minimise a risk of resistance or provide a solution in the event of established resistance.

2. Specific information for agronomic interest:

In Part A of the dRR specific to minor uses, "Intended uses", to supplement the table of Good Agriculture Practice (GAP):

- Provide a detailed rationale for the presentation of the crop in question and its significance. This description must specify the crop, surface area, and distribution in France and the EU;
- Specify the varietal types;
- Specify the growing conditions, i.e. the type of rotation, soil type, sowing/planting date and density;
- Indicate the harmful organism, referring, when appropriate, to the Ministerial Order of 31 July 2000 establishing a list of pests, plant products and other objects subject to mandatory control measures[15];

  Specify the status of the harmful organism (regulated or not, emerging, re-emerging);

  Provide a detailed rationale for the economic significance of the damage (yield, quality) and the distribution of the crop in question in the geographical area;
- Specify the growing techniques or other alternative methods aiming to control the targeted harmful organisms.

3 Additional information:

Provide:

- a letter of support from an agricultural professional organisation;

- the product's instructions for use.