

Advices to applicants in the framework of Regulation (EC) n° 1107/2009 for the evaluation of plant protection products and adjuvants (revision 4 - 13 february 2026).

Following information is complementary to EU evaluation guidance documents.

| Topics | Complementary information on : -data to be submitted -risk assessment | Guidance document or other document | Availability - y/n and language of the document | Address to obtain the document |
|--|---|---|--|--------------------------------------|
| Phys. Chem. properties and analytical methods | No complementary information to EU guidance documents. | - | - | - |
| Toxicology | <ul style="list-style-type: none"> <i>Operators, workers, residents and bystanders : for dossiers submitted after 01/01/2023</i> <i>Operators, workers, residents and bystanders : for dossiers submitted after 01/01/2016</i> Other exposure assessments not covered by the EFSA guidance document (<i>EFSA Journal</i> 2022;20(1):7032) <ul style="list-style-type: none"> - amateur : relevant exposure data to estimate exposures, - non-agricultural zones (amenities) : relevant exposure data to estimate exposures. - seed treatment (e.g. Seedtropex model or other relevant exposure data to estimate exposures). - other uses : case by case, based on exposure data according to OECD guidance or reasoned extrapolation. | <ul style="list-style-type: none"> <i>EFSA Journal</i> 2022;20(1):7032 <i>EFSA Journal</i> 2014;12(10):3874 | y - English | EFSA website |
| Residues | No complementary information to EU guidance documents. | - | - | - |

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|---------------------------|---|---|---|---|
| Efficacy | No complementary information to EU guidance documents. | - | - | - |
| Fate and behaviour | <p><u>PEC_{gw}</u> :</p> <ul style="list-style-type: none"> - FOCUS_{gw} : all scenarios used excluding Jokioinen. - Refined exposure assessment : FOCUS calculations including mitigation measures should be provided first, modelling according to national agronomic, pedologic and climatic conditions is accepted. <p><u>PEC_{sw}</u> :</p> <p>FOCUS_{sw}, all scenario used excluding D1 Step 4 calculations using Vegetative Filter Strip Modeling System (VFSSMOD) is not accepted</p> <p><u>Non crop areas</u> :</p> <ul style="list-style-type: none"> -Environmental fate exposure model Hardspec for uses on hard surfaces and railways (in case of application by a spray train) | <p>FOCUS ground water guidance documents</p> <p>-</p> <p>-FOCUS surface water guidance documents and</p> <p>-« Note d'information sur l'évaluation du risque de contamination des eaux de surface des produits phytopharmaceutiques dans le cadre du règlement (CE) n°1107/2009 : utilisation de l'outil FOCUS_{sw}»</p> <p>-</p> | <p>y - English</p> <p>-</p> <p>-y - English</p> <p>-y – French</p> <p>y - English</p> | <p>https://esdac.jrc.ec.europa.eu/projects/ground-water-</p> <p>https://esdac.jrc.ec.europa.eu/projects/surface-water</p> <p>Anses website</p> <p>Hardspec available on Health and Safety Executive website</p> |

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|---|---|--|--|--------------------------------------|
| Risk assessment for bees and pollinators | Data and risk assessment to be submitted for bees and pollinators | Note d'information sur l'évaluation des risques pour les abeilles et autres insectes pollinisateurs pour les produits phytopharmaceutiques et leurs adjuvants dans le cadre de la réglementation européenne et en lien avec les dispositions nationales de l'arrêté du 20 novembre 2021- (version 2 -13 février 2026). | y – French | Anses website |

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|---|--|--|--|--------------------------------------|
| Adjuvants | The requirements for plant protection products apply; waiving to provide data must be scientifically justified. (e.g. for Environmental fate and Ecotoxicology sections, based on European Commission guidance 2024 ¹ or any relevant information on the nature of the adjuvant) Efficacy data have to be in accordance with Eppo Standards PP 1/291 (1) which can be supplemented by CEB methods MG08 and DT 22,, published by Végéphyll (French Plant Health Association). | - | - | - |
| Assessment of pesticides used in tank-mixtures | The document clarifies the data and risk assessment to be submitted for tank-mixtures subjected to prior assessment in accordance with the French Ministerial Order of 7 April 2010 | Note to applicants on the methodology and the information to be specified for the assessment of pesticides used in tank-mixtures subject to prior assessment in accordance with the French Ministerial Order of 7 April 2010 | y – French & English | Anses website |

When the agency is acting as RMS, prior to submitting an application for marketing authorisation or extension of major use for a plant protection products and for adjuvants, at least six months before submission, the month and year of submission must be notified to the following address (ppp.zonal.depr@anses.fr) in accordance with the notification procedure described in the European guidance document "Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisation under Regulation (EC) No 1107/2009.

¹ European Commission – Guidance to provide justifications as referred in point 1.5 of the Introduction of the Annexes of Regulations (EU) No 283/2013 and No 284/2013: Problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009. PAFF-PPL-January 2024-Doc.A.07.01. 31 January 2024. <https://webgate.ec.europa.eu/dyna2/pgd/>

Upon receipt of the notification, the Anses Directorate for the Evaluation of Regulated Products will acknowledge receipt of the notification and send a pre-submission form.

Use of the pre-submission form is optional, however, it may enable applicants to clarify certain points relating to the evaluation prior to submitting a dossier.

Révision 4, mise à jour le 13/02/2026.

Révision 3, mise à jour le 10/01/2022.

Révision 2, mise à jour le 18/10/2021.

Révision 1, mise à jour le 15/10/2015.