

**Advices to applicants in the framework of Regulation (EC) n° 1107/2009 for the evaluation of plant protection products (revision 3 - 10 January 2022).**

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
<b>Phys. Chem. properties and analytical methods</b>	No complementary information to EU guidance documents.	-	-	-
<b>Toxicology</b>	<p><i>Operators, workers, residents and bystanders : for dossiers submitted after 01/01/2016</i></p> <p>Other exposure assessments not covered by the EFSA guidance document (<i>EFSA Journal 2014;12(10):3874</i>):</p> <ul style="list-style-type: none"> <li>- amateur : relevant exposure data to estimate exposures.</li> <li>- non-agricultural zones (amenities) : relevant exposure data to estimate exposures.</li> <li>- seed treatment (e.g. Seedtropex model or other relevant exposure data to estimate exposures).</li> <li>- other uses : case by case, based on exposure data according to OECD guidance or reasoned extrapolation.</li> </ul>	<p><i>Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874</i></p> <p>-</p>	y - English	EFSA website

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<b>Residues</b>	No complementary information to EU guidance documents.	-	-	-
<b>Efficacy</b>	No complementary information to EU guidance documents.	-	-	-
<b>Fate and behaviour</b>	<p><b><u>PEC<sub>gw</sub></u></b> :</p> <ul style="list-style-type: none"> <li>- FOCUS<sub>gw</sub> : all scenario used</li> <li>- Refined exposure assessment : modelling according to national agronomic, pedologic and climatic conditions is accepted</li> </ul> <p><b><u>PEC<sub>sw</sub></u></b> :</p> <p>FOCUS<sub>sw</sub>, all scenario used excluding D1</p> <p><b><u>Non crop areas</u></b> :</p> <ul style="list-style-type: none"> <li>-Environmental fate exposure model Hardspec for uses on hard surfaces and railways</li> </ul>	<p>-</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<sub>sw</sub>»</p> <p>-</p>	<p>-</p> <p>y – French</p> <p>y - English</p>	<p>-</p> <p>Anses website</p> <p>Hardspec is available on Health and Safety Executive website</p>

<b>Topics</b>	<b>Complementary information on :</b> -data to be submitted -risk assessment	<b>Guidance document or other document</b>	<b>Availability - y/n and language of the document</b>	<b>Address to obtain the document</b>
<b>Ecotoxicology</b>	Yes	Risk assessment for bees regarding toxic and systemic substance according ICPBR guidance document.	y - English	EPPO website
<b>Risk assessment for bees and pollinators</b>	Data and risk assessment to be submitted for bees and pollinators	Note d'information relative aux référentiels et leurs évolutions potentielles dans le cadre de l'évaluation des produits phytopharmaceutiques (Règlement (CE) n° 1107/2009) en ce qui concerne les abeilles et les autres pollinisateurs.	y – French	Anses website
<b>Adjuvants</b>	The document clarifies the data and risk assessment to be submitted for adjuvants	NOTE AUX PETITIONNAIRES : Projet de guide relatif aux éléments nécessaires à l'évaluation des dossiers de préparations adjuvantes pour bouillies de préparations, phytopharmaceutiques	y – French	Anses website

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
<b>Assessment of pesticides used in tank-mixtures</b>	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 / Informations aux pétitionnaires

Révision 2, mise à jour le 18/10/2021.  
Révision 1, mise à jour le 15/10/2015.