**RISK ASSESSMENT OF ACTIVE SUBSTANCES**

In the approval procedure of active substances at the EU level, the Administration of the Republic of Slovenia for Food Safety, Veterinary and Plant Protection  
evaluates active substances contained in PPPs, at the European level independently or in cooperation with other EU Member States.

1. An active substance is approved in accordance with Annex II of 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 if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3 of Regulation. The assessment of the active substance must first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment continues to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

2. The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, must meet the following requirements:  
(a) they do not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Agency to assess such effects are available, or on groundwater;  
(b) they do not have any unacceptable impact on the environment. For the measurement of residues that are relevant from the toxicological, ecotoxicological, environmental aspects and from the aspect of drinking water, generally applied methods must be used. Analytical standards must be accessible for general public.

3. A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, must meet the following requirements:  
(a) it must be sufficiently effective;  
(b) it has no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Agency to assess such effects are available; or on groundwater;  
(c) does not have any unacceptable effect on plants or plant products;  
(d) does not cause unnecessary suffering and pain to vertebrates to be controlled;

(e) it does have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the Agency to assess such effects are available;  
(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;  
(ii) its impact on non-target species, including on the ongoing behaviour of those species;  
(iii) its impact on biodiversity and the ecosystem.

4. The requirements of paragraphs 2 and 3 are evaluated in the light of uniform principles as referred to in Article 29(6).

5. For approval of an active substance, paragraphs 1, 2 and 3 are deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

6.  In relation to human health, no data collected on humans is to be used to lower the safety margins resulting from tests or studies on animals.

7. By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels must be set in accordance with Regulation (EC) No 396/2005. This derogation shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008, as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A. Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in their territory. At the same time, they shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay transmit that plan to the Commission.

8. First approval is for a period not exceeding 10 years.

9. Conditions and restrictions

Approval may be subject to the conditions and restrictions, including:  
(a) the minimum degree of purity of the active substance;  
(b) the nature and maximum content of certain impurities;  
(c) restrictions arising from the evaluation of the information referred to in Article 8 taking account of the agricultural, plant health and environmental, including climatic, conditions in question;  
(d) type of preparation;  
(e) manner and conditions of application;  
(f) submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority, (the Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge;  
(g) designation of categories of users, such as professional and non-professional;  
(h) designation of areas where the use of plant protection products, including soil treatment products, containing the active substance may not be authorised or where the use may be authorised under specific conditions;  
(i)  the need to impose risk mitigation measures and monitoring after use;  
(j) any other particular conditions that result from the evaluation of information made available in the context of this Regulation.