



EU Defines Cut-off Criteria

Replacing 91/414: New hazard-based cut-off criteria defined for the EC1107/2009 directive moves EU closer to harmonization.

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FOLLOWING more than three years of uncertainty surrounding the hazard-based cut-off criteria in the European Union, the regulatory haze is finally clearing. Consequently, registration harmonization in the EU could be more streamlined, and mutual recognition across zones becomes possible during the re-registration process.

The new Regulation (EC) No. 1107/2009 was first published Nov. 24, 2009, and it entered into force later the same year. It became applicable to be used in all member states from June 14, 2011, which means all new substances or those under Annex 1 Renewal are subject to the new regulation.

One major point of the new regulation is in the area of mutual recognition for pesticide registrations. This application for mutual recognition will be achieved by a new zonal approach, enabling applications between member states belonging to different zones possible. Further to this, another main element of the regulation implementation is cut-off criteria for risk assessments. Here, the new regulation brings some clarity, but in certain cases also confusion. In this article, we will highlight some of the critical changes to the old regulation.

New Criteria

No registration may be granted when a substance falls into one of three criteria: persistent organic pollutant; persistent bio accumulative, toxic; or very persistent, very bio accumulative. They are strict criteria but well defined (see sidebar at right).

One of the ecotoxicological cut-off criteria that are defined in ANNEX II Chapter 3.8.2 of the regulation deals with endocrine effects. A significant difference caused directly by the regulation is in relation to endocrine properties. Under the new regulation, a substance should not be approved if a generally accepted study proves it has an endocrine adverse effect to a non-target organism in the ecotoxicological area, which is not negligible under the proposed conditions of use.

As the US Environmental Protection Agency Endocrine

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Newly Defined Approval Criteria

One of the main issues for industry of 1107/2009 is the introduction of hazard-based cut-off criteria, whereby active substances will be eliminated from the evaluation process purely as a result of their classification. The fate and environmental cut-off criteria are defined in ANNEX II Chapter 3.7 of the directive. They are subdivided into three groups. If the compound (active, safener or synergist) is classified one of these groups, the registration cannot be granted. In the case of the new regulation, these criteria are very well defined. They are listed as below:

- 1) **Persistent Organic Pollutants (POP)**
- 2) **Persistent, Bio accumulative, Toxic (PBT)**
- 3) **Very Persistent, very Bio accumulative (vPvB)**

1) Persistent Organic Pollutant

Persistence:

DT50(Water) > 2 months or
DT50(Soil) > 6 months or
DT50(Sediment) > 6 months

Bioaccumulation:

BCF > 5000 or
logPow > 5

Long Range Transport:

The criteria here are measured level distance from the source, monitoring data and environmental properties
(e.g. DT50(AIR) > 2 days.

2) Persistent, Bio accumulative, Toxic

Persistence:

DT50(Marine Water) > 60 days or
DT50(Fresh/Estuarine Water) > 40 days or
DT50(Marine Sediment) > 180 days or
DT50(Fresh/Estuarine Sediment) > 120 days or
DT50(soil) > 180 days

Bioaccumulation:

BCF > 2000

eToxicity:

-NOEC (Marine and Fresh Water Organisms) < 0.01 mg/l or, Classified as Categories 1A or 1B for mutagenic and carcinogenic (for reproduction also Category 2), or Classified STOT RE 1 or STOT RE 2.

3) Very Persistent, very Bio accumulative

Persistence:

DT50 (Marine/Fresh/Estuarine Water) > 60 days or
DT50(Marine/Fresh/Estuarine Sediment) > 180 days or
DT50 (soil) > 180 days

Very Bio accumulative:

BCF > 5000

EU 1107/2009 Regulatory Zones

Zone A - Northern zone

Denmark, Estonia, Latvia, Lithuania, Finland, Sweden

Zone B - Central zone

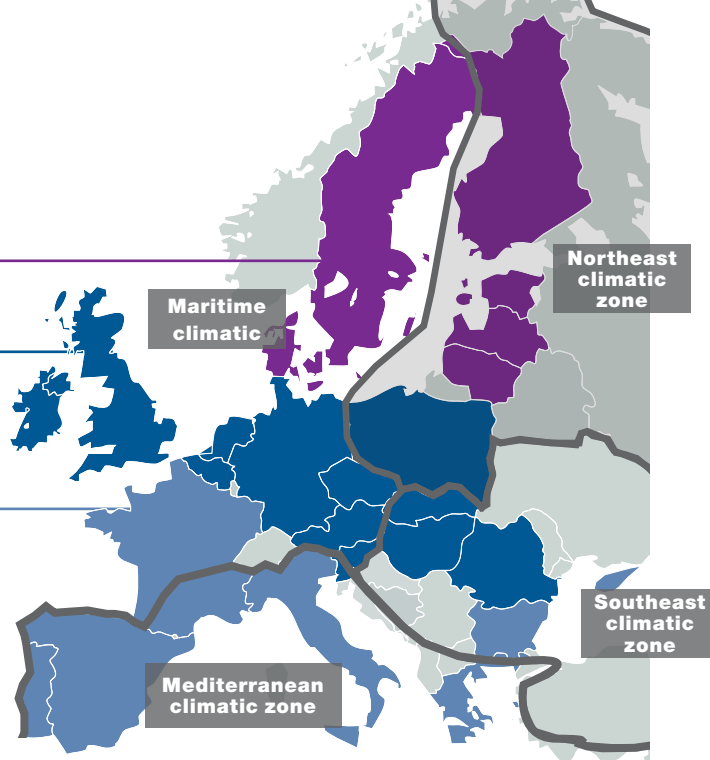
Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom

Zone C - Southern zone

Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal

The Zonal Approach

For the first time, crop protection harmonization will be considered under political boundaries instead of climatic zones, which are established by the European and Mediterranean Plant Protection Organization. The change should improve the possibility for mutual recognition.



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Disruption Screening Program is on-going, a number of data are collected that may also be used for the evaluation in the EU, just as the EPA's Office of Chemical Safety and Pollution Prevention guidelines are generally accepted. So the results of these studies, albeit momentarily – mainly the fish screen and the amphibian metamorphosis study requested in EDSP Tier 1 – may have an impact on EU registration. All GLP studies must be disclosed by the applicant and those substances that are designed for screening a risk, in turn leading to higher Tier Studies, may also have an impact on the EU registration. For this reason, a number of registrants are very conscious with regard to the EDSP Tier 1 results.

Another ecotoxicological cut-off criteria to focus on is defined in ANNEX II Chapter 3.8.3 of the regulation and deals with effects to honeybees.

For a number of years, cases have been reported where honey bees appeared to be affected as non-target organisms by the use of plant protection products. Germany and other EU countries always had a regard on these possible side effects in their national registration. Now, one chapter in the new regulation deals with the effects on honey bee colonies and their survival, taking into account the effects on honey bee larvae and behavior. New tests are devolved or modified for assessing this risk, which is now widely accepted, particularly bee brood and larvae studies under defined conditions.

Zonal Approach and Mutual Recognition

Another new approach is zonal registration, which should lead to much improved mutual recognition within the EU. For this purpose, a new zonal distribution for the EU has been introduced with a particular regard to taking into account the growing number of member states. The ANNEX I of the Regulation describes these new zones (see map).

Within these zones, one Zonal Rapporteur Member state

(Z-RMS) should evaluate the dossiers and have all relevant meetings with the applicant. The other remaining member states should then accept the decision of the Z-RMS thereby facilitating mutual recognition. However, the remaining member states can reject the decision of the Z-RMS for their territory based on various reasons, including national criteria for risk assessments – such as surface/ground water – or lack of sufficient data relevant to the European and Mediterranean Plant Protection Organization's (EPPO) climatic zones where they are located, as the EU zones are different to the EPPO climatic zones.

For example, France is now entirely in EU registration Zone C, whereas for the EPPO climatic zones it is divided between the Mediterranean and the Maritime zones. Or Poland, which is in EU Registration Zone B, but it is the only member state in this zone that is within the EPPO North-East climatic zone. So these countries may ask at least for different efficacy data, which could make mutual recognition difficult. Another example: Germany as the Z-RMS accepts data from the UK and Ireland, but Poland, as the remaining member state, does not consider the efficacy data from the Maritime climatic zone fully relevant and requests more data from the North-East climatic zone.

Overall, there are positive points as timelines for the processes are well-defined and certain rules for mutual recognition are set up for the first time. Although it might not yet be perfect, it is a good start.

The crop protection industry will continue to evaluate the rule and propose exceptions when appropriate, but in the meantime, the new rule offers superior guidance compared to the old rule, which lacked specific definitions on cut-off criteria. 🌐

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