More active substances expected to be lost due to new legislation

Aurélie Dhaussy & Euros Jones

European Crop Protection Association (ECPA)

A new regulatory system for the placing of plant protection products on the EU market was established on 14 June 2011, with the application of Regulation (EC) No 1107/2009[1]. This new piece of legislation was adopted at the end of 2009 to replace the Directive 91/414/EEC[2] which was previously ruling the plant protection products market. The new Regulation introduced even stricter criteria and procedures for the authorisation of phytosanitary products in the EU, and raises questions about the future availability of crop protection tools and hence of the competitiveness of EU agriculture.

Copyright ECPA.

The current situation of the crop protection market

Pesticides are amongst the most highly regulated chemicals in Europe. Every pesticide used in the EU must be evaluated covering everything from physical chemistry and the environment to toxicology, ecotoxicology, analytical methods and residues. Regular reviews ensure that every product on the market meets the latest safety standards. In the EU system, the active substance, which is the material responsible for the pesticide action against the target pest, weed or fungal disease, must be approved at EU level, and the formulated product must be authorised at Member State level.

The new Regulation 1107/2009 replaces the legislation that has been in place since 1991 to regulate the placing on the market of plant protection products, Directive 91/414. According to article 8(2) of this Directive, a programme was undertaken to review the active substances that were already on the market two years after the date of notification of this Directive, in conformity with the requirements which were set in the Directive. Due to the amount of substances to be reviewed, this programme was organised in four successive lists of active substances. It was completed in March 2009 and led to the removal of many pesticide-active substances from the EU market. Approximately 300 chemicals now remain approved for use,

List	Number of active substances	Substances included in Annex I of Directive 91/414 [3]	Substances not included in Annex I of Directive 91/414
1	90	55	35
2	148	34	114
3	394	115	269
4	326	111	215
Total	**958**	**315**	**643**

Source: European Crop Protection Association (ECPA); based on EU Pesticides Database[4], October 2011.

[1] *Regulation (EC) No 1107/2009, OJ L309, 24.11.2009, p1 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:EN:PDF)*
[2] *Directive 91/414/EEC, OJ L 230, 19.8.1991, p. 1 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1991L0414:20110801:EN:PDF)*
[3] *Annex I of Directive 91/414 lists the active substances authorised for use in plant protection products.*
[4] *http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection&a=1*

compared with nearly 1,000 substances that were available at the start of the programme.
In this context, investment in newer crop protection solutions continues, in order to provide newer and better solutions to farmers that meet the increasingly stringent regulatory standards in Europe and worldwide. On average, it costs €189 million and takes 10 years for a new active substance to be brought to market. Companies are also continuously developing improved plant protection formulations, with the aim of improving product effectiveness in controlling pests as well as increasing the level of safety for consumers and the environment.
While industry recognizes the need to adapt to scientific evolutions, EU standards need to remain proportional, clear and predictable, to avoid increased costs and complexity for R&D.

The new regulatory framework

In addition to the significant decrease of available active substances following the review programme conducted under 91/414, the new provisions of Regulation 1107/2009 are expected to translate into a situation where the number of tools available to EU farmers to protect their crops will further decrease. While these new provisions provide a comprehensive framework for the continued protection of human and environmental safety, they introduce a system which moves away from a risk assessment paradigm to include new hazard-based criteria that will apply upfront.

Cut-off criteria for active substances

The main new provision which all active substances contained in plant protection products will have to comply with, before being sold in the EU, are the so-called "cut-off" or exclusion criteria set in the Regulation.
While the previous EU authorisation system already assessed the risk linked to these properties, under the new system active substances triggering these criteria will not go through any risk assessment but will directly be banned. This new system, which does not consider in the first place the risk, or exposure, but only considers hazard, will lead to the loss of some active substances which have been assessed as safe for placing on the market under 91/414, sometimes even recently, according to latest scientific knowledge.
These cut-off criteria include:

- **Persistent Organic Pollutants**—POPs are defined under the Stockholm Convention and are usually considered as substances that trigger four separate criteria: persistence, bio-accumulation, toxicity, and long-range transport.
- **PBT**—This is the EU criteria for Persistence, Bio-accumulation, and Toxicity.
- **vPvB**—EU-based criteria for very Persistent and very Bio-accumulative.
- **CMR category 1 and 2**—These are substances that are "known or presumed to have the potential" to cause such effects as *C*arcinogens or *M*utagens or as being toxic to *R*eproduction. This criterion applies to substances that are currently or are to be classified under the given categories.
- **Endocrine disruptors**—This is a criterion for *adverse* health effects in humans or animals by altering the functioning of the endocrine system. Although definitions have been developed for endocrine-disrupting chemicals, no sound scientific criteria have yet been developed to identify those substances that will be classed as "endocrine disruptors."

Endocrine disruptors

Out of these new cut-off criteria, endocrine disruption appears notably problematic as there is no internationally agreed definition for it, and the interim definition introduced in the Regulation[5] raises some issues as regards its scientific validity. The Regulation requests the presentation by the European Commission of scientific criteria to define endocrine disruption by the end of 2013, and this should be based on sound science. Meanwhile it should be highlighted that the existing pesticide testing regime is already designed to identify all adverse effects, including those resulting from endocrine disruption, since the standard toxicology testing is designed to detect any adverse health effects that occur as a result of exposure to the active substance considered.

Not completely and clearly defined

An essential issue with the cut-off criteria is the fact that they are not completely and clearly defined.
The process for the POP, PBT and vPvB evaluation described in Annex II of Regulation 1107/2009 is

[5] *Annex II point 3.6.5: "(…) substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.*
In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties."

Copyright ECPA.

not sufficiently detailed to ensure a robust, harmonized and consistent interpretation of appropriate data and thereby define the real environmental hazard associated with plant protection active substances. Further guidance is necessary to ensure a meaningful implementation of such provisions. This must be available and in force before the provisions are applied to approve (or not) active substances. Substances should not be classified as PBT or vPvB substances if the criteria that are fulfilled relate to different environmental compartments (i.e. water, soil or sediment). Any consideration of combined properties is clearly invalid where disparate compartments are involved. Furthermore, assessing the environmental hazard must involve a holistic evaluation of all available data and not simply reflect a single worst case value.

According to Annex II of the Regulation an active substance, safener or synergist shall only be approved if it does not meet the cut-off criteria "*…unless the exposure to humans to the active substance, safener or synergist in a plant protection product, under realistic proposed condition of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1) (b) of Regulation No 396/2005*".
It defines negligible exposure as residue concentrations in food or feed below the default concentration of 0.01 mg/kg established in Article 18.1 of Regulation 396/2005. However negligible exposure is not fully defined in the non-dietary area. Therefore ECPA proposes to define it through a stepwise approach: negligible exposure would be guaranteed by (1) measures to minimize exposure related to professional use, mixing and loading, application machinery, protective equipment and risk-reducing measures; (2) safety check by a measurement of exposure under recommended conditions of use; and (3) observational studies to ensure continued safe use of the product.

Industry insists that there is no need to ban substances that have passed the strict risk assessments during the review programme recently completed under Directive 91/414. There is no evidence that cut-off criteria will increase safety, and it may have a negative impact with an extended use of the remaining products required to control pests and the subsequent development of resistance. The fact that the impact of the cut-off criteria have not been fully assessed at the EU level is a real concern for future crop production.
Therefore the evaluation system should continue to be based on a proper scientific risk assessment which takes into account the risks associated with the actual use of plant protection products.

Impact of the cut-off criteria

It is currently not possible to predict the impact that cut-off will have on the availability of active substances on the EU market since each active substance will first have to be thoroughly assessed. The impact of these criteria will not be immediate, since the potential bans that may result from their implementation will only occur after the fate of each chemical is assessed at the scheduled date of re-evaluation and re-approval.

Threat for availability of products

Nevertheless, the new legislation could threaten the long term availability of many existing products and industry's scope to innovate new products.
Basing decisions on one criteria alone will also lead to a situation where a new substance will not be brought to market (or will not be allowed to enter the market) even though its overall safety profile is extremely favourable compared to the products currently on the market. For example,

a substance that poses a very low level of risk to humans and the environment following a detailed risk assessment may in the future be categorized as an endocrine disruptor. Although its overall properties have been shown to be favourable as compared to its competitors, it would not be allowed onto the market.

Review

The new Regulation will not, in principle, affect authorisations granted under the current rules. However, when approvals expire, the review of approvals will be conducted according to the new Regulation. The review of current approvals is expected to start in 2012 and these will continue sequentially until approximately 2020, the majority of which will probably not be reassessed before 2015.

Serious danger that connot be contained by other available means

The cut-off criteria impact may be reduced by the possible exception granted by article 4(7) (control a serious danger to plant health which cannot be contained by other available means). It allows for certain active substances triggering the new cut-off criteria where there is evidence that they are necessary to control a serious danger to plant health which cannot be contained by other available means.

Through this clause it is recognized that the identified substances can and are today being used safely by European farmers, following their stringent assessment and approval for inscription to Annex I of Directive 91/414. However the implementation of this measure needs to be further considered, with greater flexibility to allow decision making at national level based on a strict risk assessment, and including clearer definition of how and when such derogations will apply.

As the clause is restrictive, it will discourage industry from investing in any substances that meet the criteria. It will, however, ensure the maintenance of solutions of major importance for European farmers. Many of the identified chemicals play important parts in crop protection management strategies, and, if it is applied, this derogation will help reduce the risk of further resistance to the remaining crop protection solutions, therefore ensuring that agricultural production is more sustainable.

Although the Regulation text claims that the new provisions aim at ensuring *"a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture"*[6], this was not supported by any independent scientific advice and the cut-off criteria adoption was a political decision. This was done despite the fact that the European Food Safety Authority (EFSA) was set up in 2002 in part to "provide scientific advice and scientific and technical support for the Community's legislation . . . which have a direct or indirect impact on food and feed safety."[7]

Impact on the industry

While the number of research-and-development–based companies has declined over the past decades, the number of substances being screened has increased substantially. On average, 140,000 chemical substances are screened in order to find one new chemical that can be used in plant protection. With the introduction of the cut-off criteria, the hurdles for success have been raised, and the number of new solutions will likely decrease. Industry is highly committed to minimise the impact of the new rules on the availability of plant protection products to the EU market. This requires a concerted effort by industry and all stakeholders.

Impact on agriculture

The new cut-off criteria will make sustainable agriculture more difficult. This system could particularly impact substances that are essential for the protection of minor crops and for resistance management, thus playing a key contribution in a sustainable agriculture. Without advanced pest management, roughly 50% of today's food crop production would be destroyed by pests and disease.

Some projections of the impact of the new regulation suggest a wheat yield impact of more than 8% in UK if azole fungicides are taken off the EU market[8]. Although at present we do not know how many of those substances may be removed, any reductions would have a major impact on EU agricultural production and the competitiveness of European farmers.

The increasing lack of economically viable crop protection solutions especially for minor uses has

[6] *Recital 8 of Regulation 1107/2009.*

[7] *Article 22(2) of Regulation (EC) No 178/2002, OJ L 31, 1.2.2002, p. 1 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R0178:20060428:EN:PDF)*

[8] *Report on the Impact of the loss of all azoles issued by ADAS UK Ltd and commissioned by the European Crop Protection Association, 30 September 2011 (http://www.ecpa.eu/news-item/pests/09-07-2011/595/innovative-chemistry-key-combating-fungus-infestation-europe-s-food-s)*

not only economic consequences for growers, who are confronted with lower productivity and less quality, it also raises concerns for Integrated Pest Management due to an increased danger of developing disease or pest resistance. Ultimately it may no longer be economically viable to grow certain crops in the EU, and that in turn will lead to further problems with crop rotation, biodiversity and food availability and affordability.
It is particularly important to note that the EU is taking this action at a time when the Food and Agriculture Organization is calling for a 70% increase in food production by 2050 to feed a growing world population[9]. There is an evident disconnect between policymaking on this issue and the wider issues linked to food production policy.

Further provisions for active substances which could impact product authorisations

The comparative assessment is another new provision for the authorisation process. Products containing active substances identified as candidates for substitution, according to criteria set in the Regulation[10], should undergo a comparative assessment with existing alternatives. While the Regulation's provisions provide some criteria for this assessment, these are not detailed and may lead to different interpretations among the Member States that will have to conduct it. This provision will therefore have to be implemented in a harmonized and pragmatic manner to avoid business unpredictability for producing companies and thus innovation disincentive.
A sensible implementation is also required for making optimum use of the provision allowing national provisional authorisations, which may enable the quicker placing on the market of new plant protection products identified as safe when the active substance authorisation process is delayed.

Conclusion

Further to the loss of active substance under the Directive 91/414 review programme, more active substance are expected to be lost due to the new legislation. This framework has increased uncertainty for investing companies especially due to the change from risk assessment to hazard-based cut-off.
The implementation of the new legislative system for plant protection products authorisation will have to be pragmatic and science-based in order to keep sufficient tools available to EU farmers for them to protect their crops, while protecting health and the environment.
This will be essential to sustain EU food productivity, and access to affordable fresh food for the European consumer.

About ECPA

The European Crop Protection Association (ECPA) represents the crop protection industry interests at European level. Its members include all major companies and national associations across Europe. ECPA promotes modern agricultural technology in the context of sustainable development, one which protects the health of humans and the environment, and at the same time contributes towards an affordable healthy diet, competitive agriculture and high quality of life. ECPA members support fair, science-based regulation as a guarantee to the consumer and the user of high standards and safe products.

[9] *See report "How to Feed the World in 2050" http://www.fao.org/fileadmin/templates/wsfs/docs/expert_paper/How_to_Feed_the_World_in_2050.pdf*
[10] *Annex II point 4 of Regulation 1107/2009.*