Reports

This part of the EJRR hosts reports in which our correspondents keep readers up to date on the most recent developments in different areas of risk regulation. Our aim is to fuel the debate and trigger future research on cutting-edge risk subjects. The Reports are organised under different policy sections. Further sections will be added at regular intervals. If you are interested in contributing to any of the existing sections, please contact the Reports Editor at enrico.bonadio.1@city.ac.uk

Biotechnology

This section aims to update readers on decisions related to marketing products of modern biotechnology (e.g., GMOs, animal clones) at EU level and on national measures concerning their production. Special attention is devoted to problems of competence between Member States and the EU in regulating biotechnology issues; the institutional dynamics of decision making regarding products derived from modern biotechnology; the relationship between the EFSA and the EU institutions on green biotech-related issues; the evolution of EU regulatory framework and of national attitudes towards the risks and benefits of biotechnology derived products and their production. This section will also delve into the interaction between the EU legislation and WTO law regarding advances in the application of biotechnology within the agri-food value chain.

On the New European Regulation on Plant Protection Products

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Regulation n. 1107/2009 of the European Parliament and Council of 21 October 2009 concerning the placing of plant protection products on the market entered into force on 14 December 2009 and applies as of 14 June 2011, subject to some transitional measures set out in Article 80. It shall replace gradually the current legislation on plant protection products which is laid down in Council Directive 91/414/EEC and related implementing Regulations.

Broadly speaking, the harmonized authorization system for active substances used in plant protection products, as originally set out in Directive 91/414/EEC, is maintained. Indeed, the placing on the market of plant protection products is still subject to a two-steps process whereby active substances are approved at the EU-level (with the inclusion into a "positive list" – Annex I to the new Regulation) while formulated products are authorised at the national level based on "Uniform Principles" laid down in a new implementing Regulation 546/2011[1]. However, the criteria underlying each of these two steps have changed remarkably.

From a procedural standpoint, in order to obtain an *approval* for the active substance, the applicant must first submit a comprehensive dossier on the substance, including full information on the nature and composition of the substance, details of tests carried out on crops and plants, safety data and means of detection, to a Rapporteur Member State (RMS). The RMS is then responsible for carrying out a full evaluation of the substance and submitting a draft assessment report to the Commission, the other Member States and the European Food Safety Authority (EFSA). On the basis of this assessment report, EFSA will organize a peer review of the evaluation with the other Member States and present its conclusion to the Commission within 120 days after the end of the commenting period. Based on the EFSA conclusions, the Commission will decide, through the regulatory "comitology" procedure, whether or not to include the substance in Annex I.

From a substantive standpoint, Regulation 1107/2009 introduces new hazard-based "cut-off criteria" for approval based on the intrinsic properties of the active substance, safener or synergist. In essence, the approval process should not proceed further if the substance is a carcinogen, mutagen or reproductive toxicant ("CMR"), a persistent organic pollutant ("POP"), a persistent-bioaccumulative-toxic substance ("PBT") or a very persistent and very

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1 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

bio-accumulative substance ("vPvB"). Moreover, substances meeting the criteria for endocrine disruption will be under special scrutiny (however, the Commission is yet to adopt specific criteria). However, strictly legally speaking endocrine disruption is not a cut off criterion.

Regulation 1107/2009 also has a wider scope of application. Safeners and syngergists must now be approved at EU level on the basis of the same criteria that apply to active substances. Moreover, a "negative list" of co-formulants will be drawn up by the Commission. In essence, a co-formulant will be added to Annex III to the new Regulation and may not be used in a plant protection product if either its *residues* or its *use* has harmful effects (as defined in Article 27(1)(a) and (b)). The Commission may review co-formulants at any time and may take into account *"relevant information provided by Member States"* (Article 27(3)).

Regulation 1107/2009 also contains new provisions on adjuvants. Unlike in the case of active substances, safeners and synergists, which must be approved at EU level, it is the Member States that will authorise the placing on the market of adjuvants (Articles 1 and 58(1)). The new Regulation does not lay down any procedural or substantive requirements but provides that the Commission will have to adopt further rules on the authorisation of adjuvants, including related data requirements, notification, evaluation, assessment and the decision making procedure. Until such time as the Commission has adopted such detailed rules, Member States will be entitled to apply their national provisions (if any) for the authorisation of adjuvants (Articles 58(2) and 81(3)).

After long debates and somewhat diverging case-law, Regulation 1107/2009 has now regulated parallel imports on the basis of the "common origin principle". Specifically, a plant protection product that is authorised in one EU country (so-called "Member State of origin") may, subject to granting a "parallel trade permit", be commercialised in another EU country (so-called "Member State of introduction") if the latter determines that the product is *identical* in composition to a product already authorised in its territory (so-called "reference product"). In essence, two products are considered as "identical" if they "share the same origin", *i.e.* they (i) have been manufactured by the same company (or under license), (ii) are identical in specification and content to the active substances, safeners, synergists and type of formulation, and (iii) are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of potential adverse impact on the safety of the product to human health or the environment (Article 52).

Importantly, the Regulation 1107/2009 provides that active substances shall become candidates for substitution if certain conditions are met. This means that active substances which comply with the criteria for inclusion in Annex I must nevertheless undergo an additional assessment to determine whether they qualify as "candidates for substitution" (e.g., where the Acceptable Daily Intake – ADI, Acute Reference Dose – ARfD or Acceptable Operator Exposure Level – AOEL, is significantly lower than another active substance or the substance meets two criteria for PBT).

As regards formulated plant protection products, these will continue to be authorised by national authorities in line with harmonized EU uniform principles. However, the Regulation 1107/2009 introduces compulsory mutual recognition of authorizations only among Member States within the same defined zone, with a degree of flexibility to accommodate local conditions. These include requirements that the plant protection product contains only active substances approved at the EU level, that it has been shown to have no harmful effects on human, animal or environmental health when applied properly and under normal conditions and, when used on food and feed crops, that it can be used in compliance with EU rules on maximum residue levels for agricultural products.

To that effect, three zones have been defined on the basis of relevant factors, such as similar climatic, agricultural and ecological conditions:

- North zone: Denmark, Estonia, Latvia, Lithuania, Finland and Sweden;
- Central zone: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia and the U.K; and
- South zone: Bulgaria, Spain, Greece, France, Italy, Cyprus, Malta and Portugal.

Moreover, plant protection products may be subject to a comparative assessment and substitution where there are other products presenting significantly lower risk for human health or the environment without entailing significant economic and practical disadvantages for the user. Specifically, if an active

substance is classified as a candidate for substitution, Member States are required to carry out a comparative assessment of plant protection products containing them (Article 50). They must not authorise a plant protection product, or must restrict its use, if the following conditions are met:

i. for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment; and
ii. the plant protection product or non-chemical control or prevention method referred to in (a) does not present significant economic or practical disadvantages; and
iii. the chemical diversity of the active substances is adequate to minimize the occurrence of resistance in the target organism; and
iv. the consequences on minor use authorisations are taken into account.[2]

The comparative assessment entails weighing up the risks and benefits defined in Annex IV. Essentially *"where refusal or withdrawal of an authorisation of a plant protection product in favour of an alternative plant protection product or a non-chemical control or prevention method is considered* [i.e.] *'substitution', the alternative must, in the light of scientific and technical knowledge, show significantly lower risk to health or the environment. An assessment of the alternative shall be performed to demonstrate whether it can be used with similar effect on the target organism and without significant economic and practical disadvantages to the user or not"* (Point 1 of Annex IV). In addition, substitution must only be applied (Point 2 of Annex IV):

(a) where (i) other methods or (ii) the chemical diversity of the active substances is sufficient to minimise the occurrence of resistance in the target organism; and
(b) to plant protection products where their use presents a "significantly higher level of risk" to human health or the environment; and
(c) after allowing for the possibility, where necessary, of acquiring experience from use in practice, where not already available.

Competent authorities must identify "significant differences in risk" on a case-by-case basis and by taking into account the following (Point 2 of Annex IV):

i. the properties of the active substance and plant protection product; and
ii. the possibility of exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers) directly or indirectly through food, feed, drinking water or the environment; and
iii. Other factors such as the stringency of imposed restrictions on use and prescribed personal protective equipment.[3]

Further, "[s]ignificant practical or economic disadvantage to the user" means *"a major quantifiable impairment of working practices or business activity leading to inability to maintain sufficient control of the target organism."* This is the case, for example, *"where no technical facilities for the use of the alternative are available or economically feasible"* (Point 3 of Annex IV).

Also, *"[w]here a comparative assessment indicates that restrictions on and/or prohibitions of use of a plant protection product could cause such disadvantage, then this shall be taken into account in the decision-making process. This situation shall be substantiated"* (Point 3 second paragraph Annex IV).

Further measures are provided for in relation to the inspection and monitoring on production, storage, transport and use of plant protection products. For active substances on the market when Regulation 1107/2009 enters into force (and which have been or are being subject to the ongoing review programme under Article 8(2) of Directive 91/414), a review of the authorization will be carried out in the timelines foreseen under Directive 91/414, using the new criteria laid down in Regulation 1107/2009.

In terms of data requirements, the Commission recently adopted three new implementing Regulations concerning, respectively: (i) the data requirements for active substances[4], (ii) the data requirements for plant

2 See Article 50(1) (a)–(d). When making their comparative assessment, Member States have to take into account the risks and benefits defined in Annex IV to the Proposed New Regulation. Note that Article 50(2) provides that a Member State may in exceptional cases also make a comparative assessment of a plant protection product that does not contain a "candidate for substitution" or that contains a "low-risk" active substance if a *"non-chemical control or prevention method exists for the same use and it is in general use in the Member State"*.

3 Point 2 of Annex IV states for the environment that *"if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk"*.

4 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances.

protection products[5], and (iii) the uniform principles for evaluation and authorisation (risk assessment) for plant protection products[6]. These regulations were adopted on 8–10 June 2011, within the framework of Article 84 of Regulation 1107, which required the Commission to adopt implementing measures on those points by 14 June 2011. In addition, the Commission adopted Regulation 547/2011 concerning labelling requirements for plant protection products,[7] as well as Regulation 540/2011 containing the list of active substances already approved through inclusion in Annex I to Directive 91/414, which are now transferred into the corresponding positive list set out under Regulation 1107/2009.[8]

Lastly, Regulation 1107/2009 contains important new provisions on data confidentiality and data sharing to avoid the duplication of testing of plant protection products on vertebrate animals. In short, as regards confidentiality, the Regulation now contains a positive list of data which are in principle regarded as confidential (e.g., manufacturing process, impurities unless they are toxicologically relevant, see Article 63). As regards data sharing, data owners and prospective applicants must *"make every effort"* to ensure that they share tests and studies involving vertebrate animals against *"fair share of the costs"* incurred by the data owner. Broadly speaking this obligation applies to both vertebrate and non-vertebrate animal tests. However, in the case of vertebrate studies, should the parties concerned fail to reach an agreement, the Member State authorities are entitled to refer to the studies for the benefit of the prospective applicant, while the data owner has a claim before a national arbitration panel or Court for a "fair share" of the costs. Regulation 1107/2009 does not define in detail the procedure, timing or criteria for data sharing, nor does it specify what constitutes a "fair share". Accordingly, unless the Commission adopts a guidance document on data sharing these critical aspects may be further clarified by arbitration panels and Court decisions.

In conclusion, the new Regulation has tightened the rules and process for the placing on the market of plant protection products. Behind the stated intention of achieving a high level of protection for human health and the environment, the EU has increased significantly the standards that industry will have to meet in order to commercialise its products in the future. While benefitting from a new, comprehensive and fully harmonised regulatory platform the agrochemical industry will be faced with many new hurdles and variable parameters such as the "substitution principle" and comparative assessment, amongst others, requiring a close coordination of business, scientific and legal considerations.

5 Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products.

6 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

7 Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products.

8 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

Food

This section aims at updating readers on the latest developments of risk-related aspects of food law at EU level, giving information on legislation and case law on various matters, such as food safety, new diseases, animal health and welfare and food labelling.

How Much Safety Concern Makes a Food "Unsafe"?

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Article 14 of the EU's General Food Law Regulation (178/2002) specifies that food may not be placed on the market if it is unsafe. Article 19 imposes an obligation on food business operators to withdraw products from the market if they have reason to suspect that there is a health risk. But how far do these provisions stretch in terms of providing a basis for ordering recalls? How much doubt, so to speak, needs to be raised as to the safety of a product before the food business operator must withdraw it? Focusing on two recent Danish cases, this report highlights some of the weaknesses of food safety regulations and the problems that can arise when the rules are applied in practice.

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