Regulatory News


The European Commission has adopted this regulation. Annex III to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation. In Part A of Annex III to Regulation (EC) No 396/2005, the columns for oxadiroxyl and spinetoram are replaced. Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced before 8 February 2016. (For more information: Website: http://eur-lex.europa.eu/oj/direct-access.html) CBNB


The European Commission has adopted this regulation. The active substance rescalure, as specified in Annex I, is approved subject to the conditions laid down in that Annex. The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation. (For more information: http://eur-lex.europa.eu/oj/direct-access.html) CBNB


The European Commission has adopted this regulation. Annexes II and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation. Annexes II and III to Regulation (EC) No 396/2005 are amended as follows: In Annex II, the columns for bifenazate, cyazofamid, cyromazine, dithiocarbamates, mepanipyrim, metrafenone, propamocarb, tebuconazole and thiram are replaced. Annex III is amended as follows: in Part A, the columns for boscalid, dazomet, fluazifop-P, picloram, pyridaben, pyroifenone and tebufenpyrad are replaced; in Part A, the following column for sulfoxaflor is added; and in Part B, the columns for dithiocarbamates and thiram are replaced. (For more information: Website: http://eur-lex.europa.eu/oj/direct-access.html) CBNB

Commission Implementing Regulation (EU) 2015/2233 of 2 December 2015 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance haloxyfop-P

The European Commission has adopted this regulation. The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation. Member States shall, in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing haloxyfop-P as active substance by 23 June 2016. Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 23 June 2017 at the latest. (For more information: http://eur-lex.europa.eu/oj/direct-access.html) CBNB

Regulator rings changes to cereal crop definitions

On 1 January 2015, the UK’s Health and Safety Executive (HSE) started using drilling date to define a crop as winter or spring rather than variety type. The ruling will have a huge impact on products exclusively approved for winter cereals, including Broadway Star (pyroxasulfam/lorasulfam) and Unite (flupyrsulfuron/pyroxasulfam) from Dow AgroSciences. Both products, which are approved for use in winter wheat, will still be applicable in winter varieties sown before 1 February. Winter varieties harvested on or before 1 February are now categorised as spring crops, and application of Unite and Broadway Star for these crops will be deemed illegal under HSE’s new rules. CBNB

Fungicides

Eden Research 3AEY fungicide approved in Bulgaria

Eden Research’s first agrochemical product, 3AEY, has been approved for commercial sale and use in Bulgaria, one of the top 20 wine producing countries globally. Eden uses natural microencapsulation technologies to deliver the fungicide that primarily targets botrytis on grapes. The Bulgarian approval follows several years’ worth of product efficacy trials were conducted in order to generate the data required to support the label claims of botrytis prevention and control in table and wine grapes. Bulgaria is the third of seven countries in the Southern EU zone to grant its approval for the sale and use of this product and Eden Research anticipates authorisation in the remaining member states in due course, and in time for this year’s growing season. 3AEY had already been approved in Malta and Greece.
EU approval for SOLATENOL fungicide

On 8 January 2016, Syngenta announced that its SDHI fungicide SOLATENOL (benzovindiflupyr) has been approved by the EU authorities. This registration will allow Syngenta to introduce a number of new products for the European cereal market. First sales of SOLATENOL in France are expected for the 2016/2017 season, with a total peak sales potential in Europe of $200 M. SOLATENOL is an SDHI fungicide offering an unrivalled performance against Septoria and rusts - two important diseases in Europe which can significantly impact cereals production. In trials, it has proven to be extremely consistent in providing excellent disease control on all important cereal varieties in a wide range of situations over several years. SOLATENOL offers outstanding levels of leaf protection resulting in higher yield and return on investment for the farmer. SOLATENOL is already available to growers in Latin America as ELATUS, achieving sales of more than $300 M in its first year in Brazil. In 2015, it also received approval in the US and Canada. (For more information: Syngenta International AG, Basel, Switzerland; Tel: +41 61 323 5883; Fax: +41 61 323 5880; Website: http://www.syngenta.com) CBNB

Herbicides

EFSA finds glyphosate unlikely to be carcinogenic; proposes exposure threshold

The European Food Safety Authority (EFSA) has reported that glyphosate pesticide exposure poses little risk of carcinogenicity or genotoxicity to humans, as shown in animal trials. In a report published on 12 November, EFSA experts have set threshold levels at 0.5 mg/kg for the acute reference dose (ARD), 0.1 mg/kg/d for the acceptable operator exposure level (AOEL) and 0.5 mg/kg/d for the an acceptable daily intake (ADI). The European Commission will use the report in deciding whether to keep glyphosate on the EU list of authorised products or not. CBNB

Insecticides

High Court rejects legal challenge over neonicos

The UK High Court has rejected a legal suit from Friends of the Earth to stop oilseed growers from securing special authorisation to use neonicotinoid seed treatments. The legal bid challenged a government approval for using a restricted amount of two neonicotinoid-derived products on oilseed rape crops. The court concluded on the 12 November 2015 ruling that the legal bid was “unarguable on all the grounds”. The decision was welcomed by the National Farmers’ Union (NFU), which had successfully filed for an emergency authorisation to enable farmers to use a limited amount of neonicotinoids in early 2015. The emergency authorisation allowed neonicotinoid-treated seed to be planted through 5% of the whole national oilseed rape crop area. CBNB

EFSA reviewing restricted neonicotinoid assessments

European Food Safety Authority (EFSA) will review and update its assessments of the risks to bees posed by three neonicotinoid pesticides, clothianidin, thiamethoxam and imidacloprid. The reevaluation was requested by the European Commission, which placed restrictions on the use of the substances in 2013 following assessments carried out by EFSA. The updated assessments, which will look at the use of the substances as seed treatments and granules, will be completed by January 2017. They will take into account any new data from studies, research and monitoring that has come to light since the previous assessments were carried out, in particular information submitted to EFSA following a call for data in 2015. Previously EFSA confirmed that clothianidin, thiamethoxam and imidacloprid were a risk to bees when used as foliar sprays.

North America

Biorations

EPA removes bee toxicity warning statement from label of SPEAR bioinsecticide from Vestaron Corporation

Vestaron Corporation, the leading developer of peptide-based insecticides, announced on 17 December 2015 that it has received US EPA approval to delete the bee toxicity warning statement from its SPEAR (GS-omega/kappa-Hxtx-Hv1a) biopesticide label following a review. The removal of the toxicity statement is supported by third-party topical and feeding evaluations that show SPEAR has no increased mortality or detrimental effects to honeybees. According to Vestaron, the company is leading the way in development of new insecticidal peptides with the 2016 commercialisation of SPEAR for control of thrips in glasshouses. And in early 2016, the company will be submitting additional data to the EPA on SPEAR’s effects on beneficial insects used in glasshouses. The SPEAR family of bioinsecticides utilises two new unique modes-of-action with no known resistance. This family of biopesticides is based on natural peptides which degrade to useful nutrients in the environment. (For more information: Vestaron Corporation, 4717 Campus Drive, Ste. 1200 Kalamazoo, MI 49008, USA; Web: www.vestaron.com) CBNB

Herbicides

Monsanto files lawsuit in California on listing of glyphosate

Monsanto filed a lawsuit in California seeking to prevent a flawed listing of the herbicide glyphosate under California’s Proposition 65 (Prop 65), which requires the state to maintain a “list of chemicals known to the state of California to cause cancer.” Monsanto says the listing of glyphosate would be flawed and baseless because glyphosate does not cause cancer, as has been concluded by the US EPA, the European Food Safety Authority (EFSA) and pesticide regulators around the world. Monsanto filed
the suit against California Office of Environmental Health Hazard Assessment (OEHHA) in California’s Fresno Superior Court. The company continued: Indeed, OEHHA, the very state agency that has announced its intention to add glyphosate to the Prop 65 list, determined in 2007, after conducting a rigorous and science-based assessment, that glyphosate was unlikely to cause cancer. In striking contrast, OEHHA now interprets Prop 65 to require the agency to accept the erroneous classification of glyphosate as a “probable carcinogen” by an ad hoc working group of the International Agency for Research on Cancer (IARC), based in Lyon, France, as the sole basis for the proposed listing. This interpretation of Prop 65 is unconstitutional. Moreover, IARC’s own governing documents specifically disavow any policy- or lawmaking role for its classifications, and it does not intend its classifications to carry the force of law. According to Monsanto’s vice president of regulatory affairs glyphosate does not cause cancer, so listing glyphosate under California’s Prop 65 is not warranted scientifically and would cause unwarranted concern for consumers. Based on the overwhelming weight of evidence, regulatory agencies have concluded for more than 40 years that glyphosate can be used safely. The conclusion from the IARC meeting in France was erroneous, non-transparent and based on selectively interpreted data. Monsanto is bringing this challenge forward because this intention to list is contrary to science. Regulatory agencies around the globe such as the US EPA and EFSA evaluate pesticides, including glyphosate, using thorough and robust risk assessments based on internationally recognised toxicological principles. As required by law, these evaluations consider all relevant scientific data to arrive at a conclusion about whether a pesticide could be carcinogenic. A routine US EPA registration review on glyphosate opened in 2009 and remains underway. Since the initial announcement of the IARC meeting’s classification in March 2015, regulatory bodies in the USA, Europe and Canada have publicly affirmed that glyphosate does not cause cancer.

Insecticides

US bans sulfoxaflor pesticide
On 12 November 2015, the US EPA announced that sulfoxaflor cannot be sold or distributed in the US. Sulfoxaflor is a pesticide used in controlling aphids and other insects on several crops. The decision was due to a federal appeals court ruling citing the harm of the chemical to bees and other pollinators. The EPA will allow growers to use the product only until their procured supplies last.

However ...

In with the new and reviving the old
Dow Agroscience’s new systemic and translaminar active sulfoxaflor (isoclast) is currently pending approval and could be launched in the UK market by 2018. The product is formulated for control of aphids resistant to carbamates or pyrethroids in potato, vegetable crops, and cereal. In other news, American agrochemical firm Gowan is assessing the potential registration of organophosphate active phosmet in Europe. Organophosphates have recently been scrutinised by the EU regulators.

EPA assessment claims imidacloprid threat to pollinators; Bayer CropScience responds
A new preliminary pollinator risk assessment released by EPA found the neonicotinoid insecticide, imidacloprid, shows a threat to some pollinators. EPA’s assessment, was prepared with California’s Department of Pesticide Regulation. The report concluded that imidacloprid potentially poses risk to hives when the pesticide comes in contact with certain crops that attract pollinators. EPA will conduct preliminary pollinator risk assessments on three additional neonicotinoid insecticides, clothianidin, thiamethoxam, and dinotefuran. Those reports are scheduled to be released for public comment in December 2016. A preliminary risk assessment of all ecological effects for imidacloprid, including a revised pollinator assessment and impacts on other species such as aquatic and terrestrial animals and plants will also be released in December 2016. Following EPA’s announcement, Bayer CropScience released a statement commenting on the assessment: Neonicotinoids have been widely adopted by growers because of their favorable human and environmental safety profile, especially when compared to the older products they replaced. Neonicots are critically important to today’s integrated pest management programs, allowing farmers to manage destructive pests, preserve beneficial insects and protect against insect resistance. Bayer CropScience will review the EPA document, but stated that at first glance it appears to overestimate the potential for harmful exposures in certain crops, such as citrus and cotton, while ignoring the important benefits these products provide and management practices to protect bees. We hope the final risk assessment is based on the best available science, as well as a proper understanding of modern pest management practices.

Vive Crop Protection receives EPA registration for Bifender at-plant insecticide cbnb
The US Environmental Protection Agency has approved Vive Crop Protection’s Bifender insecticide using Vive’s proprietary Allosperse delivery technology. The product contains bifenthrin, an excellent broad-spectrum insecticide, and is targeted for early-season in-furrow or soil applications. Bifender has best-in-class compatibility with starters and other liquid fertilisers and can be mixed directly with the fertiliser in the spray tank prior to application. Bifender would not clog nozzles or spray lines and is effective in harsh environmental conditions including sustained cold weather and hard water.

*CBNB: These abstracts were taken from Chemical Business NewsBase (CBNB) which is produced by Elsevier, E-mail: cbnb@elsevier.com, Website: http://www.ei.org/databases/cbnb.html