CHEMICALS AND PESTICIDES

EU chemicals and pesticides legislation aims to protect human health and the environment and to prevent barriers to trade. It consists of rules governing the marketing and use of particular categories of chemical products, a set of harmonised restrictions on the placing on the market and use of specific hazardous substances and preparations, and rules governing major accidents and exports of dangerous substances. Under the term 'pesticides' are grouped substances used to suppress, eradicate and prevent organisms that are considered harmful. They include biocidal products and plant protection products (PPPs). The most important achievement at EU level is the REACH regulation, which regulates the registration, evaluation and authorisation of dangerous substances and the restrictions applicable to them.

LEGAL BASIS

Articles 191 to 193 of the Treaty on the Functioning of the European Union (TFEU).

ACHIEVEMENTS

A. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

EU chemicals policy underwent a radical overhaul with the introduction in 2006 of Regulation (EC) No 1907/2006 (the REACH regulation). The regulation entered into force on 1 June 2007, establishing a new legal framework to regulate the development and testing, production, placing on the market and use of chemicals and replacing around 40 previous legislative acts. The aim of the REACH regulation is to provide better protection for humans and the environment from possible chemical risks and to promote sustainable development. REACH introduced a single system for all chemicals and abolished the distinction between 'new' chemicals (those introduced on the market as from 1981) and 'existing' chemicals (those listed before 1981). It transferred the burden of proof concerning the risk assessment of substances from public authorities to companies. In addition, it calls for the most dangerous chemicals to be substituted by suitable alternatives.

The European Chemicals Agency (ECHA), established under this regulation and based in Helsinki, is responsible for managing the technical, scientific and administrative aspects of REACH, and for ensuring consistency in its application. ECHA's initial job was to manage a six-month pre-registration exercise requiring firms to submit their company details as well as information on the basic substances used in production, including expected registration dates. The resulting list contains approximately 143 000 substances pre-registered by 65 000 companies. This information was used to launch a registration phase that will last until 2018. November 2010 was the first deadline for industries to register: (i) all substances at volumes of 1 000 tonnes per year (tn/y) or more; (ii) substances that are highly toxic to the aquatic environment, at volumes of 100 tn/y or more; and (iii) the most hazardous substances, whether carcinogenic, mutagenic or reprotoxic (CMRs), produced or imported at volumes of 1 tn/y or more. June 2013 was the deadline for registering all substances manufactured or

imported at volumes of 100 to 1 000 tn/y. The process will conclude in June 2018 with the registration of substances introduced on the market in quantities between 1 and 100 tn/y.

In February 2013, the Commission published a review of the REACH regulation in which it concluded that REACH does not require any changes to its enacting terms, even though progress could be made in reducing the financial and administrative burden on industries and finding alternative methods to animal testing. In 2017, the Commission conducted a second evaluation under the Regulatory Fitness and Performance Programme (REFIT), the results of which were published in COM(2018)116. The evaluation concludes overall that REACH is effective but opportunities for further improvement, simplification and burden reduction have been identified, which can be achieved by delivering the actions outlined in the report. Those should be implemented in line with the renewed EU Industrial Policy Strategy, the Circular Economy Action Plan and the 7th Environment Action Programme.

B. Classification, packaging and labelling

In order to enhance the level of protection of human health and the environment, the same criteria for identifying, and labels for describing, chemical hazards should be used throughout the EU and the world. Adopted in 2008, Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) was introduced to align the EU system to the UN Global Harmonised System (GHS). The earlier directives on dangerous substances and preparations were repealed in June 2015.

C. Export and import of dangerous substances

EU rules on the export and import of dangerous chemicals were defined in Regulation (EU) No 649/2012, which aimed to promote shared responsibility and cooperative efforts in the international movement of hazardous chemicals, and to implement the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The PIC procedure consists in sharing information on toxic chemicals and awaiting a country's explicit agreement before exporting the product in question.

D. Major accidents

Named after an Italian municipality which was contaminated by an accidental release of dioxin from a nearby industrial site in 1976, the Seveso Directive (82/501/EEC) aimed to prevent major accidents such as fires and explosions and to limit the consequences of those that do occur by requiring safety reports, emergency plans and the provision of information to the public. In 1996, the Seveso II Directive (96/82/EC) on the control of major accident hazards involving dangerous substances introduced new requirements relating to safety management systems, emergency planning and land-use planning, and strengthened provisions on inspections carried out by Member States. It transposed the Community's obligations under the Espoo Convention on the Transboundary Effects of Industrial Accidents. In the light of a number of serious industrial accidents (in Toulouse, France; Baia Mare, Romania; and Enschede, the Netherlands), and on the basis of studies on carcinogens and substances dangerous for the environment, the scope of the Seveso II Directive was extended by Directive 2003/105/EC. This directive requires the Member States to provide a detailed risk assessment of possible accident scenarios and to cover risks arising from storage and processing activities in mining and from the storage of pyrotechnic and explosive substances and of ammonium nitrate and ammonium nitrate-based fertilisers. The Seveso III Directive (2012/18/EU) was published in July 2012 after being approved by Parliament and the Council. It takes account of new UN-agreed international classifications of substances that allow better risk evaluation and handling of substances.

E. Sustainable use of pesticides

Substances used to suppress, eradicate and prevent organisms that are considered harmful are grouped under the term 'pesticide'. The term includes both PPPs (used on plants in agriculture, horticulture, parks and gardens) and biocidal products (used in other applications, for example, as a disinfectant or to protect materials). In 2009, a Pesticides Package was adopted, consisting of: Directive 2009/128/EC on the sustainable use of pesticides, aimed at reducing environmental and health risks while maintaining crop productivity and improving controls on the use and distribution of pesticides; Regulation (EC) No 1107/2009 on the placing on the market of PPPs; and Regulation (EC) No 1185/2009 concerning statistics on pesticides, which sets out rules for collecting information on the annual quantities of pesticides placed on the market and used in each Member State.

Directive 2009/128/EC required the Member States to adopt national action plans for the establishment of quantitative objectives, targets, measures and timetables in order to reduce the risks and impact of pesticide use for human health and the environment. Aerial crop spraying is banned as a general rule, and no spraying at all is allowed in close proximity to residential areas. The regulation which deals with the production and licensing of pesticides contains a positive list of approved 'active substances' (the chemical ingredients of pesticides), drawn up at EU level. Pesticides are then licensed at national level on the basis of this list.

A controversy has emerged since 2015 over the renewal of the approval of glyphosate, one of the active substances most commonly found in broad-spectrum herbicides in the world. The controversy started as a result of diverging assessments of its carcinogenicity: the International Agency for Research on Cancer, a branch of the World Health Organisation, classified glyphosate as probably carcinogenic to humans, while the European Food Safety Authority found it unlikely to pose a carcinogenic hazard to humans. The European Chemicals Agency later concluded that glyphosate did not classify as a carcinogen. Several national authorities outside the EU also came to the same conclusion. The European Commission eventually renewed the approval of glyphosate for five years in December 2017.

F. Biocidal products

Regulation (EU) No 528/2012 entered into force in 2013 in order to simplify the authorisation mechanisms and enhance the role of the ECHA in reviewing approval dossiers on the basis of stricter conditions. The legislation reflects what was established under the previous regime, with controls over the marketing and use of biocides (i.e. non-agricultural pesticides such as antibacterial disinfectants and insect sprays) so as to manage the associated risks to the environment and to human and animal health. These substances are authorised only if they appear on a positive list, while a ban applies to the most toxic chemicals — especially those that are carcinogenic or harmful to fertility, or interfere with genes or hormones (endocrine disrupters). Pursuant to the mutual recognition principle, a substance authorised in one Member State may be used throughout the EU. The recent Regulation (EC) No 1107/2009 is setting out scientific criteria for the determination of endocrine-disrupting properties of biocidal products, as well as PPPs.

G. Persistent organic pollutants (POPs)

POPs are chemical substances that persist in the environment because of their resistance to different forms of degradation (chemical, biological, etc.). They bioaccumulate through the food chain and can provoke adverse effects on human health and the environment. This group of priority pollutants consists of pesticides (such as DDT), industrial chemicals (such as polychlorinated biphenyls or PCBs) and unintentional by-products of industrial processes

(such as dioxins and furans). The EU has committed itself at international level to controlling the handling, exportation and importation of POPs (through prohibition or restriction), under the Aarhus POP Protocol to the Geneva Convention on long-range transboundary air pollution (in force since 2003) and the Stockholm Convention on POPs (in force since 2004). The EU made additional progress with Regulation (EC) No 850/2004, which complements earlier EU legislation on POPs and aligns it with the provisions of the international agreements. To a certain extent, this regulation goes further than the international agreements, emphasising the aim of eliminating the production and use of the internationally recognised POPs.

H. Asbestos

Asbestos is a mineral with a fibrous structure, which is dangerous when inhaled. It was widely used in the past for insulation and other purposes, owing to its resistance to fire and heat. Thanks to Directive 1999/77/EC, a ban on the use of asbestos has been in place in the EU since 1 January 2005. Furthermore, the extraction, manufacturing and processing of asbestos products is prohibited under Directive 2003/18/EC, which also lays down removal programme strategies to be implemented by the Member States. The same Directive commits the EU to taking action towards a global ban on asbestos.

I. Detergents

Regulation (EC) No 648/2004 harmonises the rules on the biodegradability of surfactants, the restrictions and bans on surfactants, the information that manufacturers must provide, and the labelling of detergent ingredients. It was subsequently amended in 2006 (Regulation (EC) No 907/2006), 2009 (Regulation (EC) No 551/2009) and 2012 (Regulation (EU) No 259/2012), in order to introduce new biodegradability tests to provide an enhanced level of protection for the aquatic environment. In addition, the scope of the tests has been extended to include all classes of surfactant, thereby including the 10% of surfactants that hitherto had not been covered by legislation. As regards labelling, Regulation (EC) No 907/2006 also extends the rules to include fragrance ingredients that could cause allergies, requiring manufacturers to disclose a full list of ingredients to medical practitioners treating patients suffering from allergies. As of 30 June 2013, the use of phosphates in laundry detergents is banned and the content of other phosphorus-containing compounds is limited.

ROLE OF THE EUROPEAN PARLIAMENT

Parliament played a key role in the development of the REACH regulation. It secured the insertion of certain provisions at first reading — notably, in the registration chapter, a targeted approach with regard to data requirements for existing substances produced at lower tonnages (1-10 tonnes), and the ‘one substance, one registration’ (OSOR) approach intended to minimise costs, introducing an opt-out under specific conditions. In order to limit animal testing as much as possible, Parliament secured a requirement for companies to share data from tests conducted on animals (in return for reasonable compensation), thereby avoiding the need to duplicate experiments. As regards the authorisation chapter, Parliament endorsed a stronger approach whereby all substances of very high concern may only be authorised if a suitable alternative or technology does not exist. Through its amendments, Parliament sought to favour both innovation (through time-limited authorisations of five years) and certainty (through a list of the most hazardous substances). At the end of the legislative procedure, the agreement reached between Parliament and the Council on the controversial issue of ‘authorisation/substitution’ included the requirement that a substitution plan must always be presented if suitable safer alternatives exist.

During the long discussion on the Pesticides Package in 2008, amendments by Parliament ensured the establishment of appropriately sized buffer zones for the protection of aquatic organisms, along with the introduction of protection measures for the most vulnerable groups, including the prohibition of the use of pesticides in public gardens, sports and recreation grounds, school grounds and playgrounds, and in the close vicinity of healthcare facilities. In early 2013, following the publication of a report by the European Food Safety Authority (EFSA) on the damaging effects of certain neonicotinoid insecticides, Parliament called on the Commission to take determined action to preserve bee populations. In March 2013, Parliament adopted a resolution on asbestos related to occupational health threats and prospects for eliminating all existing asbestos.

Parliament's decision of 6 February 2018 on setting up a special committee on the Union's authorisation procedure for pesticides (PEST) is a response to concerns raised about the risk posed by the herbicide substance glyphosate. The herbicide had its marketing licence renewed by EU Member States for five years in November last year. The special committee is to assess up to 12 December 2018: a) the authorisation procedure for pesticides in the EU; b) potential failures in how substances are scientifically evaluated and approved; c) the role of the Commission in renewing the glyphosate licence; d) possible conflicts of interest in the approval procedure; and e) the role of the EU agencies, and whether they are adequately staffed and financed to enable them to fulfil their obligations.

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06/2018