



LEARNING TOXICOLOGY
THROUGH OPEN EDUCATIONAL

LEGISLATIVE CORRELATIONS

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As is specified in Unit1 ESTABLISHING THE GENERAL AND SPECIFIC EUROPEAN UNION LEGISLATION FOR TOXIC POLLUTANTS, the regulation of toxic pollutants, and not only, can not be confined to normative acts which have as their primary purpose the regulation of their legal regime, because the pollution is mainly the effect of human, anthropogenic activities (individual or industrial). Thus, there is a need to regulate specifically in the framework of regulatory acts that have as their main field the legal status of that activity and specific requirements for pollutants. We consider these regulations as "legislative correlations", they complete the general legislative framework by detailing obligations, including exceptions, linking domains. Legislative correlations are also considered and the follow-up of changes due to abrogations or modifications of some related normative acts or which formed the basis of the establishment of obligations in the field investigated.

The normative acts contained in this unit are presented succinctly and do not benefit from referrals to specific links, the role of this unit being to facilitate understanding of the complexity of legislation and to open windows for those students who want to deepen the field.

1. LEGISLATIVE CORELATIONS ON GAZOUS POLLUTANTS

Correlations in this area concern the presentation of normative acts that refer to other regulatory areas but which have an effect on the reduction of atmospheric pollution with gaseous pollutants.

1. *Council Regulation (EC) No 715/2007* of the European Parliament and of the Council of 20 June 2007 on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to repair and maintenance of vehicles.

This normative act establishes:

- common technical requirements for the type approval of motor vehicles of categories M1, M2, N1 and N2 as defined in Annex II to *Directive 70/156/EEC*, and replacement parts, such as replacement pollution control devices, with regard to their emissions,
- emission limits for Euro 5 și Euro 6, regarding Mass of carbon monoxide, Mass of total hydrocarbons, Mass of non-methane hydrocarbons, Mass of oxides of nitrogen, Combined mass of hydrocarbons and oxides of nitrogen, Mass of particulate matter (PM),
- emission limit for the carbon monoxide and hydrocarbon tailpipe emissions after a cold start test.

2. European Parliament and Council Directive 94/63/EC of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations, which emerged as a result of:

- the need to reduce vapor emissions during refueling operations at fuel stations, which amounted to about 200000 tonnes per year in 1993.
- - the fact that VOC emissions from the fuel storage and distribution network are about 500000 tonnes per year or about 5% of the total human emissions of man-made volatile organic compounds in the Community, and whereas these emissions are a significant contribution to air pollution, particularly in urban areas;

This Directive establishes the average concentration of vapors evacuated from vapor recovery - a unit adapted to achieve dilution during the process - and which must not exceed 35 g/Nm³ per hour.

3. *Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products*, which

establishes maximum VOC content limit values for paints and varnishes, maximum VOC content limit values for vehicle refinishing products

4. *Directive 2009/31/EC of the European Parliament and of the Council of 23 April 2009 on the geological storage of carbon dioxide and amending Council Directive 85/337/EEC, European Parliament and Council Directives 2000/60/EC, 2001/80/EC, 2004/35/EC, 2006/12/EC, 2008/1/EC and Regulation (EC) No 1013/2006.*

The purpose of environmentally safe geological storage of CO₂ is permanent containment of CO₂ in such a way as to prevent and, where this is not possible, eliminate as far as possible negative effects and any risk to the environment and human health.

5. *Commission delegated Regulation (EU) 2017/655 of 19 December 2016 supplementing Regulation (EU) 2016/1628 of the European Parliament and of the Council with regard to monitoring of gaseous pollutant emissions from in-service internal combustion engines installed in non-road mobile machinery, which has already been completed by Commission Regulation (EU) 2017/655.*

2. LEGISLATIVE CORELATIONSON HEAVY METALS

1.1. Legislative correlations of heavy metals in the air

Correlations in this area concern:

- the right to information of states and citizens on the quality of the environment, both as EU regulation and as international regulation, and
- the connections that can be made to reduce emissions of heavy metals into the air by regulating the content of such pollutants in products.

1.1.1. The right to information

Air protection implies a joint effort of states, so communication and mutual exchange of information is necessary. These are realizing on the basis *Commission implementing Decision no. 850/2011 of 12 December 2011 laying down rules for Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council as regards the reciprocal exchange of information and reporting on ambient air quality.*

A number of emission limits are regulated only as a threshold from which special country reporting needs to be made to a specialized European register. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European pollutant release and transfer register and amending Council Directives 91/689/EEC and 96/61/EC is the one setting maximum emission limits for certain pollutants in air, water, soil depending on the type of activity over which it is mandatory to report to the European Pollutants Emissions and Transfer Register (EPTR). This integrated, coherent EPTR is a reliable database for the public, industry, scientists, insurance companies, local authorities, non-governmental organizations and other decision-makers for further comparisons and decisions on environmental issues. In short:

- the register contains information on pollutant emissions into air, water and soil as well as off-site transfer of pollutants in waste-water and waste;
- Releases are reported when the level of emissions exceeds a certain threshold and originates from one of the 65 activities listed in Annex I. The majority of these activities are also regulated under the Directive 75/442/EEC of 1970 and comprises, in particular, the establishments covered by the following sectors: energy production, mineral industry, chemical industry, waste and wastewater management, and paper and wood production and processing;

- register covers 91 pollutants listed in Annex II, including greenhouse gases, other gases, heavy metals, pesticides, chlorinated organic substances and other inorganic substances;
- the register also provides some information on pollution from diffuse sources.

Issuing this registry is the result of the application Council Decision 2006/61 of 2 December 2005 on the conclusion, on behalf of the European Community, of the UN-ECE Protocol on Pollutant Release and Transfer Registers, and is the link of EU legislation with international law.

1.1.2. Pollutants in products

Reduction of pollution according to the prevention principle can be made at source, so a number of normative acts regulate limits and / or prohibitions on the presence of heavy metals in certain products.

An example is that of *Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels* which provides in *Annex I Environmental specifications for market fuels to be used for vehicles equipped with positive-ignition engines* a lead content 0,005g/l.

This limit is in line with the provisions contained in Annex IX a Commission Regulation (EU) No 582/2011 of 25 May 2011 implementing and amending Regulation (EC) No 595/2009 of the European Parliament and of the Council with respect to emissions from heavy duty vehicles (Euro VI) and amending Annexes I and III to Directive 2007/46/EC of the European Parliament and of the Council.

1.2. Legislative correlations for heavy metals in water

Correlations in this area go beyond heavy metals and complete water protection through the:

- risks posed by medicinal products to the environment and the environment
- assessment and monitoring of the quality of bathing water.

For the risks posed by medicinal products to the environment, reference must be made to *Commission implementing Decision (EU) 2015/495 of 20 March 2015 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council.*

Article 8c regarding *Specific provisions for pharmaceutical substances* contained in *Directive 105 of 2008*, states that under Article 16 (9) of *Directive 2000/60 /EC* and, where appropriate, on the basis of the results of its 2013 study on the risks posed by medicinal products to the environment and other studies and relevant reports, the Commission, as far as possible within two years from 13 September 2013, develops a strategic approach to water pollution with pharmaceuticals.

That strategic approach shall, where appropriate, include proposals enabling, to the extent necessary, the environmental impacts of medicines to be taken into account more effectively in the procedure for placing medicinal products on the market.

In the framework of that strategic approach, the Commission shall, where appropriate, by 14 September 2017 propose measures to be taken at Union and/or Member State level, as appropriate, to address the possible environmental impacts of pharmaceutical substances, particularly those referred to in Article 8b(1), with a view to reducing discharges, emissions and losses of such substances into the aquatic environment, taking into account public health needs and the cost-effectiveness of the measures proposed.

On 14 September 2017, a first surveillance list containing up to 10 substances or groups of substances should be presented, indicating for each substance the monitoring matrices and possible methods of analysis that do not entail excessive costs. The following will be included in the first surveillance list: diclofenac (CAS 15307-79-6), 17-beta-estradiol (E2) (CAS 50-28-2) and 17-alpha-ethinylestradiol (EE2) (CAS 57-63-6).

Importantly, although pharmaceutical regulations include specifications on the existence of heavy metals in drugs but seen as a negative effect on human health, the current approach will also make the shift to environmental pollution.

A separate regulation is Directive 2006/7 / EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160 / EEC, which requires Member States to assess and monitor the quality of bathing water, ie any element of surface water where the competent authority predicts a large number of people to bathe and has not imposed a permanent ban or issued a permanent recommendation against bathing.

1.3. Legislative correlations of heavy metals in soil

Correlations in this area are made with international and EU regulations on wastes that are dangerous by their heavy metal content. The problem of waste becomes cross-border as a result of its transportation to the territory of other states for disposal.

The Basel Convention of 22 March 1989 on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, to which the Community is a part of 1994, was implemented by the adoption of Council Regulation (EEC) No 259/93, which laid down the rules on reduction and control of abovementioned shipments. The regulations have been developed, inter alia, to make the existing Community system for the supervision

and control of waste movements comply with the requirements of the Basel Convention. However, reality has imposed a legislative framework appropriate to new environmental challenges, so that Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste, repeals Regulation no. 259/93. This regulation takes into account a more stringent procedure for the transfer of waste, including hazardous waste.

An important principle of waste management requires that, where waste can not be avoided, they should be reused or recovered in order to capitalize on materials or energy. In this respect, *Directive 2006/66 / EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157 / EEC*:

- prohibits placing on the market:
 - (a) all batteries or accumulators, whether or not incorporated into appliances, that contain more than 0,0005 % of mercury by weight; the prohibition set out in paragraph 1(a) shall not apply to button cells with a mercury content of no more than 2 % by weight until 1 October 2015;
 - (b) portable batteries or accumulators, including those incorporated into appliances, that contain more than 0,002 % of cadmium by weight.
- requires Member States to achieve the following minimum collection rates:
 - (a) 25% up to 26 September 2012;
 - (b) 45% up to 26 September 2016.
- requires that recycling processes be achieved with the following minimum recycling efficiency levels:
 - (a) recycling of 65 % by average weight of lead-acid batteries and accumulators, including recycling of the lead content to the highest degree that is technically feasible while avoiding excessive costs;
 - (b) recycling of 75 % by average weight of nickel-cadmium batteries and accumulators, including recycling of the cadmium content to the highest degree that is technically feasible while avoiding excessive costs and

(c) recycling of 50 % by average weight of other waste batteries and accumulators..

However, Member States may, in accordance with the Treaty, dispose of collected portable batteries or accumulators containing cadmium, mercury or lead in landfills or underground storage when no viable end market is available. Member States may also, in accordance with the Treaty, dispose of collected portable batteries or accumulators containing cadmium, mercury or lead in landfills or underground storage as part of a strategy to phase out heavy metals which, on the basis of a detailed assessment of the environmental, economic, and social impacts, shows that this disposal option should be preferred over recycling.

2. LEGISLATIVE CORRELATIONS ON PERSISTENT ORGANIC POLLUTANTS

Legislative correlations in this area concern:

- follow up of EU legislative changes as a result of changing international regulations identified in Unit 1 (Section A);
- the legislative links of *Regulation 850 on 2004* with import / export activity, with *Regulation no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals* (Regulation REACH), with *The decision on the establishment of the list of wastes, including hazardous waste*, and the *Directive IPPC 75/2010 (Sections B to E)*.

A. Amendments to Regulation 850 of 2004

These are generated by the changes imposed by Conference of the Parties (COP) concerning the 1979 Convention or amendments to the Stockholm Convention.

In order to update the regulation of transboundary air pollution, based on the 1998 Protocol, should be followed Decisions to accept its changes. The last change is the one highlighted by Council Decision (EU) 2016/769 of 21 April 2016 on the acceptance of the Amendments to the 1998 Protocol to the 1979 Convention on LongRange Transboundary Air Pollution on Persistent Organic Pollutants.

However, the following clarifications are necessary:

- The European Union gives great importance to the need to gradually extend Annexes A, B and / or C to the Convention by including new substances that meet the criteria to be considered persistent organic pollutants (POP), taking into account the precautionary principle, in order to meet the objective of the Convention and the commitment to minimize the adverse effects of chemical substances by 2020, assumed by governments at the World Summit on Sustainable Development held in Johannesburg in 2002;
- pursuant to Article 22 of the Convention, the Conference of the Parties ("the COP") may adopt decisions amending Annexes A, B and / or C to the Convention. These decisions enter into force one year after the date of notification by the Convention depositary of an amendment but not to the parties to the Convention who do not wish to apply the amendment;
- in the case of an EU Member State that is a signatory to the Convention, it also does not adhere to any of its later amendments but to which the EU has taken the implementing decision by binding force of the act of accepting the amendment, it is imperative for that State to respect the change not individually accepted.

According to the above example, the decisions to accept the changes must be tracked.

B. Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals



Chemicals and articles the use of which is prohibited in the Union for the protection of human health or the environment, as listed in Annex V, shall not be exported. The link with the field is given by the fact that Annex V *Chemicals and articles subject to an export ban*, in Part A, indicates a number of 18 persistent organic pollutants as listed in Annexes A and B to the Stockholm Convention.

C. Regulation no. 1907/2006

The REACH Regulation establishes provisions on substances and mixtures that must be applied to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles, as well as on the placing on the market of mixtures. It is a very complex regulation, which is based on the principle that it is up to manufacturers, importers and downstream users (the production process) to ensure that they produce, place on the market or use substances that do not have adverse health effects human or environment.

D. Decision 2014/955 / EU of 18 December 2014 amending Decision 2000/532 / EC establishing a list of wastes pursuant to Directive 2008/98 / EC of the European Parliament and of the Council

We have mentioned that wastes containing persistent organic pollutants are part of the hazardous waste category. The classification of a waste as hazardous in terms of waste to which related codes may be assigned to both hazardous and non-hazardous waste shall apply the following: wastes containing polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD / PCDFs), DDT [1,1,1-trichloro-2,2'-bis (p-chlorophenyl) ethane], clordane, hexachlorocyclohexanes (including lindane) dieldrin, endrin, heptachlor, hexachlorobenzene, chlordecon, aldrin, pentachlorobenzene, mirex, toxafen, hexabromdiphenyl and / or PCBs that exceed the concentration limits indicated in Annex IV to Regulation (EC) No. No 850/2004 of the European Parliament and of the Council shall be classified as hazardous waste.

E. Decision 2010/75/UE

When POPs may occur unintentionally in some industrial activities, these activities fall under the industrial emissions regulations, which require the application of certain emission management measures.

3. LEGISLATIVE CORRELATIONS ON PESTICIDES

Legislative correlations in this area concern:

- interpretation of references to an abrogated normative act (Section A);
- reference to control regulations (Section B);
- the need to create initial and further training and certification systems (Section C);
- application of the Rotterdam Convention (section D);
- other documents (Section E).

A. The interpretation of references to an abrogated normative act

Council Regulation (EC) 396/2005 which also amends Directive 91/414 / EEC should be reported *Regulation (CE) no. 1107/2009* concerning the placing on the market of plant protection products, as the latter has repealed Directive 91/414 / EEC.

National regulations transposing Directives 86/362 / EEC, 86/363 / EEC and 90/642 / EEC with all their amendments, should no longer be applicable because they are repealed by Regulation (EC) 396/2005, at the level of the Member States, the provisions of the directive must be fully respected and not the transposition of the repealed main act (directive).

B. Reference to control regulations

Although it should be simple, looking at the changes made *Commission Implementing Regulation (EU) 2016/662 of 1 April 2016 concerning a coordinated multiannual control programme of the Union for 2017, 2018 and 2019 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin*, we find that it has been abrogated by *Commission Implementing Regulation (EU) 2017/660 of 6 April 2017 concerning a coordinated multiannual control programme of the Union for 2018, 2019 and 2020 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin*. As the regulatory act of repeal concerns control for the years 2018 and 2019, we consider that it is still applicable for the controls for the year 2017.

Another important normative act is *Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC*, which harmonises the methods of sampling of products of plant or animal origin for the purpose of determining the level of pesticide residues.

The regulations presented may be integrated with those in the field:

- health and safety at work to prevent the risks associated with exposure of workers to these products,
- control of compliance with the environmental requirements of pesticide application equipment.

C. The need to create initial and further training and certification training systems



The systems of both initial and additional training are applicable to distributors, advisors and professional users of pesticides. The certification systems aims to register these training systems so that those who use or will use pesticides are fully aware of the potential risks to human health and the environment and of the appropriate measures to reduce those risks as much as possible.

For non-professional users who in general do not have the same level of education and training in the field, it is considered that those who received initial and additional training, including certification, should be given recommendations, in particular on safe handling and storage of pesticides as well as on disposal of the packaging

D. Application of the Rotterdam Convention

The Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and dangerous pesticides international trade was approved / ratified by the EU by Council Decision 2006/730 / EC.

By Regulation (EU) No. No 649/2012 of the European Parliament and of the Council implements the Rotterdam Convention at Union level. The Regulation also implements a requirement of the Stockholm Convention on persistent organic pollutants, as it bans the export of chemicals identified as persistent organic pollutants in the Convention unless there are specific exemptions foreseen in the Stockholm Convention

The aim of the Rotterdam Convention on the prior informed consent procedure (PIC) for certain hazardous chemicals and pesticides in international trade is to promote shared responsibility and co-operative efforts among the Parties in the international trade of dangerous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use. It was developed on the basis of experience gained in implementing the London Guidelines for the Exchange of Information on Chemicals in International Trade of the United Nations

Environment Programme (UNEP), as amended in 1989, and the International Code of Conduct on the Distribution and Use of Pesticides, as amended in 1990, of the Food and Agriculture Organisation (FAO). These instruments provided for a voluntary PIC procedure.

E. Other documents

Among documents that are not binding, but by the importance of the subject, can be mentioned:

- a. Communication from the Commission to the European Parliament and the Council on endocrine disruptors and draft acts of the Commission defining the scientific criteria for their establishment in the context of EU legislation on plant protection products and biocides,
- b. European Parliament Resolution of 15 November 2011 on bee health and challenges for the beekeeping sector,
- c. Commission Recommendation of 30 May 2008 on risk reduction measures for zinc oxide, zinc sulphate and bi-zinc (orthophosphate).

The conclusion that should be retained after the trainees of this unit is that when they want to find out what the requirements are for an area, they should not stop at the regulations strictly assigned to that field but try to expand their search and to the related fields, as we have shown for each pollutant. Enlargement may concern: polluting activity; the raw materials used in that activity; products, by-products and waste; specific or general monitoring.



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