LEARNING TOXICOLOGY
THROUGH OPEN EDUCATIONAL

ESTABLISHING THE GENERAL AND SPECIFIC EUROPEAN UNION LEGISLATION FOR TOXIC POLLUTANTS

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The protection of the environment is a complex and of great importance for man, viewed both individually and collectively, and involving the interests of the present and future generations, encompasses all the relations regarding the protection, conservation, improvement and improvement of the environment and their monitoring.

These relationships and, implicitly, the law, are interdisciplinary, are not, and can not be, isolated, with a relationship of interdependence between them, so that the strict legislative delimitation in any of the areas presented below is quite difficult to be.established. It can be noticed that the social relations, the legal relations specific to a field (gaseous pollutants, heavy metals, POPs, pesticides) can not be regulated by a certain category of legal norms. Even if there is a basic normative act that can find its transpositions in the presentation of Unit 2 (National Harmonization of EU Legislation on Toxic Pollutants), the field will also be regulated by related normative acts, which will lead to the establishment of legislative correlations, which will be the subject of Unit 3 (Legislative Correlations).

The regulations (see description in Unit 2) will be presented for each area addressed, in the following order:

- general regulations and, if there is, to the extent that they exist, separately on the polluted environmental factor (air, water, soil) and separately for immissions and emissions,
- specific regulations for activities and / or products.

Since these courses are addressed to students and specialists in fields other than the law, and considering it useful a basic training, not all the normative acts involved will be accessed in specific links. For those documents considered important to achieve the objectives of the course and for those which links have been created, will be made a

specific reference to the learning unit. Each student, depending on the field of activity / interest, can access the EU's general and specific regulations on the website www.eur-lex.europa.eu.

1. GAZOUS POLLUTION REGULATIONS

Environmental quality's monitoring and, implicitly, environmental legislation regarding air pollution (atmosphere), considers three essential aspects: immissions, emissions and activities that can produce gaseous pollutants.Amongthe multitude of regulations regarding the gaseous pollutants, the course is focussed only in those regarding the nitrogen oxides, NOx, sulfur oxides (SOx), volatile organic compounds (VOC), carbon oxides (CO, CO2) and particulate matter (PM). The gaseous pollutants presented in the course mainly affect the air environmental factor, thus the pollution of other environmental factors will not be discussed.

1.1. General regulations on immissions of gaseous pollutants

Regarding immisions, at the level of the European Union, the basic normative act is **Directive 2008/50/EC of the European Parliament and of the Council on ambient air quality and cleaner air for Europe.** This directive includes general regulations on pollution of "ambient air" and applies to tropospheric air, excluding workplaces as defined by Directive 89/654/EEC where provisions concerning health and safety at work apply and to which members of the public do not have regular access.

The definitions formulated in each normative act are important, because the meaning of notions or expressions may differ from one normative act to another. The definitions with which Directive 50 of 2008 operates are contained in Article 2.

An example may be that of expression "nitrogen oxides" which:

- within the meaning of Directive 50 of 2008 means *the sum of the volume mixing ratio (ppbv) of nitrogen monoxide (nitric oxide) and nitrogen dioxide expressed in units of mass concentration of nitrogen dioxide (µg/m3),* and
- within the meaning of Directive 2193 of 2015 (regarding the limitation of emissions of certain pollutants into the atmosphere) *means nitrogen oxide and nitrogen dioxide, expressed as nitrogen dioxide (NO2).*

Directive 50 of 2008 has a number of 17 annexes regarding the protection of the atmosphere, of which great importance are:

- Annex II - *Determination of requirements for assessment of concentrations of sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter (PM10 and PM2,5), lead, benzene and carbon monoxide in ambient air within a zone or agglomeration,*
- Annex X - *Measurements of ozone precursor substances,* in which it is presented a list of volatile organic compounds recommended for measurement,
- Annex XI - *Limit values for the protection of human health.*

The text of this directive and, implicitly, the limits imposed in the corresponding annexes can be found at:
http://moodle.toxoer.com/mod/page/view.php?id=1209 for Romanian and
http://moodle.toxoer.com/mod/page/view.php?id=1197 for English.

The atmospheric pollution is an international problem, going beyond national borders, therefore it is also necessary to refer to the international regulations to which the EU is a part.

In this area, it finds application *Convention on Long-range Transboundary Air Pollution – (CLRTAP),* with the specification that the act dealing with gaseous pollutants subject to the course is the *Protocol to the 1979 Convention on long-range*

transboundary air pollution to reduce acidification, eutrophication and the level of tropospheric ozone - Gotenborg. The EU acceded to this act in June 2003 through *Decision 507 of 13 June 2003*.

Another important protocol to this Convention is *The Protocol on the control of emissions of nitrogen oxides and their cross-border flow,* accomplished in 1988 in Sofia, to which the EU joined by Decision no. 361 of 17 May 1993.

The provisions of the *Additional Protocol on the further reduction of sulfur emissions, concluded in Oslo on 14 June 1994,* are recognized by the EU by *Council Decision 686 of 23 March 1998 concerning the conclusion by the European Community of the Protocol to the 1979 Convention on Long-range Transboundary Air Pollution on the further reduction of sulfur emissions.* Based on this, its Member States will have to reduce their SO_2 emissions, in line with the emission ceilings set out in Annex II to the Protocol and the relevant Community legislation.

The EU has not yet joined to the Protocol on the Reduction of Sulfur Dioxide and their Transboundary Flow (Helsinki, 1985).

All of these are international regulations, thus they can be found on the specialized websites of their presentation.As far as they were signed, ratified by States, their content is found in national legislation, in the official language of the state.

1.2. General regulations on emissions of gaseous pollutants

The international obligations of the Union with regard to air pollution, which aim are reducing acidification, eutrophication, tropospheric ozone and particulate matter emissions, were changed in 2016 to strengthen existing reduction commitments for sulfur dioxide, nitrogen oxides, ammonia and volatile organic compounds and to

introduce new commitments for the reduction of fine particulate matter ($PM_{2,5}$), which must be respected from 2020 onwards.

Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/E with entry dates in force from 2018 to 2030, imposes new emission limits:

- sulfur dioxide (SO2), nitrogen oxides (NOx) and of non-methane volatile organic compounds' (NMVOC, COVnm) (Annex II, Table A) and
- ammonia (NH_3) and fine particles in suspension ($PM_{2,5}$) (Annex II, Table B).

These new limits can be found by accessing Directive 2284 from 2016 to: http://moodle.toxoer.com/mod/page/view.php?id=1209 for Romanian and http://moodle.toxoer.com/mod/page/view.php?id=1197 for English.

1.3. Specific regulations for emissions of gaseous pollutants

A more effective way of protecting the atmosphere from pollution with gaseous pollutants is strict regulation of activities that have the effect of producing them. EU legislation is developed for this purpose, there are regulatory acts imposing emission limits either through mandatory design requirements or through operating efficiency. Because the most important polluting activity is the combustion of fuels, I will refer to its specific legislation.

1.3.1. Emissions from combustion in installations

A. **Combustion of fuel in certain installations and small combustion devices**

This type of activity is governed by the implementing measures referred to in **Directive 2009/125 /** EC establishing a framework for the setting of eco-design requirements for energy-related products**.**This directive benefits from implementing acts in the form of the Regulation, which underlines the importance of regulating and avoiding partial or insufficient implementation at Member State level.

Two examples can highlight the diversity of regulations in this area:

- *CommissionRegulation (EU) No 813/2013* of 2 August 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for space heaters and combination heaters,
- *Commission Regulation (EU) 2015/1188* of 28 April 2015 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for local space heaters.

B. Combustion of fuel in medium combustion plants

Directive (EU) 2193 of the European Parliament and of the Council of 25 November **2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants**, defined medium combustion plants as being combustion plants with a rated thermal input equal to or greater than 1 MW and less than 50 MW, irrespective of the type of fuel they use. This Directive lays down rules to control emissions of SO_2, NOx and PM into the air from medium combustion plants, and thereby reduce emissions to air and the potential risks to human health and the environment from such emissions. This Directive also lays down rules to monitor emissions of carbon monoxide (CO).

Important in this area are the exceptions set out in Article 1, paragraph 3 and the definitions in Article 3, concidering that this directive has arisen as a result of the increase in the number and the effects of pollution on average combustion plants and

increasing the use of biomass as a fuel.The emission limit values are set out in Annex II to this Directive, but they are applied stepwise:

- from 20 December 2018, emissions into the air of SO_2, NO_x and PM from a new medium combustion plant shall not exceed the emission limit values set out in Part 2 of Annex II,
- from 1 January 2025, emissions into the air of SO2, NOx and PM from an existing medium combustion plant with a rated thermal input greater than 5 MW shall not exceed the emission limit values set out in Tables 2 and 3 of Part 1 of Annex II.

From 1 January 2030, emissions into the air of SO_2, NO_x and PM from an existing medium combustion plant with a rated thermal input of less than or equal to 5 MW shall not exceed the emission limit values set out in Tables 1 and 3 of Part 1 of Annex II.

The text of that directive and the limits imposed in the annexed annexes can be found at:http://moodle.toxoer.com/mod/page/view.php?id=1209 for Romanian and http://moodle.toxoer.com/mod/page/view.php?id=1197 for English.

C. Combustion of fuel in large combustion plants

This type of activity is covered by **Directive 2010/75 / EU on industrial emissions (Integrated Pollution Prevention and Control -** known as **the IPPC Directive)** of the European Parliament and of the Council of 7 January 2013.

The data for access and transposition of the directive can be found in section 2.1. General regulations for heavy metals in the air.

1.3.2. Use and emissions of volatile organic compounds

The use of organic solvents in certain activities and installations generates emissions of volatile organic compounds into the air (VOC), which contribute to the local and transboundary formation of photochemical oxidants,which causes damage to natural resources and have harmful effects on human health. Thus, it is necessary to take preventive measures against the use of organic solventsand to establisha requirement to comply with emission limit values for organic compounds, as well as proper operating conditions. And in this case, **Directive 75 of 2010** applies. Chapter V of the Directive refers to Special provisions applicable to installations and activities using organic solvents.

Of particular importance are the definitions in Article 57, of which I stop on the one that explains the meaning of fugitive emissions. Thus, "fugitive emission" means any emission (which does not occur as residual gases) of volatile organic compounds in air, soil and water, as well as solvents in the composition of the products. The importance of this definition results from the interpretation of Annex VII (*Technical provisions on installations and activities using organic solvents*) where in Part 2 they are established *Thresholds and emission limit values for both waste gases and fugitive emissions by types of industrial activities.*

The access and transposition dates of the directive can be found in section 2.1. General regulations on heavy metals in the air.

2. HEAVY METAL REGULATIONS

Heavy metals are direct pollutants emitted into the air, water and soils, unlike other pollutants treated in this course, which directly pollutes one environment factor directly and the others indirectly. Thus, gaseous pollutants and persistent organic pollutants (POPs) directly pollute air and indirectly soil and water, and pesticides directly pollute the soil and indirectly water and food. For these reasons heavy metals as pollutants

benefit from specific regulations for each affected environmental factor, as will be presented below.

2.1. General regulations on heavy metals in the air

2.1.1. Regulations on Immissions of Heavy Metals

The regulation, that sets the thelevel of pollutants in immissions in the air environmental factor for heavy metals at EU level, is in force **Directive 2004/107 / EC of the European Parliament and of the Council of 15 December 2004 on arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air. Directive 2004/107** contains:

- Annex I - Target values for arsenic, cadmium, nickel and benzo(a)pyrene as an average calculated over a calendar year for the total content of the PM_{10} fraction,
- Annex II - Determination of the necessary conditions for the assessment of concentrations of arsenic, cadmium, nickel and benzo(a)pyrene in the ambient air of an area or agglomeration,
- Annex III - location and minimum number of sampling points for the measurement of concentrations in ambient air and deposition rate,
- Annex IV - data quality objectives and requirements for air quality models,
- Annex V - reference methods for assessing concentrations in ambient air and deposition rate.

"The target value" means *a concentration in ambient air set to avoid, prevent and reduce harmful effects on human health and the environment as a whole, to be attained at a given time*. In this regard, Member States shall take all necessary measures to ensure that from 31 December 2012 concentrations in ambient air of arsenic, cadmium, nickel and benzo (a) pyrene used as a carcinogenic risk marker do not exceed the target values set out in Annex I. Thus, these target values are actually the maximum admissible limits of immissions.

Because the effect of these pollutants is particularly dangerous, I consider it necessary to present the target values in Annex I.

Target values[1] for arsenic, cadmium, nickel and benzo(a)pyrene (ng/m^3)	
Arsenic	6
Cadmium	5
Nickel	20
Benzo(a)pyren	1
[1]Average calculated over a calendar year in the total fraction content PM_{10}	

The Directive can be read at:
http://moodle.toxoer.com/mod/page/view.php?id=1209for Romanian and
http://moodle.toxoer.com/mod/page/view.php?id=1197for English.

Another regulatory act is **Directive 2008/50 / EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe**, which sets the following limits for lead level immissions in the ambient air factor:

- averaging time period – calendar year
- the limit value –0,5 µg/m^3
- margin of tolerance –100 %
- date when the limit value must be respected –2010 (taking into account the year 2008 for the entry into force of the Directive)

As an annual average the following concentration thresholds are accepted:

- Upper assessment threshold: 70 % of limit value (0,35 µg/m^3),
- Lower assessment threshold: 50 % of limit value (0,25 µg/m^3).

The elements of access to this Directive and its transposition can be found in the chapter on gaseous pollutants, given that the directive concerns only this heavy metal and the rest of the regulations concern gaseous pollutants.

2.1.2. Regulations on heavy metal emissions

From a legislative point of view, it was necessary to establish a general framework for the control of the main industrial activities. Priority is given to the principle of prevention through interventions at source.

In order to prevent, reduce and eliminate pollution arising from industrial activities, Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), amongst others, the limit values for emissions of heavy metals into the atmosphere as a result of certain activities.

The Directive includes air emission limit values for waste incineration plants and air emission limit values for waste co-incineration. For the rest of industrial activities with high pollution potential, prevention and control are regulated through Best Available Techniques (BAT).Requirements may be presented in form:

A. Air emission limit values for waste incineration plants

They are presented for the following heavy metals as average emission limit values (mg/Nm^3) from a sampling period of at least 30 minutes and a maximum of 8 hours. These average values cover also the gaseous and the vapour forms of the relevant heavy metal emissions as well as their compounds.

Heavy metal and compounds	**Limits** (mg/Nm3)
Cadmium and its compounds, expressed as cadmium (Cd)	0,05 (total)
Thallium and its compounds, expressed as thallium (Tl)	
Mercury and its compounds, expressed as mercury (Hg)	0,05
Antimony and its compounds, expressed as antimony (Sb)	0,5 (total)

Arsenic and its compounds, expressed as arsenic (As)	
Lead and its compounds, expressed as lead (Pb)	
Chromium and its compounds, expressed as chromium (Cr)	
Cobalt and its compounds, expressed as cobalt (Co)	
Copper and its compounds, expressed as copper (Cu)	
Manganese and its compounds, expressed as manganese (Mn)	
Nickel and its compounds, expressed as nickel (Ni)	
Vanadium and its compounds, expressed as vanadium (V)	

B. Air emission limit values for waste co-incineration plants on mg/Nm^3, considering the following heavy metals and their concentrations:

Heavy metal	**Limits(mg/Nm^3)**
Cd + Tl	0,05
Hg	0,05
Sb + As +Pb+ Cr + Co + Cu + Mn + Ni + V	0,5

A. Regulations Best Available Techniques (BAT)

Based on the Directive 75 of 2010, a series of BATs have been developed wich provide for limits for pollutants emission for the activities they regulate, in environmental factors air, water and soil,with an integrated vision both from the point of view of pollutants and from the methods of determination, analysis and monitoring. Until now, the following BATs are mandatory:

1. Commission implementing **Decision 134 /2012**of 28 February 2012 establishing the best available techniques (BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions for the manufacture of glass

2. Commission implementing **Decision 84 /2013**of 11 February 2013 establishing the best available techniques (BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions for the tanning of hides and skins
3. Commission implementing **Decision 163 /2013**of 26 March 2013 establishing the best available techniques (BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions for the production of cement, lime and magnesium oxide
4. Commission implementing **Decision 732/2013** of 9 December 2013 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for the production of chlor-alkali
5. Commission implementing **Decision 687/2014** of 26 September 2014 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the production of pulp, paper and board
6. Commission implementing **Decision 738/2014** of 9 October 2014 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for the refining of mineral oil and gas
7. Commission implementing **Decision 2015/2119** of 20 November 2015 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the production of wood-based panels
8. Commission implementing **Decision 2016/902** of 30 May 2016 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for common waste water and waste gas treatment/ management systems in the chemical sector

9. Commission implementing **Decision 2016/1032** of 13 June 2016 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the non-ferrous metals industries

Directive 2010/75 / EU on industrial emissions can be accessed at:
http://moodle.toxoer.com/mod/page/view.php?id=1209 for Romanian and
http://moodle.toxoer.com/mod/page/view.php?id=1197 for English.

Decisions implementing the directive and setting BATs are not presented in Unit 1, they are only mentioned as an informative title, and each individual learner, depending on the field of activity / interest, will access them individually on the site www.eur-lex.europa.eu.

2.2. General regulations on heavy metals in waters

2.2.1. Regulations on Immissions of Heavy Metals

The regulations on immissions of heavy metals into water, and thus the prevention and control of water pollution, are broken down into the following categories of waters: surface waters, groundwaters and sea and coastal waters. For the usefulness of the course I have only selected examples for surface waters and groundwater. Concerning immissions of heavy metals pollutants into the water factor, the provisions of Directive 105 of 2008 and of Directive 118 of 2006 apply in addition to the provisions of Directive 60/2000.

Directive 60 of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the **field of water policy constitutes the general regulatory framework for the protection of surface and groundwater**, establishing the general regime and applicable principles. The Directive has 11 annexes,

of which Annex VIII, IX and X are important for these types of pollutants.Within the directive, heavy metals are part of the *Indicative List of Major Water Pollutants*, which is found in ANNEX VIII and are specifically identified in Annex X of the *List of Priority Substances in the Water Policy Area*.References to the Directives in Annex IX - Emission Limit Values and Environmental Quality Standards should be made to **Directive 105 of 2008** on Environmental Quality Standards in the Water Sector, **because by its issuance the provisions of Annex IX were repealed.**

Directive 105 of 2008 provides in Annex I *Environmental Quality Standards for priority substancesand a number of other pollutants* in Part A: *Environmental Quality Standards* (EQS), a series of 44 priority substances to which they regulate:

- MAC - maximum admissible concentration,
- AA - the annual average and
- the unit of measure thus differentiated: [µg/l] when the EQS / AA and MAC-EQS report is madeand [µg/kg] of wet weight for the report EQS/biota.

For the usefulness of the course, we have selected only items that concern heavy metals.

Name of substance	CAS[1] number	AA-EQS [2] Inland surface waters [3]	AA-EQS [2] Other surface waters	MAC-EQS [4] Inland surface waters [3]	MAC-EQS [4] Other surface waters	EQSBiota[5]
Cadmium and its compounds (depending on water hardness classes)[6]	7440-43-9	≤0,08 (class 1) 0,08 (class 2) 0,09 (class 3) 0,15 (class 4) 0,25 (class 5)	0,2	≤0,45 (class 1 0,45 (class 2) 0,6 (class 3) 0,9 (class 4) 1,5 (class 5)	≤0,45 (class 1) 0,45 (class 2) 0,6 (class 3) 0,9 (class 4) 1,5 (class 5)	
Lead and its	7439-	1,2	1,3	14	14	

compounds	92-1					
Mercury and its compounds	7439-97-6			0,07	0,07	20
Nickel and its compounds	7440-02-0	4	8,6	34	34	

[1] CAS: Chemical Abstracts Service

[2]This parameter is the EQS expressed as an annual average value (AA-EQS). Unless otherwise specified, it applies to the total concentration of all isomers.

[3]Inland surface waters encompass rivers and lakes and related artificial or heavily modified water bodies.

[4]This parameter is the EQS expressed as a maximum allowable concentration (MAC-EQS). Where the MAC-EQS are marked as 'not applicable', the AA-EQS values are considered protective against short-term pollution peaks in continuous discharges since they are significantly lower than the values derived on the basis of acute toxicity.

[5]Unless otherwise indicated, the biota EQS relate to fish. An alternative biota taxon, or another matrix, may be monitored instead, as long as the EQS applied provides an equivalent level of protection.

[6]For Cadmium and its compounds (No 6) the EQS values vary depending on the hardness of the water as specified in five class categories (Class 1: < 40 mg CaCO3/l, Class 2: 40 to < 50 mg CaCO3/l, Class 3: 50 to < 100 mg CaCO3/l, Class 4: 100 to < 200 mg CaCO3/l and Class 5: ≥ 200 mg CaCO3/l)

The text of Directive 60 of 2008 and the content of Annexes VIII, IX and X and of Directive 105 of 2008 on environmental quality standards in the water sector can be accessed at: http://moodle.toxoer.com/mod/page/view.php?id=1209 for Romanian and http://moodle.toxoer.com/mod/page/view.php?id=1197 for English.

Directive 2006/118 / EC of the European Parliament and of the Council of 12 December 2006 **on the protection of groundwater against pollution and deterioration** shows that groundwater:

- is a valuable natural resource and as such should be protected from deterioration and chemical pollution. This is particularly important for groundwater-dependent ecosystems and for the use of groundwater in water supply for human consumption
- is the most sensitive and the largest body of freshwater in the European Union and, in particular, also a main source of public drinking water supplies in many regions

In order to ensure consistent protection of groundwater, Member States which sharing bodies of groundwater should coordinate their activities in respect of monitoring, the setting of threshold values, and the identification of relevant hazardous substances.

The Directive provides a minimum list of pollutants and their indicators for which Member States have to consider establishing threshold values. These pollutants are identified as substances or ions or indicators which may occur both naturally and/or as a result of human activities. Among heavy metals, the list includes:arsenic,cadmium,lead,mercury.

The Directive establishes that threshold values for a good groundwater chemical status are based on groundwater body protection in accordance with Annex II, Part A, points 1, 2 and 3, referring in particular to their impact on associated surface waters and on terrestrial ecosystems and wetlands which depend directly on them and their interaction with them, and shall take into account, inter alia, *knowledge of human toxicology and ecotoxicology*.

Threshold values to be set by Member States in accordance with the procedure set out in Annex II, Part A, for pollutants, groups of pollutants and pollution indicators which

have been identified in the territory of a Member State as contributing to the characterization of bodies; or groups of bodies of groundwater as being at risk, must be made taking into account, at least, the list contained in Annex II, Part B.In this list are found heavy metals pollutants, extracted above.

2.2.2. Regulations on heavy metal emissions

These are found in the framework of **Directive 75 of 2010** and specifically in the implementing acts in the form of BATs, as listed in point 2.1.2. Regulations on heavy metal emissions.

2.3. General regulations for heavy metals in soil

Soil protection, generally, does not benefit from specific regulation, such as water or air protection. The method of achieving soil protection is that of related regulations, ie activities or products that have the effect of soil pollution.

The presence of heavy metals in the soil, as pollution, is the effect of activities or the use of products that have the effect of releasing, the emission ofsuch pollutants directly or indirectly. Therefore, a series of normative acts regulating these situations have been developed. In this respect, there are regulations concerning plant protection products and concerning plant protection related activities.These include:

- *Implementing Regulation (EU) No. Regulation (EC) No 540/2011 of the European Parliament and of the Council 1107/2009 on the placing on the market of plant protection products*, which was amended and corrected by Commission Implementing **Regulation (EU) 2015/232** of 13 February 2015 as regards the conditions for the authorization of the active substance copper compound, which regulates both the copper concentrations in the active substances and the legal maximum marketing time for these products.

- Council Regulation **Regulation (EC) No 1107/2009** concerning the placing of plant protection products on the market which is set out in the chapter on pesticides.

The regulations of the Copper Compounds Regulation 232 of 2015 are found by accessing:
http://moodle.toxoer.com/mod/page/view.php?id=1209 for Romanian and
http://moodle.toxoer.com/mod/page/view.php?id=1197 for English.

The sewage sludge is obtained as a secondary element from the sewage treatment. These, if used in agriculture, are not covered by the waste regulations.It is therefore important to set limits for the hazardous substances present in their composition. **Directive 278 of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture**, in Annexes I A, I B and ICprovides the following:

- values for concentrations of heavy metals in soil to which sludge is applied;
- concentrations of heavy metals in sludge;
- maximum annual quantities of such heavy metals which may be introduced into soil intended for agriculture are given in Annexes I A, I B and IC

The Directive requires Member States to:

- prohibit the use of sludge where the concentration of one or more heavy metals in the soil exceeds the limit values which they lay down in accordance with Annex I A and shall take the necessary steps to ensure that those limit values are not exceeded as a result of the use of sludge;
- regulate the use of sludge in such a way that the accumulation of heavy metals in the soil does not lead to the limit values referred to in paragraph 1 being exceeded. To achieve this, they shall apply one or other of the procedures provided for in (a) and (b) below:

(a) to establish the maximum quantities of sludge expressed in tonnes of dry matter which may be applied to the soil per unit of area per year while observing the limit values for heavy metal concentration in sludge which they lay down in accordance with Annex I B; or

(b) ensure observance of the limit values for the quantities of metals introduced into the soil per unit of area and unit of time as set out in Annex I C.

Annex I A

Limit values for concentrations of heavy metals in soil (mg/kg of dry matter in a representative sample, as defined in Annex II C, of soil with a pH of 6 to 7)

Parameters	**Limit values[1](mg/kg of dry matter)**
Cadmium	1-3
Copper[2]	50-140
Nickel[2]	30-75
Lead	50-300
Zinc[2]	150-300
Mercury	1-1,5
Chromium[3]	—

Member States may permit the limit values they fix to be exceeded in the case of the use of sludge on land which at the time of notification of this Directive is dedicated to the disposal of sludge but on which commercial food crops are being grown exclusively for animal consumption. Member States must inform the Commission of the number and type of sites concerned. They must also seek to ensure that there is no resulting hazard to human health or the environment.

[2] Member States may permit the limit values they fix to be exceeded in respect of these parameters on soil with a pH consistently higher than 7. The maximum authorized concentrations of these heavy metals must in no case exceed those values by more than 50 %. Member States must also seek to ensure that there is no resulting hazard to human health or the environment and in particular to ground water.

[3] It is not possible at this stage to fix limit values for chromium. The Council will fix these limit values later on the basis of proposals to be submitted by the Commission, within one year following notification of this Directive.

Annex IB

Limit values for heavy-metal concentrations in sludge for use in agriculture (mg/kg of dry matter)

Parameters	**Limit values[1](mg/kg of dry matter)**
Cadmium	20-40
Copper	1000-1750
Nickel	300-400
Lead	750-1200
Zinc	2500-4000
Mercury	16-25
Chromium[1]	—

[1] It is not possible at this stage to fix limit values for chromium. The Council will fix these limit values later on the basis of proposals to be submitted by the Commission within one year following notification of this Directive.

AnnexIC

Limit values for amounts of heavy metals which may be added annually to agricultural land, based on a 10- year average (kg/ha/yr)

Parameters	**Limit values[1]** (kg/ha/yr)
Cadmium	0,15
Copper	12
Nickel	3
Lead	15
Zinc	30
Mercury	0,1
Chromium[2]	—

[1] Member States may permit these limit values to be exceeded in the case of the use of sludge on land which at the time of notification of this Directive is dedicated to the disposal of sludge but on which commercial food crops are being grown exclusively for animal consumption. Member States must inform the Commission of the number and type of sites concerned. They must also ensure that there is no resulting hazard to human health or the environment.

[2] It is not possible at this stage to fix limit values for chromium. The Council will fix these limit values later on the basis of proposals to be submitted by the Commission within one year following notification of this Directive.
The text of the directive can be accessed at:
http://moodle.toxoer.com/mod/page/view.php?id=1209for Romanian and
http://moodle.toxoer.com/mod/page/view.php?id=1197for English.

Though it seems a regulation away from the field, **Directive 2011/65 /** EU of the European Parliament and of the Council of 8 June 2011 **on the restriction of the use of certain hazardous substances in electrical and electronic equipment** has an important effect on the prevention and reduction of emissions of heavy metals into the soil. This effect of prevention and reduction occurs clearly if we consider that this equipment will become waste, which often does not benefit from proper collection and capitalization.

First, the directive requires Member States to ensure that Electronic Equipment and Appliances (EEE) placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II. Also, by the requirements of Annex II, the Directive impose that is not allowed a value greater than that of a maximum admissible concentration calculated on the weight of homogeneous materials, followed by delegated acts, to take some detailed measures to ensure compliance with these maximum concentration values, taking into account, inter alia, surface coatings.

AnnexII

Restricted substances and maximum concentration values tolerated by weight in homogeneous materials.

Restricted substances	Concentration (%)
Lead	0,1

Mercury	0,1
Cadmium	0,01
Hexavalent Chromium	0,1
Polybrominated biphenyls(PBB)	0,1
Polybrominated diphenyls ethers (PBDE)	0,1

Derogations and stages of application of this Directive are set out in Annex III or are governed by special normative acts (about 39 acts) such as:

- *Commission delegated directive (EU) 2017/1009* of 13 March 2017 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards *an exemption for cadmium and lead in filter glasses and glasses used for reflectance standards;*
- *Commission delegated Directive (EU) 2017/1011* of 15 March 2017 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards *an exemption for lead in white glasses used for optical application;*
- *Commission delegated Directive (EU) 2016/1029* of 19 April 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards *an exemption for cadmium anodes in Hersch cells for certain oxygen sensors used in industrial monitoring and control instruments;*
- *Commission delegated Directive (EU) 2016/585* of 12 February 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards *an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes;*

Directive 2011/65 / EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment can be studied at http://moodle.toxoer.com/mod/page/view.php?id=1209for Romanian and http://moodle.toxoer.com/mod/page/view.php?id=1197for English.

The delegated directives are presented only for informational purposes in order to establish a clear picture of the regulations in the field.

3. PESTICIDES REGULATIONS

Because the use of pesticides is recognised as posing threats both to human health and the environment, in its Communication of 12 July 2006 entitled '*A Thematic Strategy on the Sustainable Use of Pesticides*', the Commission adopted a strategy aiming at reducing the risks to human health and the environment resulting from the use of pesticides. Furthermore, the European Parliament and the Council have adopted Directive 2009/128/EC of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (the 'Framework Directive')

Before presenting legislation regulating pesticides, the notion of pesticides needs to be clarified. The normative act defining the notion of pesticides is **Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides**, which in Article 3 indicates that 'pesticides' means both:

(a) a plant protection product as defined in Regulation (EC) No 1107/2009;

(b) a biocidal product as defined in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing on the market of biocidal products.

The text of the directive can be accessed directly via the link indicated: http://moodle.toxoer.com/mod/page/view.php?id=1209for Romanian and

http://moodle.toxoer.com/mod/page/view.php?id=1197for English.

To understand the definitions, must be studiedthe normative acts indicated. However, it should be noted that Directive 128 of 2009, as a domain regulation, *applies only to plant protection products* as defined in **Regulation (EC) No 1107/2009** of the European Parliament and of the Council of 21 October 2009 **on the placing of plant protection products on the market.** In this sense, trough pesticides are understood products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products,

b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;

c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives;

d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;

e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.

Regulation no. 1107/2009 also applies to:

a) substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants, referred to as ‘safeners’;

(b) substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, referred to as ‘synergists’;

(c) substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, referred to as 'co-formulants

(d) substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties, referred to as 'adjuvants'.

Actual pesticides as biocides can no longer be defined by Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing on the market of biocidal products, because it was abrogated by **Regulation (EU) no 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.**

Thus, according to Regulation 528/2012 (in force), the legal meaning of pesticides in the form of biocidal products means:

- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;
- any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

More, a treated article/product that has a primary biocidal function shall be considered a biocidal product. As the normative act provides for a number of exceptions to its

application (Article 2, paragraph 2), Annex V sets out the types of biocidal products and their description in 4 main groups and 22 types of products. This regulation benefits from a number of 129 implementing acts (the last of 14 July 2017) as follows:

Type act / year	**2013**	**2014**	**2015**	**2016**	**2017**
91 implementing regulations	13	16	22	31	9
33 implementing decisions		7	7	14	5
5 delegated regulations	2	2			1

As can be seen, as a field of regulatory malpractice, due to adverse effects on the environment and human health, pesticide regulations are largely developed in the form of regulations and decisions.

The text of the two above-mentioned Regulations, Regulation (EC) (EU) No 1107/2009 concerning the placing of plant protection products on the market and Regulation (EU) 528/2012 on the making available on the market and use of biocidal products can be further developed by accessing:
http://moodle.toxoer.com/mod/page/view.php?id=1209 for Romanian and
http://moodle.toxoer.com/mod/page/view.php?id=1197for English.

The pesticide regulations also cover the maximum allowable pesticide residues in or from food and feed of plant and animal origin. This reference is made through **Council Regulation (EC) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Directive 91/414 / EEC.**

The Regulation establishes the maximum quantities of pesticide residues permitted in products of animal or vegetable origin intended for human or animal consumption.

These maximum residue levels (MRL), which are fixed by the European Commission, include:

- MRLs which are specific to particular foodstuffs intended for human or animal consumption;
- a general limit which applies where no specific MRL has been set (a 'default limit' of 0.01 mg/kg).

The MRL for all crops and pesticides may be found in the Commission's site.

Annex I to Regulation 396/2005 covers all products for which MRLs are established and other products for which harmonized MRLs are appropriate, in particular with regard to their place in the diet of consumers or in trade. Products are grouped in such a way that MRL can be established, as far as possible, for a group of similar or related products.

Annex II to Regulation 396/2005 includes MRLs previously defined by Directives 86/362 / EEC, 86/363 / EEC and 90/642 / EEC and MRL new applicable to products included in Annex I, identifying pesticide residues and maximum residue levels (mg / kg).

Annex III includes provisional MRLs that may be granted in the specific cases provided for in Article 16 of the Regulation.

The magnitude of the regulation must also be seen in the light of the fact that the normative act has 2922 pages, which can be accessed:
http://moodle.toxoer.com/mod/page/view.php?id=1209for Romanian and
http://moodle.toxoer.com/mod/page/view.php?id=1197 for English.

4. REGULATIONS ON PERSISTENT ORGANIC POLLUTANTS

Persistent organic pollutants (POPs) are chemical substances which does not degrade under normal environmental conditions due to very stable chemical structure. POP bioaccumulate through the food web, and pose a risk of causing adverse effects to human health and the environment. These pollutants are transported across international boundaries far from their sources, even to regions where they have never been used or produced. The ecosystems and indigenous people of the Arctic are particularly at risk because of the long-range environmental transportation and biomagnification of these substances. Consequently, persistent organic pollutants pose a threat to the environment and to human health all over the globe.

The first regulations in this area have emerged at international level, regulations that have been ratified by the EU as well. Therefore, these are the first to be referred to and the change to be followed.

A. The Convention on Persistent Organic Pollutants was adopted in Stockholm on 22 May 2001

This Convention is a framework, based on the precautionary principle, for elimination of production, use, import and export of the most importants 12 initial established Persistent Organic Pollutants, as well as for safe handling and disposal and elimination or reduction of releases of certain unintentional Persistent Organic Pollutants. In addition, the Convention lays down the rules for the listing of new chemicals in the Convention. The Stockholm Convention was approved on behalf of the Community by **Decision No 507 of 2006**.

B. The 1998 Protocol on Persistent Organic Pollutants to the 1979 Convention on Long Range Transboundary Air Pollution

POPs are polluting chemicals that can easily be transported by air very distantly. Cross-border air pollution over an extended radius was the subject *Convention on Long-range*

Transboundary Air Pollution – CLRTAP, a convention which, at the time of its elaboration, was of great generality. Through the 8 protocols the problems of pollution with sulfur dioxide, nitrogen oxides, VOC, heavy metals, tropospheric ozone and POP were regulated.

The Executive Body to the CLRTAP adopted the Protocol on Persistent Organic Pollutants on 24 June 1998 in Aarhus (Denmark). It focuses on a list of 16 substances comprising eleven pesticides, two industrial chemicals and three unintentional by-products.The European Community and its Member States signed the Protocol to the regional UNECE Convention on Long-Range Transboundary Air Pollution (CLRTAP) on POPs in June 1998

By *Decision no. 259 of 19 February 2004*, the Protocol has been concluded on behalf of the European Community.

C. Regulation (EC) No. 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/ EEC

Regulation (EC) 850/20041 on persistent organic pollutants was adopted in April 2004, in order to implement the Stockholm Convention and the POP Protocol under the Convention on Long-Range Transboundary Air Pollution within the European Union.

The Regulation contains provisions regarding production, placing on the market and use of chemicals, management of stockpiles and wastes and measures to reduce unintentional releases of POPs. Furthermore, the Regulation impose Member States to establish set up emission inventories for unintentionally produced POPs, national implementation plans (NIPs) and monitoring and information exchange mechanisms.

Article 12 of the Regulation requiresannual reporting by Member States on the actual production and use of POPs and triennial reporting on the implementation of other provisions of the Regulation. The Commission is required to compile the reports and integrate them with the information from the:

- European Pollutant Emission Register (EPER) established by Commission Decision 2000/479/EC

- European Pollutant Release and Transfer Register (E-PRTR) established by the Regulation (EC) 166/2006. and the

- Core Inventory of Air Emissions (CORINAIR) Emission Inventory of EMEP (Co-operative programme for monitoring and evaluation of the long range transmission of air pollutants in Europe) in a synthesis report,with a view to better managing these substances and respecting the right to environmental information for citizens.

Within the regulation is very important Annex I, which includes POP substances for *which it is prohibited*, production, placing on the market and use of substances listed in Annex I, whether on their own, in preparations or as constituents of articles. Annex I covers both substances controlled by Stockholm Convention on Persistent Organic Pollutants, or the 1998 Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants.

Of these pollutants, 7 benefit from a derogation under Article 4 (1) (b) of the Regulation, which allows a prohibited substance to appear as unintentionally contaminant trace elements in substances, preparations or articles.In this situation, a maximum concentration specific to each exception is required and the substances, articles or products in which the exceptions can be accepted are indicated.

It is also important Annex III - *List of substances subject to release reduction provisions*

An extensive reglementation under the regulation is the management of wastes containing the POPs indicated in the Annex IV *List of substances subject to waste management provisions set out in Article 7.*

In accordance with the principle of prevention, regulation is required to avoid, where feasible, contamination of this waste with substances listed in Annex IV. Waste consisting of, containing or contaminated by any substance listed in Annex IV shall be disposed of or recovered, without undue delay and in accordance with Annex V, part 1 in such a way as to:

- ensure that the persistent organic pollutant content is destroyed or irreversibly transformed,
- the remaining waste and releases do not exhibit the characteristics of persistent organic pollutants.

Therefore, it is forbidden disposal or recovery operations that may lead to recovery, recycling, reclamation or re-use of the substances listed in Annex IV.

However, waste containing or contaminated by any substance listed in Annex IV may be otherwise disposed of or recovered in accordance with the relevant Community legislation, provided that the content of the listed substances in the waste is below the concentration limits specified in Annex IV.

As can be seen, the regulations in force at EU level are those that transpose the provisions of the two above-mentioned international regulations, which take the form of a regulation, a mandatory legal form that is not transposed. **For this reason, this area is not found in Unit 2.**

In order to fully understand the current ones, it is necessary to read Regulation (EC) No. No 850/2004 of the European Parliament and of the Council of 29 April 2004 on

persistent organic pollutants and amending Directive 79/117 / EEC by accessing the related link http://moodle.toxoer.com/mod/page/view.php?id=1209 for Romanian and http://moodle.toxoer.com/mod/page/view.php?id=1197 for English.

As a conclusion of this unit we can state the following:

- the above-mentioned regulations and for which links have been created within this unit are a minimum to know for each field,
- every regulation is a starting point for further in-depth research into the field,
- most regulations are interconnected, due to the complexity of environmental and human health protection.

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