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Additional Information

1	Legal measures to prevent and manage soil contamination and to increase food
2	safety for consumer health: the case of Spain
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12	
13	Abstract

This article contains a brief overview of the European and Spanish environmental law 14 15 framework for the prevention of soil contamination, for the management of contaminated 16 soils and for consumers health protection in relation to agricultural crops. Some important aspects of the legislative framework for the prevention and management of soil 17 18 contamination include recognising the possible risk to both human health and ecosystems that certain agricultural and industrial activities pose given the use of organic and inorganic 19 chemical substances of a hazardous nature and pathogenic microorganisms. It is worth 20 highlighting the milestone that many national constitutions include about the right to the 21 environment. This right entails the obligation to protect it and to, therefore, protect soil from 22 any degradation, including contamination. Legislation that protects soil from contamination 23 and, consequently human health and ecosystems, is related mainly to agricultural activities 24 (use of sewage sludge on farmlands, use of wastewater for irrigation, use of organic 25

fertilisers and pesticides), and to industrial and commercial soil-contaminating activities. 26 27 Consumer protection may be achieved through a legal system of environmental liability. specific measures to prevent contaminants entering soil, managing contaminated soils and 28 a food traceability system. It is crucial to make the penalties for soil contamination offenses, 29 and for violators of protective prohibitions, effective, proportionate and dissuasive. Global 30 standards and guidelines on soil contamination could provide national legislative systems 31 with substantive and procedural legal mechanisms to help prevent and manage soil 32 33 contamination.

34

35 Main finding of the work

A sound legal framework for soil contamination prevention and management is not only
 critical for food production and food safety, but also for soil conservation and human health.

Keywords: soil contamination, legislation, human health, ecosystems, risk assessment

41 **1. Introduction**

The environment includes ecosystems and natural biotic and abiotic resources, such as air, water, soil, fauna and flora, and the interaction among these factors (Barboza, 1995). Humankind all over the world is confronting tremendous environmental challenges that come in the form of global warming, deforestation, desertification, contamination and loss of biodiversity (Leib, 2011). The degradation of the environment affects human health, our livelihood and ecosystems.

48 Environmental pollution and food safety are two of the most important issues of our time.

49 Soil contamination is a common worldwide concern because soil is a major food

50 production resource, and it supports each country's prosperity and security. Moreover,

51 the consequences of soil contamination negatively affect the environment, human health,

52 food safety, and soil and water quality (Lu et al., 2015; Zeng et al., 2015; Zhang et al.,

53 2015; Ma et al., 2016; Rodrigues and Römkens, 2018).

According to Tóth et al. (2016), soil plays a central role in food safety as it determines 54 the possible composition of food and feed at the root of the food chain. Soil contaminants 55 56 pose an important threat to human health as they may enter the food chain and make crops 57 unsafe to be eaten (FAO and ITPS, 2015). Many articles have dealt with the soil contamination and food safety issue, mainly in relation to heavy metals in agricultural 58 soils (Lu et al., 2015; Hussain et al., 2019; Rai et al., 2019). For example, He et al. (2019) 59 60 studied heavy metal contamination in a soil-rice grain system in Wenling (China) and found that farmland soil could pose potential risks to ecosystems, food safety and, 61 ultimately, to human health. These authors observed moderate contamination by Cd, Cu, 62 63 Zn and Ni in soil and that 20.7% of rice grain samples exceeded the Cd threshold value. Likewise, Mao et al. (2019) studied the concentrations of heavy metals in soil, and in rice 64 65 shoot and rice grain samples in the Yangtze River Delta area (China). They found that > 50% of soil samples were contaminated by high Cd and Zn levels. Some grain samples 66 exceeded the As concentrations set by a government standard for grain, while the Cu and 67 68 Zn levels fell within a range that could potentially cause health problems.

Around the world, a wide range of industrial activities, waste disposal in uncontrolled landfills, mining, applications of agrochemicals, sewage sludge, and livestock waste, and environmental accidents, have left a legacy of contaminated sites (Mirsal, 2008; Li et al., 2017; Cachada et al., 2018; Gómez-Lavín et al., 2018; Gu et al., 2018; Romero-Baena et al., 2018). Contaminated soil can be found in agricultural land, forests, and urban and industrial areas (Li et al., 2018; Sun et al., 2018). Some soil contaminants that have caused concern are polycyclic aromatic hydrocarbons (PAHs), polychlorinated biphenyl (PCBs), dioxins and furans, pesticides, heavy metals, radionuclides, and pathogenic
microorganisms. New soil contaminants, such as nanomaterials, veterinary medicines,
microplastics and surfactants, have emerged with industrialisation and globalisation (Liu
et al., 2013; Valentín et al., 2013; Hu et al., 2018a; Khelfi, 2018; Loureiro et al., 2018;
Rillig and Bonkowski, 2018).

In the Revised World Soil Charter (FAO, 2015), among the Guidelines for actions taken by Governments we find the establishment and implementation of regulations to limit contaminants from accumulating beyond set levels to safeguard human health and wellbeing, and to facilitate the remediation of contaminated soils that exceed these levels when they pose a threat to humans, plants and animals.

To protect soil against the threat of soil contamination, countries should have effective 86 laws that provide a legal basis to prevent and manage soil contamination. According to 87 88 Van Liedekerke et al. (2018), "management includes tasks such as setting up an inventory, investigations, risk assessment and remediation, and the establishment of 89 recommendations on land use (restrictions)". These laws and regulations need to be 90 supported by a clear management framework to guide all those involved in soil 91 contamination prevention, the management of legacy soil contamination, and the 92 93 remediation of future contaminated soils.

Soil contamination regulations should at least address the: i) protection of clean soils, especially the soils used for farming and forestry. Hence it is essential to monitor soil quality; ii) remediation of contaminated sites and legacy sites; iii) optimisation of the use of remediated or cleaned-up soils; iv) establishment of quality standards for both soil and groundwater; v) assessment of human and ecosystem risks; vi) definition of liability systems; vii) funding mechanisms to insure that the law is applied and to build capacity; viii) offer of technical guidance (CCICED, 2015). Furthermore, the legal system shouldalso address the soil chemical, biological and radiological contamination types.

A soil quality assessment is a key instrument to manage soil contamination. According to 102 103 Bone et al. (2010), the effects of anthropogenic contamination can be assessed by monitoring soil quality indicators over time. Typically, a soil quality assessment has 104 105 looked mainly at chemical properties, measured by chemical indicators (Bone et al., 106 2010). Filip (2002) states that in order to prevent negative ecological consequences, microbiologically-related parameters should be involved in the indication of soil quality. 107 108 Other soil quality assessment approaches involve using pollution indices (Kowalska et 109 al., 2018), screening values, and risk assessments of terrestrial and aquatic ecosystems and human health (Swartjes et al., 2008; Rodrigues et al., 2009), etc. 110

111 The Revised European Charter for the Protection and Sustainable Management of Soil 112 provides several recommendations to prevent soil contamination and to promote the restoration and rehabilitation of contaminated soils (Box 1) (Council of Europe, 2003). 113 114 The basic underlying principles in any soil contamination legislation are the prevention 115 principle, the polluter-pays principle and the rehabilitation-reclamation principle. 116 Nowadays, contamination prevention in industry generally draws more attention. 117 However, efforts in the agricultural sector are just as important. The polluter-pays principle should be followed to establish a liability mechanism. The rehabilitation-118 reclamation principle states that it is the responsibility of the present-day society to repair 119 120 as much as possible the damage that has resulted from past errors rather than passing it on to future generations. 121

122 The international community has established global regimes to minimise pollution from 123 hazardous chemicals and waste, and to support countries to take measures to fulfil this 124 objective (Petrović et al., 2014; FAO, 2018). The China Council for International Cooperation on Environment and Development states that the recommendation of
developing a Law about Soil Environment Protection in China is based on the lessons
learnt from other countries' soil environment legislative experience (CCICED, 2015).

It is worth highlighting the studies conducted by Kovalick and Montgomery (2014, 2017), which summarise the rationale and the major policy, legislation, regulatory, implementation and organisational issues involved in creating a contaminated site programme, especially for low- and middle-income countries.

132

133 2. A right-based approach to a healthy clean environment, and to adequate food

The "right to environment" is considered a solidarity or collective right. Leib (2011) categorised substantive environmental rights into six subrights: the rights of nature, the right to a clean environment, the rights to natural resources, the right to water, the right to food and, Indigenous land rights. The right to a clean environment is related with preventing pathogens, toxins and contaminants entering soil that may post a high risk for ecosystems and human health.

140 There is no doubt that humanity has taken a giant step forward in environment matters. Today the concept of a human right to a healthy environment is widely recognised in 141 142 international law and endorsed by an overwhelming number of countries (Boyd, 2012). According to Boyd (2012), the constitutions of 177 of the 193 UN member nations 143 recognise the right to a healthy environment, environmental legislation, court decisions 144 or the ratification of an international agreement. The right to a suitable environment is a 145 146 statutory right in most national constitutions. In 1976 and 1978, Portugal and Spain were 147 respectively the first countries to include the right to a healthy environment in their constitutions (Boyd, 2012). Article 66 of the Portuguese constitution states, "1. Everyone 148 has the right to a healthy and ecologically balanced human living environment and the 149

duty to defend it. 2. In order to ensure the right to the environment within an overall 150 151 framework of sustainable development, the state, acting via appropriate bodies and with the involvement and participation of citizens, is charged with: a) Preventing and 152 153 controlling pollution and its effects and the harmful forms of erosion", and Article 45 of the Spanish constitution states "1. Everyone has the right to enjoy an 154 155 environment suitable for personal development, as well as the duty to preserve it. 2. The 156 public authorities shall safeguard rational use of all natural resources with a view to protecting and improving the quality of life and preserving and restoring the environment, 157 by relying on essential collective solidarity. 3. Criminal or, where applicable, 158 159 administrative sanctions, as well as the obligation to make good the damage, shall be imposed, under the terms established by the law, against those who violate the provisions 160 161 contained in the previous clause".

Therefore, the protection of soils, as an integral part of the environment, from contamination is a duty. It should be noted that soils are finite natural resources that can be considered non-renewable within the time frame of human activities (Breure et al., 2018). The right to natural resources constitutes, along with the right to a clean and healthy environment, the building blocks of environmental rights (Leib, 2011). Nowadays, many countries recognise the right to an 'unpolluted', 'clean' and healthy environment and, consequently, to clean soils.

Another right related to healthy soils is the right to adequate food. General Comment 12 of the UN Committee on Economic, Social and Cultural Rights (CESCR) of 1999 defines the right to adequate food as the right of everyone to have physical and economic access at all times to adequate food or to means of its procurement. The UN Committee considers that the core content of the right to adequate food implies the availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from

adverse substances and acceptable within a given culture. The right to food is protected 175 176 in Article 25 of the Universal Declaration of Human Rights, in Article 11 of the International Covenant on Economic Social and Cultural Rights, and in Article 24 of the 177 178 Convention on the Rights of the Child. Article 24.2(c) states that "To combat disease and malnutrition, including within the framework of primary health care, through, inter alia, 179 the application of readily available technology and through the provision of adequate 180 181 nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution". 182

Article 51 of the Spanish constitution stipulates that public authorities shall guarantee the protection of consumers and shall, by means of effective measures, safeguard their safety and health. Article 43 recognises the right to health protection and proclaims the competence of public authorities to protect public health by means of preventive measures. According to the last two articles, public authorities should prevent soil contamination in order to protect human health.

Since air and water quality are inextricably associated with soil properties, the latter should be considered to form part of the "right to environment" and the "right to adequate food", especially if we take into account that soils contribute to biodiversity and are the basis for food production.

193

194 3. Supranational soil contamination instruments: the case of the European Union

195 Although an explicit European Union (EU) policy that focuses on soil protection does not 196 exist, there is a wide range of EU legal instruments for soil contamination prevention. The 197 European Commission (EC) considers that soil protection in this stage can be best 198 achieved via a strategy based on: 1) integration into other policies: mainly environmental, agricultural, regional development, transport and research policies; 2) soil monitoring; 3)

200 the future development of new actions based on monitoring results (EC, 2002).

201 The EU legislation that is relevant mainly for soil contamination prevention is:

Community legislation on water (such as Nitrates Directive (91/676/EEC) and Water
 Framework Directive (2000/60/EC)) sets standards to prevent surface and groundwater
 from being contaminated by hazardous substances or excessive nutrients leaking from
 soils.

- Community legislation on air pollution includes Directive 2008/50/EC on ambient air 206 quality and cleaner air for Europe, Directive 2004/107/EC on arsenic, cadmium, mercury, 207 208 nickel and polycyclic aromatic hydrocarbons in ambient air, and Directive 2001/81/EC on national emission ceilings for certain atmospheric pollutants. Contaminants in polluted 209 210 air due to emissions from industry, traffic and agriculture most likely reach soil directly 211 or with precipitation, and include heavy metals (e.g. cadmium, lead arsenic, mercury), soils-acidifying contaminants (e.g. SO₂, NO_x), and several organic compounds (e.g. 212 213 dioxins, PCBs, PAHs) (EC, 2002).

- Most directly linked to soil contamination prevention is Directive 86/278/EEC on the
protection of the environment, particularly soil, when sewage sludge is used in
agriculture.

- In more general terms, the Waste Framework Directive (2008/98/CE) requires waste is
to be disposed without endangering soil.

The objective of the Landfill Directive (1999/31/CE) is to prevent or reduce as much as
possible negative effects on the environment, particularly the contamination of surface
water, groundwater, soil, air and human health. Soil protection is achieved by combining
geological barriers and the collection of leachates.

Further specific waste legislation, such as the Waste Incineration Directive
(2000/76/EC) and the Urban Waste Water Directive (91/271/CEE), may contribute to
prevent soil contamination.

- The purpose of the Environmental Liability Directive (2004/35/EC) is to establish a
environmental liability framework based on the polluter-pays principle to prevent and
remedy environmental damage.

Recently, Paleari (2017) assessed the soil protection status in EU environmentallegislation.

231

232 4. National soil contamination instruments

Over the past four decades, many countries have introduced policies and practices to 233 manage contaminated soil (Castelo-Grande et al., 2018). Strategies to deal with soil 234 235 contamination are being developed through a variety of regulatory systems. Only in the 1970s and from that time onwards, and in response to severe damage to human health and 236 237 the environment due to soils being polluted by waste, countries all around the world have 238 begun to enact laws to both protect clean soils and to clean up existing contaminated sites (CCICED, 2015). Currently, an international common practice exists to develop laws and 239 240 regulations that protect soils. Some of these regulations are the Comprehensive Environmental Response Compensation and Liabilities Act (CERCLA) in the US, Part 241 2A of the Environmental Protection Act 1990 in the UK, the Recommended Canadian 242 Soil Quality Guidelines in Canada, the Soil Protection Act in the Netherlands, the Code 243 in the Environment (Legislative Decree No. 152/2006) in Italy, the Contaminated Soil 244 Act No. 895/2015 in Denmark, the Law on the Remediation of Contaminated Sites 245 (ALSAG 1989) in Austria, and the Soil Contamination Countermeasures Act in Japan 246 and the most recent amendments. The legal basis for soil protection in Germany is the 247

Act on Protection against Harmful Changes to Soil and on Rehabilitation of Contaminated Sites (Federal Soil Protection Act 1998) and the Federal Soil Protection and Contaminated Sites Ordinance (1999). In China, an Action Plan for the Prevention and Control of Soil Pollution was published in 2016 (Hu et al., 2018b) and the Soil Pollution Prevention and Control Law came into force in January 2019 (Li et al., 2019). Many other countries are preparing regulations for contaminated soils, such as Colombia (Arias Espana et al., 2018).

Rodrigues et al. (2009) reviewed and analysed several national contaminated land policy regimes that were already in place to assess common elements and to identify specific needs for developing of national soil policies. Li et al. (2017) reported advanced legal strategies to prevent soil contamination in the US, the Netherlands and Great Britain. Swartjes et al. (2012) reviewed the state of the art of contaminated site management in the Netherlands regarding policy framework and risk assessment tools. Li et al. (2017) collected contaminated site management policies from 31 regions in China.

Obviously, legislation and regulations on soil contamination are tailored to each country'sviews and needs.

264

5. National soil protection towards soil contamination prevention and management, and to protect consumer health: the case of Spain

Soil degradation should be avoided by taking regional, national and European measures. The numerous EU provisions must be implemented into national law. In Spain, the State has the exclusive competence over basic legislation on environmental protection, without prejudicing the powers of Spanish Autonomous Communities to take additional protection measures. Box 2 is an overview of legal instruments that protect soils from contamination and consumer health in Spain. 273

274 **5.1. Environmental Liability**

Establishing a clear liability system is basic to clarify the responsibilities for the 275 276 remediation of legacy, current and future contaminated sites. In 2007 the Law 26/2007 on Environmental Liability was enacted in Spain. It includes an administrative regime on 277 278 environmental liability. It defines land damage as contaminated land that poses a 279 significant risk for human health due to chemical or biological pollution because of organisms or microorganisms. This law develops on Article 45 of the Spanish constitution 280 on the rational use of natural resources, and two fundamental principles of EU legislation 281 282 on the environment come into effect: the principle of prevention and the polluter-pays principle. This law expects companies to respond to the damage caused to natural 283 284 resources, such as soil, water, wildlife and protected habitats, riverbanks and rivers, but 285 risks to people are not explicitly considered in it. In 2008 the Spanish Government 286 adopted Royal Decree 2090/2008, which enacts the partial implementation of the 287 regulations of the Environmental Liability Law 26/2007. In 2014 the Government 288 approved Law 11/2014 by amending Law 26/2007. Law 11/2014 introduces a new section (number 6) in Article 3, which indicates that with public works of general interest. 289 290 which are the competence of the General State Administration, this law shall be applied to any damage caused to waters and soils, among others, if they are caused by the 291 economic or professional activities listed in its Annexe III, even if there is no fraud, fault 292 293 or negligence. In 2015 Royal Decree 183/2015 was adopted by amending the regulation on the partial development of Spanish Law 26/2007, adopted by Royal Decree 2090/2008. 294

295 **5.2. Agricultural activities**

The main sources of pollutants in farmland soils include the use of sewage sludge as afertiliser, wastewater to irrigate crops, organic fertilisers and the application of pesticides.

When they are applied to soil, they contain heavy metals, poorly biodegradable trace organic compounds, and potentially pathogenic organisms, which may pollute soils and affect food safety.

301

302 5.2.1. Use of sewage sludge on farmlands

In Spain, Royal Decree 1310/1990 sets out the legal framework for the use of sewage 303 304 sludge on farmlands. While sewage sludge contains nutrients and organic matter that are beneficial for soil, it may also contain pollutants; e.g., heavy metals, organic compounds 305 and pathogens. This regulation requires sludge to be treated before being applied to 306 307 farmlands by means of biological, chemical or heat treatment, long-term storage or any other appropriate process that significantly reduced its fermentability and the health 308 309 hazards that result from its use. Sludge should be used by considering plants' nutrient 310 requirements, and that the quality of soil and of both surface- and groundwater is not impaired. This legislation sets limit values for seven heavy metals in both soil and sludge, 311 312 and it imposes restrictions by prohibiting the use of sludge on and in soil in various 313 circumstances. In Spain, the legislation of the Autonomous Basque Community (Decree 453/2013) is more advanced than in the rest of Spain as it contains restrictions for heavy 314 315 metals in soil, and also in relation to heavy metals, organic pollutants and pathogens in sewage sludge. While applying sewage sludge to farmlands, sludge is considered waste. 316 The non-compliance of the obligations that derive from Royal Decree 1310/1990 and 317 Order AAA 1072/2013 is considered an administrative infraction. The system of penalties 318 for waste-related infractions is set out in the Law 22/2011 on Waste and Contaminated 319 Soils. 320

The European Commission (EC, 2008) provides an overview of key EU legislation thatinfluences sewage sludge.

323

324 5.2.2. Use of treated wastewater

Water availability is essential for agriculture to reach sustainable crop production. 325 Agricultural production is a water-intensive low-return industry (Rodell et al., 2018). 326 Worldwide, the agricultural sector accounts for 85% of the global blue water (surface or 327 groundwater) use (Shiklomanov, 2000). Rodell et al. (2018) observed that freshwater is 328 329 rapidly disappearing in many of the world's irrigated agricultural regions. According to Flörke et al. (2018), urban water demand will increase globally by 80% by 2050, while 330 climate change is altering the timing and distribution of water. Droughts occur naturally, 331 332 but climate change has generally accelerated hydrological processes to make them set in more quickly and more intensely (Mukherjee et al., 2018). Therefore, more water is 333 required to face the rising demands of irrigation, population increase and rapid 334 335 urbanisation. The UN Sustainable Development Goal on Water (SDG 6) specifically targets a substantial increase in recycling and safe reuse globally by 2030. The potential 336 337 role of treated wastewater reuse as an alternative water supply source has been well 338 acknowledged and is included in international, EU, national and regional strategies. Water reuse is a priority area in the Strategic Implementation Plan of the European 339 340 Innovation Partnership on Water, and maximisation of water reuse is a specific objective of the Communication "Blueprint to safeguard Europe's water resources" (EC, 2012). 341

In Spain, Royal Decree 1620/2007 sets the legal framework to reuse treated wastewater (ASERSA, 2017; Navarro, 2018). For the purposes of this Royal Decree, water reuse is defined as the application of water before it is returned to the public water domain or the coastal-marine domain, which has undergone the suitable wastewater treatment process or processes set out in the corresponding effluent disposal permit, as well as any other necessary processes to accomplish the required quality for its ultimate use. This

regulation establishes basic conditions for reusing treated wastewater by taking into 348 349 account the quality criteria for its reuse according to its intended use. For agricultural uses, it distinguishes three water qualities. Quality 1 for crop irrigation using a system 350 351 whereby reclaimed water comes into direct contact with edible crop parts that are to be eaten raw. Quality 2 for a) crop irrigation for human consumption using application 352 353 methods that do not prevent water coming into direct contact with edible plant parts, 354 which are not eaten raw, but after an industrial treatment process; b) irrigation of pasture 355 land for milk- or meat-producing animals. Quality 3 for a) localised tree crop irrigation whereby reclaimed water is not allowed to come into contact with fruit for human 356 357 consumption; b) irrigation of ornamental flowers, nurseries and greenhouses whereby reclaimed water does not come into contact with crops; c) irrigation of industrial non-358 food crops, nurseries, silo fodder, cereals and oilseeds. For the three qualities, Royal 359 360 Decree 1620/2007 establishes maximum acceptable values of intestinal nematodes, Escherichia coli, B, As, Be, Cd, Co, Cr, Cu, Mn, Mo, Ni, Se, V, and refers to other 361 362 legislation for organic contaminants. This regulation also contemplates environmental 363 uses, such as irrigation of woodlands and green areas, silviculture and aquifer recharge. When treated wastewater is used for aquifer recharge, the amount of total nitrogen and 364 365 nitrates must be limited. The non-compliance of the obligations that derive from the terms and conditions of water reuse concessions and permits is subject to the penalties laid out 366 under Heading IV of the amended Water Act. However, the infractions committed by 367 those responsible for maintaining water quality from the delivery point of reclaimed water 368 to the usage location are regulated by Chapter VI of the General Law on Health 14/1986 369 370 (MARM, 2010).

371

372 5.2.3. Use of organic fertilisers

Fertilisers can contain substances that may potentially pose a risk for human and animal 373 374 health, and also for the environment. Royal Decree 506/2013 (modified by Royal Decree 535/2017 and Royal Decree 999/2017) sets the legal framework for using inorganic and 375 376 organic fertilisers. This regulation considers that using fertiliser products made from organic waste must consider a maximum limit value for both pathogens and heavy metals 377 378 (Table 1). It is important to point out that regulations advance, and nowadays many 379 countries require analyses for not only total chromium, but also for hexavalent chromium that is toxic and can cause cancer if found in high levels. Exposure to chromium occurs 380 from eating contaminated food or drinking water, or by breathing contaminated 381 382 workplace air. Regarding non-compliance, the provisions of Royal Decree 506/2013 are applied, and Royal Decree 1945/1983 regulates infringements and penalties related to the 383 384 protection of both consumers and agri-food production, without prejudicing any other 385 legislation that may be applicable in the affected area.

386

387 5.2.4. Use of pesticides

388 Plant protection products (also referred to as 'pesticides') applied to crops can enter soil and pose the risk of negatively affecting non-target species in both terrestrial and aquatic 389 390 ecosystems. Pesticides can contaminate soil in several ways, and in the area where they are applied, by improper disposal of empty pesticide containers, waste disposal in 391 landfills or while pesticides are being produced. According to Silva et al. (2019), soil 392 contamination by pesticide waste has become an issue of increasing concern given 393 some pesticides' high soil persistence and toxicity to non-target species. The Law 394 43/2002 on Plant Health is the basic legislative framework that allows administrations to 395 396 take the necessary phytosanitary measures to prevent and eradicate harmful organisms that could pose a risk to crops and forest masses. Among its objectives we find the 397

prevention of risks for humans, animals and the environment from using pesticides. 398 399 Before any pesticide can be placed on the market or be used, it must be approved by National Authorities. Royal Decree 971/2014 aims to regulate the procedure followed 400 to assess plant protection products. In this assessment, it should be taken into account 401 that the leaching of pesticides may be influenced by the effect of soil properties (e.g. 402 organic carbon and clay content) on transformation and adsorption. Royal Decree 403 404 1311/2012 establishes an action framework to ensure the sustainable use of plant protection products. The sustainable use of pesticides implies establishing systems for the 405 collection and safe disposal of empty packaging and remnants of pesticides and systems 406 407 for the safe disposal of expired pesticides. As pesticides are hazardous products, containers of pesticides should be managed by their owners as hazardous waste by them 408 409 following the provisions set out in the Law 22/2011 on Waste and Contaminated Soils, 410 which includes penalties for those that leave, pour or dispose uncontrolled hazardous waste. However, given the particular characteristics of pesticide packaging and the 411 412 volume of generated waste, Royal Decree 1416/2001 on the packaging of phytosanitary 413 products was established to reinforce the shared responsibility, producer responsibility 414 and polluter-pays principles. Royal Decree 1416/2001 requires pesticide packaging to be 415 placed on the market following a deposit and return system or an integrated management 416 system.

In order to protect consumers, the European Commission sets maximum residue levels
(MRLs) for pesticides, i.e. the highest levels of pesticide residues that are legally tolerated
in or on food or feed, including imported products.

420

421 5.3. Industrial and commercial activities

The following instruments regulate soil contamination due to industrial and commercial activities: Law 22/2011 on Waste and Contaminated Soils, Royal Decree 9/2005 that provides a list of potentially soil-contaminating activities, criteria and standards to declare soils as being contaminated, and Royal Legislative Decree 1/2016 recast the text of the Integrated Contamination Prevention and Control Act.

427 Law 22/2011 on Waste and Contaminated Soils defines contaminated soil as a soil 428 whose characteristics have been negatively altered by the presence of hazardous 429 chemical components from anthropogenic activities and at concentrations that imply an unacceptable risk for human health or the environment, and have been declared 430 431 contaminated by Regional Authorities. This legislative act establishes that the Government will approve and publish a list of potentially soil-contaminating activities, 432 433 and the owners of potentially soil-contaminating activities are required to periodically 434 submit reports to the corresponding Regional Authority containing any information that may serve as a basis to declare that a soil is contaminated. The requested 435 436 information shall allow the detection of: i) improper use, the handling or management of 437 hazard substances; ii) an inappropriate design of facilities; and iii) poor conditions of facilities and circumstances that lead to an environmental risk being suspected. Declaring 438 439 soil as contaminated makes the parties responsible for contamination take the necessary actions to proceed with its remediation. Regional Authorities will form an 440 inventory with the soils declared as contaminated. The Regional Authority will draw 441 up a list of priority actions on soil decontamination based on its risk to human health 442 and the environment. The law establishes the parties responsible for remediating 443 contaminated soils and allows agreements to be reached between the responsible 444 parties and those authorised by the Regional Authority for the remediation and 445 restoration of contaminated soils. The law allows economic incentives to be established 446

with public funding to help cover the costs of cleaning up and restoring contaminated
soils, but it takes into account that the possible capital gains of soil should revert to the
public administration that funded the economic incentive .

Lastly, the law allows voluntary soil remediation and restoration, but the competent body
of the Regional Authority shall approve the remediation and restoration project
beforehand.

453 Royal Decree 9/2005 establishes the criteria and standards required to determine if soil 454 is contaminated. The criteria for establishing whether soil is contaminated include a risk that is unacceptable for human health or ecosystems. Spain has adopted risk-based 455 456 land management (RBLM). According to Kuppusamy et al. (2017), RBLM integrates risk assessment practices with more traditional site-specific investigations and 457 remediation activities, and RBLM is considered to be practical, scientifically 458 459 defensible and cost-effective. Soils that require a risk assessment are soils for which analytical evidence exists that the concentration of any contaminant is higher than the 460 461 screening values (called "generic reference level (GRL)" in Spanish legislation), soils 462 that present concentrations of total petroleum hydrocarbons above 50 mg/kg, and for the protection of ecosystems when bio-toxicity is demonstrated based on any of the 463 464 biotests referred to in Annexe III.2 of this Royal Decree. This bio-toxicity is assessed using a battery of terrestrial and aquatic organisms (Box 3). Royal Decree 9/2005 465 defines the elements that contain a risk assessment. There are some situations in which 466 467 no risk assessment is available, but soil can be determined as contaminated (see Box 3). These situations are: 1) when the concentration of any contaminant in soil exceeds 100 468 times the established GRL for the protection of human health; 2) in terrestrial ecosystems, 469 470 when the lethal or effective median concentration, $L(E)C_{50}$, for soil organisms obtained in toxicity tests is lower than 10 mg of contaminated soil/gram of clean soil; 3) in aquatic 471

ecosystems when the lethal or effective median concentration, $L(E)C_{50}$, for aquatic 472 473 organisms obtained in toxicity tests is lower than 10 ml of leachate/litre of clean water. Therefore, a soil quality assessment is approached with screening values and site-specific 474 475 risk assessments. Royal Decree 9/2005 considers three land use scenarios for human health: industrial, residential and others (those which are neither urban nor industrial, 476 477 and are suitable for carrying out agricultural, forestry and livestock-raising activities). 478 The owners of the potentially soil-contaminating activities shall be required to submit a 479 preliminary report to the competent body to assess the possibility that significant contamination has occurred or may occur. The preliminary report must contain 480 481 information about: pavement (type, condition, percentage of the total covered surface), drainage network, wastewater treatment network, accidents or irregularities that have 482 483 occurred at the site, hazardous materials consumed, intermediate or end products of a 484 hazardous nature, waste or by-products generated, the form of storage of each product or waste, production areas and historical activities. If it is necessary to establish, extend or 485 486 close a potentially soil-contaminating activity, it is mandatory to analyse soil to 487 determine its quality because this will facilitate the assignation of responsibilities in a future soil contamination case. If a potentially contaminating activity is restricted, soil 488 489 quality must be assessed to study if the activity has had any negative effects on soil quality (MMA, 2007). Some Spanish Autonomous Communities have developed 490 technical guidelines to analyse in which cases a report must be submitted to the 491 Regional Authority. By way of example, the technical guideline of the Autonomous 492 Community of Madrid describes the content of the report that a newly established 493 potentially soil-contaminating activity shall include. It includes both an initial 494 495 characterisation and a subsequent analytical characterisation. If the historical activity of the site is unknown, the analytical characterisation shall include for soils the 496

following: pH, electrical conductivity, organic matter, clay, total petroleum 497 498 hydrocarbons (TPH) and heavy metals (As, Cu, Cr, Co, Cd, Ni, Pb, Hg, Zn); for groundwater: pH, electrical conductivity, TPH and heavy metals (As, Cu, Cr, Co, Cd, 499 500 Ni, Pb, Hg, Zn). If a potentially soil-contaminating activity is stopped, a detailed characterisation and a risk assessment shall be carried out. The system of penalties of 501 the Law 22/2011 on Waste and Contaminated Soils for industrial and commercial 502 503 activities that can contaminate soils include both actions and omissions that violate this 504 law, which are considered administrative infractions. Infractions are classified as minor, serious and very serious. Very serious infractions are considered when failing to carry out 505 506 the works of cleaning up and restoring soil that has been declared as contaminated in line with the Regional Authority's requirements, and when failing to fulfil the existing 507 508 obligations arising from voluntary or conventional agreements for the clean-up and 509 restoration works of contaminated soils. Such infractions entail paying fines that range from 901 to 1,750, 000 euros, depending on the seriousness of the infraction. 510

Royal Legislative Decree 1/2016 on approving the recast text of the Integrated Pollution Prevention and Control Law aims to prevent, reduce and control atmospheric, aquatic and edaphological pollution by establishing a preventive system and the integrated control of pollution to achieve global environmental protection. Regional Authorities may consider that the industrial activities which are subject to this regulation do not need to submit the reports requested by Royal Decree 9/2005 because the requested information is included in the documents submitted to request integrated environmental authorisation.

518

519 5.4. Food safety and health protection

520 Currently in Spain, food safety policies are not integrated with soil contamination
521 management policies. However, the compliance of the aforementioned regulations entails

a reduced risk of pollutants entering the food chain. The Law on Food Safety and 522 523 Nutrition 17/2011 regulates food traceability. According to Opara (2003), traceability in relation to a product "represents the ability to identify the farm where it was grown and 524 525 sources of input materials, as well as the ability to conduct full backward and forward tracking to determine the specific location and life history in the supply chain by means 526 of records". Royal Legislative Decree 1/2007, modified by Law 3/2014, is of particular 527 528 importance for the protection of consumers as traceability is mentioned as a quality 529 control system.

530

531 **6.** Conclusions

Soil is a resource that should be protected to guarantee sustainable development. Soil 532 quality should be preserved to avoid propagating harmful elements through the food 533 534 chain. Many people all over the world are suffering from health risks because they live 535 near highly contaminated sites. We all have the right to a clean environment, to adequate 536 food and to health, which means that we should maintain soils healthy to obtain healthy 537 food and to preserve both human health and ecosystems. Both the EU and Spain have legal instruments to prevent soil contamination, but the EU has no legal soil 538 539 contamination framework. Spanish legislation clearly defines contaminated soil in its legislation on both the environmental liability and soil contamination due to industrial 540 and commercial activities. Spanish legislation on agricultural activities has been oriented 541 to establish guidelines that preserve soils and consumer health by limiting contaminants 542 from sewage sludge and wastewater entering soil. Moreover, with wastewater it 543 establishes soil quality criteria and lays down mandatory limit values for certain 544 545 contaminants in soil for sewage sludge. Due to industrial and commercial activities, Spanish legislation for soil contamination develops a decision-making process that 546

follows a risk-based approach where a site-specific risk assessment is the main decision 547 548 support tool to guarantee the remediation of polluted soils. It takes into account that remediation should ensure permanent solutions and should be carried out by applying the 549 550 best available techniques. It can be stated that Spain has a regulatory system that includes measures to prevent soil contamination, to manage polluted soils, and to develop an 551 552 environmental liability system. However, there are still some elements that can further 553 enrich the regulatory system; for example, introducing food safety into the current 554 regulations on soil contamination, or providing an alignment between groundwater policies and soil quality policies. Spanish legislation could also introduce economic, 555 556 social and other factors into risk management. It is also important to prepare technical guidelines that clarify the implementation of risk assessments and that introduce into risk 557 558 assessments new research insights into this topic. For example, in Spain a risk assessment 559 of contaminated soils is based on determining the total contaminant concentration. However, Brand et al. (2013) assumed that only the bioavailable fraction is capable of 560 561 exerting adverse effects on the soil ecosystem, which is why they suggested taking 562 bioavailability into account to make more effect-based risk assessments. Similarly, Kuppusamy et al. (2017) pointed out that the consideration of contaminant bioavailability 563 564 may lead to a more sophisticated risk-based approach being developed. However, Ren et 565 al. (2018) studied the effect of exogenous carbonaceous materials (ECMs) on the bioavailability of organic pollutants. These authors observed that, in most cases, the 566 sorption behaviour of ECMs decreases the bioavailability of organic pollutants, but the 567 568 physiological properties of soil organisms complicated this. Other key points include 569 supporting sustainable green remediation strategies and supporting land re-use on site 570 because it provides environmental benefits by preventing large volumes of waste being transported to landfills. Introducing measures that decrease unsustainable remediation 571

solutions (dig and dump) is needed; e.g., increasing landfill taxes. In Spain, Royal Decree
9/2005 makes no difference between legacy and current contaminations. Therefore, midand long-term plans are needed for the remediation of legacy contaminated soils.

A contaminated soil management framework provides benefits to the environment and human health. It also offers a legal framework for the remediation and restoration of contaminated soils and, hence, the use and maintenance of the economic value of soil. This paper could be useful to policymakers and stakeholders in Spain, and it also sets a legal reference for other countries.

580

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792 Captions for Boxes and Table 1

- Box 1. Recommendations for preventing soil contamination, and for promoting therestoration and rehabilitation of contaminated soils (Council of Europe, 2003).
- Box 2. Overview of legal instruments to protect soils from contamination and consumerhealth in Spain.
- Box 3. Criteria to determine if a soil is contaminated in Spain (Royal Decree 9/2005).
- Table 1. Criteria applicable to fertiliser products made from waste and other organiccompounds in Spain.

800

801 **Boxes:**

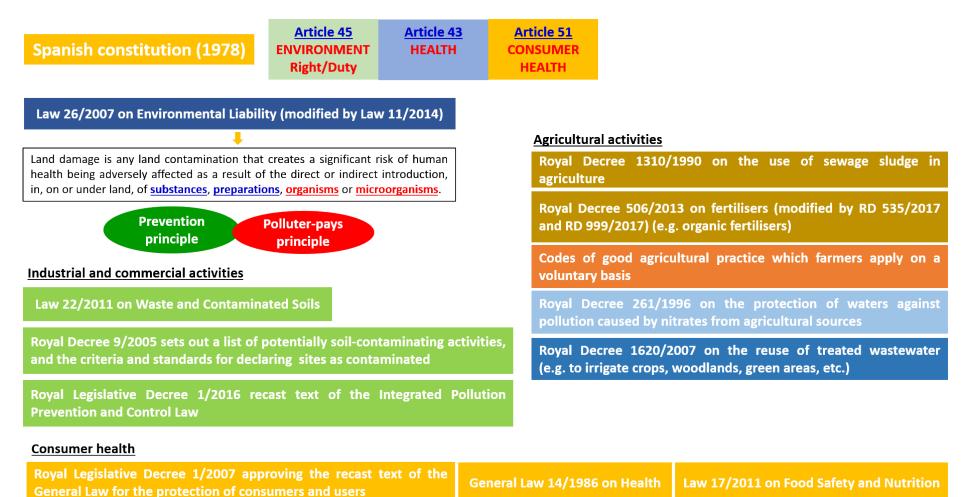
802 Box 1. Recommendations for preventing soil contamination, and for promoting the

restoration and rehabilitation of contaminated soils (Council of Europe, 2003).

Prevention of soil contamination	 Strict control of installations, storage areas and dumps, that are above or below ground. Permanent monitoring of sites and surrounding areas. Any incidents should be immediately and appropriately dealt with. Any change in site ownership should be preceded by an environmental audit and should be reported to the public authorities.
Restoration of contaminated soils	 Systems enabling the identification of potential harm to soil resources, and appropriate action being taken. Spatial and town planning regulations that include measures to ensure that any subsequent use of former polluted sites is suitable, and based on risk assessments. Determining with the technical and financial responsibility for restoring contaminated soil according to the "polluter-pays principle". Selection of restoration techniques using physical, chemical or biological processes. However, it may be preferable to sometimes leave polluted sites as they are to avoid reactivating certain contaminants that have been immobilised.

805

Box 2. Overview of legal instruments to protect soils from contamination and consumer health in Spain.



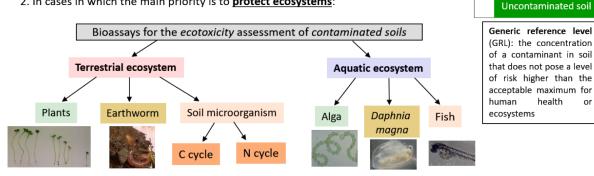
Box 3. Criteria to determine if a soil is contaminated in Spain (Royal Decree 9/2005).

Soil shall be declared contaminated after determining that an unacceptable risk A risk assessment is made for the protection of human health or ecosystems exists given the presence of any chemical contaminant.

No risk assessment is made

100 x GRL 1. In cases in which the main priority is to protect human health: when the concentration in soil of any chemical contaminant exceeds 100 times the established GRL set to protect human health in accordance with land use.

2. In cases in which the main priority is to protect ecosystems:



The lethal or effective median concentration, L(E)C₅₀, for soil organisms obtained in toxicity tests:

- ✓ OECD* 208 (Test of Seedling Emergence and Growth of Terrestrial Plants) ✓ OECD 207 (Acute Earthworm Toxicity Test)
- ✓ OECD 216 (Soil Microorganisms: Nitrogen Transformation Test)
- ✓ OECD 217 (Soil Microorganisms: Carbon Transformation Test)
- ✓ or such tests that may be regarded as equivalents for assessment
- purposes by the Minister of the Environment

is lower than 10 mg of contaminated soil/gram of clean soil.

* Organisation for Economic Co-operation and Development

The lethal or effective median concentration, L(E)C₅₀, for aquatic organisms obtained in toxicity tests:

GRL

Contaminated soil

Potentially

contaminated soil

Risk assessment

or

- ✓ OECD 201 (Algal Growth Inhibition Test)
- ✓ OECD 202 (Daphnia magna Immobilisation Test)
- ✓ OECD 203 (Fish Acute Toxicity Test)
- ✓ or such tests that may be regarded as equivalents for assessment purposes by the Minister of the Environment

carried out with leachates obtained using the standard DIN-38414 method, is lower than 10 ml of leachate/litre of clean water.

809

Heavy metal	Concentration limits Solids (mg kg ⁻¹ dry matter) liquids (mg kg ⁻¹)				
	Class A*	Class B ^{**}	Class C***		
Cd	0.7	2	3		
Cu	70	300	400		
Ni	25	90	100		
Pb	45	150	200		
Zn	200	500	1000		
Hg	0.4	1.5	2.5		
Cr total	70	250	300		
Cr VI	Non-detectable	Non-detectable	Non-detectable		
Pathogens	Maximum limit values No Salmonella species in 25 g finished product 1000 CFU/g product				
Salmonella spp.					
Escherichia coli					

Table 1 Criteria applicable to fertilizer products made from waste and other organic compounds in Spain.

* Class A: The content of heavy metals does not exceed any of the values in column A. ** Class B: The content of heavy metals does not exceed any of the values in column B. *** Class C: The content of heavy metals does not exceed any of the values in column C.