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Towards the definition of specific protection goals for the environmental risk assessment of chemicals: a perspective on environmental regulation in Europe**

Running title: Defining protection goals for chemicals

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ABSTRACT

This critical review examines the definition and implementation of environmental protection goals for chemicals in current European Union (EU) legislation, guidelines and international agreements to which EU countries are party. The European chemical industry is highly regulated and prospective environmental risk assessments (ERAs) are tailored for different classes of chemical, according to their specific hazards, use patterns and environmental exposure profiles. However, environmental protection goals are often highly generic, requiring the prevention of ‘unacceptable’ or ‘adverse’ impacts on ‘biodiversity’ and ‘ecosystems’ or the ‘environment as a whole’. This review aims to highlight working examples, challenges, solutions and best practices for defining specific protection goals (SPGs), which are seen to be essential for refining and improving ERA. SPGs hinge on discerning acceptable versus unacceptable ‘adverse’ effects on the key attributes of relevant, sensitive ecological entities (ranging from organisms to ecosystems). There are some isolated examples of SPGs for terrestrial and aquatic biota in prospective ERA guidance for Plant Protection Products (PPPs). However, SPGs are generally limited to environmental/nature legislation requiring environmental monitoring and retrospective ERA. This is due mainly to the availability of baseline defining acceptable versus unacceptable environmental effects on the key attributes of sentinel species, populations and/or communities, such as reproductive status, abundance or diversity. Nevertheless, there are very few regulatory case examples in which SPGs incorporate effect magnitude, spatial extent and temporal duration. We conclude that more holistic approaches are needed for defining SPGs, particularly with respect to protecting population sustainability, ecosystem function and integrity, which are implicit in generic protection goals, and explicit in the International Programme for Chemical Safety (IPCS) definition of adverse effect. A possible solution, which the chemical industry is currently assessing, is wider application of the ecosystem services approach proposed by the European Food Safety Authority (EFSA) for the risk assessment of PPPs.

KEY WORDS: ERA, ecosystem services, environmental regulations, Europe, specific protection goals

INTRODUCTION

The chemical industry is highly regulated and the assessment of new products to ensure human and environmental safety prior to registration and authorisation in the European Union (EU) can incur significant costs (CSES 2012; ECPA 2013). In each case, for chemicals with hazardous properties, a tiered environmental risk assessment (ERA) is performed, beginning with the estimation of exposure profiles based on chemical use, volumes and physico-chemical properties. According to the 'ecological threshold option' (Table 1), which allows only negligible population- and ecosystem-level effects, exposure profiles are then compared with ecotoxicological effects data for environmentally relevant and sensitive test species. The results are extrapolated using assessment factors to protect 'sensitive populations' potentially subjected to chemical exposure in the wild (Brock et al 2006; Beder et al 2006; Hommen et al 2010). Alternatively, as a consequence of the often short-term, seasonal application of plant protection products and some biocides, ERAs for these chemicals may be based on the 'ecological recovery option'. This option takes into account the recolonization potential of exposed species and also considers effects on predator or prey species not directly affected by chemical exposure (EFSA 2013a; ECHA 2015; EFSA 2016a).

Despite highly developed environmental principles (Table 1), extensive regulations (Table 2) and internationally standardised test guidelines (OECD 2015), environmental protection goals for chemical registration remain vague, e.g. requiring the prevention of unacceptable or adverse impacts on biodiversity and ecosystems. Given the variability and complexity of ecosystems it is difficult to determine if these generic protection goals are being met. This uncertainty has led to widespread use of assessment (safety) factors in order to ensure protection of the most sensitive and vulnerable species in the wild, and therefore the 'environment as a whole'. Assessment factors adopted in effects assessment in ERA are intended to account for: i) natural variability in the environment; ii) multiple chemical exposure profiles; iii) extrapolation of chemical effects from model species to other species and from individual laboratory test organisms to wild populations; iv) ecological factors, including interactions between species and between physical, biological and other chemical stressors (Box 1, after Chapman 2002; Hommen et al 2010; EC 2012a). Since use of assessment factors in ERA follows a generalised framework, the resulting predicted no-effect concentrations for chemicals (PNECs), or regulatory acceptable concentrations (RACs) that address the ecological threshold option, are also generic. Therefore these benchmark concentrations need to be protective of all species that may occur in the relevant environmental compartments. This may mean that, for some locations, where habitats are unsuitable for certain sensitive taxa, ERAs for individual chemicals may be over-protective, and this could result in unnecessary restrictions on chemical use. Defining safe concentrations for chemicals for different locations or ecological scenarios could overcome this potential over-conservatism.

Environmental variability across Europe encompasses numerous geographically and biologically distinct 'eco-regions'. These regions contain a range of land use/land cover types (Meissle et al 2012; EC 2014), water body types (Water Framework Directive (WFD: 2000/60/EC) and 'ecologically relevant' species, which are potentially exposed to numerous different environmental pressures (Chapman 2002; Ibrahim et al 2013; Meissle et al 2012). The European Commission (EC) has highlighted the benefits of adopting a more spatially explicit approach for chemical ERA, in combination with a more holistic assessment of "higher hierarchical levels of ecological organisation (meta-populations, communities, ecosystems), the main goals of environmental protection". The EC argue that adopting these approaches would "take better account of environmental complexity and take advantage of numerous technological advancements….for improving the realism of exposure and effect assessment and for reducing the uncertainty in ERA" (EC 2012a). The complementary use of retrospective and prospective approaches is also recognised as important for improving ERA (Ragas 2011; Boxall et al 2012; EC

2012a). In Europe prospective and retrospective ERA approaches are incorporated within different Regulations and Directives. For example, the aquatic risks of pesticides may be evaluated prospectively under the Plant Protection Product Regulation (PPPR: EC 1107/2009), during use via the Sustainable Use of Pesticides Directive (SUPD: 2009/128/EC and retrospectively via the WFD. Unfortunately, the feed-back mechanisms between these Regulations and Directives are not yet appropriately implemented in all Member States. In addition to the drive to improve ERA for protecting biodiversity, ecosystems and the environment as a whole, the EC has developed a Biodiversity Strategy. This strategy has the aims of "halting the loss of biodiversity and the degradation of ecosystem services in the EU by 2020, and restoring them in so far as feasible, while stepping up the EU contribution to averting global biodiversity loss" (EC 2011a). The EU Biodiversity Strategy also recognises the need for "full implementation of environmental/ nature legislation" to protect biodiversity and ecosystem services.

In the following review of EU legislation and EU-binding international agreements governing the environmental safety of chemicals, we cover a broader range of regulatory instruments than previously considered for prospective ERA (prior to chemical product registration) and retrospective assessment under the Water Framework Directive (Brock et al 2006; Hommen et al 2010). These broader instruments, including consolidated environmental and nature conservation legislation, International Conventions, and supporting guidance documents, provide a 'catch-all' or environmental 'safety net' (Figure 1) covering the life-cycle of chemicals from initial development to manufacture, use and disposal. Consistency between regulatory instruments and their applicability across the EU is promoted by the adoption of generic protection goals. However, generic goals create uncertainty and, as previously described, inevitably result in conservatism in ERAs. The aims of this critical review are to compare and contrast EU environmental regulatory frameworks for chemicals and to highlight challenges, solutions and best practices for specifying environmental protection goals.

DEFINING ENVIRONMENTAL PROTECTION GOALS

Prospective approaches

Environmental complexity and variability present major challenges for assessing the environmental risks of chemicals in prospective ERA, prior to the registration and authorisation of new substances (Chapman 2002; Ibrahim et al 2013; Meissle et al 2012; EC 2012a; EC 2014). Consequently the ‘precautionary principle’ (UN Convention on Biological Diversity (CBD) 1992) is cited widely in the environmental regulation of chemicals (Tables 2-4). Precaution is implicit within the generic protection goals, which are applied across all chemical sectors, from basic commodity chemicals regulated under the Regulation Evaluation and Authorisation of Chemicals Directive (REACH: EC 1907/2006), to specialty chemicals regulated under the PPPR, Biocidal Products Regulation (BPR: EU 528/2012) and Medicinal Products for Human Use Directive (MPHU: 2001/83/EC) (Table 2). Examples of generic protection goals include:

- General commodity chemicals – REACH specifies “no significant adverse effects in any environmental compartment”
- Plant Protection Products - PPPR and Biocidal Products - BPR specify “no unacceptable environmental effects, including impacts on biodiversity and the ecosystem”
- Pharmaceuticals - MPHU and Medicinal Products for Veterinary Use Directive MPVU (2009/9/EC) aim to prevent “any risk of undesirable effects on the environment”

Conversely, specific protection goals (SPGs) are scarce in legislation and guidance concerning the prospective ERA of chemicals (Table 2). SPGs specify “entities that need to be protected, the attributes and/or functions of those entities, as well as the magnitude, temporal and spatial scales of effects on those attributes and/or functions that can be tolerated, without impacting the general protection goal, and the required degree of certainty with which the protection goal defined should be achieved" (EFSA 2010). In practice, chemically-based protection goals are often more clearly specified than biologically- or ecologically-based protection goals. For example, REACH, PPPR, BPR and MPVU all specify maximum chemical residue limits in soil, groundwater, animal feed and human food (and animal excreta/dung, in the case of MPVU regulated veterinary chemical products). REACH also demands the prevention of significant effects on food chains, but these effects are not defined or quantified. Similarly, the PPPR aims to prevent 'significant' effects on the 'viability' of non-target species populations, biodiversity and ecosystem services, but again the terms significant and viability are not substantiated. Instead a precautionary approach is taken for protecting these ecological entities. For example, the risk of secondary poisoning by chemicals in the food chain is assessed under the BPR, PPPR, MPHU and MPVU Directive using threshold bioaccumulation factors often predicted from physical chemistry partitioning studies, rather than in vivo studies, which account additionally for metabolism and excretion. A precautionary approach is also advocated in specific guidance for tiered risk assessment of PPPs for aquatic organisms (EFSA 2013a), which stipulates i) protection of individual vertebrate organisms from acute toxicity (mortality) and ii) protection of vertebrate populations from chronic effects, without the option for recovery (with no stipulation of magnitude nor duration of effect). Furthermore, individual-level protection is stipulated more widely in risk assessment guidance for regulated products and non-target vertebrates (EFSA 2016a) and endangered species (EFSA 2016b) also including invertebrate and plant taxa (Habitat Directive HD 1992; IUCN 2016). However, it is important to note that implementation of individual- and species-defined SPGs can be hampered by significant differences in the sensitivity and recoverability of individuals and differences between endangered versus surrogate test species. In other rare cases environmental protection goals are highly specific, such as the environmental protection goals recommended for bees in the EFSA guidance for plant protection products (EFSA

2013b). This guidance requires the measurement and linkage of PPP exposure to "colony-relevant population changes". In this case it is critically important to evaluate the effects of PPPs in relation to other environmental factors potentially impacting upon the viability of bee colonies. Therefore moving from generic protection goals to SPGs, and operationalising the latter for the prospective ERA of PPPs or other chemical products is not straight forward.

Retrospective approaches

The importance of retrospective impact assessment (for example as undertaken under the WFD) for informing prospective ERA is widely recognised (Ragas 2011; Boxall et al 2012; EC 2012a). Cross-validation of pro- and retrospective assessments is advocated in the PPPR and other chemical regulations, including the BPR and the Pharmacovigilance Regulation (EU 1235/2010) under the MPHU Directive. Unlike prospective ERA, there are several examples of SPGs being used in retrospective ERA and environmental monitoring (Tables 3 and 4), and these generally fall into two categories. The first category contains population-level goals for indicator species, identified using a reductionist approach typified by the Oslo Paris Convention's Ecological Quality Objectives (OSPAR 2010) (e.g. focusing on priority chemicals and individual biomarkers or population trends for indicator species, Table 4). The second category contains more holistic community or ecosystem-level goals (e.g. protection of ecological communities reflecting biological quality status defined under the WFD, or entire habitat features under the HD, Table 4). These SPGs provide valuable working examples for guiding prospective ERA, helping to justify the selection of ecological entities (e.g. population, functional group or community) and their key attributes (e.g. biomass or function) as reliable indicators of ecosystem health. Quantifiable changes in these attributes, versus acceptable limits or reference values, should ideally be defined in terms of magnitude of change, spatial scale and temporal scale (EFSA 2010; 2016c). All three dimensions are considered in the setting of SPGs under: i) OSPAR e.g. "ecological quality objective” of <10% decline in recruitment (5 year rolling average) for defined sub-populations of 5 species of North Sea seals (OSPAR 2010); ii) WFD “biological water quality classification” based on species diversity, abundance, distribution and trends; iii) the Habitats Directive (HD 1992) “favourable conservation status” based on: species population dynamics, long-term viability and natural range; habitat species richness, structure and function, extent and trends, necessary for their long-term maintenance (EC 2011b; EC 2012b). Critically, in each of these cases, the main focus is on magnitude of change, while spatial and temporal dimensions are constrained by pre-defined monitoring regions, water bodies or habitats and reporting cycles.

DEFINING ADVERSE ENVIRONMENTAL EFFECTS

The definition of SPGs hinges on the ability to discern acceptable versus unacceptable ‘adverse’ effects on relevant, sensitive ecological entities (e.g. single species populations, functional groups, communities, habitats, ecosystems) and their key attributes requiring protection.

Qualitative definitions of adverse effects

EU regulations concerning prospective ERA of chemicals require no ‘unacceptable’, ‘undesirable’, ‘harmful’ or ‘adverse’ effects on biodiversity, ecosystems or the environment as a whole (Tables 2 and 3). Definitions of these terms (here generally referred to as adverse) in environmental legislation and chemical sector-specific guidance (Table 5) tend to focus on individuals. This focus differs from the stated high-level environmental protection goals aimed at populations, communities and ecosystems (Table 2). For example, the WHO/UNEP/OECD/ILO International Programme for Chemical Safety (IPCS 2004) definition of adverse effect (see below) is adopted under REACH, PPPR and the BPR, with the exclusion of the terms ‘system’ and ‘(sub)population’. The context of the term ‘system’ is ambiguous in the IPCS definition and could refer to an in vivo system (e.g. endocrine system) or an eco-system.

IPCS definition of adverse effect: “a change in the morphology, physiology, growth, development, reproduction, or life span of an organism, system, or (sub)population that results in (i) an impairment of functional capacity, (ii) an impairment of the capacity to compensate for additional stress, or (iii) an increase in susceptibility to other influences” (IPCS 2004; after Bayne 1975).

(i) The impairment of functional capacity (at the ecosystem-level), is elaborated under the Environmental Liability Directive (ELD) (2004/35/CE) and the Control Of Major Accident Hazard (COMAH) Directive (2012/18/EU), and supporting guidance (DETR 1999; CDOIF 2013). These documents refer to the “long-term maintenance of … the functions of habitats”, including defined statutory protected and undesignated land-based habitats and water bodies. In addition, some specific ecosystem functions are protected in several chemical and environmental regulations. For example, maintaining biodegradation by microbial communities is a protection goal for ecosystems including: soil in the BPR, PPPR and the MPHU Directive; sewage in REACH and the MPHU Directive; animal dung in the MPVU Directive (Table 2).

(ii) With respect to impairment of the compensatory capacity of individuals, populations and ecosystems, guidance for the Convention on Biological Diversity (CBD 1992; CBD SBSTTA 2000) and Habitats Directive (HD) (92/43/EEC) specifically refers to the preservation of ecosystem integrity, including ‘the capacity for self-regulation’. Similarly, the PPPR and the ELD consider the potential for populations to ‘recover’ or ‘regenerate naturally’, following chemical exposures or spills (Tables 2 and 3).

(iii) In terms of susceptibility to additional stress or other influences, the PPPR and BPR both require the consideration of possible cumulative and interactive (synergistic) effects (of co-formulated chemical mixtures / products and relevant metabolites or transformation products) on biodiversity and ecosystems. Exposure risks from metabolites and transformation products derived from human and veterinary pharmaceuticals are also considered specifically under the MPHU and MPVU (if they individually constitute or exceed 10% of the parent compound). The potential ‘long-range’ or ‘transboundary’ transport of some chemicals is also acknowledged in PPPR, BPR, the Air Quality Framework Directive (AQFD) (2008/50/EC) and the Stockholm Convention (SC) (1972). Defining acceptable versus unacceptable limits of exposure for such chemicals inevitably requires the assessment of cumulative risks from multiple emission sources, with all the additional inherent uncertainties involved.

Whilst ERA addresses some functional aspects of adverse effect, (e.g. on population-relevant endpoints quantifying survival, development and reproductive output), “impairment of the capacity to compensate for additional stress…and other influences” are, with the exception of higher tier mesocosm and/or field-based studies, not taken into account. Instead toxicity studies are generally performed by exposing sensitive model species to chemicals, whilst maintaining them under otherwise constant, optimal conditions in the laboratory (Forbes et al 2008; Forbes et al 2011). This latter approach does not account for spatial and temporal variability in the environment, contributing to compounding uncertainties in ERA (Box 1).

Quantitative definitions of adverse effects

Prospective approaches

Quantitative definitions of the terms ‘impairment’, ‘unacceptable’, ‘undesirable’, ‘harmful’ or ‘adverse’ are generally lacking in chemical regulations and supporting guidance documents for prospective ERA (Table 2; Table 5). For the majority of chemicals the significance of population-level effects, required for deriving PNECs or RACs, is based on statistically significant laboratory effects data for individual test organisms, rather than on ecologically significant effects measured or predicted for wild populations (Forbes et al 2008; 2011; Brown et al 2014). The ERA of plant protection products also includes the option for appropriate assessments under field conditions of: the population density and viability of non-target species (including keystone and/or indicator species); biodiversity (e.g. overall species richness of ecological communities); and ecosystem services (EFSA 2013a). However, there is still a lack of clarity in the definition of unacceptable impacts on each of these ecological entities in terms of magnitude, spatial extent and temporal duration (see EFSA 2010; Nienstedt 2012, EFSA 2016c). Consequently ecological recovery, the return of an ecological entity (e.g. population) to its normal operating range (e.g. for an attribute such as population abundance), indicating the absence of long-term effects, may be used as an alternative decision criterion for plant protection products under PPPR (Hommen et al 2010; EFSA 2016a). For example, if the test system also contains vulnerable representatives of the potential sensitive taxonomic group(s), recovery within eight weeks is generally considered to be acceptable for plant and invertebrate animal populations and communities, following the simulated seasonal application of plant protection products (EFSA 2013a). However, recovery from short-term exposures to plant protection products may take longer for species with slow population growth and/or recolonization rates (Moe et al 2013) and for isolated populations and/or more complex communities (EFSA 2016a). For example in some vulnerable or endangered species, recovery may take up to three to five generations (Kattwinkel et al 2012; IUCN 2015).

Retrospective approaches

According to retrospective assessments under COMAH, the ecological significance of chemical spills is gauged against threshold periods of 1 year for water bodies and 3 years for terrestrial habitats, or longer for more 'severe' impacts qualifying as 'major accidents to the environment' (CDOIF 2013). In any event, when attempting to define recoverable or acceptable ecological effects versus unacceptable, adverse effects, it is crucial to recognise that "ecosystems change, including species composition and population abundance" (Malawi Principle 9: CBD SBSTTA 2000). Retrospective environmental assessments (Tables 3 and 4) have the advantage of historical baselines for established 'reference' sites, which are capable of quantifying natural variability, including random stochastic variation, natural succession, seasonal cycles and long-term climate change. Each of these factors can influence individual survival, growth, reproduction and movement/migration, population abundance and biomass, community and ecosystem composition. Therefore, unless their influences are quantified, these factors have the potential to confound the environmental assessment of chemical effects (Underwood 1991; Moe et al 2013). Ecological baselines are fundamental to environmental quality assessment under the Water Framework Directive (WFD) (2000/60/EC), Marine Strategy Framework Directive (MSFD) (2008/56/EC), Oslo Paris Convention 1992 (OSPAR) (Table 4) and the Thematic Soil Strategy (TSS) (COM/2006/0231, COM/2006/0232) (Table 3) and retrospective evaluation of chemical impacts under the ELD and COMAH (Table 3).

There is considerable potential for retrospective assessment to inform prospective ERA, including via the derivation and validation of specific protection goals. However, the metrics used to quantify environmental effects in the field (biological entity, attribute, magnitude of effect, temporal and geographical scale of the observed change) are unlikely to match all of those measured prospectively in regulatory tests, particularly those conducted in the laboratory.

ALTERNATIVE APPROACHES FOR DEFINING ENVIRONMENTAL PROTECTION GOALS

The need for a more holistic approach

The traditional threshold effect approach employed in ERA, which aims to protect the most sensitive species in the wild by accepting only negligible population effects, may fail to deliver the aspirational goals set by environmental legislation for protecting biodiversity, ecosystems or 'the environment as a whole', for a number of reasons. Although populations are widely considered to be the 'operational taxonomic units' of choice for species protection and conservation (IUCN 2015), they may not always be the most suitable for ecosystem-level protection. This is due to lack of consideration of ecological integrity, species interactions (Slocombe 1993) and other ecological interactions and selective pressures, which promote evolutionary divergence within and between species (Sneath and Sokal 1973), potentially affecting their susceptibilities to chemicals (Brown et al 2009; 2014). Consequently, no single model species or population will be the most susceptible to all chemicals and protective of all other species and populations, and therefore a more holistic approach is called for. Furthermore, the operational taxonomic units of species and populations cannot be applied readily to micro-organisms due to lack of discrimination and understanding of the population ecology of individual species (Koeppel and Wu 2013). Microbes are a critical component of ecosystems. They constitute 25-50% of global biomass (Whitman et al 1998; Kallmeyer et al 2012) and provide an enormous pool of biological and genetic diversity supporting numerous ecosystem services ranging from water purification to climate regulation (Millennium Ecosystem Assessment (MEA) 2005). Therefore, rather than relying on more traditional 'population ecology' metrics for microbial communities, it may be argued that protection goals based on microbial meta-genomic and/or functional trait diversity would be more relevant. Trait-based approaches (Baird et al 2008; De Bello et al 2010) may be used more widely to discriminate the ecological functions and the sensitivities of other plant and animal groups (and life-stages), potentially providing greater resolution in exposure and effects assessment in ERA. However, trait evolution, particularly the evolution of life-history traits may vary considerable from place to place, even for the same species (Spromberg and Birge 2005), thus highlighting the need for spatially explicit ERA.

The benefits of adopting a more holistic and spatially explicit ecosystem approach for chemical ERA have been articulated recently in EFSA's "Scientific opinion on the development of specific protection goal options for environmental risk assessment of pesticides" (EFSA 2010; Nienstedt et al 2012) and in the EC's discussion paper "Addressing the new challenges for risk assessment" (EC 2012a). Crucially, the ecosystem approach takes into account: variability in chemical exposure (temporal and spatial); variability of ecosystems and their vulnerability to stressors; interactions of toxicants with other environmental factors; ecological interactions within and between species. In contrast with the traditional threshold effect (PNEC) approach, which aims to protect all species/populations everywhere, the ecosystem approach helps determine SPGs for ecological entities and attributes, which are representative and require protection at specific locations. The argument for defining SPGs for different habitats is that goals will be more environmentally relevant and they will take into account other locally acting stressors and constraints, in addition to the chemical(s) being risk assessed.

Development of the ecosystem approach

The concept of the ecosystem approach dates back to the 1950s (Waylen 2014) and, alongside economic and social development, is seen as integral to the sustainable management of Earth's biological resources according to the United Nations (UN) Convention on Biological Diversity (CBD 1992). Crucially, the ecosystem approach recognises the importance of sustainable, self-organising and complex ecosystems, which maintain a degree of stable functioning across time, and that a system is healthy if it maintains its complexity and capacity for self-organisation (Norton 1992). Over the last two to three decades, the terms ecosystem management, ecosystem approach and latterly the ecosystem services approach (Table 6) have been used increasingly and often inter-changeably, despite the subtle differences between these terms (Waylen et al 2014).

The importance of protecting ecosystem services (or amenities) from chemical exposure has been recognised for several decades. For instance, the UN's Group of Experts on the Scientific Aspects of Marine Pollution (GESAMP 1986) defined marine pollution as: "The introduction by man, directly or indirectly, of substances or energy into the marine environment (including estuaries), which results in such deleterious effects as harm to living resources, hazards to human health, hindrance to marine activities including fishing, impairment of quality for use of sea water and reduction of amenities". This definition remains largely unchanged under the current MSFD: "Direct/indirect introduction (via human activity) into the marine environment, of substances or energy, or underwater noise, resulting in (or likely resulting in) deleterious effects to living resources and marine ecosystems, including; biodiversity loss, human health hazards, hindrance of marine activities, impaired sea water quality, or general impairment of sustainable marine goods and services use". A key point, which is often overlooked in the current EU regulatory context, is that chemicals only represent one type of stressor that can impact on these ecosystem service protection goals.

Despite the maturity of the ecosystem service concept and its relevance to environmental regulation, current definitions of ecosystem-level protection goals in ERA remain blurred. For example, the protection of ecosystem structure and function are both commonly referred to in EU environmental and chemical regulations (Figure 1, Table 2). This is understandable given that ecosystem structure and function (including resilience / integrity) are intrinsically linked (Malawi Principle 5: CBD SBSTTA 2000). However, whereas protection of ecosystem function takes into account functional redundancies among similar species, the explicit protection of ecosystem structure, incorporating all species, is far more demanding (EFSA 2014). By focusing on functional groups or service-providing units (SPUs), the derivation of ecosystem service-based protection goals would undoubtedly be more transparent and environmentally focused than the current paradigm, which attempts to protect all species' populations, everywhere, all of the time.

Ecosystem services approach

In general terms, the ecosystem services approach involves establishing the linkages between ecosystem structures and process functioning and between different types of ecosystems and habitats in the landscape, which are essential for the maintenance of service providing units, which in turn contribute directly or indirectly to valued human welfare benefits (Turner and Daily 2008) (Table 6). The main perceived benefits of adopting such an approach in ERA include: (i) Improved linkage between ERA and risk management by focusing on protection of entities that matter to people (EC 2013); (ii) Systematic and transparent identification of specific protection goals for ecosystems and biodiversity, which require protection according to recent or recently amended EU regulations (e.g. BPR, ELD, PPR) (Tables 1-3); (iii) Quantification of potential environmental impacts, taking into account ecological trade-offs and spatial variation, acknowledging that delivery of all ecosystem services cannot be maximized at the same place and time e.g. food production is maximised in agricultural systems at the expense of some other services (EFSA 2010); (iv) Quantification of socio-economic impacts and trade-offs following the valuation of ecosystem services (Hanley and Barbier 2009).

The utility of the ecosystem services approach for weighing the environmental risks versus the benefits of chemicals is perhaps most apparent for PPPs, since their benefits in terms of safeguarding or enhancing crop yields in managed agricultural systems can be assessed directly against their positive and negative impacts on the surrounding landscape (EFSA 2010; Nienstedt et al 2012). However, the ecosystem services approach also has potential application in other chemical sectors, whose products offer socio-economic and environmental benefits, including supporting or enhancing ecosystems services. For example, biocidal products designed for water purification, pest regulation and invasion resistance, and medicinal products used for control or treatment of disease. Like pesticides, some chemicals are deliberately applied to the environment at specific locations (e.g. oil dispersants, biofouling agents), while others are emitted to air and/or discharged in waste streams during production or after use. Therefore chemical impacts may sometimes occur downstream in the environment, rather than in proximity to their use or disposal, and consequently trade-offs between risks and benefits may be more difficult to assess. Nevertheless, the identification of key service providing units (e.g. non-target species assemblages, functional groups or populations), which may be vulnerable to chemical exposure, enables specific protection goals to be identified where ecosystem services are most likely to be affected, both spatially and ecologically (i.e. at the population, functional group, community or habitat level). Depending on the service providing units and ecological entities identified, there may be a need to develop a range of ecological scenarios, representing spatial variations in the environment, and novel assessment endpoints and methods for operationalising ecosystem service-based specific protection goals (Munns et al 2015). Therefore adopting an ecosystem services approach will better target ERA and may reduce assessment costs for PPPs, but could increase assessment costs for other chemical sectors compared to existing cost estimates (CSES 2012; ECPA 2013), if novel higher tier testing is required.

CONCLUSIONS AND RECOMMENDATIONS

Regulations and guidelines for chemical environmental risk assessment (ERA) and environmental impact assessment (EIA) have consistent, high level, aspirational goals for protecting the environment as a whole, including biodiversity and ecosystems. Whereas generic population- and ecosystem-level protection goals are common to all chemical sectors, specific protection goals (SPGs) are conspicuously lacking. The lack of SPGs in prospective ERA is largely a consequence of environmental variability and uncertainty in defining acceptable versus unacceptable (adverse) effects. Ultimately the lack of scientific consensus on the acceptability of environmental effects in

ERA leads to reliance on the precautionary principle, which places the burden of proof of chemical safety on industry. In turn, all chemical sectors rely on generic predicted no-effect concentrations (PNECs), which incorporate arbitrary safety margins to ensure the protection of ecological populations per se. Alternatively, specific protection goals (SPGs) are more evident in wider environmental / nature legislation, requiring environmental monitoring, impact assessment and retrospective ERA. The contrast between prospective and retrospective ERA is due mainly to the existence of tangible baselines or reference conditions, which, in the latter case, help to define acceptable versus unacceptable environmental effects. In some circumstances these SPGs are derived using a reductionist approach and rely on population-based indicators of ecosystem health (e.g. OSPAR), while, in others, SPGs are more holistic and therefore more in tune with the concept of the ecosystem approach (e.g. protection of entire habitat features under the Habitats Directive, or protection of aquatic ecological communities under the Water Framework Directive). An alternative, but not yet fully operational solution for deriving SPGs is the ecosystem services approach. This approach has been developed for plant protection products (PPPs) (EFSA 2010; Nienstedt et al 2012) and other chemical stressors that fall under the remit of EFSA (EFSA 2016c). The key advantages of the ecosystem approach are that it enables a holistic and transparent assessment of the possible environmental effects of PPPs from the near-field to the landscape scale, by identifying ecological entities, attributes and associated ecosystem services that require protection. The approach also accounts for spatial variability, taxonomic diversity and functional redundancy in ecosystem service provision. However, it is recognised that further work is required to quantify acceptable levels (magnitudes) of effects on ecosystem services, taking into account temporal (as well as spatial) variation in capacity and resilience (integrity) in service provision. We suggest that better protection of the environment as a whole could be facilitated by developing and, where appropriate, adapting the EFSA Ecosystem Services approach (EFSA 2010; EFSA 2016c) for use with chemicals other than those that fall under the remit of EFSA. To initiate this process we therefore recommend that case studies are undertaken to evaluate the potential of the ecosystem services approach to derive SPGs for a range of chemicals from basic industrial chemicals to specialty chemicals and designer consumer care products.

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Figure 1: EU environmental legislation and international agreements regulating chemicals cited in tables: Table 2 (red boxes); Table 3 (red/green boxes); Table 4 (green boxes)

[Adapted with permission from the European Oil Industry Federation CONCAWE]

Box 1: Major sources of uncertainty in ERA

Natural background variability in the environment
• Spatial variation, including geology, topography / bathymetry, habitat and climate.
• Temporal variation, including environmental stochasticity, diurnal and seasonal cycles, longer-term environmental change e.g. climate change.
Representation of chemical exposure profiles
• Numerous possible environmental exposure scenarios, influencing both the exposure (environmental fate, bioavailability) and effects of chemicals.
• Spatial and temporal variability associated with chemical exposures. (Constant exposure is normally assumed in ERA).
Extrapolation of chemical effects
• Laboratory to field extrapolation i.e. from ecotoxicological tests conducted under controlled conditions (generally in the laboratory) to populations in the wild.
• Endpoint extrapolation from organism-level effects to population-level effects and above.
• Species extrapolation from a few sensitive 'model' species to all species in the environment, beset by inter-species and intra-species (i.e. inter-population and site-specific) variation in vulnerability to chemicals.
Ecological factors, including interactions
• Variation in species' ecological life-histories, which influence chemical exposure, effects and recovery.
• Interactions among different stress factors (physical, biological and other chemical factors) that may affect ecosystem health and interact with chemical effects.
• Interactions among individuals, populations and biological communities potentially leading to indirect ecological exposures (e.g. bioaccumulation and biomagnification) and chemical effects within food chains and ecosystems.

Adapted from Chapman 2002; Hommen et al 2010; EC 2012a.

Table 1: Environmental principles adopted in the prospective and retrospective ERA of chemicals - requiring environmental protection goals at different levels of biological organisational (underlined) (Adapted from Brock et al 2006; Beder 2006)

Environmental principle	Description	Definitive text / source
Prospective risk assessment		
Precautionary principle	Avoid any pollution of the environment and ecosystems - occurrence of damage is uncertain and cannot be predicted clearly.	« Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. » (UN Rio Declaration on Environment and Development (CBD 1992), Principle 15).
Pollution prevention principle	Prevent pollution of the environment and ecosystems i.e. prevent pollution at source, minimise environmental damage, reduce risk of harm, avoid transboundary pollution - occurrence of damage is probable if no measure is taken to reduce pollutant load or concentration below a safe threshold.	International – « States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction. » (UN Stockholm Declaration on the Human Environment (1972): Principle 21). National – « The principle of preventive and curative action, as a priority at source, of damage to the environment and this by using best available techniques at reasonable costs » (French Environmental Code: Article L 110-1 para. II).
Ecological threshold option	To protect populations of aquatic organisms, effects assessment schemes are developed that allow derivation of regulatory acceptable concentrations on the basis of: The ecological threshold option (ETO), accepting negligible population effects only.	EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters EFSA (2013a).
Ecological recovery option	The ecological recovery option (ERO), accepting some population-level effects, if ecological recovery takes place within an acceptable time period.	EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters EFSA (2013a).
Community recovery principle	The abundance and structure of natural populations and communities vary in space and time- reductions in population abundance are tolerable as long as they are within the natural range of variability, and the recovery of populations is likely, whereas long-term effects are unlikely.	« EU Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species. » Uniform principles for evaluation and authorisation of plant protection products (PPPs) (EU Regulation (546/2011) Annex Part 1 C) (EC 2011c).
Functional redundancy principle	A decrease in biodiversity might be tolerated for some situations or ecosystems, as long as the ecological function is maintained.	« Owing to ecological redundancy, ecosystem structural endpoints are generally more sensitive to PPP application than functional endpoints » (EFSA 2014). « Ecosystem functioning and resilience depends on ecosystem structure, dynamic relationships

Environmental principle	Description	Definitive text / source
		within species, among species and between species and their abiotic environment, as well as the physical and chemical interactions within the environment. The conservation and, where appropriate, restoration of these interactions and processes is of greater significance for the long-term maintenance of biological diversity than simply protection of species (biodiversity) » (UNEP 1998: Malawi Principle 5).
Retrospective risk assessment		
Polluter pays principle	Environmental abatement, mitigation and/or clean-up costs for significant environmental pollution / damage must be met by the polluter.	« In the event of any incident or accident significantly affecting the environment, Member States shall take the necessary measures to ensure that … the operator immediately takes the measures to limit the environmental consequences and to prevent further possible incidents or accidents … take any appropriate complementary measures that the competent authority considers necessary to limit the environmental consequences and to prevent further possible incidents or accidents » EU Industrial Emissions Directive (IED) (2010/75/EU).

Table 2: EU legislation and international agreements with ecological protection goals relating to chemicals and requiring prospective ERA for product registration/authorisation

<table>
<tr><th rowspan="2"></th><th colspan="5">European Legislation</th><th>International Agreement</th></tr>
<tr><th>Registration Evaluation Authorisation and restriction of Chemicals [REACH] Regulation
EC 1907/2006</th><th>Plant Protection Products Regulation [PPPR]
EC 1107/2009</th><th>Biocidal Products Regulation [BPR]
EU 528/2012</th><th>Medicinal Products for Human Use Directive [MPHU]
2001/83/EC</th><th>Medicinal Products for Veterinary Use Directive [MPVU]
2009/9/EC</th><th>Strategic Approach to International Chemicals Management [SAICM] 2006</th></tr>
<tr><td rowspan="2">High-level protection goals</td><td colspan="3">Protect human (and animal [PPPR, BPR]) health and the environment via the Precautionary Principle</td><td colspan="2" rowspan="2">- Prevent undesirable environmental effects due to the use and/or disposal of human [MPHU] / veterinary [MPVU] medicinal products
- Assess environmental impacts for all new marketing authorisations, indications and extensions</td><td rowspan="2">Manage chemicals to minimise significant adverse human health and environmental effects by 2020</td></tr>
<tr><td>No significant adverse effects in any environmental compartment</td><td colspan="2">No unacceptable environmental effects, including impacts on biodiversity and the ecosystem</td></tr>
<tr><td rowspan="2">Chemical protection goals (incl. chemical contamination in biota / food chains)</td><td colspan="3">Chemical hazard:
(a) human health effects; (b) physico-chemical properties; (c) environmental effects; d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) chemicals
- Apply restrictions
- Substitute higher risk substances with lower risk alternatives</td><td>Chemical hazard:
- Screen for PBT hazards in lipophilic active pharmaceutical ingredients (i.e. with log K_{ow} >4.5) and those constituting potential endocrine disruptors (i.e. affecting reproduction at concentrations <0.01 μg/L).</td><td>Chemical hazard: [see MPHU, PPPR, BPR]
- Extra requirements for products containing genetically modified organisms</td><td rowspan="2">- Prevent use of high risk chemicals by 2020
- Minimise release of high risk chemicals by 2020
- Reduce hazardous waste generation, and ensure hazardous waste management
- Substitute high risk chemicals with lower risk alternatives</td></tr>
<tr><td colspan="5">- Risk assessment and exposure mitigation of active substances (incl. micro-organisms [BPR]), relevant major metabolites (≥10% of parent and/or with comparable toxicity to parent compound), and risk assessment of formulated products [BPR, PPPR]. Specific measures for PPPs [Sustainable Use of Pesticides Directive: SUPD] to minimise/prevent exposures to statutory protected areas [BD, HD, WFD (see Table 3)], the aquatic environment, drinking water supplies and sewage systems
- Maximum residue limits set for food (treated animals and excreta [MPVU]), soil and groundwater</td></tr>
<tr><td>Ecological protection goals</td><td>No significant adverse effects on ecological populations, food chains and communities</td><td colspan="4">No unacceptable effects in non-target species [PPPR, MPVU] / any compartment [BPR, MPHU]; surface waters, groundwater, soil, air [PPPR, MPVU], sewage treatment plants [BPR, MPHU], excreta [MPVU]</td><td>Protect vulnerable ecosystems in decision making</td></tr>
</table>

<table>
<tr><th rowspan="2"></th><th colspan="5">European Legislation</th><th>International Agreement</th></tr>
<tr><th>Registration Evaluation Authorisation and restriction of Chemicals [REACH] Regulation
EC 1907/2006</th><th>Plant Protection Products Regulation [PPPR]
EC 1107/2009</th><th>Biocidal Products Regulation [BPR]
EU 528/2012</th><th>Medicinal Products for Human Use Directive [MPHU]
2001/83/EC</th><th>Medicinal Products for Veterinary Use Directive [MPVU]
2009/9/EC</th><th>Strategic Approach to International Chemicals Management [SAICM] 2006</th></tr>
<tr><td rowspan="2">Ecological entities considered</td><td colspan="6">Non target organisms (aquatic and terrestrial); plants, invertebrates (incl. dung organisms [MPVU]), vertebrates, soil micro-organisms [PPPR, BPR, MPVU], microbiological activity of sewage treatment plants [REACH, MPHU]</td></tr>
<tr><td>Organisms representing relevant exposed compartments</td><td>Target organisms (plant products)</td><td>Target organisms</td><td>(see REACH column)</td><td>Target organisms (animals)</td><td>(see REACH column)</td></tr>
<tr><td rowspan="2">Assessment criteria (critical attributes) identified for ecological entities</td><td>Direct effects:
- Survival, growth, development, reproductive success, function (microbial activity, respiration, biodegradability)</td><td colspan="2">Direct effects:
Non-target species acute or chronic effects, incl.
- survival and development
- harmful effects on animal health
- behavioural effects</td><td colspan="3">Direct effects:
(see REACH column)</td></tr>
<tr><td colspan="6">Indirect effects: Secondary poisoning via the food chain (all); evolution of resistance incl. anti-microbial resistance [BPR, MPHU, MPVU]</td></tr>
<tr><td rowspan="2">Assessment endpoints / indicators (measured / monitored)</td><td>Risk Characterisation Ratio compares predicted environmental concentration (PEC) with generic, multi -species and -trophic level predicted no effect concentration (PNEC) (see EU TGD)</td><td>Toxicity Exposure Ratios compare predicted exposure concentration with effect concentrations for a range specific endpoints spanning microbe function (e.g. nitrogen cycling) to individual health parameters (e.g. bird’s egg shell thickness)</td><td colspan="4">Risk Characterisation Ratio compares the predicted environmental concentration (PEC) with the generic, multi -species and -trophic level predicted no effect concentration (PNEC) (see EU TGD)</td></tr>
<tr><td colspan="6">Assessment endpoints are stipulated in approved test guidelines referred to in the EU Technical Guidance Document (TGD) and sector-specific guidance</td></tr>
<tr><td rowspan="2">Indicator targets / thresholds for acceptable versus unacceptable effects or status</td><td colspan="6">Adopt ecological threshold principle in EU TGD - use PEC/PNEC <1</td></tr>
<tr><td></td><td>Ecological recovery option may also be applied</td><td colspan="2">Retrospective risk assessment via: information on adverse environmental effects [BPR]; eco-pharmacovigilance [MPHU] (see Pharmacovigilance Regulation EU 1235/2010)</td><td></td><td></td></tr>
</table>

Table 3: EU legislation and international agreements with ecological protection goals relating to chemicals and requiring prospective ERA and/or retrospective environmental surveillance, monitoring and impact assessment

	European Legislation									**International Convention**
	Environmental Liability Directive [ELD] 2004/35/CE	**Control of Major Accident Hazard Directive [COMAH] 2012/18/EU**	**Sewage Sludge Application Directive [SSAD] 86/278/EEC**	**Air Quality Framework Directive [AQFD] 2008/50/EC**	**Groundwater Protection Directive [GPD] 2006/118/EC**	**Environmental Quality Standards Directive [EQSD] 2008/105/EC**	**Industrial Emissions Directive [IED] 2010/75/EU**	**European Pollutant Release and Transfer Register [E-PRTR] Regulation EC 166/2006**	**Thematic Soil Strategy [TSS] COM/2006/0231 COM/2006/0232**	**Stockholm Convention [SC], 2001**
High-level protection goals	Prevent (and remedy): Environmental damage ('Polluter pays' principle) [ELD]; major accidents ('Precautionary principle') [COMAH]; human health and environmental hazards associated with sewage sludge; soil and agricultural product quality impairment [SSAD]			Protect human health and the environment as a whole		- Reduce priority substance pollution	- Protect human health and the environment as a whole - Remedy environmental damage	- Provide public access to information on pollutant releases and off-site transfers, and track trends	- Protect soil & sustainable use - Preserve soil functions - Manage soil use and risks	- Protect human health and the environment from Persistent Organic Pollutants (POPs)
				- Combat atmospheric emissions at source - Set ambient air quality objectives						
					Prevent, reduce and/or remediate (via the 'Precautionary' and 'Polluter pays' principles): Deterioration and chemical pollution of groundwater [GPD]; environmental damage at source from priority hazardous substance emissions [EQSD]; industrial pollution [IED]; pollution and human health impacts [E-PRTR], soil degradation [TSS], harmful impacts of POPs, including transboundary impacts requiring international cooperation, conciliation and funding [SC]					
Chemical protection goals (focusing on chemical	Prevent and/or remedy release of Classification Labelling and Packaging Regulation [CLPR] (EC 1272/2008) and [COMAH] -listed dangerous substances		Set limit values for listed substances		Maintain good groundwater chemical status via: - Limiting	- Set Environmental Quality Standards (EQSs) for	Integrated approach: - Set industry emission limit values (ELVs)	Threshold pollutant release values (loads) for reporting	- Address soil contamination at source - Identify, monitor and	- Eliminate production / use and properly dispose / remediate POPs
			Minimum	Set critical						

	European Legislation									International Convention
	Environmental Liability Directive [ELD] 2004/35/CE	**Control of Major Accident Hazard Directive [COMAH] 2012/18/EU**	**Sewage Sludge Application Directive [SSAD] 86/278/EEC**	**Air Quality Framework Directive [AQFD] 2008/50/EC**	**Groundwater Protection Directive [GPD] 2006/118/EC**	**Environmental Quality Standards Directive [EQSD] 2008/105/EC**	**Industrial Emissions Directive [IED] 2010/75/EU**	**European Pollutant Release and Transfer Register [E-PRTR] Regulation EC 166/2006**	**Thematic Soil Strategy [TSS] COM/2006/0231 COM/2006/0232**	**Stockholm Convention [SC], 2001**
contamination in biota / food chains)	Prevent and/or remedy release of: [WFD, CLPR, PPPR, BPR] -listed hazardous substances		periods following sludge application before use of pasture or harvesting of crops	values which may directly affect some receptors, but not humans	pollutant input - Preventing [WFD, CLPR, PPPR, BPR] - listed hazardous substance input	priority substances and priority hazardous substances	- Adopt best available techniques (BAT)		remediate historically contaminated sites [via ELD]	listed in Annex A - Minimise (using BAT) exposure from production and use of POPs in Annex B & C
Ecological protection goals	No adverse impact on: - Biodiversity: Natural habitats and protected species - Water: Ecological quality or potential. - Land: natural resources and services affecting human health	Avoid permanent or long-term damage to: - Terrestrial habitats - Freshwater habitats - Marine habitats - Groundwater	Prevent contamination of: - Agricultural crops - Livestock	Avoid, prevent or reduce harmful effects on: - Vegetation - Natural ecosystems	Conserve groundwater quantity, chemical quality, and dependent ecosystems	Prevent chemicals from causing: - Acute and chronic aquatic toxicity - Accumulation in the ecosystem - Habitat and biodiversity loss - Threats to human health	Report: Direct emissions to: - Air - Water Indirect emissions to land	Report releases to: - Air - Water - Land	Protect soil structure and function (incl. ecosystem services)	Prevent adverse effects to human health and the environment, incl. from toxicological interactions involving multiple chemicals
Ecological entities considered	Listed protected species & natural habitats ([ELD]: biodiversity; [COMAH]: terrestrial) [WFD] (Annex V) listed biological quality elements Land: resources and services	Agricultural habitats	- Agricultural crops - Livestock	- Vegetation - Natural ecosystems	Groundwater: - As a resource - Ecosystems - Dependent ecosystems - River basin management	Aquatic biota	None specified	None specified	Soil associated ecosystem services	Humans: Arctic indigenous communities, pregnant women. Arctic eco-systems: incl. top predators (due to

	European Legislation									**International Convention**
	Environmental Liability Directive [ELD] 2004/35/CE	**Control of Major Accident Hazard Directive [COMAH] 2012/18/EU**	**Sewage Sludge Application Directive [SSAD] 86/278/EEC**	**Air Quality Framework Directive [AQFD] 2008/50/EC**	**Groundwater Protection Directive [GPD] 2006/118/EC**	**Environmental Quality Standards Directive [EQSD] 2008/105/EC**	**Industrial Emissions Directive [IED] 2010/75/EU**	**European Pollutant Release and Transfer Register [E-PRTR] Regulation EC 166/2006**	**Thematic Soil Strategy [TSS] COM/2006/0231 COM/2006/0232**	**Stockholm Convention [SC], 2001**
	unspecified				plans under [WFD]					biomagnification)
Assessment criteria (critical attributes) identified for ecological entities	Biodiversity Long-term maintenance of: - Distribution/area - Structure - Habitat function - Survival - Species density Water: See [WFD] Annex V Land: See [ELD] Annex 1	- (See [ELD] column) - See domestic guidance within Member States (MSs)	Chemical concentrations and loads in; soil [SSAD], air [AQFD], groundwater [GPD]		Groundwater quantity criteria	Chemical criteria in: - Water (primarily) - Sediment - Biota	- ELVs for water and air - Baselines for monitoring - Soil and - Groundwater contamination	Chemical (loads) for releases to: - Air - Water - Land	Long-term maintenance of soil: - Structure - Function	-Bioconcentration /accumulation factors (measured or predicted using Log K_{ow}) - Reproductive health
Assessment indicators measured / monitored	- Number of individuals - Density / area - Functions of natural resources affected - Species / habitat rarity (local to regional level) - Population dynamics - Human health impacts		Chemicals only (see Annexes 1A, 1B and 1C [SSAD]; Annexes II & XIII [AQFD])		Chemicals and conductivity in groundwater [GPD], water [EQSD] (see Annexes I & II)	- Chemicals in biota (see Article 3)	Chemicals only (polluting substances listed in Annex II)		Indicators likely linked to main threats	- Presence, levels and trends in humans and environment - Transport, fate transformation - Effects on human health and environment (including reproductive health)
Indicator targets /	Effects assessed against 'baseline	- Significant damage	Chemicals only (see Annexes 1A, 1B and 1C [SSAD];		Chemicals and conductivity in	EQSs represent: - Annual	Chemicals only (see ELVs in Annexes V-VIII [IED]; Annex II		Thresholds and scope still	- Persistence threshold (half-life

	European Legislation									**International Convention**
	Environmental Liability Directive [ELD] 2004/35/CE	**Control of Major Accident Hazard Directive [COMAH] 2012/18/EU**	**Sewage Sludge Application Directive [SSAD] 86/278/EEC**	**Air Quality Framework Directive [AQFD] 2008/50/EC**	**Groundwater Protection Directive [GPD] 2006/118/EC**	**Environmental Quality Standards Directive [EQSD] 2008/105/EC**	**Industrial Emissions Directive [IED] 2010/75/EU**	**European Pollutant Release and Transfer Register [E-PRTR] Regulation EC 166/2006**	**Thematic Soil Strategy [TSS] COM/2006/0231 COM/2006/0232**	**Stockholm Convention [SC], 2001**
thresholds for acceptable versus un-acceptable effects or status	condition', considering: - 'Favourable Condition Status' for habitats [HD] Article 1 - Natural species and habitat fluctuations - Recovery potential	defined in [ELD] Annex 1 - Area and duration of major accidents [COMAH Annex VI]	Annexes II & XIII [AQFD]		groundwater (see Annexes I & II)	averages for long-term protection - Maximum allowable concentrations for short-term protection from chemical exposure	[E-PRTR])		under development	in months) water 2, soil 6, sediment 6 months Bioconcentration / accumulation factor 5000 (or Log K_{ow} 5)

Table 4: EU legislation and international agreements with ecological protection goals also affecting chemicals and requiring prospective ERA and/or retrospective environmental surveillance, monitoring and impact assessment (Adapted from JNCC/DEFRA 2014)

	European Legislation				**International Conventions**			
	Marine Strategy Framework Directive [MSFD] 2008/56/EC	**Habitats Directive [HD] 92/43/EEC**	**Birds Directive [BD] 79/409/EEC**	**Water Framework Directive [WFD] 2000/60/EC**	**Convention on Biological Diversity [CBD] (1992)**	**OSPAR Convention [OSPAR] 1992**	**Bonn Convention on Migratory Species [CMS] 1979**	**Convention on the Law of the Sea [UNCLOS] 1982**
High-level protection goals	Achieve 'Good Environmental Status' (GES) in marine waters by 2020 Take action at source to avoid pollution	Maintain / restore natural habitats and species of Community interest to 'Favourable Conservation Status' (FCS) Establish Natura 2000 Special Areas of Conservation network	Conserve, protect and manage all wild birds species, and set rules for their exploitation Establish Special Protection Areas (SPAs)	Protect, enhance and restore all surface water bodies Achieve good surface water status by 2015 and 2027	Conserve biological diversity, ensure sustainable use and fair and equitable sharing of benefits of genetic resources	Prevent and eliminate pollution, protect the OSPAR maritime area against adverse effects of human activities	Conserve migratory species and their habitats Agreements between Range States to conserve species listed in Appendix II	Provide law and order in the world's oceans and seas Protect and preserve the marine environment and exploit resources in accordance with this Prevent, reduce and control marine pollution
Chemical protection goals (focusing on chemical contamination in biota / food chains)	GES descriptors: (2010/477/EU) 8. Contaminant levels don't give rise to pollution effects. 9. Contaminant levels in fish/ shellfish are safe for human consumption	Not defined	Not defined	Achieve 'Good Chemical Status' by 2015 and 2027 (see Sections 1.2 and 2.3)	Not defined	Reduce environmental inputs and concentrations of Priority Hazardous Substances. Prevent pollution by continuous reduction of discharges.	Not defined	Prevent, reduce and control marine pollution
Ecological protection goals	Prevent significant impacts / risks to marine biodiversity, ecosystems, human health or legitimate	See [HD] FCS assessment criteria targets (see [HD] Annex E and EU Guidance (EC 2011c)	Maintain species population levels to meet ecological, scientific,	Achieve good ecological status by 2015 and 2027 (see [WFD] Annex V and Section 1.2)	2011-2020 Strategic Plan: 20× 'Aichi' Biodiversity Targets for 2015	Regional Assessment defines % targets for criteria used in the QSR regional assessment	Long-term species viability No range reduction Sufficient	Not defined

	European Legislation				International Conventions			
	Marine Strategy Framework Directive [MSFD] 2008/56/EC	**Habitats Directive [HD] 92/43/EEC**	**Birds Directive [BD] 79/409/EEC**	**Water Framework Directive [WFD] 2000/60/EC**	**Convention on Biological Diversity [CBD] (1992)**	**OSPAR Convention [OSPAR] 1992**	**Bonn Convention on Migratory Species [CMS] 1979**	**Convention on the Law of the Sea [UNCLOS] 1982**
	uses of the sea		cultural and economic requirements		or 2020 Contracting Parties may set individual targets	process (see Tables A2.1 and A3.1 (OSPAR 2009))	habitat for long-term population maintenance	
Ecological status classes	GES Sub-GES	Favourable Unfavourable (inadequate/bad)	Not defined	Ecological status: High, Good, Moderate, Poor, Bad	Not defined	Good Moderate Poor	Not defined	Not defined
Ecological entities considered	All EU marine biodiversity (see Annex III, Table 1)	[HD] -listed natural habitats and species (see Annexes I, II, IV and V)	All naturally occurring wild birds species (see Annexes I, II and III)	Biological quality elements (see Section 1.2.1)	All biological diversity	All North-East Atlantic maritime habitats and species	[CMS] -listed migratory species (see Appendix I and II)	Vulnerable, rare or declining marine habitats and species (globally) Migratory species
Assessment criteria (critical attributes) identified for ecological entities	GES descriptors (2010/477/EU) for biodiversity and ecosystems: 1.Marine biodiversity 2. Invasive alien species (IAS) 4. Marine food web structure, abundance 6. Sea bed ecosystem integrity – structure & function	Habitat: - Range, area, structure and function Species: - Range, habitat, population size and condition	- Population size and trends - Breeding distribution and range size / trends - Main pressures and threats - SPA coverage and conservation	Biological quality elements (see Section 1.1)	Strategic goals EU 2011-2020: Maintain/restore 1. Biodiversity 2. Ecosystems and services 3.Sustainable agriculture and forestry 4. Sustainable fisheries 5. Control of IAS	Habitat: - Range, extent, condition Species: - Range, population size and condition	Population dynamics and viability Species: - Range, habitat, distribution and abundance	Not defined
Assessment indicators measured / monitored	GES descriptors 1,4,6,8,9 (2010/477/EU) (See details in EC, 2010)	No EU-level indicators UK: Common Standards Monitoring for protected sites and FCS indicators.	Not defined	Indicators determined via intercalibration across MSs (see WFD-TAG UK classification tools WFD-TAG 2014)	Indicators under development likely to include: - Breeding bird populations - Priority species and habitats - Protected areas	-Seal population trends -Harbour porpoise by-catch -Fisheries spawning stock biomass and size -Eutrophication	Not defined	Not defined

	European Legislation				**International Conventions**			
	Marine Strategy Framework Directive [MSFD] 2008/56/EC	**Habitats Directive [HD] 92/43/EEC**	**Birds Directive [BD] 79/409/EEC**	**Water Framework Directive [WFD] 2000/60/EC**	**Convention on Biological Diversity [CBD] (1992)**	**OSPAR Convention [OSPAR] 1992**	**Bonn Convention on Migratory Species [CMS] 1979**	**Convention on the Law of the Sea [UNCLOS] 1982**
					- Sustainable fisheries - Invasive species - Marine ecosystem integrity	-Imposex -Oiled sea birds -Hazardous substance levels in seabird eggs -Plastic particle levels in fulmar stomachs		
Indicator targets / thresholds for acceptable vs unacceptable effects or status	Not defined	Not defined	Not defined	Class thresholds determined via inter-calibration across MSs within Geographic Inter-calibration Groups	Not defined	Each indicator (Ecological Quality Objective - EcoQO) has an associated target value for the North Sea Region only	Not defined	Not defined
Geographic scope	MS waters from baseline (excluding transitional waters) to Exclusive Economic Zone (EEZ), including extended continental shelf and [WFD] coastal waters	Designated habitats within MSs. Marine waters out to EEZs, including continental shelf, and [WFD] transitional and coastal waters	EU MS territory	All EU MS territory water bodies in river basins, including transitional and coastal waters one nautical mile from baseline	Within national jurisdiction limits of 193 Contracting Parties globally	North-East Atlantic maritime area	Any State that exercises jurisdiction over any part of the range of that migratory species	Territorial seas of coastal states out to 12 nautical miles from the baseline of 157 Contracting Parties
Baseline conditions	OSPAR Guidance: Conditions in line with prevailing physiographic, geographic and climatic conditions	EC Guidance: Favourable reference values Range and area viability (habitats), or range and population size (species) Can use a 1994 baseline (UK) or	Agreed baseline of 1979 for all MSs	Conditions that are not, or are minimally anthropogenically impacted (i.e. conditions specified for each water body / habitat type)	Varied baselines used and must be articulated for several targets within the 2011-2020 Strategic Plan for Biodiversity	EcoQOs use varied baselines: Threatened or declining habitats / species use historic, recent or current /rolling baseline QSR assessment uses former natural	Not defined within CMS. UK has used [HD] baselines for species also listed on that Directive	Not defined

	European Legislation				International Conventions			
	Marine Strategy Framework Directive [MSFD] 2008/56/EC	**Habitats Directive [HD] 92/43/EEC**	**Birds Directive [BD] 79/409/EEC**	**Water Framework Directive [WFD] 2000/60/EC**	**Convention on Biological Diversity [CBD] (1992)**	**OSPAR Convention [OSPAR] 1992**	**Bonn Convention on Migratory Species [CMS] 1979**	**Convention on the Law of the Sea [UNCLOS] 1982**
		historical data, where appropriate				conditions as baseline		

Table 5: Definitions of adverse (unacceptable, harmful) effects in international guidance and EU legislation concerning prospective ERA of chemicals

International guidance	Organism-level definition	Population to ecosystem-level definition
WHO/UNEP/ILO International Programme on Chemical Safety (IPCS) Online glossary of terms on chemical safety: http://www.ilo.org/legacy/english/protection/safework/cis/products/safetytm/glossary.htm	"Abnormal, undesirable or harmful effect to an organism, indicated by some result such as mortality, altered food consumption, altered body and organ weights, altered enzyme levels or visible (pathological) change. An effect may be classed as adverse effect if it causes functional or anatomical damage, causes irreversible changes or increases the susceptibility of the organism to other chemical or biological stress. A non-adverse effect will usually be reversed when exposure to the chemical ceases."	Definition not extended to populations
IPCS Risk Assessment Terminology Part 1 (IPCS 2004)	"Change in the morphology, physiology, growth, development, reproduction, or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences."	
EU Technical Guidance Document (TGD) on Chemical Risk Assessment (EC 2003)	Neurotoxicity, behavioural effects and endocrine disrupting effects.	Definition not extended to populations
	Adverse effects on microbial activity in sewage treatment plants. Adverse effects on soil functions such as filtration, buffering capacity and metabolic capacity.	
EU legislation and guidance	**Organism-level definition**	**Population to ecosystem-level definition**
Registration Evaluation Authorisation and restriction of Chemicals (REACH) Regulation EC 1907/2006 REACH Definitions and REACH Acronyms: http://www.reach-compliance.eu/english/REACH-ME/engine/sources/definitions.html	"Change in morphology, physiology, growth, development or lifespan of an organism which results in impairment of its functional capacity or impairment of its capacity to compensate for additional stress or increased susceptibility to the harmful effects of other environmental influences."	Definition not extended to populations
Plant Protection Products Regulation (PPPR) Article 4 (EC 1107/2009) Uniform principles for evaluation and authorisation of plant protection products PPPs Regulation (546/2011) Annex Part 1 C (EC 2011c)	"Impact on non-target species, including on the ongoing behaviour of those species." "Impact on biodiversity and the ecosystem." "Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species."	
EU legislation and guidance	**Organism-level definition**	**Population to ecosystem-level definition**
Criteria for identifying Endocrine Disruptors in the context of the implementation of the [PPPR] and [BPR]. EU ROADMAP 06/2014: http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf	"Change in morphology, physiology, growth, development or lifespan of an organism which results in impairment of its functional capacity or impairment of its capacity to compensate for additional stress or increased susceptibility to the harmful effects of other environmental influences."	Definition not extended to populations

Biocidal Products Regulation [BPR] (EU 528/2012) Guidance on the Biocidal Products Regulation, Volume IV Environment, Part B Risk Assessment (ECHA 2015)	"The protections goals for biocides have only been phrased in general terms but at present biocide risk assessment generally considers the population in the case of aquatic algae, vascular plants and invertebrates, individuals to populations in the case of vertebrates and populations to functional groups in the case of aquatic microbes. This implies that for most organisms at risk that are studied in micro-/mesocosm tests the selected measurement endpoints should relate to relevant population-level endpoints, more specifically the attributes survival/growth and abundance/biomass" In addition "… mutagenic effects and toxic effects on reproduction by a chemical indicate a toxic potential"	
Medicinal Products for Human Use Directive (MPHU) (2001/83/EC) Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use (EMA 2006) EMEA/CHMP/SWP/4447/00corr 2, refers to the TGD	"Guidance on the assessment of adverse effects is given in the EU TGD" (see International guidance above).	
Medicinal Products for Veterinary Use Directive (MPVU) (2009/9/EC) Guideline on Environmental Impact Assessment for Veterinary Medicinal Products Phase II, CVMP/VICH/790/03-FINAL (EMA 2004)	Adverse effects / impacts - mortality and sub-lethal effects.	Definition not extended to populations
	"Impacts of greatest potential concern are usually those at community and ecosystem function levels, with the aim being to protect most species. However, there may be a need to distinguish between local and landscape effects."	
Classification Labelling and Packaging Regulations [CLPR] (EC 1272/2008)	Hazard classification groups: Carcinogen, mutagen, or reprotoxicant (CMR), endocrine disrupting chemical (EDC). Toxic or very toxic or harmful chemicals defined by specific hazard statements	Definitions not extended to populations

URLs were accessed in January 2016

Table 6: Definitions of ecological terms

Term	Definition	Definitive text / source
Biodiversity	"the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems"	(UN Convention of Biological Diversity (CBD 1992), Article 2)
Natural capital	"the biophysical components of ecosystems - land, water, air, minerals, biodiversity"	Costanza 2008
Ecosystem	"the system composed of physical-chemical-biological processes active within a space-time unit of any magnitude" "a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit"	Lindeman 1942 CBD 1992
Ecosystem approach	"environmental management based on our best understanding of the ecological interactions and processes necessary to sustain ecosystem composition, structure and function"	Christensen et al 1996
Ecosystem services	"the benefits people derive from ecosystems – the support of sustainable human well-being that ecosystems provide"…. arising from the interaction of society, the built economy, and ecosystems (social, built and natural capital)	Costanza et al 1997; MEA 2005; Costanza et al 2014.
Ecosystem services approach	establishing "the linkages between ecosystem structures and process functioning…which are understood to…lead directly or indirectly to valued human welfare benefits"	Turner and Daily 2008
Ecological entity	"any particular part of an ecosystem, including a species, a group of species, an ecosystem function or characteristic, or a specific habitat or biome"	Oxford dictionary
Service providing unit	"the collection of individuals from a given species and their characteristics necessary to deliver an ecosystem service" "the quantification of organism, community, or habitat characteristics required to provide an ecosystem service in light of beneficiary demands and ecosystem dynamics"	Luck et al 2003 (original definition) Luck et al 2009 (current broader definition)

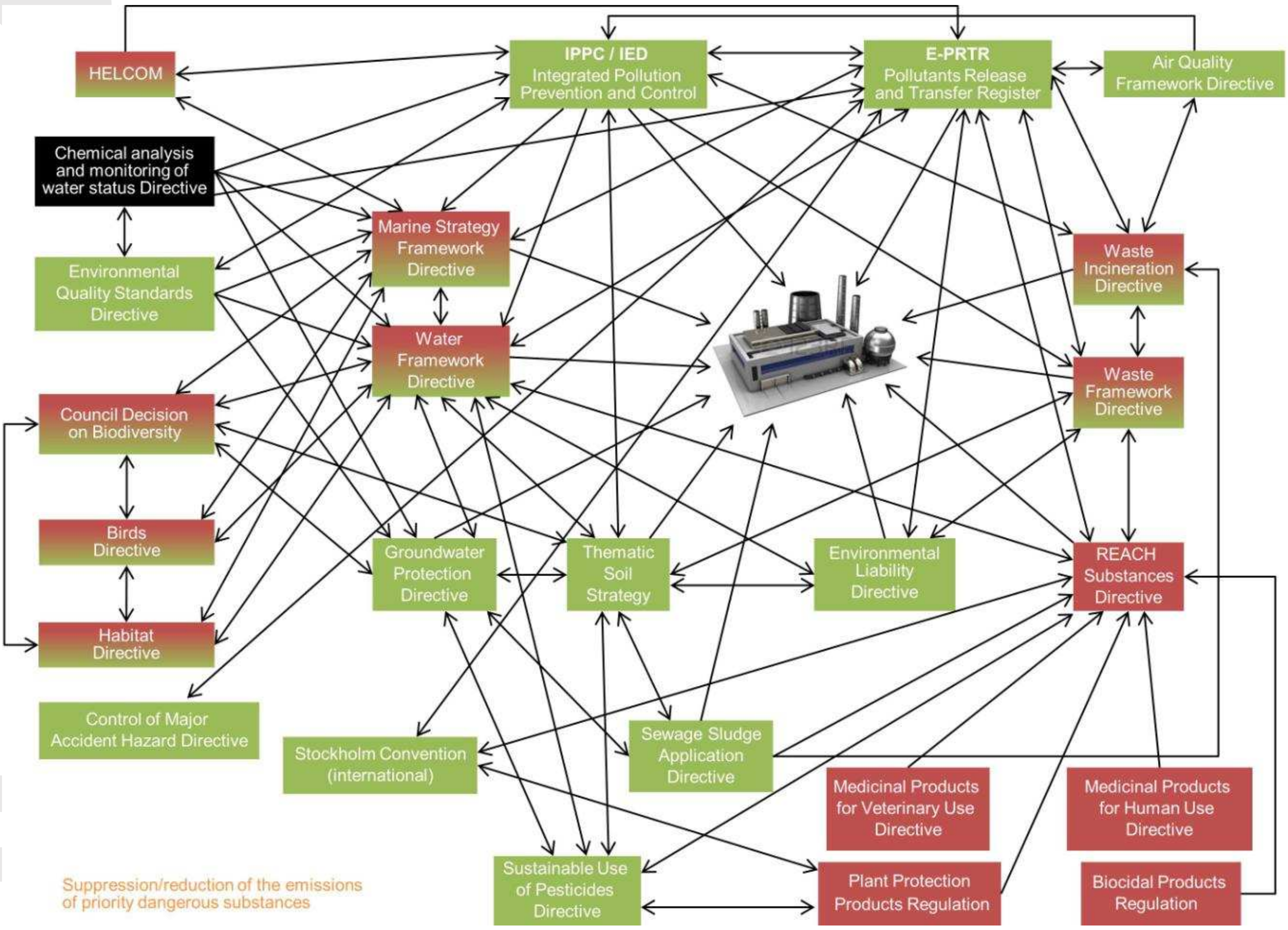
HELCOM
IPPC / IED
Integrated Pollution Prevention and Control
E-PRTR
Pollutants Release and Transfer Register
Air Quality Framework Directive
Chemical analysis and monitoring of water status Directive
Marine Strategy Framework Directive
Environmental Quality Standards Directive
Water Framework Directive
Waste Incineration Directive
Waste Framework Directive
Council Decision on Biodiversity
Birds Directive
Habitat Directive
Groundwater Protection Directive
Thematic Soil Strategy
Environmental Liability Directive
REACH Substances Directive
Control of Major Accident Hazard Directive
Stockholm Convention (international)
Sewage Sludge Application Directive
Medicinal Products for Veterinary Use Directive
Medicinal Products for Human Use Directive
Sustainable Use of Pesticides Directive
Plant Protection Products Regulation
Biocidal Products Regulation
Suppression/reduction of the emissions of priority dangerous substances

Figure 1