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7. Contaminants of Emerging Concern

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Abstract:

'Contaminants of emerging concern' are often described as emerging contaminants or emerging pollutants, and some of them are indeed novel substances or materials, such as nanoparticles or new pharmaceuticals. Others though have been with us for decades (or longer) but our understanding of their effects is increasing, especially in combination and at low levels. They are often managed along with heavy metals, where the ill effects have been long understood. They include antiseptics, solvents, pharmaceuticals, pesticides, and personal care products. These chemicals may have substantial effects in trace levels in the aquatic environment; if similar effects become apparent for humans, that has implications for both water and wastewater treatment. A wide subset of law and policy, at international and national levels, is relevant for their management and this chapter provides an overview of some of the relevant regulation, in the context of rapidly developing science.

Introduction

This chapter will examine the policy and law relevant to the management of what are often described as 'emerging pollutants', or 'emerging contaminants'. However, although some are novel, often it is the effects of these substances which are emerging. The website of the US Environment Protection Agency (USEPA) states: *These are often generally referred to as "contaminants of emerging concern" (CECs) because the risk to human health and the environment associated with their presence, frequency of occurrence, or source may not be known* (USEPA, undated (a)). Sauve and Desroisiers (2104) agree that 'contaminants of emerging concern' is a more appropriate description, and that is the terminology used herein, whilst recognizing that 'emerging pollutants', though less accurate, is widely used.

These substances can be defined and classified in different ways. Geissen *et al* (2015, p.58) include in their definition synthetic and naturally occurring chemicals, which may not be monitored but which may impact on human health or ecology. They note that *[i]n some cases, release of emerging pollutants to the environment has likely occurred for a long time, but may not have been recognized until new detection methods were developed. In other cases, synthesis of new chemicals or changes in use and disposal of existing chemicals can create new sources of emerging pollutants.'*

This chapter will begin with an explanation of some of the main categories of pollutants, the uses to which they are put, and the potential consequences for the health of humans and aquatic ecosystems. It will then examine the approaches to their management, related to each of these consequences; including broad water quality approaches and specific rules relevant to both drinking water and wastewater treatment.

Definitions and Types of Emerging Pollutants

Contaminants of emerging concern may be used in a wide variety of products. Balderacchi *et al* (2014) include antiseptics, antioxidants, corrosion inhibitors, flame retardants, gas propellants, plasticizers, pharmaceuticals (prescribed, non-prescribed and drugs of abuse), solvents, stimulants (such as caffeine), and surfactants; and a range of 'personal care products' including fragrances and sunscreens. Pesticides and biocides are an important group with obvious potential toxicity. Some are combustion byproducts. Some are naturally occurring and others synthetic, and they include organic and inorganic compounds. (Geissen *et al* 2015; Deblonde *et al* 2011). Individual products may include a number of constituent chemicals, and the effects of combinations of these chemicals, and their effects at low dosage and in combination, may not be well understood. Nanoparticles and microbeads are also defined as emerging pollutants, and many of these are a component (sometimes *the* component) of concern; for example, in personal care products. Further, they may behave differently, and have different environmental effects, than the same compounds or elements at larger scale (which may themselves be toxic; Mar *et al* 2013).

There is an obvious relationship with the management of hazardous substances generally, not just in the water environment. Some hazardous substances are long-established, have well-recognised effects either individually or in combination and are managed accordingly in environmental and health and safety laws, but at lower doses or in combination, knowledge of effects may still be emerging. For example whilst the harmful effects of some metals, such as mercury or lead, have long been recognised, the impacts of trace quantities of metals is now also being recognised, Heavy metals are often addressed in the same literature as contaminants of emerging concern, and managed under the same monitoring and control regimes.

What is clear is the scale of the problem. Van der Ohe et al (2011) state that there are 14 million chemicals in existence, and 100,000 are produced on an "industrial scale". Schriks *et al* (2010) also note that more than 100,000 chemicals are registered in Europe; and that 300m tonnes of synthetic compounds are discharged annually. The NORMAN network is a network of reference laboratories, research centres and related organisations for monitoring of 'emerging environmental substances' and was established by the EU in 2005. In 2015, its list of individual substances of concern has 1036 entries (NORMAN List, 2015).

Impacts and Consequences

Chemicals enter the environment in different ways. They may be emitted to the atmosphere, for example during combustion, evaporation or in propellants. They may end up in landfill, which may be better or more poorly regulated. They may be discharged into wastewater systems, through industrial processes or domestic waste water (including household cleaners, and personal care products, and unused medicines), or may be metabolised by humans or animals (pharmaceuticals). Human wastes may (or may not) enter a wastewater system and may (or may not) be subject to treatment; animal wastes may enter watercourses without treatment (or may be diverted to a wastewater treatment plant). Discharges to air and to land may end up in the water environment, where depending on solubility, the compounds may be taken up by aquatic lifeforms or end up in sediments. If in sediments, they may remain for considerable periods of time, but may find new pathways to new receptors if the sediments are disturbed, for example by dredging or otherwise affecting the structure of a river. The chapter will look only briefly at the management of air pollution and solid waste, but will focus on management of contaminants in the water environment.

In cases where severe negative consequences on human health (and ecosystems) have become manifestly obvious, such as the use of certain early-generation pesticides, there have been outright bans on specific chemicals on human health grounds. Where these substances are persistent and bio-accumulative, they may continue to be detected in human and animal tissue over prolonged periods of time. Many other substances which are recognised as toxic, persistent and bio-accumulative continue to be manufactured and used for different purposes around the globe, with (variable) management frameworks intended to ensure the safety both of those using them directly, and those who will be exposed to them once released to the environment.

Schriks *et al* (2010) investigated 50 "chemicals of emerging concern", of which 10 had established values for drinking water; they derived provisional guideline values for the others and then assessed the prevalence of these in the waters of the Meusel and the Rhine, concluding that there was a "significant safety margin" between the guideline values and the actual prevalence. However the determination of safe doses tends to be assessed in relation to individual compounds rather than combinations, in relation to adults rather than children, and to identify short-term acute effects rather than possible chronic effects of long-term low-dose exposure. Pal *et al* (2010) identified dozens of studies of the occurrence of various pharmaceuticals in the US and the EU between 2006-2009, in the water environment, in wastewater and in terms of ecotoxic effect, and noted that the effects of many compounds are poorly understood, especially at low levels and in combination.

A wide-raging review of "hazardous chemicals of concern" in the freshwater environment was undertaken by the European Environment Agency (EEA) in 2011 (European Environment Agency 2011). This review noted that many chemicals can affect aquatic life and human health, and that evidence is emerging as to the additive and cumulative effects. In 2013 the EEA with the EU's Joint Research Council (European Environment Agency / Joint Research Council 2013) assessed the relationship between environment and human health, including chapters on chemical pollution, nanotechnology and the water environment. One conclusion was that such complex challenges require systematic policy solutions. This chapter will attempt to assess whether such solutions are yet forthcoming.

Many contaminants of emerging concern may also be endocrine disrupters. Endocrine disrupters interfere with the actions of hormones and in the last decade, much more information has emerged as to their potential impacts on aquatic life and on human health. Most obviously, contraceptives are endocrine disrupters but so too are many other compounds, including a wide range of pharmaceuticals as well as numerous other substances and products. In the US, the EPA's first list of substances for screening as potential endocrine disrupters in 2006 had 67 compounds, and the second list in 2013 contained 109. These include pesticides as well as pharmaceuticals (USEPA undated b). In 2012 the World Health Organisation (WHO) and the United Nations Environment Programme (UNEP) issued their second report on endocrine disrupters (Bergman *et al* 2012) and found that some 800 chemicals were "known or suspected" to interfere with hormone receptors, synthesis or conversion. This report also notes the increase of endocrine disorders in both wildlife and humans. "Intersex" fish are well documented; see for example Jobling and Owen, 2013. The WHO / UNEP report identifies the following human health impacts as being on the rise and linked to endocrine disrupters: low sperm counts; genital malformations; adverse pregnancy outcomes; neuro-behavioural disorders; endocrine-related cancers; obesity and type 2 diabetes.

International Frameworks for chemical management

The sound management of chemicals is relevant, *inter alia*, to environmental management frameworks and to sustainable development, as well as human health. It was mandated in Agenda 21 (UN 1992, chapter 19) and the Johannesburg Plan of Implementation, (UN 2002 para.23). The sound management of chemicals is also noted in the new Sustainable Development Goals (SDGs); (UN General Assembly 2015, para.34). The SDGs make specific provision in Goal 3 ("healthy lives and wellbeing") but also in the 'water' goal (Goal 6) and Goal 12 ("sustainable consumption and production").

There are numerous initiatives, and relevant international law, at global and regional levels. UNEP is responsible for three related global "Chemicals Conventions" - the Basel Convention on Transboundary Movements of Hazardous Wastes (UNEP 1989); the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (UNEP 1998); and the Stockholm Convention on Persistent Organic Pollutants (UNEP 2001). At regional level, for example, the UN Economic Commission for Europe (UN/ECE) manages the Geneva Convention on Long Range Transboundary Air Pollutants (UN/ECE 1979) and its Protocols, including one on Persistent Organic Pollutants. Not every chemical managed under these Conventions will still be of "emerging concern" today; the Geneva Convention was agreed as a response to better understanding of the impacts of oxides of sulphur in causing acid rain in the 1960's and 1970's. But many of substances of emerging concern will also be hazardous substances to which these broad frameworks are relevant. Further, both sets of conventions regularly review their protocols, and listed substances, to address new concerns identified by the science literature. Health and safety legislation is also relevant, for example the International Labour Organisation's Conventions on Safety in the Use of Chemicals at Work (ILO 1990) and on the Prevention of Major Industrial Accidents (ILO 1993).

Similarly, there are numerous policy initiatives at different levels. The Strategic Approach to International Chemicals Management (SAICM) was adopted by UNEP's Governing Council in 2006 in Dubai with the agreement of 140 countries. SAICM has adopted resolutions on *inter alia*, endocrine disruptors, nanoparticles, and chemicals in products; and is currently considering the impacts of pharmaceuticals (SAICM / UNEP / WHO, undated). The UN/ECE has developed a "Globally Harmonized System of Classification and Labelling of Chemicals" (UN/ECE 2003) which is open to all states who wish to participate; and states were encouraged to do so by the Johannesburg Declaration (UN 2002, para.23). Regular revisions to this system again enable the management of new compounds, or newly recognized effects.

Clearly it is not possible to address every aspect of the management of chemicals generally in this chapter. But it is worth noting that air pollutants fall to land, and contaminate water; and poor management of solid waste also causes water pollution in different ways, most obviously from leachate from landfills or from historically contaminated sites. The problem is multi-faceted, but the chapter will focus on the management of pollutants directly into the water environment; the management of drinking water quality; and the management of wastewater; and will make particular reference to the European Union (EU). This is partly because the EU is a major manufacturer of chemicals, and partly because of a highly developed suite of water and environmental laws. The chapter will also draw some comparisons with law in the (Federal) US.

The EU and Chemical Management

In 2009, the EU had one third of the global chemicals market, with 29000 manufacturers and 1.2m employees (European Commission 2009). The REACH Regulation (European Commission 2006) on the Registration, Evaluation, Authorisation and Restriction of Chemicals, established a European Chemical Agency and operates on the principle of "No Data No Market". Producers and importers of one tonne or more of chemicals must register them with the European Chemicals Agency. There is an obligation to share data; industry should manage risk by providing information on the effects of constituent chemicals, and there is a recognition that there is insufficient information. Some chemicals are especially problematic ("substances of very high concern") and these should be progressively phased out as substitutes become available. In 2013, more than 9000 registration dossiers had been submitted under REACH (European Chemicals Agency, undated). The EU also has a Regulation on the Classification, Packaging and Labelling of Substances and Mixtures (European Commission 2008), which in turn implements the UN/ECE's Classification System. As these are Regulations they apply directly in Member States without further transposition into domestic law. The EU is also part of the Strategic Approach to International Chemicals Management.

The EU has extensive legislation relating to both industrial air pollution (for example, the Industrial Emissions Directive, European Parliament and Council 2010) and to waste management (for example, Framework Directive on Waste, European Parliament and Council 2008a; Landfill Directive, European Parliament and Council 1999). These may implement the international and regional instruments noted above; made in the form of Directives, they subsequently need transposed into domestic law by Member States. There is a European Pollutants Release and Transfer Register (European Commission 2006a), covering both industrial emissions and waste. The Industrial Emissions Directive applies to emissions to all environmental media and a wide range of industrial activities and processes.

Water Quality Management in the EU

The Water Framework Directive (European Parliament and Council 2000, WFD) sets a framework for water policy in the EU's member states. It requires a system of river basin planning, managing surface water and groundwater together and taking a "combined approach" to point source and diffuse pollution, utilising both environmental quality (ambient) standards and emission limit values. It has an overall objective of "good" ecological status for surface waters, which entails the management of chemical quality, but also a biological assessment, and the management of the hydrology and morphology of the river. The ecological status of surface waters is assessed by a complex set of measures of different types, and if deficient, should be actively improved by member states to achieve "good", unless a series of exemptions and extensions apply (Art.4, and see also chapter 4). States should establish a programme of measures in their river basin management plans to improve the status of waterbodies that are not yet "good" (Art.11). There is an explicit focus on supporting aquatic life under the WFD and the biological assessment looks at the diversity distribution and age of fish populations. The WFD then is the overarching mechanism for addressing the wider impacts of contaminants of emerging concern on the aquatic environment.

The WFD works with other relevant legislation, mainly but not exclusively water legislation, some of which is especially important to contaminants of emerging concern. Some of these were already in existence and some have been developed since the WFD. Prior legislation includes the Drinking Water Quality Directive (European Parliament and Council 1998) and the Urban Wastewater Treatment Directive (European Council 1991), each of which will be considered separately below. The WFD requires states to map "protected areas" including drinking water abstraction points, with the specific goal of minimising subsequent treatment (Art.7). The EEA specifically notes drinking water protection zones as a way of minimising the effects of harmful chemicals on human health (EEA 2011).

Pollutants in Groundwater

The Groundwater Directive (European Parliament and Council 2006, GWD) was made under the WFD (Art.17) and sets EU-wide quality standards for nitrates and pesticides (Annex I). The former is derived from EU legislation on nitrates (European Commission 1991a) and the latter from pesticides legislation, addressed below. Member States are also required to identify substances in groundwater of especial concern in that state (or at river basin level), for which that state should set its own "threshold values" (Art.3). A list of pollutants for which Member States were to consider establishing threshold values is provided in the Directive (Annex II), including metals and two synthetic substances (Trichloroethylene, PCE, and Tetrachloroethylene, TCE, widely used as solvents). The Annexes are subject to revision – in 2013 and every six years (Art.10) - and an EU FP7 project, GENESIS, looked *inter alia* at emerging pollutants to make recommendations over these revisions. Balderacchi *et al* (2014) recommended that the two synthetics in Annex II should be moved to Annex I and have EU-wide quality standards established, as these two substances are "*excellent indicators of the groundwater pollution by multi-source diffuse-type urban pollution*". These pollutants especially derive from current and historic industrial sources and poorly regulated waste management facilities, and may find their way into ground (and surface) water by leaching, by deposition from air or through surface water and road drainage systems. Balderacchi *et al* (2013) also noted that pharmaceuticals and personal care products (and caffeine, which they describe as "ubiquitous") are indicators of contamination from household waste, either from wastewater, or via the use of sewage sludge on land; whilst benzene and MTBE are indicators of fuel and pollution from vehicles. They noted that although two synthetics are identified in Annex II, Member States are setting threshold values for 62.

Pollutants in Surface Waters

The Priority Substances Directive (European Parliament and Council 2008, 2013, PSD) is also made under the WFD (Art.16) and creates EU-wide quality standards for surface waters for a list of (now, in the 2013 revision) 45 substances and groups of substances. Their use should be progressively reduced (WFD Art.17). These include 21 Priority Hazardous Substances, the discharge of which should be ceased or phased out. The list of substances is also inserted into Annex X of the WFD. The PSD sets maximum allowable concentrations (or sometimes, annual averages) for background concentrations in water, or sometimes, in biota or sediment. The substances in the PSD include pesticides, solvents, and metals. In general, these substances are likely to be toxic, persistent and bio-accumulative. Treated as priority substances, and included in the list, are a small subset of pollutants for which the EU had already set standards, including mercury and cadmium. In addition, Member States may designate pollutants of especial concern nationally – "specific pollutants" - and manage these with the PSD list. As well as human health, the chemical standards in place in the PSD are intended to safeguard aquatic ecosystems.

The PSD is the obvious vehicle for managing the risks to the water environment of emerging pollutants. The Commission was required to review the list by 2013 and periodically thereafter (WFD Art.16, PSD Art.8) and these revisions were specifically intended to allow identification of chemicals that should be placed on that list. In 2011, van der Ohe *et al* published an analysis of 500 chemicals that could potentially be added to the 33 in the original 2008 list, or, be designated as specific pollutants by Member States; and proposed new methods for risk assessment to prioritise actions.

Although the 2013 revisions added several substances to the list, several others that were proposed were instead placed on a "watch list", to be further monitored (Art.8, PSD 2013), with the aim of developing a "strategic approach" by 2015, and measures by 2017. The substances on the "watch list" include the main constituent of many contraceptives; and a commonly used anti-inflammatory. Like the PSD List, these would be categorised as contaminants of emerging concern. The proposal caused much opposition by Member States (Council of the European Union, 2012) and the decision not to place at least some of these substances on the List was in part because of the cost of requiring their removal at wastewater treatment plant (EEA / JRC 2012, ch.6).

Drinking Water Quality

The purpose of the Drinking Water Quality (DWQ) Directive, and similar instruments in other jurisdictions, is to safeguard human health. The Directive establishes a list of mandatory parameters for DWQ for all but the smallest supplies (less than $10m^3$/day or serving less than 50 people). In turn these reflect the guidelines published by the World Health Organisation (WHO, 2004). Provision of water of the acceptable quality normally requires treatment, though there is (not just in the EU) recognition that protection of drinking water catchments is a way or reducing, if not eliminating, treatment costs. The WHO suggests water safety planning as a holistic approach from source to tap, including source protection; the WFD requires source protection; in the US, the New York scheme for the protection of the Catskills is one of the oldest, and perhaps the most famous example (Appleton, 2002). This approach will also contribute to the safeguarding of aquatic ecosystems, and other ecosystem services.

The WHO guidance is extensive; both it and the DWQ Directive already establish safe levels for some individual substances that may be of "emerging concern". However the concerns raised at the beginning of this chapter, that the additive and cumulative effects of some substances might manifest at much lower levels, remains valid. In addition, many substances are not routinely monitored for in drinking water; or, the tests available will not detect the level of substance that is present. Although one would expect – and it is usually the case – that standards for treated drinking water would be tighter than standards for the water environment, Balderacchi *et al* (2013) note that in Canada, standards for some substances in the freshwater environment, designed to protect aquatic health, are lower than the corresponding drinking water standards in the EU. The science continues to develop, and to drive policy and law, but the timings are uncertain and the feedback and feedforward loops are imperfect.

Wastewater Treatment

Insofar as the substances in question are found in, for example, pharmaceuticals, personal care products, or cleaning products, then in most of the developed world, their residues will find their way into a domestic wastewater system, which may be subject to various levels of treatment, in plant ranging from large municipal processes to septic tanks and other small on-site treatment. In much of the developing world, even if there is a sewerage system to remove wastewater, as much as 90% of domestic wastewater may not be treated but simply discharged to a watercourse (UNEP, 2010). Alternatively domestic human waste may be managed by non-waterborne sanitation, which is effectively a solid waste problem that may still result in pollution of water depending on the disposal arrangements. Industrial wastewater is likely to be subject to a trade effluent regime and increasingly, businesses are looking to be more water (and wastewater) efficient, treating their own effluent either as part of their water supply demand management, or to reduce the costs of the trade effluent consent, or both. Nonetheless, in the developing world an estimated 70% of industrial wastewater also goes untreated (UNEP 2010). Yet wastewater is a valuable resource that should be not just treated but also recaptured and reused, to close loops in the water cycle as well as protect human and ecosystem health (for some recent valuation work, see UNEP 2015).

Wastewater contains valuable nutrients and can be a source of energy, but also pathogens, metals, and other contaminants, including substances of emerging concern as well as substances where the concerns are well established. The extent to which any group of contaminants is removed will vary depending on the levels of treatment. It is expected that states will (at least) have a basic set of chemical standards to protect both human health and aquatic life (Helmer and Hespanol, 1997). These may be ambient standards for receiving waters, as in the EU's PSD, or emission standards for plant, or both, and would be applied through some sort of permit system. In many jurisdictions these apply to both municipal wastewater treatment plant and to any industry pre-treating its effluent and discharging directly under an individual permit.

In the EU, there is specific legislation, the Urban Waste Water Treatment Directive (European Council 1991, UWWTD) requiring a norm of "secondary treatment" as defined and working with the WFD. The UWWTD has entailed significant capital investment by Member States. Essentially, it requires collection systems and treatment at various levels, for biodegradeable wastewater (human waste and also, for example, food waste). Collection systems are not required where this would be excessively costly or would produce no environmental benefit (Art.3) but the same level of environmental protection must be provided (for example by individual systems). There was a staged system of implementation beginning with the largest "agglomerations" by population equivalent. Small communities (or industries) with population equivalent of less than 2000 do not need to implement the UWWTD but instead must have "appropriate treatment" sufficient to meet all other relevant EU quality standards (Art.7). Larger communities discharging to coastal or estuarine waters may be designated as "less sensitive" and be subject to only 'primary treatment' (Art.6).

The usual level of treatment required is "secondary treatment" as defined (biological treatment by digestion process). Annex I sets standards for 3 parameters, biochemical oxygen demand, chemical oxygen demand and total suspended solids. Where the discharge is made into "sensitive" waters (subject to eutrophication) additional 'more stringent' (tertiary) treatment may be required, such as ultraviolet treatment, and standards are also set for total phosphorous and total nitrogen. Both sludge and treated wastewater should be reused "wherever appropriate" (Arts.14, 12). As evidence builds around the emerging effects of pollutants, whether in combination or at low levels, and for both human health and aquatic ecology, the implications for both reuse of water and use of sludge also grow.

If the PSD was to be amended to include more pharmaceuticals or personal care products, or to establish more stringent limits, then this would have implications for the nature and extent of wastewater treatment. During the discussions on the revision of the PSD, in a commentary piece in *Nature*, Owen and Jobling (2012) noted that the cost of introducing appropriate technology to strip out ethinyl estradiol (a commonly used constituent in the contraceptive pill) completely from wastewater might amount to £30bn for England and Wales, and called for a public debate. Their focus was on aquatic ecology; they noted that fish species had been seen to "collapse" in a Canadian lake with the introduction of the relevant hormone at "vanishingly small levels". The debate did not happen – or at least, only amongst the few: the chemicals industry, water services sector, environmental regulators and policymakers. But Owen and Jobling have also suggested that given the immense difficulties with establishing cause and effect, and the huge numbers of endocrine-disrupting synthetic chemicals in the environment, it might be appropriate to use the well-documented impacts on fish (and the precautionary principle regarding human health) as an indicator and a driver to take action.

The specific technology giving rise to the £30bn figure was the use of granular activated carbon filters. These are sometimes used in drinking water treatment plant, and are one of the most expensive forms of drinking water treatment. They would be used, for example, where there is a risk of contamination by certain pesticides. In a wastewater context, their use would require both capital and maintenance expenditure well in excess of current costs. However, in a more detailed analysis for the European Environment Agency, Jobling and Owen (2013) also examined other novel or additional treatments for wastewater, and other relevant pollutants. They found that good results could also be obtained from other "tertiary" treatments including ozonation and also sand filters. These might have additional capital costs but the operational and maintenance costs are not as high as granular activated carbon filters. They found that the extent of dilution is important, and therefore relatively densely populated countries with small river systems, such as England, were particularly at risk. They also noted that in many other European countries, unlike the UK, tertiary treatment is much more common in municipal works. Their research was primarily focused on one oestrogen, which is particularly difficult to degrade and particularly problematic for fish; so they also considered the possibility of the development of a different product, with different active ingredients, and the possibility of product control as a solution will be returned to further below. However, more effective treatment of municipal wastewater would address a wide range of pharmaceuticals, personal care products, other household products and also some industrial and agricultural contaminants, insofar as these are going through such treatment plant. Some of the health effects of endocrine disruptors have recently been confirmed (EurActiv 2016).

Other studies carrying out field work have also suggested that tertiary treatments (ozonation, but also advanced oxidation, filtration and activated carbon) produced far more effective removal of a range of problematic products and substances than secondary treatment alone. Schaar *et al* (2010) investigated the effect on 29 substances (pharmaceuticals, personal care products and commonly occurring endocrine disruptors) of an additional ozonation process subsequent to biological treatment and to denitrification. They found that a retention time in excess of 10 days (during the biological process) was helpful, but that subsequent ozonation produced much better results. Rosal *et al* (2010) found similarly good results for ozonation in a study of 70 substances at a Spanish treatment works.

Much work is also underway on the management of nanoparticles in wastewater treatment – which may interfere with, or simply not be treated by, conventional treatment processes (Yang, Zhang and Hu, 2013; Mar *et al* 2013). As "nanoparticles" describes size, rather than indicating function or effect, it could be noted that whilst many of these are a component (sometimes the component) of concern in, for example, a personal care product, equally nanotechnology is itself being used in developing treatment options.

Whichever technique is used, there will be additional – potentially substantial – costs for water services suppliers and ultimately the public served by these systems. In the EU, the costs of implementing the UWWTD as it currently stands were high for the then 15 EU Member States following its introduction in 1991, and are an ongoing problem for the 13 new entrants since (European Commission 2013). Although the UWWTD as such is probably unique, the need to have appropriate treatment of wastewater, that protects both human and aquatic health, is common to all countries whatever their stage of development. Meantime, in any jurisdiction, very small, onsite systems such as septic tanks, which are often privately owned and maintained, will offer only biological treatment; and wastewater that finds its way into watercourses through surface water drainage, or by direct runoff, will not be treated at all. These last two routes include urban diffuse pollution, containing household and industrial chemicals and combustion byproducts especially from traffic; and agricultural runoff.

Agricultural Pollution

Agricultural pollution is a large topic, including the management of fertilisers, pesticides, and veterinary pharmaceuticals, as well as management of soil (to address erosion, salinity, carbon management). Forestry, and other rural land uses, may also deposit fertilisers or impact on soil quality or carbon deposits, but in terms of 'emerging' concerns, pesticides and pharmaceuticals are most relevant. Similarly, each of these may also be used in urban and domestic contexts, but at scale, agricultural use is more relevant here. It has been estimated that more than 5000 tonnes of antibiotics and 5 tonnes of hormones are employed in the European meat production (Balderacchi *et al* 2014); Schriks *et al* (2010) estimate that 140m tonnes of fertiliser and 'several million' tonnes of pesticides are applied to land each year. Large pig and poultry production in the EU is covered by the Industrial Emissions Directive which should entail the proper management of all wastes from these activities, but smaller scale production, or extensively reared livestock, may impact directly on watercourses, potentially causing pollution by nutrients and pathogens as well as metabolised pharmaceuticals.

In terms of pesticides, which may include herbicides, biocides, fungicides and insecticides, some 400 active substances are in use in Europe (Balderacchi *et al* 2013), with 39 compounds being monitored at national level under the GWD, including 16 which are no longer sold, but which are persistent, especially in sediment or groundwater, and bio-accumulative. In the EU the DWQ Directive sets a maximum limit of 0.1 ug/L for (the active ingredient of) any individual pesticide, and a maximum in total of 0.5 ug/L. The same limit is found in the GWD Annex I, as an EU-wide standard. There have been restrictions on the use of these products for some time; the current Regulation (European Commission 2009a), along with implementing Regulations, enables the harmonised assessment and where necessary restriction of these products; whilst a separate Directive addresses their safe use (European Parliament and Council 2009a). Very recently, the European Parliament decided to re-approve glysophate despite concerns over its carcinogenic properties, but for 7 years instead of the customary 15 (EurActiv 2016a).

New generation pesticides such as neo-nicotinoids are less persistent but bring different and novel problems, especially concerns on effects on bees and other pollinators. These are being scrutinised in many countries; the EU has brought in some restrictions (European Commission 2013a), and their use has been challenged successfully in the US Supreme Court (*Pollinator Stewardship Council v USEPA*, 2015). Court action was also raised Ontario, Canada (CBC News, 2014), in both cases by associations of bee-keepers. The EU has published new guidance (European Food Safety Agency, EFSA, 2014) and an Opinion on the science (EFSA 2012).

'Sulfoxaflor' was the specific neonicotinoid subjected to the US challenge, The US Court held that the EPA's studies, on which consent for sulfoxaflor was based, were flawed; and that it needed to collect more data. It is troubling to note that the EU restrictions apply to three other specific neonicotinoids (clothianidin, thiamethoxam and imidacloprid), which are still permitted in the US; yet the EU has recently authorised sulfoxaflor, finding it less likely to cause harm.

These rules apply to "plant protection products", i.e., for agriculture and similar uses; other biocides, for example insecticides, anti-fouling paint or disinfectants, are managed under the REACH system. In an agricultural context especially, all states should have domestic legislation and policy, such as best practice guidance, to safeguard workers as well as consumers. In their work on prioritisation and risk assessment, von der Ohe *et al* (2011) note that 74% of the substances they identified as "high" or "very high" risk were pesticides; that pesticides cause contamination despite the system for pre-market approval; and that new active ingredients for pesticides are introduced on the market faster than monitoring programmes can be developed.

Regulatory Frameworks in the US

An analysis of the regulatory frameworks in the US specific to pharmaceuticals (Eckstein, 2015) looked *inter alia* at the principal Federal legislation, as well as some state rules. As with this chapter, he also reviewed a wide range of scientific literature identifying the problem and the weaknesses of the current solutions. He found that there were a wide variety of approaches and standards, but no systematic management of most pharmaceuticals. He also examined initiatives to promote return of unused drugs to pharmacies and other suppliers, which can reduce the volume of discharge to sewer, but this is only a small part of the problem.

Unsurprisingly, US legislation creates control regimes performing similar functions to those applicable in the EU. The Resource Conservation and Recovery Act, (US Congress 1976) manages hazardous substances and waste, with a 'cradle-to-grave' approach; but excludes wastewater which is covered by the Clean Water Act (US Congress 1972). Eckstein notes the difficulties with hazard assessment of the large numbers of active ingredients in pharmaceuticals (and other hazardous substances covered by the Act). Other Federal US rules also relevant to the broad topic would include the Clean Air Act (US Congress 1970) managing industrial air pollution, and the Insecticide, Fungicide, and Rodenticide Act, (US Congress 1996) managing pesticides. Of course all of the principal Acts from the 1970s have been much amended, and are supplemented and implemented by regulation, guidance and state legislation.

The Clean Water Act manages the use and quality of freshwaters, using similar tools and mechanisms to the EU WFD and national rules. States should designate quality standards, and allowable water uses, within their jurisdiction, and discharges are regulated by the EPA or by state authorities. The system establishes total maximum daily loads for specific pollutants and requires permits for discharges. However the Clean Water Act does not set standards for most pharmaceuticals and the permitting system does not address these.

The Safe Drinking Water Act establishes limits for listed substances similar to the EU DWQ Directive. The subsidiary regulations establishing the list can also mandate specific treatment technologies. Eckstein notes that the EPA can develop a "candidate list" of substances not yet subject to a standard, and that this was recently done, with 104 substances. However, although 287 pharmaceuticals were identified for possible inclusion, all but one were subsequently removed. This seems very similar to the discussions on the revision of the EU PSD list. The only pharmaceutical included was nitro-glycerine, placed on the list for its explosive, rather than medicinal, uses.

Conclusions

There is little evidence in the legal literature of any state or jurisdiction (in the EU, the US or elsewhere) making comprehensive provision for the management of pharmaceuticals or other contaminants of emerging concern. As discussed above, some may be "caught" by general controls on discharges to fresh or marine waters; or disposal of solid wastes (not just sewage sludge) to landfill; or management of industrial air pollution. They may be managed by rules on wastewater treatment, or identified in drinking water standards. But despite the science evidence of impacts on both human health and aquatic ecosystems, there is little policy response as to how to manage cumulative effects or effects at very low doses. In many cases the availability of appropriate monitoring techniques is limited, and the assessment of risks and hazards struggles to keep pace with the rapid development of new compounds and products.

Usually, as with all waste management issues, tackling the problem at source is the best approach. Yet although citizens may be concerned about substances and products in the environment or impacting on health, source management is particularly difficult for pharmaceuticals or personal care products. Any suggestion of limiting either is likely to be very challenging for policymakers. Attempts to challenge and restrict the use of pesticides have also proved very difficult. The scientific "burden of proof" is one issue, and the precautionary principle seems sorely neglected.

From the research surveyed in this chapter, one approach would be to introduce tertiary treatment for wastewater. Yet this would be very costly, and would not address surface water runoff (urban or rural), or wastewater that is not treated, or emitted only to small onsite systems. Other possibilities are to work with manufacturers, and consumers, to identify new products which are less problematic – yet the constant introduction of new products into the market is part of the problem. In some ways the problem seems insurmountable, and there are no easy solutions. Meantime the public debate still needs to happen. Perhaps a combination of high-profile environmental campaigns, and increased concerns over human health, will keep the issue high enough on the public agenda to maintain the interest of policymakers, as well as scientists.

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