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Evaluation of the proposed EU regulation on minimum requirements for water reuse for irrigation

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Summary

Reuse of domestic waste water for irrigation could play an important role in water resource management. Waste water is already often indirectly reused in agriculture by irrigating with surface water in which treated waste water is discharged and diluted. In direct water reuse, waste water is treated to such an extent that it is suitable for irrigation. The European Commission has published a proposed regulation for direct water reuse for irrigation with the aim to support responsible reuse of waste water for irrigation purposes by harmonized minimum quality requirements and risk management. The proposed regulation also specifies processes related to permits and obligations on the sharing of information on reuse. Researchers from KWR Watercycle Research Institute have evaluated the performance of the proposed regulation in the Dutch context, focusing on microbial and chemical risks, and the performance of the regulation for water reuse in the Netherlands. It is concluded that the proposed regulation is very generic The minimum quality requirements that are specified focus only on general quality and public microbial health. Specific comments are made about these minimum requirements and where they might fall short to adequantely protect human health. No minimum requirements for chemicals are specified. The Water Reuse Risk Management Plan, which is a multidisciplinary and exhaustive task, should determine if/which minimum requirements for specific chemicals in specific settings are needed to manage public health and environmental health risks. However, this is costly and requires expertise that likely exceeds that of the responsible stakeholders. The reference situation for irrigation of crops in the Netherlands is the use of groundwater or surface water. Especially the latter that can be impacted by discharges of urban waste water treatment plants. Intentional reuse generally offers better control and management possibilities than such de facto reuse. However, intentional reuse conforming to the proposed regulation asks for a detailed understanding of the benefits and risks of reuse for agricultural practices. As this requires specific expertise and is costly, the proposed regulation might unintendedly stimulate indirect reuse. Our main recommendation is to provide more (supra)national guidance information to support operators and regulators to efficiently prepare Water Reuse Risk Management plans that are sufficiently protective for human and environmental health.

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1 Introduction

1.1 Water reuse

The frequency and intensity of droughts have increased over the last 30 years, and this trend is expected to continue. More efficient management of freshwater resources may contribute to the alleviation of water scarcity across the EU. Water abstraction for agricultural irrigation accounts for about a quarter of total freshwater abstracted, which can rise to 60% in Southern and South Eastern Europe, and up to 80% in certain river basin districts (FAO 2016). Reuse of domestic waste water for irrigation could play an important role in water resource management.

Other reuse purposes can be industrial or potable reuse. Per reuse purpose, different water quality standards can be relevant. The proposed EU regulation on minimum requirements for water reuse for irrigation (EC, 2018) focuses on water reuse for irrigation. A distinction can be made between direct and indirect reuse. In direct water reuse, waste water is treated to such an extent that it is suitable for irrigation. In indirect reuse, treated waste water is discharged into groundwater or surface water bodies before reclaiming it. In light of the proposed regulation, it is important to recognize that in many EU settings, there is de facto indirect reuse in agricultural (and industrial and potable) water supply. Effluent of sewage treatment plants is discharged into rivers, lakes and streams and this effluent ends up, in more or less diluted form, into the water abstracted for irrigation, aquaculture and drinking water supply. Current waste water treatment practice provides only a limited barrier against microbial and chemical hazards, hence these hazards are also present in water that is currently used for irrigation (as well as for other purposes such as drinking water supply). In direct reuse settings, advanced waste water treatment techniques produce an effluent quality that can have a better water quality than surface water. In such settings, adequate management and control of chemicals and microbial hazards is critical.

Examples of water reuse worldwide (Voulvoulis et al. 2018).
Windhoek, Namibia and Belgium Waste water reclamation plant for drinking water production (direct potable use).
Berlin, Germany. Waste water recharges surface water lakes which recharge aquifers through infiltration. Groundwater is abstracted for drinking water production.
California, US. Groundwater is replenished with treated waste water for drinking water production.
Israel. Waste water is treated and reused for irrigation in agriculture and public works.
Singapore. Mainly non-potable applications of treated waste water.
EU. Reuse of treated waste water (mainly Spain, Italy, France, Greece and Cyprus).
International Space Station. Waste water is recycled to drinking water.

1.2 Aim of the proposed regulation

The need to address management of water resources at the EU level to prevent problems of scarcity and droughts was recognized in the EU's blueprint to safeguard Europe's water resources (COM 2012/763), which re-emphasized that water saving must be a priority and all possibilities to improve water efficiency should be explored. This includes the use of treated waste water from urban waste water treatment plants as an alternative water resource, in situations where the environmental impact is low. In particular for irrigation purposes, water reuse can be relevant and cost-effective, while the maintenance of public health and environmental protection needs to be ensured.

The European Commission has now published a proposed regulation for water reuse for irrigation purposes entitled 'Proposal for a Regulation of the European Parliament and of the Council on minimum requirements for water reuse' (EC, 2018). The aim of the proposed regulation is to support responsible reuse of waste water for irrigation purposes, wherever this is relevant and cost-effective, while ensuring the maintenance of a high level of public and environmental health protection. The proposed regulation sets minimum quality requirements for different types of agricultural reuse (Annex I in the proposed regulation) and requires the development of a Water Reuse Risk Management Plan (Annex II) for public and environmental health hazards.

It is envisaged that harmonized minimum requirements on the quality of reclaimed water and monitoring thereof, and risk management plans will support water reuse and the free movement of agricultural products irrigated with reclaimed water. The aim of the Water Reuse Risk Management Plan is to identify and manage human and environmental health risks in a proactive manner. In the proposed regulation, risk management is defined as 'a systematic management that consistently ensures that safety of water reuse in a specific context'. Key risk management tasks should thus result in identification of additional water quality requirements that may be necessary to sufficiently protect human health and the environment.

Implementation of the regulation is expected at the earliest in 2021, and is intended to include the development of transparent, traceable and accessible water reuse risk management plans to control human and environmental health risks and to be able to inform the public and to promote confidence in water reuse for irrigation. Obligations of the Member States to inform the public, EU Commission, European Environmental Agency and the European Centre for Disease Prevention and Control on the reuse of water are included in the proposed regulation: quantity and quality of supplied water, granted or modified supply permits and compliance therewith.

Drought and water shortage in NL 2018

Availability of water of sufficient quality is critical for water-dependent economic sectors and society in general. The EU economic impact of the 2003 drought has been estimated to minimally EUR 8.7 billion (EC, 2007).

In the summer of 2018, water shortage due to drought, low water supply via the large rivers resulted in water quality issues in the Netherlands related to salinization and microbial growth, problems for shipping and water locks due to low water levels, and low groundwater levels. For agriculture in the Netherlands the drought resulted in loss of production due to a shortage of water resulting in restriction in the use of surface water for irrigation (LCW, 2018; Rijksoverheid, 2018).

1.3 Contents of the proposed regulation

1.3.1 The explanatory memorandum

The proposed regulation for water reuse for irrigation purposes includes a 13-page explanatory memorandum in which the objectives, legal basis and evaluation of the proposal are described, and the specific provisions (articles) in the regulation are explained. Earlier related communications, resolutions, development goals and opinions of the EU Council, Commission and Parliament are also listed.

An impact assessment resulted in the choice for a regulation with a 'fit-for-purpose' approach as the legal instrument. This allows necessary flexibility in transposition of the requirements to local contexts, due to its stimulating nature on research and innovation and due to the fact that a regulation can come into force much faster than amendments to existing directives. The proposed regulation is aimed to be complementary and coherent with existing EU legislative framework on water, and related United Nations policies such as Sustainable Development Goals (SDGs) and targets. It is noted that water reuse is already identified and encouraged in existing EU instruments such as the Water Framework Directive and the Urban Waste Water Treatment Directive, although these do not specify conditions for reuse. Six EU Member States (Cyprus, Greece, Spain, France, Italy and Portugal) currently have requirements on water reuse in place in legislation or national non-regulatory standards. Other existing risk management frameworks for water reuse are listed in the textbox below.

Existing risk management frameworks for water reuse

WHO 2017a. Potable reuse: Guidance for producing safe drinking-water.

WHO 2006. Guidelines for the safe use of waste water, excreta and greywater. Vol. II Waste water use in agriculture.

Australia 2006. Australian Guidelines for Water Recycling: Managing Health and Environmental Risks (Phase I).

Australia 2008. Australian Guidelines for Water Recycling: Managing Health and Environmental Risks (Phase II). Augmentation of drinking water supplies.

CPDH (California). (2015). Regulations Related to Recycled Water. Title 22 Code of Regulations.

Californa Waterboards (2018). Draft amendment to the recycled water policy.

ISO/TC 282 for Water Reuse.

1.3.2 The proposed Water Reuse Risk Management Plan

Reclamation plant operators will be primarily responsible for the quality of reclaimed water and routine monitoring thereof. To this aim, a step-wise Water Reuse Risk Management Plan is included (Annex II in the proposed regulation). In a risk based approach towards safe water reuse, water safety is not only based on end product testing, but on all risk management activities. The Water Reuse Risk Management plan is to be based on the key risk management principles as defined in Annex II of the proposed regulation. Technical specifications to supplement the key risk management tasks will be developed in the form of a delegated act (a supplement to non-essential elements of a legislative act).

Figure 1.1. Key risk management tasks to include in the Water Reuse Risk Management Plan (modified from Annex II in the proposed regulation).

To ensure safe and responsible use of reclaimed water, supply is allowed on the basis of a permit, granted by competent authorities in the Member States. A Water Reuse Risk Management Plan with a description on how the specific reuse scheme will comply with the minimum requirements (Annex I) and additional requirements emerging from the Water Reuse Risk Management Plan (Annex II) is required for such a permit. The rules for the permit are to be determined at EU level, while details of permit granting procedures as well as the acceptance of the descriptions on how to meet the minimum requirements and the specific requirements in the Water Reuse Risk Management Plan are to be determined by Member States using existing procedures that will be adapted to the requirements of the proposed regulation. It is emphasized that this regulation does not preclude food business operators from obtaining water quality complying with relevant regulations addressing microbial risks in fresh fruits and vegetables. The same competent authorities will verify compliance and necessary measures by reclamation plant operators to ensure compliance. In case of non-compliance, the supply of reclaimed water should be suspended immediately if a significant risk is caused to human health or the environment. In case of infringements of the provisions of the proposed regulations, penalties are to be lay down and implemented by Member States.

Information on monitoring requirements and verification of compliance by Member States will be made public on-line using detailed rules regarding the format and presentation of the information, which will be determined by the commission. A requirement for impact and performance evaluation is also included which is defined in article 13 of the proposed regulation and expected 6 years after entry into force of the regulation. A clause is included that allows adaptation of the minimum requirements and key risk management tasks in the regulation based on technical and scientific progress. The regulation also includes obligations of relevant actors in the permitting procedure, including information exchange between competent authorities of Member States, and compliance checks.

Agricultural irrigation (from Annex I of the proposed regulation)
Agricultural irrigation means irrigation of the following types of crops:
a) food crops consumed raw, meaning crops which are intended for human consumption to be eaten raw or unprocessed;
b) processed food crops, meaning crops which are intended for human consumption not to be eaten raw but after a treatment process (i.e. cooked, industrially processed);
c) non-food crops, meaning crops which are not intended for human consumption (e.g. pastures, forage, fiber, ornamental, seed, energy and turf crops).

1.3.3 The proposed water quality standards

The minimum requirements for all irrigation reuse schemes and monitoring thereof that have to be complied with to use reclaimed water for agricultural irrigations are defined in article 4 of the proposed regulation. The minimum requirements (standards and monitoring) are included in Section 2 of Annex I in the proposed regulation. Under Annex II, additional water quality requirements that are site or scheme specific are to be determined.

Brief descriptions of the proposed water quality standards for all reuse schemes are included in Table 1.1. Potential additional water quality requirements are discussed in the next chapters. For different categories of crops and irrigation methods, different reclaimed water quality classes are defined (Table 1.2), with different requirements with regard to the included water quality standards. Different treatment options are also included ('indicative technology targets'), but these are not further explained.

Validation monitoring procedures are also described for application before a reclamation plant is put in operation, for the first time or after modifications. For the most stringent water quality class (class A) validation monitoring entails the monitoring of reduction performance targets for indicator pathogens of each group of pathogens (bacteria, viruses, protozoa). All analyses used for routine and validation monitoring should be in accordance with EN ISO/IEC-17025 certification or other standards that ensure equivalent quality.

Competent Authorities in Member States that are responsible for permits can also set any additional conditions for water quality in relation to additional requirements proposed in the Water Reuse Management Plan or any other condition that is deemed necessary to further mitigate risks to human health or the environment (article 7 of the proposed regulation).

1.3.4 Evaluation process by the EC and independent scientific advise

The evaluation process of the proposed regulation included public stakeholder consultations, expert consultation in the framework of the Common Implementation Strategy for implementation of the Water Framework Directive to be included in impact assessment reports. Proposed minimum requirements by JRC were presented to selected experts from academia, the water sector and WHO, also in public events and scientific opinions of the independent Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and the European Food Safety Authority (EFSA) were considered. JRC developed a technical report as the scientific support for the development of the proposed legal instrument on minimum quality requirements for water reuse at EU level for agricultural irrigation and aquifer recharge (Alcalde-Sanz and Gawlik, 2017).

The independent Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) reacted to the proposed regulation (Rizzo et al. 2018). They concluded that the methodology chosen is appropriate and many important elements are included, but a number of key aspects are lacking: contaminants of emerging concern in waste water, spread of antibiotic resistance, and risks associated with treatment of waste water (disinfection by-products). The potential of effect-based bioanalytical tools is not considered. Microbial risks are insufficiently addressed, and it is noted that radiological hazards have not been addressed. The methodology on which the selection of minimum requirements in the EU proposed regulation relied is unclear. SCHEER recommends that guidance/criteria are defined for the development of case-by-case assessments of minimum requirements, using a tiered approach including screening and modelling efforts, to ensure that comparable health and environmental protection is achieved across EU Member States. In the guidance material, lists of chemicals and biological agents with target values should be included.

Table 1.1. Water quality standards included in the proposed regulation

Water quality standard	Description
E. coli (cfu/100)	*E. coli* are used as indicators of the presence of fecal material in water, and the possible presence of pathogens that may pose health risks to people exposed to the water body. As a microbial water quality standard, acceptable levels of *E. coli* are measured in colony forming units (cfu) per a volume of water.
BOD_5 (mg/L)	Biological Oxygen Demand (BOD) is the amount of dissolved oxygen needed by microorganisms to break down organic material in a given water sample, and depends on the degree of organic pollution in water. As a technical quality standard in waste water treatment, the BOD value is expressed in milligrams of oxygen consumed per volume of water during incubation at 20 °C for a certain amount of time.
TSS (mg/L)	Total suspended solids (TSS) is the dry weight of suspended particles in a sample of water. This material is trapped in a filter that is analyzed using a filtration apparatus. As a technical quality standard in waste water treatment, TSS is expressed as the total amount of suspended material per volume of water.
Turbidity (NTU)	Turbidity is the cloudiness of water caused by the presence of particles. As a technical quality standard in waste water treatment, turbidity is scored based on light measurements through the water sample.
Legionella spp. (cfu/L)	Certain types of *Legionella spp.* can cause a pneumonia-type illness (Legionnaires' disease) and mild flu-like illness. As a microbial water quality standard, *Legionella spp.* are measured in colony forming units (cfu) per volume of water.
Intestinal nematodes (helminth eggs) (egg/l)	Nematodes are intestinal, parasitic worms, living in and feeding on living hosts, disrupting their hosts' nutrient absorption which causes weakness and disease of the host. As a microbial water quality standard, nematodes are measured as number of eggs per volume of water.

Table 1.2. Classes of reclaimed water quality, allowed agricultural use in combination with an irrigation method, indicative technology targets and reclaimed water quality requirements and minimum monitoring frequency thereof between brackets (modified from Table 1, 2 and 3 from Annex I of the proposed regulation).

<table>
<tr><th>Reclaimed water quality class</th><th>Crop category</th><th>Irrigation method</th><th>Indicative technology target</th><th>E. coli (cfu/100)[1]</th><th>BOD_5 (mg/L)[2]</th><th>TSS (mg/L)[2]</th><th>Turbidity (NTU)[2]</th><th>Other</th></tr>
<tr><td>A</td><td>all food crops, including root crops consumed raw and food crops where the edible part is in direct contact with reclaimed water</td><td>all irrigation methods</td><td>secondary treatment, filtration and disinfection</td><td>≤10 or below detection limit [once a week]</td><td>≤10 [once a week]</td><td>≤10 [once a week]</td><td></td><td rowspan="4">Legionella spp.[1]: <1000 cfu/l where there is risk of aerosolization in greenhouses [once a week]

Intestinal nematodes (helminth eggs)[2]: ≤1 egg/l for irrigation of pastures or forage [twice a month or based on number of eggs in influent of reclamation plant]</td></tr>
<tr><td>B</td><td rowspan="2">food crops consumed raw where the edible part is produced above ground and is not in direct contact with reclaimed water, processed food crops and non-food crops including crops to feed milk- or meat-producing animals</td><td>all irrigation methods</td><td>secondary treatment and disinfection</td><td>≤100 [once a week]</td><td rowspan="3">25 mg/L O_2 [monthly or twice a month depending on size of the treatment plant] (according to Council Directive 91/271/EEC on urban waste water treatment)</td><td rowspan="3">35 [monthly or twice a month depending on size of the treatment plant] (according to Council Directive 91/271/EEC on urban waste water treatment)</td><td>n.a.</td></tr>
<tr><td>C</td><td>drip irrigation only</td><td>secondary treatment and disinfection</td><td>≤1000 [twice a month]</td><td>n.a.</td></tr>
<tr><td>D</td><td>industrial, energy, and seeded crops</td><td>all irrigation methods</td><td>secondary treatment and disinfection</td><td>≤10000 [twice a month]</td><td>n.a.</td></tr>
</table>

1. Compliant with requirement if indicated values are met in at least 90% of the samples and none of the samples exceeds the maximum deviation limit of 1 log unit from the indicated value
2. Compliant with requirement if indicated values are met in at least 90% of the samples and none of the samples exceeds the maximum deviation limit of 100% of the indicated value

1.4 This report

It is evaluated by researchers from KWR Watercycle Research Institute for the Dutch Ministry of Infrastructure and Water Management what this proposed regulation for reuse of domestic waste water for irrigation implies for public and environmental health risk assessment and management in the Dutch context, and can be sufficiently protective for human health and the environment in the Netherlands. To this aim, it is evaluated if critical aspects in hazard and risk assessment of microbial and chemical origin are included in the proposed regulation. A number of water reuse schemes in the Netherlands are described, for which the proposed regulation may become relevant when it shall apply. In the proposed regulation a reclamation plant is defined as an urban waste water treatment plant or other plants that further treat urban waste water. It is expected that in most cases in the Netherlands, the source for water reuse for irrigation is the effluent from domestic sewage treatment plants. To get insight in the performance of the proposed regulation, the steps in a Water Reuse Risk Management Plan are followed for the Haaksbergen water reuse scheme. This research is aimed to answer the following questions:

A. Are all elements of a Water Reuse Risk Management Plan included in Annex II of the EU proposal for regulation on minimum requirements for water reuse for irrigation?
B. Are the minimum requirements for water reuse for irrigation (Annex I of the EU proposal for regulation on minimum requirements for water reuse for irrigation) sufficiently protective for human health and the environment?
C. What information is needed to complete a human health and environmental risk assessment (as part of the Water Reuse Risk Management Plan) and is this information readily available?
D. What specific water quality standards to be included in monitoring can be derived from the risk assessment?
E. What knowledge gaps exist that result in uncertainties in the risk assessment?

2 Hazards and risks of water reuse

In the proposed regulation a hazard is defined as 'biological, chemical, physical or radiological agent that has the potential to cause harm to people, animals, crops or plants, other terrestrial biota, aquatic biota, soils or the general environment'. Independently of the hazard and severity thereof, there is only a risk if exposure occurs. In the proposed regulation a risk is defined as 'the likelihood of identified hazards causing harm in a specified timeframe, including the severity of the consequences'. Relevant hazards of water reuse for health and the environment can differ with different categories of irrigation, different exposed populations (such as agricultural workers or consumers), different land use types and soil and hydrological properties.

This chapter evaluates whether microbial and chemical hazards and risks are sufficiently considered in the EU proposal for regulation on minimum requirements for water reuse for irrigation. Knowledge gaps are defined and recommendations are formulated how to collect the necessary information. By referring to a list of EU legislations from which requirements and obligations are also to be taken into account, other requirements are indirectly included. The contents of these EU legislations are not considered in detail, but it is analysed whether microbial and/or chemical risks for humans and/or the environment are considered in these directives and regulations.

2.1 Microbial hazards

2.1.1 Microbial hazards for water reuse

Pathogens that can be found in waste water are diverse in characteristics and behaviour and include bacteria, viruses, protozoa and helminths (Table 2.2). Many of these pathogens are enteric pathogens, which infect the intestinal tract of humans and cause diarrheal disease. They are shed by infected persons in high concentrations in the faeces (some also via urine) and enter domestic waste water. They can survive for days to months outside the host. Most of these enteric pathogens do not grow or survive indefinitely in water. Hence, the prevalence and concentration of these pathogens in waste water reflects the types and rates of disease in the community. For common enteric pathogens, such as *Campylobacter,* norovirus and *Cryptosporidium,* this means that they are generally present in domestic waste water as it reaches the waste water treatment plant. For more rare pathogens, concentrations and frequency of occurrence is usually lower, except during epidemics. Ranges of reported concentrations in untreated waste water are provided in Table 2.2. As a general note, care should be taken in interpreting microbial data as reported pathogen concentrations can be derived using different methods, such as microscopy, culture and detection of genetic material using polymerase chain reaction (PCR). Culture-based methods tend to be time consuming and are not available for all pathogens but have the advantage of detecting living organisms. Tests using PCR and next generation sequencing are much quicker and are powerful tools for detecting the physical presence of microbial pathogens or components of pathogens, but do not generally determine viability or infectivity.

The routes of transmission of disease from exposure to waste water is gastrointestinal disease following ingestion of enteric pathogens, but other routes of transmission such as inhalation of aerosols or dermal contact can also lead to disease. Contact is generally much more prominent in sewage (treatment) workers than in the general population.

In contrast to the enteric pathogens, who live inside the host, so-called free-living pathogens, such as *Legionella pneumophila*, mycobacteria, and *Acanthamoeba* which are generally transmitted by routes other than ingestion, can grow under favourable conditions in treated (waste)water and associated biofilms, and, in some cases, can survive within amoeba in water systems (Marciano-Cabral et al, 2010).

2.1.1.1 Viruses

A wide range of human viruses occurs in domestic waste water. These viruses are very small (0.02 to 0.3 µm), a fraction of the size of bacteria. Many of these viruses are enteric viruses, viruses that infect the intestinal tract, cause gastroenteritis (inflammation of the stomach and intestines, with diarrhea, stomach ache, nausea, fever as general symptoms) and are shed via fecal matter. For these viruses, waterborne transmission is well-established and many outbreaks of gastro-enteritis via sewage-contaminated waters have been reported. Several of these viruses can also cause other, sometimes more serious illnesses, such as poliovirus causing poliomyelitis and hepatitis A and E virus causing liver infections. Other viruses are associated with other diseases, such as polyomavirus, for which an association with certain types of cancer is suggested, but not established.

In general, viruses are more resistant to environmental stresses than many bacteria, and some viruses persist for long times in waste water and sludge. Similar to bacteria and protozoan parasites, viruses can be physically removed or inactivated (Myrmel et al., 2006). However, due to the relatively small size of typical viruses, sedimentation, activated sludge and filtration processes are less effective at removal. Significant virus removal can be achieved with ultrafiltration membranes, possibly in the 3- to 4-log range. For viruses, inactivation by chemical or UV disinfection can be effective, provided the systems are well-designed and operated and can consistently deliver an effective dose. UV disinfection of viruses requires relatively higher doses of UV compared to inactivation of bacteria and protozoa.

Data on virus occurrence in domestic waste water are scarce. The Netherlands is among the countries where most environmental virus data are available, but also here the data are collected in research studies and not in monitoring of the treatment plants, and are hence patchy in time and space.

Bacteriophages, such as coliphages and F+RNA phages, are viruses that infect bacteria; they do not cause infections in humans and are often used as indicators, particularly indicators of the removal of viruses by water treatment processes.

Occasionally, new viruses emerge as human pathogens. These viruses usually have an animal host, but can make ‘the jump’ from animals to humans and may have a link with waste water. Relatively recent examples are avian influenza (H5N1), severe acute respiratory syndrome, coronaviruses (SARS) and Ebola virus. The risk of acquiring these viruses via waste water is very low (WHO, 2014; 2017a).

Table 2.1. Microbial hazards for water reuse

Pathogen	Disease	Concentration in sewage (per liter)
Viruses		
Adenovirus	Respiratory disease, eye infections, gastroenteritis (serotype 40 and 41)	Up to 10^4
Astrovirus	Gastroenteritis	
Enteroviruses	Gastroenteritis, heart anomalies, meningitis, respiratory illness, nervous disorders, others	Up to 10^6
Hepatitis A and E virus	Infectious hepatitis	
Norovirus	Gastroenteritis	Up to 10^6
Parechovirus	Gastroenteritis, respiratory illness	
Parvovirus	Gastroenteritis	
Polyomaviruses		
Rotavirus	Gastroenteritis	Up to 10^5
Sapovirus		
Bacteria		
Campylobacter	Gastroenteritis, reactive arthritis, Guillain-Barré syndrome	Up to 10^5
Enteropathogenic *Escherichia coli*	Gastroenteritis and septicemia, hemolytic uremic syndrome (HUS)	
Helicobacter	Chronic gastritis, ulcers, gastric cancer	
Legionella	Respiratory illness (pneumonia, Pontiac fever)	
Leptospira	Leptospirosis	
Mycobacteria (non-tuberculous)	Respiratory illness (hypersensitivity pneumonitis), skin infections	
Pseudomonas	Skin, eye, ear infections	
Salmonella	Salmonellosis, gastroenteritis (diarrhea, vomiting, fever), reactive arthritis	Up to 10^6
Salmonella typhi	Typhoid	
Shigella	Shigellosis (bacillary dysentery)	Up to 10^4
Staphylococcus	Skin, eye, ear infections, septicemia	
Vibrio cholera	Cholera	Up to 10^6
Yersinia	Yersiniosis, gastroenteritis, and septicemia	

Pathogen	Disease	Concentration in sewage (per liter)
Bacteria that are particularly resistant to antibiotics		
ESBL	Various infections with bacteria resistant to Extended Spectrum Beta Lactamases	
CRE	Various infections of Carbapenem Resistant *E. coli*	
VRE	Various infections of Vancomycin Resistant Enterococci	
Protozoa		
Acanthamoeba	Granulomatous amebic encephalitis	
Cryptosporidium	Cryptosporidiosis, diarrhea, fever	Up to 10^5
Cyclospora	Cyclosporiasis (diarrhea, bloating, fever, stomach cramps, and muscle aches)	
Entamoeba	Amebiasis (amebic dysentery)	Up to 10^2
Giardia	Giardiasis (gastroenteritis)	Up to 10^5
Microsporidia	Diarrhea	
Naegleria fowleri	Amebic meningitis	
Toxoplasma	Toxoplasmosis	
Helminths		
Ascaris	Ascariasis (roundworm infection)	Up to 10^3
Ancylostoma	Cutaneous larva migrans (hookworm infection)	
Echinococcus	Hydatidosis (tapeworm infection)	
Enterobius	Enterobiasis (pinwork infection)	
Necator	Necatoriasis (roundworm infection)	
Strongyloides	Strongyloidiasis (threadworm infection)	
Trichuris	Trichuriasis (whipworm infection)	Up to 10^2
Taenia	Taeniasis (tapeworm infection), neurocysticercosis	

Extracted from WHO Guidelines on Potable Reuse (WHO 2017a).

2.1.1.2 Bacteria

Bacteria are microscopic organisms ranging from approximately 0.2 to 2 μm. Common bacterial pathogens in the human population in the Netherlands are *Campylobacter* and *Salmonella* (de Wit et al., 2001). These bacteria are therefore also generally present in domestic waste water. Some data from the Netherlands are available for *Campylobacter* in domestic waste water that also carried waste water from the poultry industry (which is also commonly contaminated with *Campylobacter*) (Koenraad et al. 1994).

Enteric bacterial pathogen levels in waste water are lowered by conventional waste water treatment, but significant concentrations are still present in the secondary effluent. Because of their density, bacteria do not settle as individual cells or even colonies. Bacteria can adsorb to particulate matter or floc particles, and these particles settle during sedimentation, secondary clarification, or during an advanced treatment process such as coagulation/ flocculation/sedimentation. Bacteria can also be removed by using a filtration process that includes sand filters, or membrane processes. Bacteria can also be inactivated by disinfection. In a few waste water treatment plants in the Netherlands, additional disinfection is employed to protect bathing areas from contamination, which typically reduces the concentration of viable bacteria significantly.

As indicated, some bacterial pathogens are not enteric and do not get shed with the faeces, but can multiply in water and waste water treatment processes under the right conditions. An important example is *Legionella pneumophila,* that is present in activated sludge systems (Medema et al. 2004). *Legionella pneumophila* is transmitted via aerosols released from waste water aerators and other waste water or sludge treatment processes.

Recent studies show that bacteria that are particularly resistant against antibiotics are present in domestic and hospital (and agricultural) waste water (Schmitt et al, 2017; Taucer et al, 2016) in the Netherlands. The removal of these bacteria by conventional waste water treatment is comparable to the non or less resistant bacteria, but the removal of the resistance-genes may follow a different trend as a result of horizontal gene transfer or selection of a resistant subpopulation in some water treatment processes.

2.1.1.3 Protozoa and helminths

Parasites with a waterborne transmission route are usually excreted in faeces in an environmentally robust stage, such as spores, cysts, oocysts, or eggs, which can be very resistant to environmental stresses such as desiccation, heat, freezing, and sunlight. Most parasite spores, cysts, oocysts, and eggs range in size from a few to 60 μm (substantially larger than bacteria). Helminths can be present as the adult organism, larvae, eggs, or ova. The eggs and larvae, which range in size from about 10 μm to more than 100 μm, are resistant to environmental stresses. In reclaimed water, protozoa and helminths can be physically removed by sedimentation or filtration because of their relatively large size. Protozoa and helminths may be resistant to disinfection by chlorination or other chemical disinfectants, but may be inactivated using UV disinfection.

Of this group, infections with *Cryptosporidium, Giardia, Toxoplasma* and *Entamoeba* are more prevalent in the Dutch population than for the other protozoa and helminths. Some data are available on *Cryptosporidium* and *Giardia* in domestic waste water in the

Netherlands and the removal by conventional waste water treatment (Medema et al. 2001).

2.1.2 Evaluation of proposed minimum requirements

For all classes of irrigation, minimum requirements are set for the microbial parameters *E. coli, Legionella spp.* and helminth eggs. Other minimum requirements can be associated to microbial safety: required turbidity levels in Class A are incorporated to evaluate filtration performance and safeguard disinfection performance (to some extent, since 5 NTU is still high for adequate disinfection processes). *E. coli* is a general indicator of the level of fecal contamination, but in this proposed regulation it is used to indicate whether the treatment is capable of reducing the level of fecal contamination to such an extent that safe reuse is possible. Since *E. coli* is very sensitive to disinfection process, more sensitive than viral and protozoan hazards, the value of *E. coli* is less for disinfection schemes. For class A, this is at least partially compensated by the validation monitoring requirement for phages and spores (the more persistent indicators), but for the other classes this is not. This may give a wrong sense of safety for schemes that rely on disinfection.

Legionella spp. is taken as parameter, while the vast majority of severe infections is due to *Legionella pneumophila.* Water systems may contain many different types of *Legionella,* including non-pathogenic types. We would therefore recommend to focus monitoring and risk management on *Legionella pneumophila.* The requirement for *Legionella spp.* is in greenhouses where there is a risk of aerosolization. This is a relatively high-risk setting for *Legionella pneumophila*¸ given water temperatures in irrigation systems. However, several urban waste water systems have been associated with *Legionella pneumophila* outbreaks, particularly linked with waste water influenced by high organic/high temperature waste streams such as from breweries or paper mills. We would recommend to include this in the hazard and risk assessment in the Water Reuse Risk Management Plan. The risk of workers in close proximity of (spray) irrigation or other aerosol generating conditions should be incorporated in this plan.

Helminth eggs seems a bit overdone, particularly for Class A systems, as the validation monitoring will demonstrate high removal of (indicators for) smaller parasites such as *Cryptosporidium.* Hence, meeting the Class A requirement should be very adequate in protecting against helminth eggs and the monitoring of helminth eggs would be more appropriate as consequence of a site-specific Water Reuse Risk Management Plan than as generic parameter.

For Class A, validation monitoring is required to establish whether treatment performance targets are met. These are defined as required Log removal values of bacterial (5 log), viral (6 log) and protozoal (5 log) pathogens are met and can be determined by monitoring of E.coli, somatic coliphages and spores of *Clostridium perfringens* (or spore-forming sulphate-reducing bacteria, which is incorrect and should be spore-forming sulphite reducing clostridia since these are faecal indicator spores) as indicators. Overall, the use of the validation monitoring indicators is adequate to cover the treatment performance with respect to all enteric bacterial, viral and protozoan pathogens. However, no guidance is provided on the intensity of validation monitoring that is required. It could be argued that this will be harmonized across the Member States through the required contact between Member States, but we would advise on giving some guidance on validation monitoring requirements.

The point of compliance for the validation of the treatment performance is the outlet of the reclamation plant. Conventional waste water treatment systems reach in general 1-2 log removal and would therefore need to install additional treatment/disinfection processes.

Given the dependence of microbial counts on the methods applied, it is recommended to include reference to the ISO methods for *E. coli*, somatic and F+ specific phages and *Clostridium perfringens.* The footnote to the table indicates that validation monitoring can also be carried out using *Campylobacter,* rotavirus and *Cryptosporidium* as reference pathogens. For *Campylobacter* and *Cryptosporidium*, relatively well-established standard methods exist that are available in some Member States that may want to select for such an approach. The use of the reference pathogens provides a more specific validation, but at significantly higher costs. For rotavirus, no standard method is available and virus monitoring (research) labs are available in only some Member States. For virus detection, culture methods exist that only detect infectious virus particles but are complex and very expensive. Also molecular methods (qPCR) exist, but the concentrations are usually much (10-1000 fold) higher than with cell culture methods and they are less suitable for the validation of disinfection methods since they may also pick up inactive virus particles. The JRC selected rotavirus on the basis of the infectivity. In the EU setting, other enteric viruses are more prominent and present in higher concentrations in waste water, such as noroviruses and adenoviruses. Adenoviruses are more resistant to UV disinfection and hence more critical for such systems.

2.1.3 State-of-the-science / innovative methods

The state of knowledge on the presence of microbial hazards in waste water in the Netherlands is “patchy” at best. Several research studies have monitored one or a few waste waters in the Netherlands for a single or a few of the microbial hazards for one year, usually capturing at least part of the temporal variation by taking monthly samples for one year. These are presented (as maximum value) in Table 2.2. Many of these data were collected around two decades ago. The spatial variation is not well represented, except for the recent study on ESBL E.coli and CRE of Schmitt et al. (2017) that sampled 100 waste waters throughout the country (once). An operator of a reclamation plant will therefore not have site specific data on these pathogens.

A limitation of collecting pathogen data is the complexity and costs of the pathogen methods. The development of real-time quantitative polymerase chain reaction (PCR) analyses (LeCann et al. 2004; Van den Berg et al. 2005) has made pathogen analysis more accessible than the conventional cell-culture methods, but still requires purification and processing. This technique could serve as a relatively simple and cheap screening tool for pathogens in waste water, although it also does not give information about the viability/infectivity of pathogens. waste water

In the Australian guidelines for water recycling (2006), the authorities have opted for a generic approach. Rather than having all operators monitor the concentration of all pathogens at each reclamation plant, they have selected reference pathogens (one bacterial pathogen (*Campylobacter*), one virus (Adenovirus) and one parasite (*Cryptosporidium*)) on which concentration data were available from waste water in the Australian context and selected the 90-percentile of these data as the default waste water concentration. The most critical pathogens for the safety of the reuse system were selected as reference pathogens, so adequate control of these pathogens would imply adequate control of each of the pathogens. This is valid for the enteric pathogens. Other pathogens, such as *Legionella pneumophila,* are not covered by this approach and need to be assessed separately. This approach would also be valid for the Netherlands, provided a proper justification of the selection of the reference pathogens is made and recent data on their concentrations in waste water become available.

For antibiotic resistant bacteria in waste water, recent data are available for ESBL *E. coli* and Carbapenem resistant *E. coli* (Schmitt et al., 2017). There are several more particularly resistant micro-organisms of concern (BRMO, RIVM 2018), but not all of them are relevant for the water cycle. There is discussion about the significance of the water route for human exposure to antibiotic resistant bacteria. WHO has indicated that discharge and exposure via waste water should be kept as low as reasonably achievable (WHO, 2018). In this context, it will be difficult for operators of reclamation plants to evaluate the risk of antibiotic resistance in their reuse scheme. It would be beneficial to provide more guidance on this subject, to select a reference antibiotic resistance (bacterium and/or gene(s)) and method for analysis to be able to meet the WHO ALARA guideline also for waste water reuse schemes. ESBL E.coli could be a suitable candidate, given that it is widespread, one of the resistant bacteria of concern, good methods are available for enumeration in waste water and they are present in relatively high concentrations.

New methods are becoming available in the research setting for the analysis of microbial hazards, particularly metagenomics. By analysing the total microbial DNA content in a water sample, information can be collected on bacterial pathogens, virulence genes, antimicrobial resistance genes, mobile genetic elements etc. These are powerful research tools that will become available for routine screening, but this will take a number of years of research and development, of the methods, the bioinformatics, the quantification etc.

2.2 Chemical risks

In this section, chemical risks for humans and the environment of water reuse are described, as well as possible effects on crops, and new and innovative methods to evaluate risks are described. Risks of chemicals for human health or the environment can be estimated based on toxicological information, the effects of chemicals and safe exposure levels, and the realistic exposure that is occurring. Exposure levels can be monitored, but in a risk management scheme it is very useful if exposure levels can be predicted, for example based on (expected) levels in waste water, treatment efficiency, distribution and degradation in water, soil and air, and absorbance in plants. The information needed and possible knowledge gaps are described.

2.2.1 Chemical hazards

Tens of thousands of chemicals are used routinely in industry, agriculture, health care and households, and will end up in waste water collections systems (Table 2.1). If industrial effluents and/or sewage water from health care institutions are also included in the waste water, different or more anthropogenic chemicals may be present, or in higher concentrations. Concentrations of anthropogenic chemicals depend on the number and type of industries that discharge their waste into the waste water and on treatment prior to discharge. There can also be other (unexpected) sources of chemicals, such as agricultural runoff or leaks from storage tanks. Domestic waste is known to be a source of a wide range of chemical hazards, including, those in faecal material and laundry, and kitchen and bathroom discharges (pharmaceuticals, natural steroidal hormones, personal care products), but also via disposal of excess products (paints, oils, garden pesticides and unused pharmaceuticals), or algal toxin production in waste water storage or environmental buffers. Waste water can thus present a continually evolving composition of chemicals in complex mixtures due to developments in local circumstances and industrial activities.

In the WHO guidelines for water reuse for irrigation (2006), hazards for human health associated with waste water use in agriculture include exposures to skin irritants (cause not defined, could be chemicals or cyanobacterial toxins), heavy metals (arsenic, cadmium, lead, mercury), halogenated hydrocarbons (dioxins, furans, PCBs) and crop protection chemicals (WHO 2006). There are in particular concerns for emerging organic chemicals that are mobile and persistent in the water cycle (Arp et al. 2017), such as perfluorinated chemicals (PFAS).

Contaminants can also be formed during the treatment process, in the form of disinfection by-products. For example, advanced oxidation (H_2O_2-UV) may lead to by-products (Heringa et al., 2011; Vughs et al. 2018). Disinfection by-products are formed by reactions between disinfectants and organic and inorganic constituents of water, and depend on concentrations of organic components, ammonia, bromide and iodide in the source water, the type of disinfectant used and process parameters. Production of disinfection by-products from UV disinfection depends on factors such as the UV dose and the production of secondary reactive radicals which may catalyse chemical transformations. Treatment of waste water may lead to generation of high amounts and unique disinfection by-products (WHO 2017a).

During irrigation with reclaimed water, chemicals can also reach the groundwater. This may add to other chemicals that may be present in the soil, due to anthropogenic activities related to the land-use, infiltrating surface water, by historical contamination or activities in the sub-soil (Ter Laak et al. 2012). The vulnerability of groundwater aquifers depends on soil characteristics and groundwater hydrology (Mendizabal et al. 2012, Van Wezel et al. 2009). The amount and number of anthropogenic chemicals present in soil likely increases with higher percentages of infiltrated surface water. Chemical properties, such as persistence and mobility, are reflected in spatio-temporal patterns of chemical occurrence in groundwater after emissions (Kodešová et al. 2015).

Table 2.2. Chemicals potentially present in waste water or produced during treatment (modified from WHO 2017a)

heavy metals	polychlorinated biphenyls
personal care products	synthetic industrial chemicals
antiseptics	cyanobacterial toxins
pharmaceuticals	desinfection by-products
flame retardants	volatile organic compounds
dioxins	crop protection chemicals
nanomaterials	steroidal hormones (estrogenic and androgenic)
inorganic chemicals	per- and perfluoralkyl substances
	petroleum components
	plant hormones

2.2.2 Human health and environmental risk assessment

Human health chemical risk assessment is the procedure to get insight in potential adverse health effects associated with exposure to chemicals. Risk is a function of 1) level of exposure and 2) toxicity of the chemical. Safe intake levels are derived from toxicological information, which can be used to derive safe levels in drinking water, or other matrices relevant for exposure of humans to chemicals (food, soil, air). In cases where insufficient information is available to derive a safe exposure level, the Threshold of Toxicological Concern (TTC) can be used, which is not chemical-specific and conservative (Baken et al. 2018). Carcinogenicity and effects on development and reproduction are of the highest concern, and other effects have also been indicated relevant for exposure to chemicals via water, including (treated) waste water. These are for examples effects related to xenobiotic metabolism, modulation of hormone systems and adaptive stress responses (reviewed in Dingemans et al. 2018).

Irrigation with (treated) waste water may introduce chemicals in the soil, which may affect human health by transfer through the food chain, or via contamination of surface water and groundwater. Humans can thus be exposed to chemicals in reclaimed water via many different exposure routes (Figure 2.2), for example via direct contact with water (dermal and oral), transfer of chemicals to produce via soil, and contamination of produce. For exposure via consumption of crops, the degree of absorbance of the chemical in plants is also a critical factor. The exposure also depends on activities of the exposed individuals or populations. While the plant operator may come in direct contact with reclaimed water (in particular if aerosols are formed), this exposure route is less relevant for other people, although they may be exposed via consumption of crops irrigated using reclaimed water (cooking has little or no impact on the amounts of chemicals in crops). The relative relevance of different exposure routes will differ per situation. This depends on the type of irrigation, type of crop, and behaviour of chemicals in the soil that are present in the reclaimed water.

In waste water streams, metals and inorganic chemicals are generally present in higher concentrations (µg to mg per L) while pharmaceuticals and personal care products, when detected, are generally present in lower concentrations (ng to µg per L) (WHO 2017a). In most cases, reported concentrations were below those that would be associated to health risks (WHO 2017a). Nevertheless, this needs to be verified for each water reuse situation based on actual measurements.

Possible health protection measures to reduce exposure to chemicals are reducing concentrations of chemicals in the reused water (by preventing that chemicals reach the waste stream, or treatment processes for removal) and restricting access to irrigation fields and structures. Although this may be of less relevance in the Netherlands, access to safe drinking water and recreational water can also be used as a risk management measure.

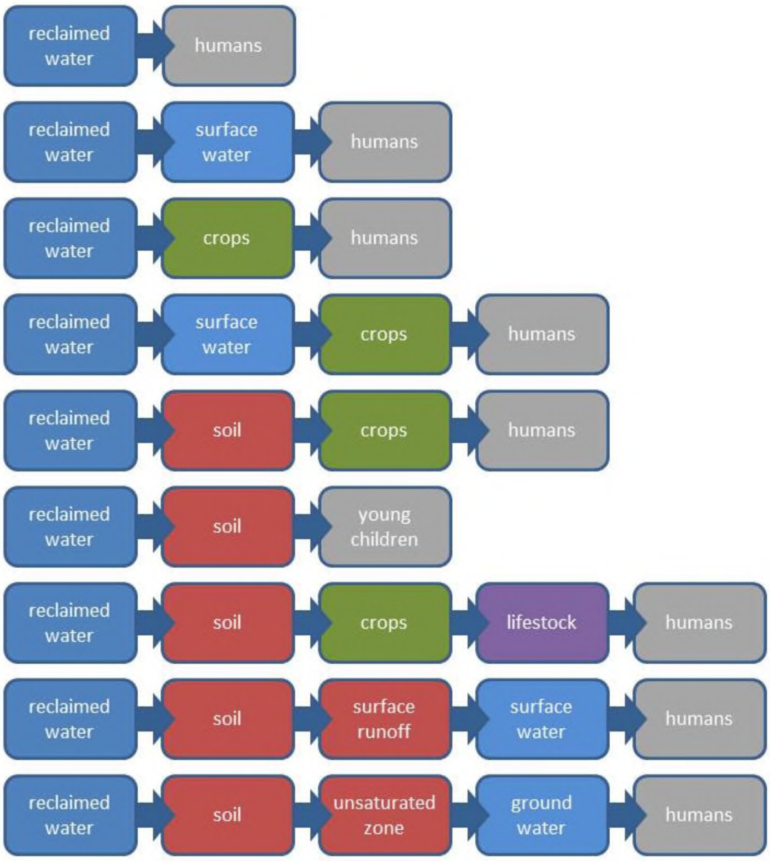

Figure 2.1. Exposure routes by which humans can be exposed to chemicals in reclaimed water. In the case of water reuse for irrigation, the direct exposure route (reclaimed water > humans) is in particular via dermal exposure and inhalation of aerosols. Other exposure routes (not included in the figure) can be via ingestion of soil by lifestock, ingestion of contaminated crops by lifestock, and via airborne particulates and inhalation of evaporated compounds from the soil. .

Human health protection in the context of irrigation has been mainly based on maximum concentrations in the soil. Chemicals are introduced in the soil via irrigation, but can also degrade in the soil. Biodegradation rates in the soil depend on residence time, sorption to the soil, uptake in plants, soil passage, physico-chemical properties of the micropollutant, and seasonal changes in temperature and rainfall. Absorption of high molecular weight chemicals in plants is unlikely (WHO 2006), but these chemicals can adhere to crops irrigated with (treated) waste water. For inorganic elements, their concentrations in waste water-irrigated soils may slowly rise with each successive waste water application.

For chemicals of potential health concern that have been detected in waste water maximum concentrations of chemicals in soil irrigated with (treated) waste water were calculated by the WHO (2006) based on health-based guidance values (acceptable daily intake), the transfer of chemicals from (treated) waste water via soil and plants to humans, and intake of chemicals via consumption of grain, vegetable, root/tuber crops and fruit. Such maximum values were calculated in particular for elemental metals and crop protection chemicals. Assumptions in the exposure scenario included that most exposed individuals were adults whose entire consumption consisted of waste water irrigated food resulting in exposure of maximally 50% of the acceptable daily intake. Information of the presence of emerging chemicals in drinking water is available in a recent review paper by Baken and co-workers (2018), and information on emissions of chemicals in STP effluent can be found in the Watson-database (Rijkswaterstaat 2000). However, not for every emerging chemical, the needed information for such an analysis may be completely available, and a different exposure scenario may be more appropriate for the Netherlands.

There have been cases of health problems in crop consumers caused by high levels of metals due to accumulation in soil (field studies, demonstration projects and laboratory studies are reviewed in WHO 2006). Absorbance of metals in plants occurs after a critical threshold concentration in the soil is reached and the metal is in a mobile phase. The capacity of the soil to bind metals depends on the pH of the soil. Examples of metals that often have been detected in waste water (worldwide) are cadmium, copper, molybdenum, nickel and zinc. In particular for cadmium and nickel, human health hazards are known.

In the current WHO Guidelines for drinking water quality (WHO 2017b), health-based guideline values are included for chemicals from different sources. The different categories are naturally occurring chemicals, chemicals from industrial sources and dwellings, chemicals from agricultural activities, and chemicals used in water treatment or materials in contact with drinking water. Lists of chemicals for which no guideline values are derived, including rationales for this decision. Example lists of guideline values for parameters included in water quality monitoring (physical and organoleptic parameters, elements, microbiological indicators, disinfection-byproducts, biological parameters and trace contaminants) are included in the WHO guidelines for potable reuse, and methods to derive indicative guideline values for emerging chemicals are also described in detail (WHO 2017a). Not all of the chemicals listed in these guidelines are of (high) relevance for the Dutch situation, and the degree of exposure to chemicals via irrigation with reclaimed water is lower in comparison to exposure via drinking water. Although potable reuse is outside of the scope of the proposed regulation, these lists can be used as a starting point. A list of the most relevant chemicals for (validation) monitoring of reclamation plants can be based on the known or expected presence in waste water, Maximum Residue Level on plants (indicating a human health relevance of exposure via food), criteria for groundwater (from the Groundwater directive) and crop requirements. Minimum requirements (target values) for these chemicals need to be further defined based on relevant exposure routes and expected or realistic worst-case fate and transport of chemicals from the release from the STP to human exposure.

As human health risks, environmental risks depend on exposure and effects. Environmental quality standards are commonly based on the 5th percentile of effective concentrations in effect-studies in model species for different relevant taxa (protecting >95% of relevant species). There are many methods and approaches available for environmental risk assessment, and it was recently concluded based on a joint workshop of the Norwegian Scientific Committee for Food and Environment and the European Food Safety Administration (EFSA) that harmonization is urgently needed (Finne and Wendell 2018). Chemicals present in reclaimed water for irrigation may also impact agricultural productivity, especially through salt content. For many chemicals, limit concentrations of chemicals in water are based on crop requirements, and not on human health concerns. Some chemicals, such as sodium chloride, boron and selenium are much more toxic to plants than to humans, and leaf damage may occur from spraying crops with water containing high concentrations of sodium or chloride ions, or with high residual chlorine. Waste water also contains nutrients that can be useful for crop production, such as nitrogen, phosphorus, potassium and organic matter. Organic matter of human, animal or plant origin is rapidly decomposed in soil, resulting in the formation of non-toxic organic compounds such as humic and fulvic acids (WHO 2006). Also nutrients should be present in the right concentrations to not damage crops or the environment. Required concentrations of nutrients may vary in different crop production stages. In the case of nitrogen, overly high quantities may result in the leakage of nitrate, a human health hazard, in groundwater sources for drinking water. Within the context of the EU Water Framework Directive, lists of environmental quality standards are published for priority pollutants and riverbasin-specific pollutants (EU Directive 2008/105/EC) and these can be used in combination with information on known or expected presence in waste water and crop requirements to generate a list of the most relevant chemicals for (validation) monitoring of reclamation plants.

2.2.3 Risk based monitoring and innovative approaches

Worldwide, water regulations prescribe water quality standards for a selection of chemicals. Due to increased knowledge on possible effects and analytical possibilities, the number of chemical parameters included in monitoring programs of water utilities increased in the last decade. In accordance with the European Drinking Water Directive (EU DWD), utilities aim at a tailored risk-based monitoring program. This means more flexibility in monitoring to reduce obsolete analyses and to concentrate on the most relevant issues at hand, provided that the protection of human health is ensured. To this aim, the principles of risk management through Hazard Analysis and Critical Control Point (HACCP; van Wezel et al. 2010) and WHO water safety plans (Kot et al. 2015) can be followed.

Risk-based monitoring programs can be designed based on knowledge on the chemical composition of the waste water and effluent, in analogy with risk-based monitoring programs for drinking water production where information on source water and produced drinking water is used (Sjerps et al. submitted). Moreover, the status and vulnerability of the receiving water bodies (e.g. water in the unsaturated zone, groundwater) should be mapped before the irrigation with reclaimed water is started. In some cases, this information is available, and in other cases this may need to be collected as part of the Water Reuse Risk Management Plan. Analysis of the chemical water quality of (filtered) influent and effluent in different STPs can also give information on the results of variations in treatment on removal efficiency. Several approaches are available to prioritize chemicals for inclusion in risk-based monitoring (see Appendix for additional information):

1) Bioanalytical tools for effect-based monitoring and effect-directed analysis
2) Non-target screening approaches
3) Human biomonitoring

The workflow for risk-based monitoring as proposed by KWR Watercycle Research Institute (Sjerps et al. submitted) based on target chemicals and connected to a feed of new relevant chemicals based on HRMS suspect screening, is currently being developed further in the Dutch drinking water sector in dialogue with the Dutch competent authority (Human environment and Transport Inspectorate). It is foreseen that a variant may be developed for Water Reuse Risk-based monitoring. As exposure to chemicals via irrigation with reclaimed water is much less in comparison to exposure via drinking water, and innovative techniques may be labour and cost intensive to be included in routine requirements, it is expected that a risk-based monitoring workflow for water reuse for irrigation can suffice with only part of the available technologies proposed in the workflow for drinking water purposes.

Bioanalytical tools give information on the integrated effect of mixtures of chemicals related to a specific health effect. This can also give a health-based insight in the water quality of reclaimed water, and variation thereof between STPs and in time. In the recent proposal for amendment of the Policy for Recycled Water by the California Water Boards (California Water Boards, 2018), the use of bioanalytical screening tools is required in an initial assessment and baseline monitoring phases. Specific bioanalytical tools are included: a calux bioassay for activation of the estrogen receptor to detect chemicals with endocrine effects and a calux bioassay for activation of the aryl hydrocarbon receptor to detect chemicals with dioxin-like effects, and a method for evaluating the effect-based monitoring results and response action are also provided in the proposed amendment. It may not be feasible currently to include non-target screening methods and human biomonitoring although these approaches have the potential to identify long-term trends in exposure related to water reuse.

International networks and recent EU projects working on emerging chemical and microbial risks (not exhaustive)
NORMAN network - www.norman-network.net
COST Action NEREUS ES1403 - www.nereus-cost.eu
PROMOTE - www.ufz.de/promote/
SOLUTIONS - www.solutions-project.eu
DEMOWARE - http://demoware.eu/en
ANSWER MSCA ITN - www.answer-itn.eu

2.3 Reference to other EU legislation

EU legislations to which is referred in the proposed regulation are included in Table 2.1. These directives and regulations cover microbial and/or chemical risks for humans and/or the environment.

There are however also other legislations in the EU legislative frameworks on chemicals with respect to (indirect) impact on water quality that are not included in the EU proposal for regulation on minimum requirement for water reuse for irrigation. Most of the EU legislation related to the impact on the receiving environment (immission) is referred to in the EU proposal for reuse (except the directive related to the marine environment). Some but not all of the legislation related to reduction of emission to the environment are included. No legislation related to market introduction and approved use, like the REACH legislation, and other legislation restricting use of (veterinary) pharmaceuticals, plant protection products, biocides, and chemicals used in food, cosmetics and electronics is referred to in the EU proposal.

It remains unclear why some EU directives and regulations are referred to and other are not, or which requirements from these legislations should be included in Water Reuse Safety Planning.

Table 2.3. Requirements and obligations to take into account in risk assessment (modified from Annex II of the proposed regulation)

	Aim	Microbial risks		Chemical risks	
		human	environment	human	environment
Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources	reduce and prevent water pollution from nitrates	-	-	x	x
Council Directive 98/83/EC on the quality of water intended for human consumption	drinking water protected areas	x	-	x	-
Directive 2006/118/EC on the protection of groundwater against pollution and deterioration	prevent groundwater pollution	-	-	x	x
Directive 2008/105/EC on environmental quality standards in the field of water policy (amendments in annexes: 2013)	meet the environmental quality standards for priority substances and certain other pollutants	-	-	x	x
Directive 2000/60/EC establishing a framework for Community action in the field of water policy	meet the environmental quality standards for pollutants of national concern (i.e. river basin specific pollutants)	-	-	x	x
Directive 2006/7/EC concerning the management of bathing water quality	meet the bathing water quality standards	x	-	-	-
Council Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture	protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture	-	-	x	x
Regulation (EC) No 852/2004 on the hygiene of foodstuffs	hygiene of foodstuffs and addressing microbiological risks in fresh fruits and vegetables	x	-	-	-
Regulation (EC) No 183/2005 laying down requirements for feed hygiene	requirements for feed hygiene	x	x	x	x
Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs	comply with the relevant microbiological criteria	x	-	-	-
Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs	requirements regarding maximum levels for certain contaminants in foodstuffs	-	-	x	-
Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin	requirements regarding maximum residue levels of pesticides in or on food and feed	-	-	x	-
Regulation (EC) 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption	requirements regarding animal health	x	-	-	-
Commission Regulation (EC) 142/2011 laying down health rules as regards animal by-products and derived products not intended for human consumption	requirements regarding animal health	x	-	-	-

2.4 Conclusions and recommendations

- Waste water generally contains multiple microbial and chemical hazards.
- The composition continually evolves and chemicals are present in complex mixtures due to developments in local circumstances.
- Irrigation with (treated) waste water may introduce microbial and chemical hazards on the crops and in the soil, which may affect human health by transfer through the food chain, or via contamination of surface and groundwater.
- For all classes of irrigation, minimum requirements are set for the microbial parameters *E. coli, Legionella spp.* and helminth eggs. Other minimum requirements can be associated to microbial safety: required turbidity levels in Class A are incorporated to evaluate filtration performance and safeguard disinfection performance (to some extent, since 5 NTU is still high for adequate disinfection processes).
- Since *E. coli* is very sensitive to disinfection process, more sensitive than viral and protozoan hazards, the value of *E. coli* is less for disinfection schemes. For class A, this is at least partially compensated by the validation monitoring requirement for phages and spores (the more persistent indicators), but for the other classes this is not. This may give a wrong sense of safety for schemes that rely on disinfection.
- *Legionella spp.* is taken as parameter, while the vast majority of severe infections is due to *Legionella pneumophila.* Water systems may contain many different types of *Legionella,* including non-pathogenic types. We would therefore recommend to focus monitoring and risk management on *Legionella pneumophila.*
- We recommend to include the risk of *Legionella pneumophila* transmission in other settings than greenhouses in the hazard and risk assessment in the Water Reuse Risk Management Plan. The risk of workers in close proximity of (spray) irrigation or other aerosol generating conditions should be incorporated in this plan.
- Meeting the Class A requirement should be very adequate in protecting against helminth eggs and the monitoring of helminth eggs would be more appropriate as consequence of a site-specific Water Reuse Risk Management Plan than as generic parameter.
- For Class A, validation monitoring is required to establish whether treatment performance targets are met. Overall, the use of the validation monitoring indicators is adequate to cover the treatment performance with respect to all enteric bacterial, viral and protozoan pathogens. We recommend to give guidance on validation monitoring requirements.
- The point of compliance for the validation of the treatment performance is the outlet of the reclamation plant. Conventional waste water treatment systems reach in general 1-2 log removal and would therefore need to install additional treatment/disinfection processes for Class A reclamation schemes.
- Given the dependence of microbial counts on the methods applied, it is recommended to include reference to the ISO methods.
- In the EU setting, other enteric viruses are more prominent and present in higher concentrations in waste water, such as noroviruses and adenoviruses. Adenoviruses are more resistant to UV disinfection and hence more critical for such systems.

- No minimum requirements for chemicals are included in the proposed regulation, the Water Reuse Risk Management Plan should determine if/which minimum requirements for specific chemicals in specific settings are needed.
- Minimum requirements at point of release should depend on the fate of microbial and chemical hazards in the environment and exposure routes to humans. Relevant factors are known but hazard-specific information is often lacking.
- Reference is made to existing legislation but this is not readily accessible for the responsible parties and it is not clear which requirements are most relevant in reuse cases.
- Lists of relevant chemicals for monitoring of reclamation plants can be based on waste water levels, minimum requirements for food and environmental targets, and fate and transport of chemicals between release from the reclamation plant and exposed humans/environment,
- A variation can be made on risk-based monitoring programs as currently in development for drinking water, including innovative methods such as bioanalytical tools.

3 Water reuse for irrigation in the Netherlands

Despite yearly average rain surplus, periods of drought are experienced regularly in the Netherlands. Changes in the climate may lead to more frequent, longer and more extreme drought periods (Klein Tank et al., 2014). Unless there is sufficient water available for irrigation, this may lead to reduced crop yields. Sewer treatment plants (STPs, Figure 3.1) and waste water treatments plants (WWTPs) generate a near-continuous supply of effluent, which may be used to prevent reduced yields resulting from drought.

Until the end of the 1970s, there were many cases where domestic waste water and waste water from dairy and potato factories (containing nutrients such as nitrogen and phosphorus) were used for irrigation of crops in fields near the supply. In the years after, the use of waste water was mostly abandoned due to increasing load of nutrients and industrial emissions of chemicals. This resulted in groundwater quality problems at the irrigated fields as well as a threat to near drinking water sources. Moreover, nutrients were commercially available in the form of fertilizers. In the 1990s, a number of options for the use of treated waste water were explored in the Netherlands. It was already concluded that this can be economically responsible (especially in greenhouses and the cultivation of trees and plants), and that transport via the soil may lead to improved water quality of surface waters. Practical implementations were however not followed-through (Cirkel et al. 2017).

Reuse of treated waste water in crop irrigation fits clearly in the concept of the circular economy and a number of pilots are ongoing (conducting extended treatment for irrigation in greenhouses, or subirrigation for groundwater supply). Vreman et al. (2018) provide an overview of waste water reuse projects/initiatives in the Netherlands. It is expected that the number of reuse cases will increase. The main drivers for reuse of effluent are 1) reduced availability of freshwater (either groundwater or surface water), 2) water scarcity problems resulting from groundwater extraction, and 3) reduction of nutrient load of surface water. In all applications, the impact on groundwater, soil, crop quality and the potential impact on drinking water sources will depend on the effluent source and treatment, and will need to be evaluated on a case-by-case basis.

3.1 Water reuse systems

Use of treated waste water for irrigation is not common practice in the Netherlands. However, several water reuse systems are in place in the Netherlands that apply different water sources and treatment options. In this paragraph, some examples of systems are described as well as relevant experiences and learning-points (based on Cirkel et al, 2017). A complete overview of current projects and new initiatives is given by Vreman et al. (2018).

Early studies

At the NIZO food research institute, small-scale irrigation has been used and investigated, and a number of other feasibility studies were designed. In the 1990s, a number of options for the use of highly treated effluent of STP Ruurlo for groundwater recharge in landgoed de Wiersse (Gelderland) were explored (sprinkle irrigation, surface irrigation, infiltration via drains or a closed network of ditches) although not put into practice (Binnendijk et al., 1993, Vissers et al., 1994).

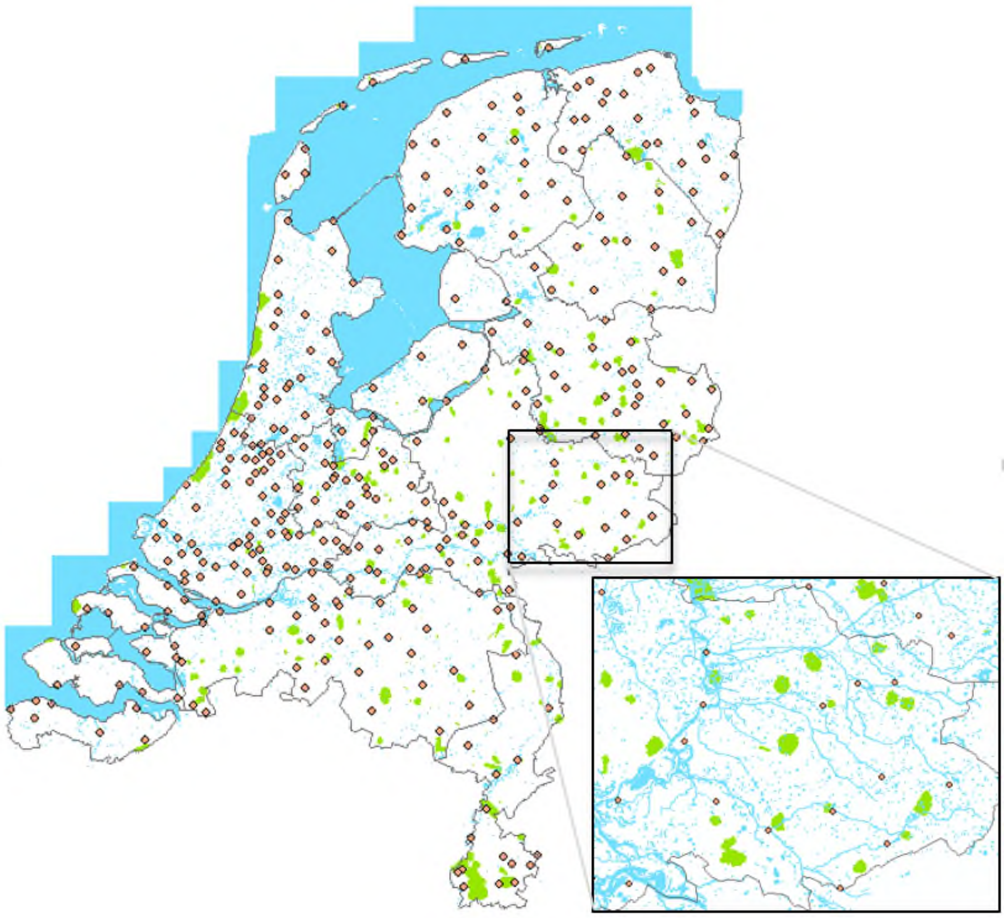

Figure 3.1. Locations of sewer treatment plants in the Netherlands (red dots), surface water (blue) and groundwater protection areas (green) (modified from Cirkel et al. 2017).

Haaksbergen

A pilot project has been setup in Haaksbergen (the eastern part of the Netherlands), in which treated waste water (STP) is applied to a corn field by subirrigation (Figure 3.2) during the growing seasons of 2015-2018, using a climate adaptive drainage system. While the water availability for the crop increases significantly, much attention is being paid to quantify the emission of contaminants of emerging concern, like pharmaceuticals, to the root zone and the deeper groundwater. The chemical composition of treated domestic waste water is different from infiltrating excess rainfall water and natural groundwater. In the pilot project, the bromide-chloride ratio and traces of pharmaceuticals in the treated waste water are used as a tracer to describe water and solute transport in the soil system. Focus of this pilot study is on quantifying potential contamination of both the root zone and the deeper groundwater with pharmaceutical residues. A field monitoring network has been installed at several locations in the vadose zone and the local groundwater system, which enables to measure vertical solute profiles in the soil water by taking samples.

The Haaksbergen case is a water reuse application in the Netherlands to which the proposed EU regulation applies.

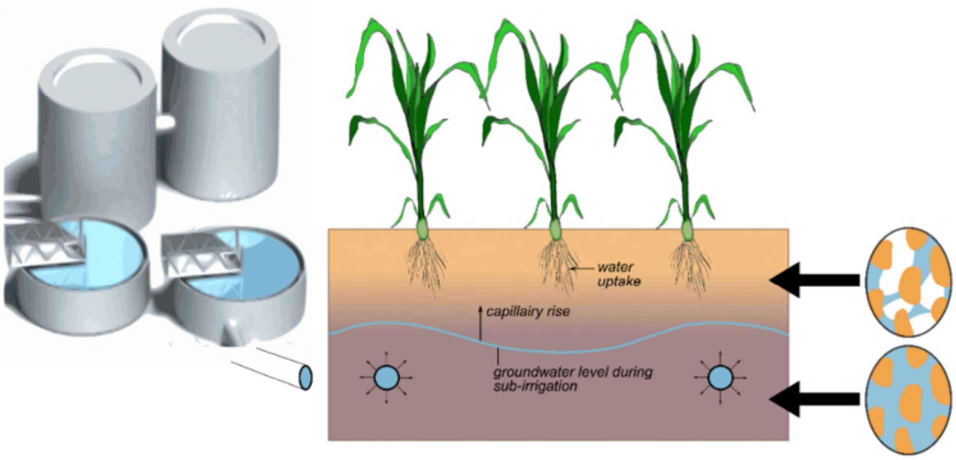

Figure 3.2: Schematic of Haaksbergen irrigation site. Subirrigation via drains with continuous water supply, with which the water table and the soil moisture regime could be controlled actively.

Boer bier water

A pilot study to examine the effects of the use of waste water in a subirrigation system has taken place at the Bavaria Beer Brewery in the south of the Netherlands. The Bavaria Beer Brewery extracts a large amount of groundwater and discharges treated waste water to the surface water. At the same time, neighbouring farmers invest in sprinkler irrigation to maintain their crop production during drought periods. This leads to increasing pressure on the regional groundwater and surface water availability. To reduce the water footprint of the brewery and the abstractions of farmers, excess waste water is delivered to a nearby field by subirrigation. A subirrigation system has been installed by using subsurface drains, which are interconnected through a collector drain, and connected to an inlet control pit for the treated waste water to enter the drainage system. Several groundwater wells were installed to measure the effect of the subirrigation on the groundwater levels as well as soil moisture sensors to determine the effect on soil moisture (Figure 3.3). This pilot has run for three years (2016-2018). During these years, the groundwater levels and soil moisture were increased during the summer compared to the situation without subirrigation. Drought stress in the field could be prevented with these higher groundwater levels. In 2017 a total of 430 mm of excess waste water was delivered to the field. For this case, the source is industrial waste water and although there is a link to irrigation of crops, it would appear that the proposed regulation does not apply.

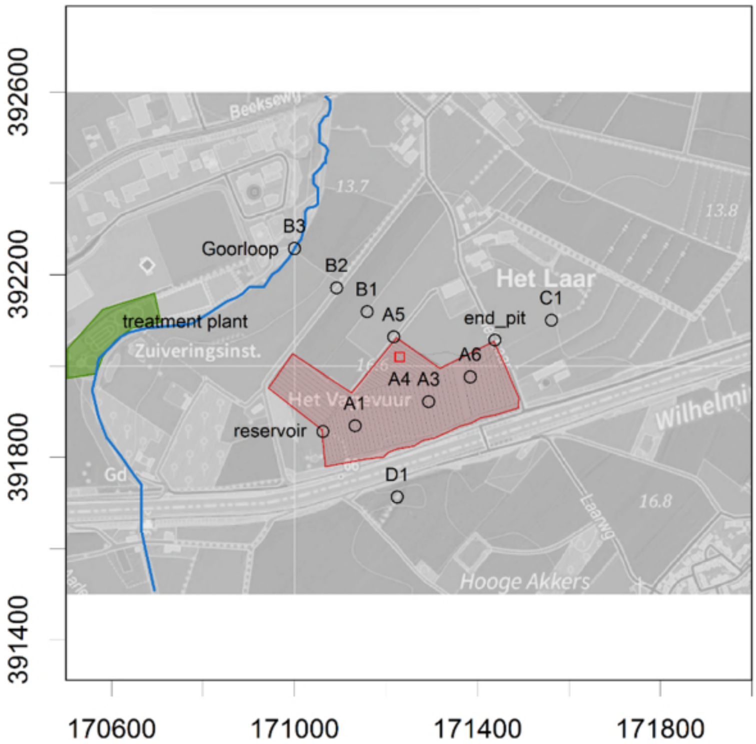

Figure 3.3: Monitoring network (points) for the Bavaria-case, where treated waste water from the Bavaria Brewery (green) is used for subirrigation of an and agricultural field (red).

Suikerunie

Effluent from the Suikerunie sugar factory is reused for irrigation in greenhouses after treatment using rapid filtration, ultra-filtration and reversed osmosis and subsoil storage of the water (ASR-Coastal system, Figure 3.4; Zuurbier et al. 2018). By storing water in autumn, this is available for irrigation during the spring and summer. Critical aspects that need to be considered when implementing this system include transparent communication, demonstration of the principles to the stakeholders and a clear organisational structure with clear roles and responsibilities for every involved party. For this case, the source is industrial waste water and while there is a link to irrigation in greenhouses, it would appear that the proposed regulation does not apply.

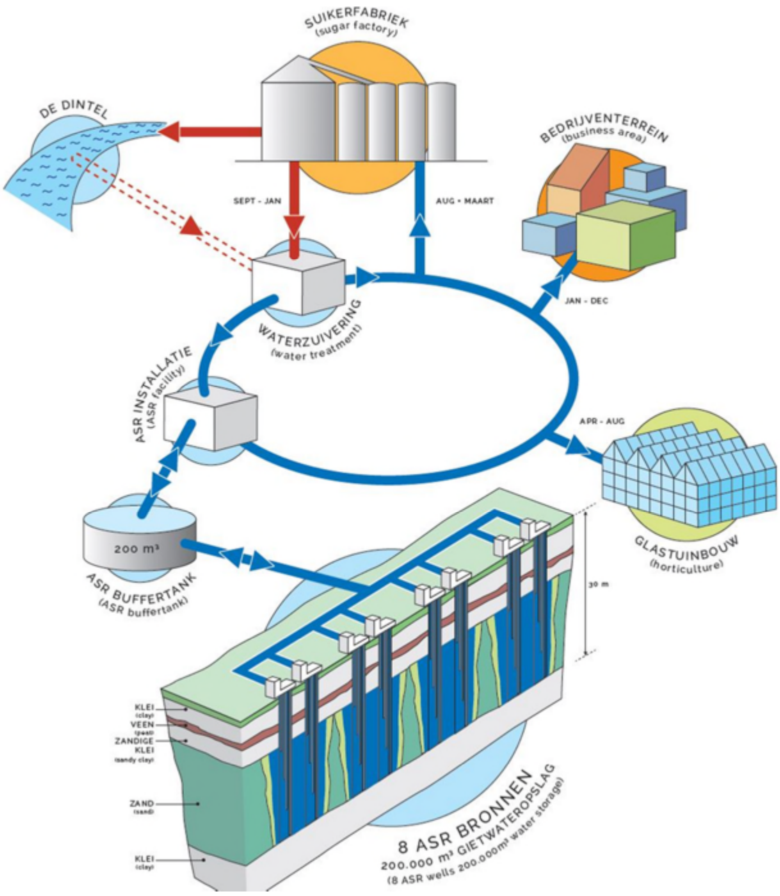

Figure 3.4. Set-up of the sustainable water supply system in Dinteloord (Zuurbier et al. 2018),

La Trappe

LaTrappe brewery and the OLV Koningshoeven Abbey, Berkel-Enschot (NL) have the aim to treat different waste waters generated on site and make as much water and nutrients as possible available for reuse. Together with Water Board De Dommel, University Ghent and BioPolus, SEMiLLA Circular Systems has successfully performed a feasibility study for the application of MELiSSA technology for water treatment on site to close the water cycle and move towards a Zero Liquid Discharge Abbey and brewery. The planning of the implementation of different high tech closed loop life support technologies from space in the brewery is ongoing. The aim is to remove contaminants from the waste water from the brewery and other food production at the abbey by tropical plants that are watered using the waste water (greenhouse based plant root enhanced fixed bed bioreactor). The Metabolic Network Reactor (MNR) plants support an active microbial community that protects the plants from high loading rates, making them compact and suitable for application even in dense urban areas, even in cold climates. The plantmicrobe reactor generates a very similar effluent stream as the hydroponic compartment envisioned for the production of fit-for-use water and the growing of biomass during space missions. At the Abbey, the treated water will be reused for irrigation of the surrounding fields. For this case, the source is industrial waste water and while there is a link to irrigation of crops, it would appear that the proposed regulation does not apply.

3.2 De facto indirect water reuse in the Netherlands

Both domestic waste water treatment plants and industrial waste water treatment plants mainly discharge their treated effluent on the fresh surface water that may be used for irrigation purposes (hence: de facto indirect water reuse). Locally, such emissions may impact the water quality of the surface water. In some cases during summer, in particular at the Pleistocene uplands, the water in some streams can consist of mainly effluent. The water that reaches the Netherlands from Germany and Belgium via the large rivers also partly consists of effluent from WWTPs. The ratio between such effluent and other water sources is mainly determined by the weather and the degree of urbanization. In rainy periods, there is more dilution with rain and drainage water from the surface waters in comparison to dry spells. In periods with extreme precipitation, more occurrences of the overflow of untreated sewage water may occur, and the performance of treatment plants may be impacted, both resulting in impact on the water quality.

It has been demonstrated that in periods with high precipitation, an impact by effluent from sewage treatment plants can be measured for 17% of surface water units in the Netherlands, while during low discharges up to 35% may be impacted (Coppens et al. 2015). In recent research, also the impact of emissions from industrial waste water treatment plants on Dutch surface water quality was derived, demonstrating that a third of the surface water sites where water is abstracted for drinking water production may be influenced (van Wezel et al. 2018). The spread of by effluent impacted surface waters may further increase by applying water redistribution measures such as the Klimaatbestendige Wateraanvoer (KWA). Thanks to extensive treatment for drinking water production, microbes and chemicals in drinking water are reduced to absence or to levels that are not relevant for human health. Yearly studies by the Dutch Human Environment and Transport Inspectorate show that the Dutch drinking water is reproducibly conforming to the legal quality standards (ILT, 2016). A report has been published recently by RIVM on the potential risks of contaminants of emerging concern that were detected (2013-2015) in surface water sources for drinking water at levels exceeding the signalling value of 0.1 micrograms per litre. For each of these chemicals, the measured concentration remained well below the provisional guideline value, indicating that they do not pose a health risk via drinking water (van Leerdam et al. 2018).

In many cases water from streams consisting of a high fraction of effluent is directly applied to crops by sprinkle irrigation, or for groundwater recharge, resulting in potential exposure to human pathogens and/or organic micropollutants. Intentional reuse generally offers better control and management possibilities than de facto re-use. Intentional reuse offers also possibilities to use the capacities of soil passage to deliver cleaner effluents to the surface water system. The possible benefits and risks of intentional indirect reuse for agricultural practices are currently studied extensively in the RUST project as funded by NWO. However, as intentional reuse according to the proposed regulation asks for a more in-depth understanding of the system, the proposed regulation might create and unintended push for de facto reuse.

3.3 Water reuse for aquifer recharge in the Netherlands

Although the proposed regulation is focusing on agricultural irrigation, aquifer recharge to prevent or reduce salinization is another source of demand for (reclaimed) freshwater. In the Netherlands, a major concern for the groundwater bodies is salinization which can be ameliorated by aquifer recharge with freshwater. Therefore, Dutch authorities generally have a positive attitude towards such activities. For a permit, limits are in particular defined for pesticides and nutrients.

For aquifer recharge the Water Framework Directive (WFD) and in particular the underlying Groundwater Directive (GWD) is the overarching framework. Current and future aquifer recharge applications thus have to comply with this Directive and its principles to prevent and limit pollution. Based on this principle, the quality of the infiltrated water should be at least as high as the local groundwater quality. Depending on the need for improving the groundwater quality to support a sustainable (groundwater) environment additional limits may be applied. The WFD and GWD overarch relevant legislation in all European countries, and each member state converts these directives into national legislation. In other EU member states, authorities and policy makers are more hesitant towards aquifer recharge, mainly related to the uncertainties about possible effects of infiltration on groundwater quality.

3.4 Conclusions

Looking at the water reuse initiatives in the Netherlands, there are only a handful of intentional reuse schemes for irrigation. Most of these schemes use industrial rather than urban waste water as source and would not fall under the proposed regulation.

The reference situation for irrigation of crops in the Netherlands is the use of groundwater or surface water. Especially the latter can be impacted by discharges of urban waste water treatment plants (and/or combined sewer overflows) and therefore could contain microbial and chemical hazards that have urban waste water as source. We have labelled the use of surface water impacted by urban waste water as de facto indirect reuse. Similar health hazards apply as to reclamation plants directed towards reuse of urban waste water. However, as the proposed regulation is expected to have a significant burden on cost/resources of the operator (costs for increased treatment (class A) and/or costs for preparing a Water Reuse Risk Management Plan demonstrating safety with regards to public and environmental health risks), the proposed regulation may create an incentive for remaining in the reference situation (of de facto indirect reuse) over dedicated water reclamation.

4 Feasibility of the proposed regulation

In this chapter, the feasibility of the proposed regulation is illustrated and evaluated using the climate adaptive sub-surface irrigation using effluent of the sewage treatment plant at Haaksbergen. The aim is to illustrate critical aspects of water quality assessment and evaluate the applicability of the EU proposal for regulation on minimum requirements for water reuse for irrigation. For each Key Risk Management Task (Figure 1.1), we evaluated what information is needed, if this information is available and what efforts are needed in case it is not readily available. When considering the different Key Risk Management Tasks, the impact of potential differences between sites are also considered, such as potential differences in the quality of STP influent (with regard to human pathogens and organic micropollutants), different irrigation techniques and differences in soil composition. Relevant parameters, uncertainties and knowledge gaps are identified.

Figure 4.1: Left: view of the STP, Bolscherbeek and the pilot field in which effluent is used for subsurface irrigation. Right: The Bolscherbeek is supplied with effluent from the Haaksbergen sewage treatment plant. This exceeds the natural basic drainage in the summer period (Photographer: Bas Worm, Waterschap Vechtstromen).

4.1 Responsibilities

For producing and supplying reclaimed water, the risk management (defined in article 5 in the proposed regulation) should be performed by the operator of a reclamation plant in cooperation with relevant parties (e.g. the end-user of the reclaimed water, the urban waste water treatment plant that supplies water to the reclamation plant if different from the reclamation plant). The operator of infiltration facility Haaksbergen is Water Board Vechtstromen. The effluent is normally discharged to the Bolscherbeek, managed by the same Water Board. Other stakeholders are the end-user of the reclaimed water (the farmer(s)) and the Dutch Competent Authority. The Dutch competent authority is to be decided upon. Urban waste water discharge permits are usually given by Water Boards or the National Water Authority for national waters. Permits for discharges on/in soil are given by city councils and in specific cases the Province. In terms of auditing compliance with the proposed regulation, the authority could be the ILT (Human environment and Transport Inspectorate) or the body that provides the permit. Following the proposed regulation, the Water Board is the operator in the Haaksbergen case and has the main responsibility for the quality of the reclaimed water, and can thus also be considered responsible for getting the other stakeholders involved. The competent authority would be the city council or the province. When water from the reclamation plant is discharged in a surface water body before use, the Water Board would be the operator as well as the competent authority under the proposed regulation, however these responsibilities should be separated. Moreover, potential implications of legal responsibilities are unclear.

One of the aims of the proposed Water Reuse Risk Management Plan is to identify hazards, risks and preventive measures, as well as additional requirements to mitigate potential risks that should be included in the permit. In article 6 of the proposed regulation, the application process for a permit or its modification is defined, including a list of documents to be provided by the applicant. Applications are to be submitted to the competent authority of the Member State in which the reclamation plant will operate. The application will include the following: 1) a Water Reuse Risk Management Plan, and 2) a description of how the reclamation plant will comply with the minimum and additional requirements for water quality and monitoring. Articles 7, 8 and 9 define the obligations of relevant actors in the permitting procedure (including information exchange between competent authorities of Member States) and compliance check. There is a permit for the current pilot set-up in Haaksbergen for supplying water to the agricultural field. Normally the effluent would be discharged directly to the surface water. In periods of drought, farmer could irrigate via sprinkling from the same surface water. A Water Reuse Management Plan was not included in this process. Following the proposed regulation, a permit application for Haaksbergen should be submitted by the Water Board, and reviewed as well as checked for compliance by the Dutch Competent Authority.

4.2 A Water Reuse Risk Management Plan for Haaksbergen

Key risk management task 1. Describe the water reuse system

The waste water treatment plant is operated by the Water Board, so they have the required information on the sources, treatment steps, technologies and quantities of the effluent of the reclamation plant, as well as materials used, lay-out, monitoring and alarms, operations and procedures. However, the Water Board does not have detailed information readily available from the point of release to the point of use, and the supply infrastructure in between, while these are necessary to determine the reuse class and may be critical for potential risks. To obtain this information, the Water Board needs to involve the relevant stakeholders. In the proposed regulation, only all irrigation methods (with an emphasis on spray or other direct contact irrigation methods) or drip irrigation are mentioned. In the Haaksbergen pilot, the soil passage in the Climate Adaptive Drainage System (CAD) is a subsurface irrigation that can be considered also as additional treatment step which is expected to reduce public health risks associated with both chemicals and microorganisms as compared to direct irrigation. This is not accounted for in the proposed regulation. Also other innovative irrigation methods could reduce public and potentially also environmental health risks but the proposed regulation does not provide an incentive for such innovations as it focuses on reclaimed water quality.

The activities of particular end-users may change over time; for example the type of crop, diverging from the activities included in Water Reuse Risk Management Plan at the moment of permit application. Periodical permit revision may thus be needed, or using the most strict requirements based on worst case conditions (represented in the proposed legislation as class A). Further research is needed to assess whether applying strict requirements would result in restrictions in water reuse applications.

Haaksbergen reuse pilot

The pilot project has been set-up in a 5.5 ha corn field in sandy soil, with loam and confining clay layers at 3 and 10 m-soil surface, respectively, next to the domestic STP Haaksbergen (Figure 4.1). In this field, treated waste water (TWW) has been applied by sub-irrigation during the growing seasons 2015 -2018, using a Climate Adaptive Drainage (CAD) system. The chemical composition of this TWW differs as the sewage system mixes sewage and rainwater. For scientific purposes, the bromide-chloride ratio and pharmaceuticals in TWW are used thus far to describe water and chemical transport in the soil system. A field monitoring network has been installed enabling sampling of vertical profiles in the vadose zone and groundwater. Both groundwater levels and soil moisture conditions are measured continuously. The CAD system consists of a series of subsurface drains, interconnected by a closed collector drain which ends in a drainage pit with an outlet. This drainage pit is equipped to continuously manage the drainage basis.

Key risk management task 2. Identify potential hazards and the potential for hazardous events

Potential hazards include the presence of pathogens and micropollutants. In general, the generic composition of Dutch waste water is known and information available in the Watson database (Rijkswaterstaat. 2000). For specific hazards, some research studies have assessed the presence and concentrations in urban waste water. Site specific monitoring of STPs in the Netherlands is focused on restricting the release of nutrients to the environments, and there is hardly any local (site-specific) information on the presence of microbial or chemical hazards. STP effluent in general contains quite a range of contaminants (like metals, pharmaceuticals and pathogens) and these are normally discharged to the surface water. So, in general, an ‘operator’ has very limited site-specific information about microbial and chemical hazards and additional research is required. They can infer water quality from research studies in Dutch waste waters. For Haaksbergen, this is also the situation.

Although the soil passage in the CAD system may reduce discharge of chemicals and pathogens to surface water, and improve the public and environmental health risks associated with this discharge, research is needed to assess the potential public and particularly environmental health risk of contamination of adjacent groundwater and soil. The proposed regulation does not call for a holistic evaluation of public and environmental health risks, comparing the risks of the current versus the new reclamation situation. To be able to evaluate the public health risks for the Haaksbergen case, the risk of plant uptake of contaminants via the CAD system has to be compared with drip or spray irrigation.

Site-specific information may be collected with monitoring campaigns and risk-based monitoring approaches (see paragraph 2.2.3). It would be useful to follow a tiered approach. We would recommend that as first tier, a generic database is compiled describing the ‘default’ concentrations of microbial and chemical hazards in Dutch urban waste water, through a review of the available data from research studies. The second tier could be a monitoring campaign that is implemented only if the site specific assessment indicates the presence of relevant contaminants that are not in the database or that there are indications that the concentration of certain contaminants may deviate significantly from the default (for instance through the presence of a specific industrial discharge on the urban waste water).

Hazardous events are notoriously difficult to predict. Some events are relatively more common, such as heavy rainfall events, but others such as accidental or intended spills in urban waste water are rare, but both may give peaks in the concentration of hazards in waste water. Incidental treatment failures may also cause higher concentrations of hazards to enter the irrigation system. In Haaksbergen (as in many STPs) no additional measures, other than are common at the WTP, are taken. Additional measures may be needed (for example installation of buffer tanks or rerouting of “peak event” water to be discharged to surface water), depending on the use of the reclaimed water.

Key risk management task 3. Identify the environments, populations and individuals at risk

Whether the environment, population or individuals are at risk depends on exposure routes (see also chapter 2). To be able to evaluate environments and populations at risk, more information is needed on the fate and behaviour of pathogens and chemicals in the soil, to what degree they may reach parts of the crops that will be consumed by humans or cattle and to what degree it reaches different environments. This is true for the Haaksbergen case, but also for other reuse schemes. The transport of pathogens and chemicals in the soil largely depends on the composition of the soil, which may not always be readily available although some information can be found in soil maps (Dutch Soil information system; WUR 2018). Moreover, information needed to model fate in the environment of new emerging chemicals may not be available. Also here, we recommend that national or even EU decision-making tools and databases with information on soil transport are needed to identify whether a water reuse application may result in increased environmental exposure (soil, surface water and groundwater) on or near the irrigation site as compared to the reference situation, resulting in potential risk for ecology or humans.

In the case of infiltration facility Haaksbergen, an crude evaluation of exposed populations and individuals can be made, as transport routes are known to some degree: 1) direct contact of the effluent with above-ground plant parts is prevented by supplying irrigation water from below the root zone, 2) crops are not used for human consumption but for feed, 3) there is not direct contact of people to the water by supplying via a closed system. Properties of the soil layers are known and can be used to determine exposed environments. The impermeable clay layer present at 10-12 m below soil surface is expected to prevent leaching to deeper groundwater. Hence, infiltrated water will leave the system via the CAD system and the surface water and via the surface water after soil passage.

Key risk management task 4. Conduct a risk assessment covering both environmental risks and risks to human and animal health

This key risk management task consists of a site-specific risk assessment following the principles as described in chapter 2 for microbial and chemical risks. For this the Water Board is responsible in Haaksbergen as operator of the reclamation facility. For a risk assessment, information is needed on measured or modelled exposure concentrations of relevant pathogens and organic micropollutants, dose-response information and safe concentrations (Guideline Values for humans, Environmental Quality Standards for soil and water). Site-specific exposure of humans, cattle and the environment has to be measured or modelled. This is a very extensive and complex task, that requires extensive resources. Again, we envisage that a generic risk assessment is much more feasible, looking at the information about the concentrations of hazards in urban waste water, the efficacy of treatment processes and public health and environmental water quality standards. A site specific assessment can be focussed on parameters that are different than the ‘defaults’.

In addition to the requirements under Annex II, Annex I specifies the minimum water quality requirements and the monitoring needed. Haaksbergen would fall in Class C (non-food crops for feeding animals) and this would mean there are quality requirements for the effluent of the reclamation facility (*E. coli,* BOD, total suspended solids, turbidity and helminth eggs). The primary objective for these requirements is hygienic quality. Given the nature of the use of the water in Haaksbergen (subsurface irrigation) there will not be direct exposure to the water (except during repairs or maintenance of the irrigation system). The monitoring under Annex I will therefore cause additional costs but will provide very limited benefit in this case.

Validation monitoring to show adequate log removal of bacteria, viruses and parasites is not required for infiltration facility Haaksbergen. This is only required for Class A (food crops consumed raw and where the edible portion is in direct contact with reclaimed water). A general comment about the validation monitoring requirement in the proposed regulation is that more guidance is needed on how to conduct such monitoring. This will support operators on what is needed and how adequate validation can be achieved and support harmonisation of this (potentially costly) monitoring exercise between reclamation systems and Member States. The Australian recycling guidelines provide an example of validation monitoring guidance.

For many chemicals safe levels are available in national and international legislation, but for many more (emerging) chemicals such values are not available. This deficiency can be remediated by deriving new standards (in the Netherlands by the RIVM) and using innovative methods for chemical risk assessment (see 2.2.2).

Key risk management task 5. Specify requirements for water quality and monitoring that are additional to and/or stricter than those specified in Annex I

Annex II states that, based on the risk assessment, additional or stricter monitoring requirements may need to be established to protect humans and the environment, such as (heavy) metals, crop protection products, disinfection by-products, human and veterinary pharmaceuticals and emerging chemicals in general, and antimicrobial resistance. As indicated under task 4, it is unlikely that the risk assessment will lead to stricter requirements for the requirements under annex I for Haaksbergen. For spray irrigation class A schemes, other viruses and antimicrobial resistance make yield more additional/stricter requirements. For Haaksbergen, the (heavy) metals, and a selection of emerging chemicals are being monitored in the saturated and unsaturated zone for scientific purposes. No additional measurements are done by the operator. Ideally, monitoring strategies are uncomplicated (making use of innovative methods) and preferably only included analyses of effluent water quality at the point of release from the WTP.

Following the proposed regulation, determining whether additional requirements are needed requires the operator to compare the outcome of the risk assessment to acceptable levels of risk or water quality. The proposed regulation provides no further guidance on this, except for referring to other EU regulations under task 4 (see chapter 2). Translating these regulations or other environmental health criteria to minimum requirements for reclaimed water is a complex task, even for experts in water risk assessment, and exceeds the current expertise of the Water Boards and the competent authorities. Here again, we recommend that the Commission uses their power to adopt delegated acts supplementing the proposed regulation with technical guidance on the risk management tasks to provide more specific guidance on the task of deriving additional minimum requirements on the basis of the risk assessment. A database with acceptable risk levels or water qualities for different reuse purposes would greatly facilitate the implementation of the proposed regulations. The complexity of the task makes it unlikely that requirements for effluent quality will be derived site-specifically, although safe levels in effluent depend on the characteristics of the reuse application. This may be solved by using the most strict requirements (based on worst case conditions), but this might require additional treatment of reclaimed water. Further research is needed to determine the cost-benefit of applying strict requirements.

Key risk management task 6. Identify preventive measures

A number of examples of preventive measures are given in Annex II (including table 1) of the proposed regulation. A general comment on the proposed regulation is that the examples in Annex II are inconsistent with the main text of the regulation, since the point of compliance is the water leaving the reclamation plant and these examples are all measures to be taken at the site of irrigation. So there is no incentive in the regulation for preventive measures after the point of compliance and these should also not be necessary, as the water leaving the reclamation plant is treated to the required level of safety already. The example measures include restrictions in the harvest of produce that is wet irrigated or dropped on the soil, grazing of (dairy) cattle on wet irrigated pastures, packaging of fodder, feeding of cattle with fodder irrigated with reclaimed water. These restrictions are differentiated for different water quality classes. There is some information available on the efficacy of preventive measures, although these are often related to cases in developing countries and further research is needed to assess whether these methods are also applicable in the Netherlands. In Haaksbergen, the CAD system is a underground systems preventing aerosol exposure or aboveground contact with plants, and the system cannot be accessed by unauthorized persons. For new water reclamation initiatives, a decision-making tool to identify Critical Control Points and the need of (different types of) preventive measures including a database of water treatments options can be used to design a safe reuse system.

Key risk management task 7. Ensure that adequate quality control systems and procedures are in place

In general, operational monitoring is applied at STPs. The *relevant parameters* as meant in the proposed regulation is related to operational monitoring of the performance of the treatment processes to verify that they produce the intended reclamation water quality. Examples are disinfectant dose/residual and filter effluent turbidity. This is not general practice in the current STPs and will need to be implemented. Also in Haaksbergen, the quality control systems and procedures related to the plant operation are installed by the operator (Water Board). Following the proposed regulation, this may need to be expanded to ensure that the reclamation plant produces water that continuously meets the minimum requirements (both standard and additional requirements emerging from task 5).

Key risk management task 8. Ensure that environmental monitoring systems are in place that will detect any negative effects

To assess permit compliance, monitoring should take place at the point of compliance (where water leaves the reclamation plant). Following the proposed regulation, this would need to be expanded to include also (part of) the rest of the water reuse system from the water leaving the reclamation plant (point of compliance) to the point of use and in environments 'downstream' for example to study potential accumulation of chemicals in the soil. Without further guidance, this will likely be an exhaustive effort as all relevant transport routes may need to be monitored. In the current situation (including Haaksbergen), environmental monitoring systems are not in place, except from monitoring for research purposes. It is the plant operator who is responsible for ensuring that environmental monitoring systems are in place, while not every location of use of the reclaimed water may be accessible to the Water Board. Hence, other stakeholders who are responsible for other areas and irrigation processes related to the water reuse should be involved in this risk management task, such as the farmer who is responsible for food product quality and the Provinces who are responsible for groundwater quality.

Key risk management task 9. Ensure that an appropriate system is in place to manage incidents and emergencies

For emergencies at the WWTP (e.g. treatment failures or spills) the Water Boards will need to adapt the current emergency management plans for reclamation. Emergencies may lead to a reclamation water quality that is not acceptable and the water may be diverted to be discharged away from the reclamation site. Emergencies may also lead to temporary closure of the water treatment. The farmer needs to be informed in case of an emergency and the impact on reclamation water quality needs to be established. The installation of a buffer system which allows a delay before the effluent is used for irrigation can be used as a risk mitigation measure.

4.3 Conclusions and recommendations

We evaluated the availability of site-specific information about the concentrations of microbial and chemical hazards, the ability to derive site-specific human and environmental exposures, the assessment of the public and environmental health risk and the derivation of additional/stricter minimum requirements.

We conclude that:

1. there is not always sufficient site-specific water quality data available. Many research studies are available on the presence and concentration of microbial and chemical hazards, and site-specific information is available in the Watson database. A review of this information to develop a (supra)national database of ‘default’ hazards and concentrations to be used in the risk assessment would be more efficient. The site-specific risk assessment and monitoring could then be directed towards any site-specific deviations from the default.
2. the tasks of determining exposure and the public and environmental health risk assessment, as well as the derivation of additional minimum reclaimed water quality requirements, are too complex and resource-intensive for individual operators. We suggest that the fate and transport of the hazards in the environment and public and environmental health consequences of the hazards (no-effect levels, safe concentrations etc.) are all included in the (supra)national database and operators can extract this information to generate a Water Reuse Risk Management Plan. We suggest that this could be delegated acts supplementing the proposed regulation with technical guidance on the risk management tasks.

The proposed regulation does not provide an incentive for innovations in irrigation or farming practice itself, as it focuses on reclaimed water quality.

The examples of preventive measures in Annex II are all preventive measures to be taken at the site of irrigation. Since the point of compliance is the water leaving the reclamation plant, there is no incentive for preventive measures after the point of compliance as the water leaving the reclamation plant is treated to the required level of safety already.

Ensuring adequate control, environmental monitoring and emergency management requires additional effort of the operator to implement for reclamation schemes. Particularly the environmental monitoring will likely be an exhaustive effort as all relevant transport routes may need to be monitored. This reaches beyond the span of direct control of the operator (Water Board) and would require collaborative monitoring programs with other stakeholders, and the development of a (supra)national database on which only deviations from the default are to be monitored site-specifically.

The farmer needs to be informed in case of an emergency and the impact on reclamation water quality needs to be established. The installation of a buffer system which allows a delay before the effluent is used for irrigation can be used as a risk mitigation measure.

The Dutch competent authority is to be decided upon. Urban waste water discharge permits are usually given by Water Boards or the National Water Authority for national waters. Permits for discharges on/in soil are given by city councils and in specific cases the Province. In terms of auditing compliance with the proposed regulation, the authority could be the ILT (Human environment and Transport Inspectorate) or the body that provides the permit.

We note, as in chapter 3, that in the current reference situation of de facto indirect reuse, no requirements are set and that if the requirements under the proposed regulation are too demanding, this may drive operators to continue with the reference situation rather than invest in reclamation.

5 Conclusions and recommendations

Several research questions were considered in this research (for details see paragraph 1.4), related to:

- The elements in the proposed Water Reuse Risk Management Plan (question A);
- The protection of human and environmental health (question B);
- The availability of information required for a risk assessment (question C);
- Water quality standards (question D); and
- Knowledge gaps (question E).

The conclusions and recommendations with regard to the performance of the proposed regulations are listed below, to answer these research questions and with regard to the performance of the proposed regulation in the Netherlands.

The Water Reuse Management Plan

The main elements of a risk management plan are included in the proposed Water Reuse Management Plan. However, to complete the plan is an **exhaustive effort** and likely exceeds the expertise of the responsible stakeholders. The tasks of determining exposure and the public and environmental health risk assessment, as well as the derivation of additional minimum reclaimed water quality requirements, are too complex and resource-intensive for individual operators. In particular for adequate **control, environmental monitoring and emergency management** considerable efforts are required of the operator of reclamation schemes. Environmental monitoring will likely be an exhaustive effort as all relevant transport routes may need to be monitored. This reaches beyond the span of direct control of the operator (Water Board or commercial operator) and would require collaborative monitoring programs with other stakeholders. Better guidance is needed for preventive measures and in cases of emergencies. Some examples are included of preventive measures but these are all downstream the point of compliance where reclaimed water should already be of the required quality. The installation of buffer systems which allows a delay before the effluent is used for irrigation in cases where an impact on reclamation water quality is expected can be used as a risk mitigation measure.

Moreover, several **important aspects are lacking** in the Water Reuse Risk Management Plan, such as the potential application of innovative methods such as effect-based monitoring, and guidance documents for all activities related to key risk management tasks are needed.

Protection of human and environmental health

Overall, the proposed regulation is very generic. Annex I provides only a few **minimum requirements**, focussed on general quality and public microbial health. No minimum requirements for chemicals are included in the proposed regulation. The Water Reuse Risk Management Plan should determine if/which minimum requirements for specific chemicals in specific settings are needed to manage all public health and environmental health risks. Different requirements are included in the proposed regulation for different categories of crops. Both for microbiological and chemical hazards, highest risks can be expected for food crops category A. A **precautionary** option is to set regulations based on the most susceptible food crops (category A). Another risk management option is to limit reuse to category B and further.

Target values for ***E. coli*** are included as minimum requirements and indicator microorganisms in the proposed regulation. However, since *E. coli* is very sensitive to disinfection processes, more sensitive than viral and protozoan hazards, the value of *E. coli* for disinfection schemes is limited. For class A, this is at least partially compensated by the validation monitoring requirement for phages and spores (the more persistent indicators), but for the other classes this is not. This may give a wrong sense of safety for schemes that rely on disinfection.

Also ***Legionella*** *spp.* is included as parameter, while the vast majority of severe infections is due to *Legionella pneumophila.* Water systems may contain many different types of *Legionella,* including non-pathogenic types. We would therefore recommend to focus monitoring and risk management on *Legionella pneumophila.* We recommend to include the risk of *Legionella pneumophila* transmission in other settings than greenhouses in the hazard and risk assessment in the Water Reuse Risk Management Plan. The risk of workers in close proximity of (spray) irrigation or other aerosol generating conditions should be incorporated in this plan.

In the EU setting, other enteric viruses are more prominent and present in higher concentrations in waste water, such as **noroviruses and adenoviruses**. Adenoviruses are more resistant to UV disinfection and are more critical for such systems.

Meeting the Class A requirement is expected to be adequate in protecting against **helminth** eggs and the monitoring of helminth eggs would be more appropriate as consequence of a site-specific Water Reuse Risk Management Plan than as generic parameter.

For Class A crop production, **validation monitoring** is required to establish whether treatment performance targets are met. Overall, the use of the validation monitoring indicators is adequate to cover the treatment performance with respect to all enteric bacterial, viral and protozoan pathogens. We recommend to give guidance on validation monitoring requirements. Given the dependence of microbial counts on the methods applied, it is recommended to include reference to the **ISO methods**.

Information availability

Not all information that is needed for the Water Reuse Risk Management Plan in its current form is readily available. The proposed regulation asks for **site-specific information** which is often not readily available and requires additional research. We recommend to use generic information about concentrations of microbial and chemical hazards instead, as this is adequate for most cases and hazards and more cost-efficient. Many research studies are available on the presence and concentration of microbial and chemical hazards. Also the Watson database contains data on many chemical hazards in urban waste water that could be used to derive 90-percentile data on concentrations of chemical hazards.

It would be efficient to review this information to develop a (supra)**national database of 'default' hazards and concentrations** to be used in the risk assessment. The site-specific risk assessment and monitoring could then be directed towards any site-specific deviations from the default.

We suggest that the fate and transport in the environment, resulting possible exposures, hazards and realistic public and environmental health risks of the hazards (no-effect levels, safe concentrations etc.) are all included in the (supra)national database and operators can extract this information to generate a Water Reuse Risk Management Plan. We suggest that this could be **delegated acts** supplementing the proposed regulation with technical guidance on the risk management tasks. For this database, choices on data-use, 90% etc. are to reflect the appropriate application of the Precautionary Principle and have to be made transparently and consistent with other EU legislation.

Water quality standards

In the proposed regulation, relevant additional water quality standards should follow from the risk assessment process in the Water Reuse Risk Management Plan. Water quality is to comply also to **existing legislation** on microbial and chemicals risks for humans and the environment, but it should be made more explicit to responsible operators and authorities which requirements are considered most relevant. Recommendations on microbial water quality standard are listed above under 'Protection of human and environmental health' considering the proposed minimum requirements.

Lists of **relevant chemicals** for monitoring of reclamation plants can be based on waste water levels, minimum requirements for food and environmental targets, and fate and transport of chemicals between release from the reclamation plant and exposed humans/environment.

Translating these regulations or other environmental health criteria to minimum requirements for reclaimed water is a complex task, even for experts in water risk assessment, and exceeds the current expertise of the Water Boards and the competent authorities. Here again, we recommend that the Commission uses their power to adopt delegate acts. Our advice would be to focus here on a limited set of **indicator chemicals** from different classes of use and with different physicochemical properties, that are known to occur in high concentrations in the effluents, are relevant for crop food quality and in accordance to chemicals on the priority lists under WFD.

A variation can be made on **risk-based monitoring** programs as currently in development for drinking water, including innovative methods such as bioanalytical tools as also proposed in other parts of the globe.

Knowledge gaps

Minimum requirements at point of compliance should depend on the **fate of microbial and chemical hazards in the environment** and exposure routes to humans. Relevant factors are known, however hazard-specific information is lacking for various emerging chemicals and pathogens and this is the main knowledge gaps that results in uncertainties in the risk assessment.

Application and performance of the proposed regulation in the Netherlands

Looking at the **water reuse initiatives** in the Netherlands, there are only a handful of reuse schemes for irrigation. Most of these schemes use industrial rather than urban waste water as source and would not fall under the proposed regulation. Moreover, the point of compliance for the validation of the treatment performance is the outlet of the reclamation plant. Conventional waste water treatment systems reach in general 1-2 log removal and would therefore need to install additional treatment/disinfection processes before they can be included in Class A reclamation schemes. The proposed regulation does not provide an incentive for innovations in irrigation or farming practice, as it focuses on reclaimed water quality.

The Dutch **competent authority** is to be decided upon. Urban waste water discharge permits are usually given by Water Boards or the National Water Authority for national waters. Permits for discharges on/in soil are given by city councils and in specific cases the Province. In terms of auditing compliance with the proposed regulation, the authority could be the ILT (Human environment and Transport Inspectorate) or the body that provides the permit.

In the current **reference situation** of de facto indirect reuse, no requirements are set. If the requirements under the proposed regulation are too demanding this might drive operators to continue with the reference situation rather than invest in reclamation. Therefore, the development of generic databases on hazards and the derivation of generic (precautionary) realistic exposure levels will be needed in order to stimulate efficient non-potable water reuse.

Main conclusion

Intentional reuse conforming to the proposed regulation asks for a detailed understanding of the benefits and risks of reuse for agricultural practices. As this is an exhaustive effort which requires specific expertise and is costly, the proposed regulation might unintendedly stimulate indirect reuse.

Main recommendation

For the proposed regulation to stimulate reuse, we recommend to provide more (supra)national guidance information to support operators and regulators to efficiently prepare Water Reuse Risk Management plans that are sufficiently protective for human and environmental health.

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Appendix I

Additional information on innovative methods for risk-based monitoring and water reuse safety planning

I.1 Bioanalytical tools

A plethora of *in vitro* bioassays is developed in the context of chemical risk assessment and clinical diagnostics to test effects on different biological processes. Such assays can also be implemented in effect-based monitoring water quality. Measuring water quality using bioanalytical tools requires guidance in the most appropriate selection of relevant bioassays, and effect-based trigger values (EBT) to interpret responses in bioanalytical tools.

For water quality assessment, carcinogenesis, adverse effects on reproduction and development, effects on xenobiotic metabolism, modulation of hormone systems, DNA reactivity and adaptive stress responses are considered as the most relevant toxicological endpoints. Ongoing research explores the applicability of new bioanalytical tools (e.g. Louisse et al. 2018), including for other potential health effects associated with chronic low-dose exposure to chemicals (Dutch Health Council 2014).

Because of the sensitivity of specific *in vitro* bioassays in combination with sample concentration, responses of chemicals may be (far) below exposure concentrations that are relevant for human health effects. To interpret whether a potential risk exists, effect-based trigger values (EBT) are used. Different approaches are proposed to derive EBTs, including EBTs based on 1) relative ecotoxicity potency, 2) health-based threshold values for chronic exposure in humans and kinetics of reference chemicals, and 3) read-across from (drinking) water guideline values (reviewed in Dingemans et al. 2018). Ongoing research aims at differentiating EBT that can distinguish the potential for low, acceptable and increased human health risks.

By fractionation of chemical mixtures (making less complex partial mixtures), and combining with chemical-analytical methods, bioanalytical tools can also be used to identify the chemicals that cause a particular effect (Zwart et al. 2018).

Bioanalytical tools have not yet been included in water quality legislation, mainly because of the fact that there is ongoing discussion on EBT methodologies for bioassay response interpretation. Nevertheless, bioanalytical tools are mentioned as promising tools in the WHO guidelines for Potable Reuse (WHO 2017a) and they are already implemented in the Netherlands for surface water quality assessment (in combination with chemical analysis in the SIMONI framework; Van der Oost et al. 2017). Guidance material on the selection and interpretation of bioanalytical tools is currently being developed in the context of the ‘Kennisimpuls Waterkwaliteit’, as part of the ‘Delta-aanpak Waterkwaliteit en Zoetwater’.

Bioanalytical tools give information on the integrated effect of mixtures of chemicals related to a specific health effect. This can also give a health-based insight in the water quality of reclaimed water, and variation thereof between STPs and in time.

I.2 Non-target screening methods

The traditional target analysis required by regulatory bodies to monitor micro contaminants in water resources are not producing an exhaustive answer to the quality of that water. More and more chemical compounds are designed to metabolise and breakdown faster in the human body or the environment. Furthermore sewage treatment plants which are receiving domestic and industrial waste water are mainly designed to reduce the amount of ammonia and nitrogen and to some extent micro contaminants. Traditional biological treatment is not effective for all chemical compounds and new chemical transformation products can emerge. New post treatment steps (using ozone or UV) can help to transform chemical compounds but also this step can produce unwanted by-products. Some of these metabolites and emerging transformation products are more persistent than others and their fate in the environment is not known. Non-target screening based on high resolution mass spectrometry (HRMS) can give information on the potential presence of chemicals that are not included in target analyses. Depending on the dynamics of the water body analysed the chemical fingerprint obtained by HRMS can be used to monitor changes. The separation of the water sample on a chromatographic column is revealing information on the physio chemical properties of the chemical compound. This information on the polarity of the compound can also be used to predict their fate in the environment. The intensity relative to an internal standard may already give information on changes in exposure concentrations of a chemical. If HRMS information is linked to information om chemicals available in databases, suspect chemicals can be derived who may be identified (confirmed) in further research The advances in HRMS equipment have resulted in data which can reveal a brutoformula of the chemical compound by using the information in the mass spectrum acquired. Abundancies of carbon, nitrogen, sulphur and halogen isotopes will help to determine an unequivocal formula. Further fragmentation experiments can help to determine the definite structure but always a final confirmation with a reference standard is needed. But it is not always needed to elucidate the structure of the compound. The combination of an accurate mass and the retention time is a very valuable piece of information to track specific chemicals in the environment. Non-target screening methods are also mentioned as promising tools in the WHO guidelines for Potable Reuse (WHO 2017a). Importantly, data files from current-state full scan HRMS analyses can be archived and evaluated retrospectively to investigate trends in exposure (Hollender et al. 2017), for example related to water reuse and the potential accumulation of chemicals within the water cycle.

I.3 Human biomonitoring

Human biomonitoring is the measurement of (low levels of) chemicals in body fluids or tissues, which is the internal exposure resulting from chemical exposure through all possible exposure routes (inhalation, dermal exposure, ingestion). Measuring concentrations in large amounts of people reveals reference (background) values in a population. Based on measured internal concentrations, it can be estimated whether a population may be at risk. Moreover, based on internal concentrations, chemicals can be prioritized for remedial actions, and it can be evaluated whether the chosen measures reduce exposure.

In the ongoing EU (Horizon 2020) project HBM4EU (hbm4eu.eu), the possibilities of human biomonitoring to support chemicals regulations and policy making in the EU (Ganzleben et al. 2017). They propose that derived no-effect levels (DNELs) are translated into biomarker concentrations (also named biomonitoring equivalents) that can be used as an indication that there is a human health risk.

By human biomonitoring and the generation of cohort data, it is also possible to reveal trends in exposure levels, for example those potentially resulting from long-term consumption of crops irrigated with reclaimed water. Also for more acute (accidental) exposures, human biomonitoring can be used. Instead of measuring exposure concentrations in the environment, human biomonitoring can give information on the nature and quantity of chemicals that are absorbed in the body, and can help to relate internal exposure to potential (sub)clinical symptoms.

However, not for every chemical exposure levels can be investigated with human biomonitoring. In the report 'Biomonitoring for small scale chemical incidents' by RIVM (2012) is outlined which chemicals can be investigated with biomonitoring (dependent on biokinetic properties), what is needed for testing (technologies and logistics) and suggests procedures for risk communication.

It was recently recommended by the Dutch National Institute for Public Health and the Environment (RIVM) that human biomonitoring efforts should start with cadmium and lead, based on possible exposures (via food, cigarettes and dust) close to health-based guidance values, and the fact that these chemicals are known to cause kidney damage, which can non-invasively be determined by measuring proteins in humans. Cadmium is also included in the HBM4EU as a priority substance. Both cadmium and lead are water-relevant chemicals, and maximum soil concentrations based on human health protection are included in the WHO 2006 guidelines for reuse in agriculture (WHO

I.4 Prioritization

Chemicals for which exposure information is available need to be prioritized for inclusion in monitoring programs. In literature several prioritisation methods for chemicals of emerging concern (CEC) have been developed that make use of target monitoring data, non-target and suspect screening data, exposure models and chemo-informatics, or using combined approaches (reviewed in Sjerps et al. submitted). Although the reclaimed water is not meant for drinking, provisional health-based drinking water guidelines or the Threshold of Toxicological Concern (TTC; Baken et al. 2018) can be used for a human health-based prioritization of chemicals that are of concern for human health. If chemicals are prioritized based on TTC, it is recommended to derive a provisional health-based drinking water guideline if this is absent. Detection criteria need to be defined to result in monitoring frequencies. For example, a chemical that is identified in the waste water but not in the reclaimed water may have a lower monitoring frequency than a chemical that is detected also in the reclaimed water.

Chemicals that are marked based on suspect/non-target screening (new chemicals or transformation products) need to be prioritized for further confirmation and analysis. For most of the suspects provisional health-based drinking water guidelines are not available, but the suspects can be prioritized based on semi-quantitative occurrence concentrations combined with in vitro toxicity information extracted from the ToxCast database (Brunner et al. submitted). In ongoing research, structured, semi-automated workflows are being developed for prioritisation and confirmation (Hollender et al. 2017). Once confirmed, measured and deemed of relevance, a former suspect can be added to target monitoring.

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