European Commission

Scientific Committee on Health, Environmental and Emerging Risks

SCHEER

Scientific advice on

Proposed EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge

Scientific Committees

on Consumer Safety

on Health, Environmental and Emerging Risks

The SCHEER adopted this document by written procedure on 9 June 2017

ABSTRACT

Following a request from the Commission, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) reviewed the report prepared by the European Commission Joint Research Centre on "Proposed EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge".

The SCHEER concludes that, while the methodology chosen is appropriate and the report considers many important elements, the document is deficient in key details. The SCHEER recommends that the description of the methodology be extended and detailed guidance be provided on how minimum quality requirements should be derived. The SCHEER is of the opinion that, in its current form, the minimum quality requirements proposed provide insufficient protection both to environmental and human health.

Keywords: water reuse, agricultural irrigation, aquifer recharge, minimum quality requirements

Opinion to be cited as:

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http://ec.europa.eu/health/scientific_committees/experts/declarations/scheer_wg_en

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In addition, the Commission relies upon the work of other Union bodies, such as the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

The SCHEER

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1. SUMMARY

The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) reviewed the report prepared by the European Commission Joint Research Centre on "Proposed EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge".

Four questions were posed, namely: Is the methodology used by the JRC considered appropriate? Do the proposed minimum quality requirements provide sufficient protection against environmental risks that may be associated with water reuse for agricultural irrigation and aquifer recharge? Do the proposed minimum quality requirements provide sufficient protection against human health risks that may be associated with water reuse for aquifer recharge? And have any risks been overlooked?

The SCHEER concludes that, while the methodology chosen was appropriate and the report considers many important elements, the document is deficient in key details. The SCHEER recommends that the description of the methodology be extended and detailed guidance be provided on how minimum quality requirements should be derived.

In the opinion of the SCHEER, the report inadequately addresses (i) contaminants of emerging concern (CECs), (ii) antibiotic resistance spread through urban wastewater treatment plants' (UWWTPs) effluents, and (iii) possible risks associated with disinfection and/or advanced treatment of urban wastewater (e.g. formation of disinfection by products and related toxicity). Therefore the SCHEER is of the opinion that, in its current form, the minimum quality requirements proposed provide insufficient protection both to environmental and human health.

The SCHEER supports the case-by-case approach proposed, but recommends that common criteria be defined for the development of case-by-case assessments, in order to ensure comparable minimum quality requirements across EU Member States.

2. MANDATE FROM THE EU COMMISSION SERVICES

2.1. Background as received from the Commission

Europe is facing increasing incidences of water scarcity and droughts affecting many of its regions; water reuse can help address this issue but its potential remains largely untapped in the EU. The opportunity to take action at EU level with a view to increasing water reuse was identified in the 2012 Commission Communication "A Blueprint to Safeguard Europe's Water Resources"[1]. Water reuse for irrigation or industrial purposes is considered to have a potentially lower environmental impact and to potentially cost less than other alternative water supplies (e.g. water transfers or desalination), but it is only used to a limited extent in the EU. Because of an inconsistent national legislation across Member States (MS) and a limited public awareness about actual risks and benefits, water reuse tends to be a costly practice subject to distrust from the general public; potential obstacles to the free movement of agricultural products irrigated with reused water is an additional risk deterring investments. The Commission's intention to address this issue, possibly by setting common EU-wide environmental/health standards, was noted with interest by the Council at that time[2].

On 2 December 2015, the European Commission presented the new circular economy package "Closing the loop - An EU action plan for the Circular Economy"[3]. It includes a number of actions to promote further uptake of water reuse at EU level, in particular as a measure to address water scarcity as an integral part of efficient water resources management. These actions were planned to be developed in 2016-2017 and will focus on overcoming the main barriers to the untapped potential for water reuse wherever it is cost-efficient and safe for health and the environment. In particular, the Commission announced that in 2017, it planned to table a legislative proposal on minimum quality requirements for water reuse in irrigation and aquifer recharge.

An Inception Impact Assessment (IIA) for this initiative[4] was published by the Commission in April 2016 with the intention to inform stakeholders and citizens. This document describes the problem to be tackled and the objectives to be achieved and explains why EU action is needed and its added value. It elaborates on issues related to subsidiarity, possible policy options and the likely impacts of each option.

DG Environment is leading this initiative in the Commission and mandated the Joint Research Centre (JRC) of the European Commission to elaborate the basis for the proposal. The JRC will issue by the end of 2016 a (technical) report proposing minimum quality requirements for reuse categories on agricultural irrigation and aquifer recharge covering the relevant aspects (e.g. water quality, application, monitoring). These requirements should ensure a high level of health and environmental protection and thus build public confidence in reuse practices.

As all initiatives by the European Commission are likely to have significant economic, environmental or social impacts, this proposal will undergo impact assessment. The proposal together with its impact assessment will be subject to an Opinion by the Regulatory Scrutiny Board (RSB), tentatively in late spring 2017.

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[1] COM(2012)673 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0673&from=en

[2] Council conclusions 17872/12 http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/134398.pdf

[3] COM(2015)614 http://eur-lex.europa.eu/resource.html?uri=cellar:8a8ef5e8-99a0-11e5-b3b7-01aa75ed71a1.0012.02/DOC_1&format=PDF

[4] http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_006_water_reuse_instrument_en.pdf

To ensure that the proposed EU minimum quality requirements appropriately address risks and ensure a high level of health and environmental protection, scientific advices of the European Food Safety Authority (EFSA) and of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) are requested.

2.2. Methodology used in JRC's technical report

The work to be conducted by the JRC has resulted into a final technical report entitled 'Minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge'[5], version 3.3. February 2017, proposing minimum quality requirements for two specific reuse categories: agricultural irrigation and aquifer recharge. These requirements should ensure a high level of health (human and animal health) and environmental protection and thus provide public confidence in reuse practices. Both people and animals (livestock) who would potentially be exposed are taken into consideration regarding health protection, and environmental protection is taken to mean that no deterioration of surface and ground waters, soil, biota, and air would be permissible.

The final JRC document includes the following requirements for water reuse practices in agricultural irrigation and aquifer recharge:

- Water quality parameters:
  - Physical parameters
  - Chemical parameters including sum parameters, heavy metals and organic pollutants
  - Biological parameters considering bacteria, virus, protozoa, and helminths

- Monitoring requirements:
  - Sampling points
  - Frequencies

The minimum quality requirements for each type of use will consider the following aspects:

Agricultural irrigation

- Type of crops to be irrigated
- Application conditions

Aquifer recharge

- Type of groundwater use
- Application conditions

Existing reference guidelines for water reuse applications are to be considered and where possible adapted to the EU specific regulatory framework on health and environment protection. In particular, the minimum quality requirements need to ensure a full consistency with related EU legislation (i.e. Water Framework Directive, Drinking Water Directive, Urban Wastewater Directive, Groundwater Directive) and a high level of protection for human and animal health and the environment. The existing national legislations on water reuse in MS will be consulted and taken into account to develop the minimum quality requirements.

[5] https://circabc.europa.eu/w/browse/c5da4b87-9ced-44d0-af8c-02a472fe984f

2.3. Terms of reference

The SCHEER is requested to provide scientific advice on the minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge as proposed by the JRC. More specifically, the SCHEER is asked to express its opinion on the following points:

- Is the methodology used by the JRC to develop the minimum quality requirements on water reuse considered appropriate to address environmental risks associated with water reuse for agricultural irrigation and aquifer recharge, and with human health safety for aquifer recharge?
- Do the proposed minimum quality requirements provide sufficient protection against environmental risks that may be associated with water reuse for agricultural irrigation and aquifer recharge?
- Do the proposed minimum quality requirements provide sufficient protection against the human health risks that may be associated with water reuse for aquifer recharge?
- Have any risks been overlooked, and if so how should they be taken into account?

2.4. Timeline

- December 2016-January 2017: Transmission of the final report by the JRC
- April-June 2017: Delivery of the SCHEER Opinion

3. OPINION or CONCLUSIONS

Proposed EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge

3.1. Question 1:

Is the methodology used by the JRC to develop the minimum quality requirements on water reuse considered appropriate to address environmental risks associated with water reuse for agricultural irrigation and aquifer recharge, and to address human health risks associated with aquifer recharge?

The SCHEER is of the opinion that overall, the methodology could be considered appropriate, since in principle the approach of monitoring, as an assessment of exposure, combined with relevant (eco-) toxicity data, as hazard assessment, provides a science-based risk assessment. The SCHEER is also of the opinion that the general proposed case-by-case approach in MSs is appropriate to deal with the determination of minimum water quality requirements for water reuse. However, the JRC report does not include a detailed methodology and further refinement to the general methodology is required to facilitate the development of minimum quality requirements for water reuse in the EU.

The SCHEER is of the opinion that the methodology described in Annex 1 provides a good overview of available methods for risk assessment; however, the SCHEER recommends that the JRC document adopts some of these methods in a more prescriptive manner (e.g. the quantitative microbial risk assessment should be part of any case-by-case evaluation).

The SCHEER considers it appropriate to follow the methodology adopted by other International Bodies and Regulatory Authorities such as the World Health Organisation (WHO), 2006, the US Environmental Protection Agency (EPA)2006, 2008, 2009, 2012, the International Organization for Standardization (ISO), 2015, the Australian Guidelines for Water Recycling and the Australian Drinking Water Guidelines (NRMMC-EPHC-AHMC (2006) NRMMC-EPHC-NHMRC (2008, 2009) NHMRC-NRMMC 2011). This methodology provides specific guidelines, with the aim of developing minimum quality requirements in the EU and its Member States. In the opinion of the SCHEER, a clearer and more detailed account should be given as to why a specific guideline was adopted. The institutional guidelines provide water quality values for many substances, but the way in which the values were determined has not been presented nor critiqued in the JRC report.

All the guidelines identify an important role for monitoring- and the JRC report similarly relies on monitoring as the main risk assessment method, including validation, operational and verification monitoring. In the opinion of the SCHEER, monitoring should not be considered as the first option in the risk assessment process. Monitoring is more often used as the last tier in a tiered approach, with screening and estimation techniques such as modelling occurring in the earlier tiers. The SCHEER considers that it is not practicable to monitor all relevant biological and chemical agents in the development of water reuse plans. It therefore recommends that the JRC develop more detailed guidance on how to apply the tiered approach to setting minimum quality requirements for water reuse in the EU. The guidance should include a list of chemical and biological agents and relevant toxicity data.

The SCHEER is of the opinion that there is no difference in the procedures to derive MQRs for agricultural irrigation or for aquifer recharge.

3.2. Question 2:

Do the proposed minimum quality requirements provide sufficient protection against environmental risks that may be associated with water reuse for agricultural irrigation and aquifer recharge?

The SCHEER is of the opinion that in their current form, the minimum quality requirements proposed provide insufficient protection against environmental risks; the evidence to support this response is summarised below. Firstly, the JRC's report includes numerical values for a few parameters, but provides no explanation about the sources of these values nor of why they were selected. Secondly, the SCHEER considers the number of parameters to be insufficient to provide protection against environmental risks. Finally, a detailed guidance on how MSs and risk managers should derive the proposed minimum quality requirements is missing.

3.2.1 General comments

The possible origins of health and environmental risks as a consequence of water reuse in agricultural irrigation are listed in section 4.6.1 of the JRC report without any precise indication of quality requirements or guidelines for risk characterisation.

In section 5.2.1 of the JRC report, an environmental risk assessment is requested to assure that the use of reclaimed water for aquifer recharge has no adverse effects on environmental matrices. No indication or references are provided on the procedures and guidelines to be used for such an assessment, nor are the bodies identified that should carry out this RA. In section 5.5 of the JRC report a list of relevant measures is indicated without clarification on how to perform them.

Quantitative quality requirements are reported in Table 1 of the JRC report for a small number of basic parameters (Biochemical Oxygen Demand (BOD), Total suspended solids (TSS), turbidity, *E. coli*). Otherwise, lists of parameters are proposed but without any quantitative indication of (minimum) quality requirements. For example, Table 3 of the JRC report provides a list of parameters that should be monitored, but no indication of the quality requirements (limits) is given. Moreover, the list in Table 3 only includes general physico-chemical properties (pH, conductivity, SAR) and inorganic parameters. No mention is made of additional parameters such as the WFD priority chemicals and other organic pollutants (contaminants of emerging concern (CEC), such as pharmaceuticals, personal care products, microplastics etc.) that are frequently observed in urban wastewater treatment plants (UWWTP) effluents. These parameters are briefly mentioned in chapter 6 of the JRC report as CEC (see Qn 4 response). However, some have been monitored in surface waters for decades (see, among others: Ternes, 1998; Zuccato *et al*., 2000). The SCHEER recommends that quantitative minimum values be developed by the EC for the parameters in Table 3 of the JRC report. MSs could then propose stricter standards on a case-by-case basis if so wished.

The SCHEER agrees with the JRC that taking into account site-specific conditions on a case-by-case basis by MSs in setting water quality requirements is an appropriate approach. However, there is a need to define precise criteria for the development of the case-by-case requirements, in order to ensure a comparable minimum level of protection in all MSs. These criteria are not developed in the JRC report. In addition, using the tiered approach (see Qn 1) it is questionable whether the case-by-case approach would be necessary in all situations, since many non-critical cases will be filtered out in an earlier tier.

In particular, for agricultural irrigation purposes, the environmental characteristics needed for defining these case-by-case conditions should be clearly listed.

For example:

- soil properties;
- crop properties;
- climatic and meteorological conditions;
- presence of protected and/or sensitive areas, etc.

A good example of the application of a tiered approach is the EU-methodology for the evaluation of groundwater and surface water as developed by the FOCUS-group and as amended by the EFSA. In that risk assessment the 4 groups of environmental characteristics mentioned above are taken into account (FOCUS, 2017). In section 4.5 of JRC's report, a number of preventive measures are listed "*that are mandatory for MSs to consider in order to reduce potential adverse effects on health and environmental matrices, according to site specific conditions*." There is no doubt that all the preventive measures listed in the section are relevant. However, all the statements are vague and not clearly defined. The SCHEER is of the opinion that more details should be included in order to make the guidelines more prescriptive. For example:

- The need for establishing wastewater source control programs is highlighted. However no guidelines or rules are proposed for planning this source control.
- The evaluation of site characteristics (i.e. soil, waters, climate, crops, nutrient balance) is required. However, there is no mention of the vulnerable soil characteristics that should be controlled, of the hydrogeological properties that need to be defined in order to protect groundwater, of how irrigation water characteristics may be defined in order to achieve the objectives of the WFD, etc.
- Many other measures are listed without clear indications of how to apply them.

3.2.2 "Sensitive areas" and case-by-case basis

In the opinion of the SCHEER, precise guidelines and criteria should be established at the European level to define sensitive areas in order to ensure a comparable level of protection across the European Union. These general criteria are needed because the concept of "sensitive areas" is controversial and may be applied in a very different manner in the MSs. A typical example is the definition of sensitive areas for the control of eutrophication, determining different quality standards for nutrients in UWWTP effluents. Some MSs (e.g. some Scandinavian countries) apply the most conservative standard everywhere, practically extending the concept of sensitive areas to the whole territory that is considered vulnerable to eutrophication processes. Other MSs apply a less conservative concept of sensitive areas. For example, in Italy, only the basins of lakes are defined as sensitive areas for eutrophication problems.

In section 4.6.3 (and 5.6.3) of the JRC report, which concerns physico-chemical parameters, only Biochemical Oxygen Demand (BOD), Total Suspended Solids (TSS) and turbidity (the same as those listed in Table 1 of the JRC report) are described in detail. The SCHEER considers that a detailed description of these basic parameters is not necessary in the report. The parameters listed in Table 3 of the JRC report (pH, conductivity, metals and other inorganic parameters) are also mentioned. Setting threshold values and minimum quality requirements according to site-specific and case-by-case conditions is delegated to MSs. However, it is the opinion of the SCHEER that criteria for setting thresholds and minimum requirements should be established at the European level in order to harmonise procedures in the different MSs.

As for agricultural irrigation, as well as for aquifer recharge (chapter 5 of the JRC report), many tasks are assigned to the MSs without clearly defining precise criteria. For example, MSs are requested to assess the removal capacity of the vadose zone on a case-by-case basis without any indication as to how the assessment should be made.

3.2.3 Microbiological risk

It is the opinion of the SCHEER that microbiological risk associated with water reuse for agricultural irrigation and aquifer recharge is not sufficiently addressed in the JRC document. In relation to wastewater (reclaimed water) monitoring, the only point of compliance recommended is "*the final reclaimed water effluent after adequate treatment* ". The control of possible wastewater storage before reuse for agricultural irrigation was generically addressed "… *reclaimed water for irrigation may suffer changes that affect its chemical and biological quality (e.g. microbial regrowth, nitrification, algae growth, natural decay of microorganisms*)" in paragraph 4.5 of the JRC report. Unfortunately, under typical operating conditions implemented in UWWTPs, in terms of either disinfectant dose or UV-C radiation intensity, disinfection processes cannot completely inactivate indigenous microorganisms, which can regrow after treatment as suitable environmental conditions occur (Li *et al*., 2013; Fiorentino *et al*., 2015; Giannakis *et al*., 2016), thus, possibly, resulting in stored wastewater not being in compliance with the standards set in Table 1 of the JRC report.

The JRC document also fails to address the contribution of UWWTPs effluents to the risk of antibiotic resistance transfer through wastewater reuse for agricultural irrigation. In spite of the broad literature available on antibiotic resistance in wastewater, only a couple of papers were briefly discussed. While the JRC report recognises that "*some pathogens may survive on crop surfaces and in soils with the potential to be transmitted to humans or animals or to groundwater or surface water*", it does not take into account that antibiotic resistant bacteria (ARB) may follow the same fate thus resulting in an additional threat to humans and the environment. UWWTPs effluents contain high bacterial loads which harbour antibiotic resistant genes that have a potential to be propagated amongst the bacterial community (Rizzo *et al*., 2013; Vaz-Moreira *et al*., 2014). In particular, antibiotic resistance has accumulated in the environment, humans and other animals over the years, and old antibiotics (such as aminopenicillins, sulfonamides, tetracyclines or erythromycin) are today ineffective against bacterial groups formerly susceptible to those drugs. The time elapsed between the emergence of a new resistance gene in clinical settings and its detection in municipal wastewater is short and bacteria resistant to new antibiotics, mainly or exclusively used in hospitals, are being detected in urban wastewater worldwide (Manaia *et al*., 2012; Rizzo *et al*., 2013; Miyahara *et al*., 2011). According to the data available in scientific literature on ARB in UWWTPs effluents, the amount of ARB that can be discharged in wastewater irrigated fields is very high and these organisms may proliferate in soils and/or plants (Becerra-Castro et al., 2015).

The fate of ARB and antibiotic resistance genes (ARGs) in soils after wastewater irrigation is still poorly understood. However, two types of negative consequences can be anticipated: i) some ARB can proliferate in soil or plants, behaving as an invasive species; and ii) some ARGs can be horizontally transferred from wastewater bacteria to soil or plant bacteria (Becerra-Castro et al., 2015).

The SCHEER is of the opinion that the JRC document should recommend to MSs that disinfection and advanced treatments be selected and operated to address the corresponding limits of *E. coli* set in Table 1 of the JRC report as well as to minimise the release of ARB, while complying with disinfection by-products (DBPs) concentration and toxicity requirements. Table 6 of the JRC report should be improved/updated to include missing processes. As new (chemical) disinfectants and advanced oxidation treatment methods are developed and applied, unregulated DBPs and/or toxic oxidation intermediates may form (Rizzo, 2011), which would not be monitored.

In order to control microbial regrowth risk, "*the point of compliance of the reclaimed water quality*" should also include storage facilities just before wastewater reuse.

Finally, considering that biological processes in UWWTPs affect the type and amount of bacterial population by promoting exponential growth compared to raw wastewater, the SCHEER considers that it would be more suitable to evaluate "*performance targets of the selected indicators*" (Paragraph 4.3, L801-804) with regards to the advanced treatment by measuring the concentrations of the target organisms before and after the advanced treatment (a different approach may be used for MBR). If so, Table 5 of the JRC report should be revised accordingly.

In conclusion, the SCHEER is of the opinion that the JRC report does not propose minimum quality requirements sufficient to provide protection against environmental risks associated with water reuse for agricultural irrigation and aquifer recharge. The disinfected wastewater should comply with the minimum microbiological quality parameters.

3.3.Question 3:

Do the proposed minimum quality requirements provide sufficient protection against the human health risks that may be associated with water reuse for aquifer recharge?

The understanding of the SCHEER on the meaning of the Terms of Reference is that water reuse does not include the production of drinking water, as sufficient standards for many water constituents are already in place in the EU (e.g. national and EU drinking water standards, WHO Drinking Water Guidelines, etc.).

The SCHEER is of the opinion that the proposed minimum quality criteria do not provide sufficient protection against microbiological and chemical risks to human health associated with water reuse for aquifer recharge. The risk related to microbial regrowth is not sufficiently addressed.

3.3.1 General comments

The parameters that are listed in Table 3 for monitoring comprise mainly heavy metals and parameters relevant for crops (e.g. nutrients like phosphorus, nitrogen etc.). In its Guidelines for the safe use of wastewater, excreta and greywater, the WHO (2006) addresses different chemical groups besides heavy metals (see also Qn 4). The JRC might consider expanding the list of parameters for monitoring with other relevant chemicals (e.g. those identified by the WHO or other regulatory bodies). Monitoring of those additional chemicals may be based on a case-by-case decision regarding the origin of the wastewater and the probability of their presence.

The WHO (2006) also lists maximum tolerable soil concentrations of various toxic chemicals (see also Qn 4) based on aspects relating to human health protection. The JRC might consider recommending that these concentrations not be exceeded as a result of aquifer recharge.

In addition, guidance on a procedure to set minimum quality requirements (e.g., on the basis of toxicity, persistence or carcinogenic, mutagenic or toxic for reproduction properties of chemicals or groups of chemicals) for chemicals of emerging concern.

In Table 7 of the JRC report - Minimum reclaimed water quality criteria for managed aquifer recharge - other criteria should be added in accordance with Table 3. The SCHEER recommends organic and inorganic chemicals as well as nutrients be included (all of which were identified as important by other regulatory bodies e.g. in the Australian Environment Protection and Heritage Council documents NRMMC-EPHC–NHMRC, 2008, 2009).

3.3.2. Microbiological risk

It is worth noting that detection of ARB and ARGs in disinfected wastewater and in soil is technically challenging and, when they occur at very low levels, it may be difficult to quantify them by using commonly used techniques (e.g. qPCR), in spite of their potential biological impact (e.g. facilitating horizontal gene transfer). Therefore, "the risks of transmission of antibiotic resistance from the environment to humans must be managed under the precautionary principle, because it may be too late to act if we wait until we have concrete risk values" (Manaia, 2017).

The JRC document should clearly recommend to MSs that disinfection and advanced treatments should be selected and operated to address the corresponding limits of *E. coli* set in Table 1 while complying with DBPs concentration and toxicity requirements recommended in the subsequent paragraphs.

3.4. Question 4:

Have any risks been overlooked, and if so how should they be taken into account?

Although strictly speaking, risks have not been overlooked in the JRC document, the SCHEER has identified several issues it considers as having been overlooked or not sufficiently addressed in the document. These issues are enumerated and elaborated in the following paragraphs.

Aquifer recharge. In case of aquifer recharge, injection of water is not mentioned specifically in the JRC report. Water injection above approximately 30cm is different from a surface recharge, as passage through the soil takes place. Although aquifer recharge through infiltration may reduce the contaminant load of the reused water, this will be less so the more mobile the chemical is. Appropriate data about persistent mobile organics are scarce and very limited (Reemtsma *et al*., 2016) and for these compounds the SCHEER proposes that a more conservative approach be adopted (e.g. TTC, see for example Malchi *et al*., 2014). Deeper water injection is considered inappropriate for this reason.

Contaminants of emerging concern. The JRC document addresses contaminants of emerging concern in chapter 6 and in Annex II. The SCHEER welcomes the attention paid to these compounds, but is of the opinion that they need to be addressed more explicitly in the document. Although in most cases health risks from chemicals present at trace concentrations can be considered negligible, there may be chemicals requiring more specific consideration. The spread of CECs into the environment as well as wastewater treatment methods for removing CECs before effluent disposal or reuse have been widely investigated in recent years. The JRC document appears to have overlooked ongoing efforts at EU level to identify chemical, microbiological and toxicity indicators to control and possibly minimise the CECs-related risk for human health and environment (see e.g. NORMAN network and EU projects such as PROMOTE, SOLUTIONS, etc.). In spite of these efforts and the widely available literature, the JRC document does not adequately introduce possible risks related to the release of CECs in the environment nor support the conclusions with sufficient relevant and updated references. Chapter 6 is centred around a few references (Paranychianakis *et al*., 2015, Prosser and Sibley, 2015 and Drewes *et al*., 2013). The document refers to and seems to adopt the "development of a science-based framework to guide the identification of CECs that should be monitored or otherwise regulated, including the context of reclaimed water use, especially for potable use" (l.1948-1950) and identifies the need for a short list of meaningful indicator measurements. The conclusion from the Paranychianakis and Prosser & Sibley papers that "uptake, translocation and the accumulation of a wide range of emerging chemicals in crop tissues is in overall low and does not pose significant risks for public health" is - according to the SCHEER - based on a limited number of chemicals (n=22) and does not take into account that for the majority of CECs no hazard assessment has been made so far and therefore no proper risk assessment can be made yet. Disinfection by-products for example may be present in reclaimed water exceeding action levels set for the protection of human health in drinking water (see US-EPA, 2012). Therefore, a more balanced approach for CECs is needed, taking into account current knowledge and/or using the principle of Threshold of Toxicological Concern (TTC). The conclusions from the Prosser and Sibley paper have been criticized (Malchi *et al*., 2015) and accumulation of mobile, polar, water-soluble persistent organics and pharmaceuticals in edible parts of plants has been demonstrated in several studies, sometimes at concentrations above the TTC (e.g., Dettenmaier *et al*., 2009, Herzke *et al*., 2013, Felizeter *et al*., 2014, Malchi *et al*., 2014).

The US-EPA (2012) presented a good overview on organic chemicals including CECs which may be present in wastewater and may pose a risk to human health. The US-EPA document also gives a good overview on the efficacy of various treatments for removing selected chemicals. This information should be included in the JRC document.

As an example, in its 'Guidelines for the safe use of wastewater, excreta and greywater' the WHO (2006) addresses different chemical groups besides heavy metals, i.e.

- Antibiotics - Risk of increase in antibiotic resistance, especially if the concentrations are low.
- Cyanobacterial toxins – High acute neuro- and hepato-toxicity and long term toxicity for vertebrates incl. humans
- Phthalates and phenols - Consumption of water coming from aquifers recharged through wastewater irrigation. These compounds have been found in aquifers used for human drinking-water supplies that have been inadvertently recharged through wastewater irrigation. Some of these chemicals may have endocrine disrupting properties.
- Halogenated hydrocarbons (dioxins, furans, PCBs) - Not absorbed by plants, but may contaminate surfaces if plants are not peeled or washed before consumption, then accumulate in the food chain.
- Pesticides and their residues - Risk mostly related to pesticide application practices.
- Skin irritants and sensitisers - hazard related to a combined exposure to microorganisms and chemicals
- Polar chemicals that may accumulate in crops and vegetables

The SCHEER suggests that the JRC expand Table 3 - the list of parameters for monitoring - with the most important chemicals identified by WHO, EU (watch list) or other regulatory bodies, taking into account the more recent studies on the toxicity of CECs. Monitoring of those additional chemicals may be based on a case-by-case decision regarding the origin of the wastewater and the probability of their presence.

The WHO also lists maximum tolerable soil concentrations of various toxic chemicals based on aspects regarding human health protection. The JRC might consider recommending Member States to adopt guidelines that wastewater irrigation should not result in exceeding these concentrations.

Furthermore, the SCHEER is of the opinion that the radiological hazards of water reuse have not been addressed in the JRC document (apart from a definition being given) and that antibiotic resistance is also not addressed sufficiently (see answers to Qns 2 and 3 for additional detail).

While the JRC report recognises that "some pathogens may survive on crop surfaces and in soils with the potential to be transmitted to humans or animals or to groundwater or surface water." (L999-1000), it does not take into account that antibiotic resistant bacteria may follow the same fate, thus resulting in an additional threat to humans and the environment.

3.4.3 Microbiological risks

The JRC does identify antibiotic resistance as a risk in water reuse in chapter 6. While recognising that this is an area of active research, the SCHEER's view is that the JRC document could have provided more specific recommendations as outlined below.

The JRC document should clearly recommend MSs that disinfection and advanced treatments should be selected and operated to address the corresponding limits of *E. coli* set in Table 1 of the JRC report, while complying with the DBPs concentration and toxicity requirements recommended in the subsequent paragraphs.

The control of microbial regrowth risk, "the point of compliance of the reclaimed water quality" should also include storage facilities just before wastewater reuse (L748-749).

In addition, the contribution of UWWTPs effluents to the risk of antibiotic resistance transfer through wastewater *reuse* for agricultural irrigation should be addressed. It is worth remarking that detection of ARB and ARGs in disinfected wastewater and in soil is technically challenging and when they occur at very low levels it may be difficult to quantify them by commonly used techniques (e.g. qPCR), in spite of their potential biological impact (e.g. facilitating horizontal gene transfer). The SCHEER is of the opinion that a realistic first step to control the spreading of antibiotic resistance would be to incorporate the measurement of antibiotic-resistant *E. coli* when measuring "total" *E. coli* in UWWTPs effluents, a parameter that is already part of the listed minimum quality requirements in the JRC document. In particular, cefotaxime (a third-generation cephalosporin that is on the WHO essential list of medicine) resistance is a good indicator for human sources of antibiotic resistance. It is associated with a wide diversity of antibiotic resistance genes that are widespread in the environment and of great clinical concern, in particular with extended spectrum beta lactamases (ESBL). ESBL producing *E. coli* are widespread in the community and a potential source of human infections (Mesa *et al*., 2006). Accordingly, Table 1 of the JRC document may be revised by adding to *E.coli* values ≤1 (or below detection limit), 10, 100 and 1000 CFU/100 mL cefotaxime resistant *E. coli* for A, B, C and D reclaimed water quality classes, respectively. These values correspond to 10% of resistance prevalence – which is a compromise between adequacy to monitor wastewater resistance levels and the feasibility of analyses. Although the proposed values take into account practical issues related with the analytical procedure, they also express important facts related to the water quality and human health risks (infective doses for some pathogenic *E.coli* or *Shigella* can be as low as 10-500 cells (Schmid-Hempel and Frank, 2007).

3.5. Conclusions

While the JRC document considers many of the important elements in proposing EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge, the SCHEER is of the opinion that the JRC document does not propose minimum quality requirements necessary to provide protection against environmental risks associated with water reuse.

The SCHEER is of the opinion that more details could and should be included in order to make the guidelines more prescriptive.

The SCHEER considers it appropriate to follow the methodology adopted by other international bodies and regulatory authorities (including the WHO, EPA, ISO, Australian Environment Protection and Heritage Council), which provide specific guidelines, with the aim of developing minimum quality requirements in the EU and the MSs. In the opinion of the SCHEER, a clearer and more detailed account should be given on the reasons why a specific guideline was adopted.

The SCHEER recommends that the list of organic and inorganic chemicals as well as nutrients be extended in the water quality criteria (Table 7 of the JRC document) when assessing environmental and eco-toxicological risks. Quantitative minimum quality requirements should be proposed for relevant physical-chemical properties and priority chemicals, not only for a very few basic parameters of water quality (such as BOD, TSS, turbidity, *E. coli*). Detailed guidance is missing on how MSs and risk managers should derive the proposed minimum quality requirements.

The SCHEER is of the opinion that defining minimum water quality requirements on a site specific, case-by-case basis is an appropriate procedure. However, the site specificity depends on the characteristics of environmental conditions and scenarios, not on MSs. Therefore, for ensuring comparable minimum quality requirements in the EU, common criteria must be defined for the case-by-case assessments. For the same reason, the concept of sensitive areas must be better defined and described.

It is the opinion of the SCHEER that microbiological risk associated with water reuse for agricultural irrigation and aquifer recharge is not sufficiently addressed in the JRC document. The JRC document should clearly recommend MSs that disinfection and advanced treatments should be selected and operated to meet the corresponding *E. coli* limits while complying with DBPs concentration and toxicity requirements. The contribution of UWWTPs effluents to the risk of antibiotic resistance transfer through wastewater reuse for agricultural irrigation should be addressed, including the need for, and guidance in, setting EU-wide quality criteria that address microbial contamination including antimicrobial resistance issues and regrowth.

The SCHEER welcomes the attention paid to CECs, but is of the opinion that they need to be more explicitly addressed in the document. Although in most cases health risks from chemicals present at trace concentrations can be considered negligible, there may be chemicals requiring more specific consideration. The spread of CECs into the environment as well as wastewater treatment methods for removing CECs before effluent disposal or reuse have been widely investigated in recent years. The JRC document appears to have overlooked ongoing efforts at EU level to identify chemical, microbiological and toxicity indicators to control and possibly minimise the CECs-related risk for human health and environment.

Finally, the SCHEER is of the opinion that there is a value and a sense in defining EU-wide minimum quality requirements to ensure the same level of health and environmental protection in all MSs.

4. MINORITY OPINIONS

None.

5. METHODOLOGY USED

For this Scientific Advice, the SCHEER reviewed the JRC's report entitled 'Minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge', version 3.3. February 2017[6].

[6] https://circabc.europa.eu/w/browse/c5da4b87-9ced-44d0-af8c-02a472fe984f

6. REFERENCES

Ayuso-Gabella, N., Page, D., Masciopinto, C., Aharoni, A., Salgot, M., Wintgens, T. (2011). Quantifying the effect of Managed Aquifer Recharge on the microbiological human health risks of irrigating crops with recycled water. Agricultural Water Management, 99, 93-102.

Becerra-Castro, C., Lopes, A.R., Vaz-Moreira, I., Silva, E.F., Manaia, C.M., Nunes, O.C. (2009). Wastewater reuse in irrigation: A microbiological perspective on implications in soil fertility and human and environmental health. Environment International 75, 2015, 117-135.Dettenmaier EM, Doucette WJ, Bugbee B. Chemical hydrophobicity and uptake by plant roots. Environ Sci Technol., 43, 324-329.

Drewes, J. E., Anderson, P., Denslow, N., Olivieri, A., Schlenk, D., Snyder, S.A., Maruya, K.A. (2013). Designing monitoring programs for chemicals of emerging concern in potable reuse - what to include and what not to include? Water Science and Technology 67(2), 433-439.

Felizeter, S., McLachlan, M., de Voogt, P. (2014). Root uptake and translocation of perfluorinated alkyl acids by three hydroponically grown crops. J. Agric. Food Chem. 62, 3334–3342.

Fiorentino, A., Ferro, G., Castro Alferez, M., Polo-López, M.I., Fernández-Ibañez, P., Rizzo, L. (2015). Inactivation and regrowth of multidrug resistant bacteria in urban wastewater after disinfection by solar-driven and chlorination processes. Journal of Photochemistry and Photobiology B: Biology 148, 43–50.

FOCUS (2017). http://esdac.jrc.ec.europa.eu/projects/focus-dg-sante (as accessed 11 May 2017)

Giannakis, S., Voumard, M., Grandjean, D., Magnet, A., De Alencastro, L.F., Pulgarin, C. (2016). Micropollutant degradation, bacterial inactivation and regrowth risk in wastewater effluents: Influence of the secondary (pre)treatment on the efficiency of Advanced Oxidation Processes. Water Research 102, 505-515.

Herzke, D., Huber, S., Bervoets, L., D'Hollander, W., Hasjlova, J., Pulkrabova, J., Brambilla, G., De Filippis, S. P., Klenow, S., Heinemeyer, G., de Voogt, P. (2013). PFAS in vegetables collected in four European countries; raw and processed products. Environ Sci Pollut Res 20, 7930-7939.

ISO 16075 (2015) Guidelines for Treated Wastewater Use for Irrigation Projects. International Organization for Standardization, Geneva, Switzerland

Levantesi, C., La Mantia, R., Masciopinto, C., Böckelmann, U., Ayuso-Gabella, M.N., Salgot, M., Tandoi, V., Van Houtte, E., Wintgens, T., Grohmann, E. (2010). Quantification of pathogenic microorganisms and microbial indicators in three wastewater reclamation and managed aquifer recharge facilities in Europe. Science of The Total Environment 408, 4923-4930.

Li, D., Zeng, S., Gu, A.Z., He, M., Shi, H. (2013). Inactivation, reactivation and regrowth of indigenous bacteria in reclaimed water after chlorine disinfection of a municipal wastewater treatment plant. Journal of Environmental Sciences 25, 1319-1325.

Malchi, T., Maor, Y., Tadmor, G., Shenker, M., Chefetz, B. (2014). Irrigation of root vegetables with treated wastewater: Evaluating uptake of pharmaceuticals and the associated human health risks. Environ. Sci. Technol. 48, 9325-9333.

Malchi, T., Maor, Y., Chefetz, B. (2015). Comments on "Human health risk assessment of pharmaceuticals and personal care products in plant tissue due to biosolids and manure amendments, and wastewater irrigation" Environ. Int. 82, 110–112.

Manaia, C.M. (2017). Assessing the Risk of Antibiotic Resistance Transmission from the Environment to Humans: Non-Direct Proportionality between Abundance and Risk. Trends in Microbiology, http://dx.doi.org/10.1016/j.tim.2016.11.014, in press.

Manaia, C.M., Vaz-Moreira, I., Nunes, O.C. (2012). Antibiotic resistance in waste water and surface water and human health implications. In: Barceló, D. (Ed.), Emerging Organic Contaminants and Human Health. Springer-Verlag, Berlin Heidelberg, pp. 173–212.

Miyahara, E., Nishie, M., Takumi, S., Miyanohara, H., Nishi, J., Yoshiie, K., et al., (2011). Environmental mutagens may be implicated in the emergence of drug-resistant microorganisms. FEMS Microbiol. Lett. 317, 109–116.

NRMMC-EPHC-AHMC (2006) Australian guidelines for water recycling: managing health and environmental risks: Phase 1. National Water Quality Management Strategy. Natural Resource Management Ministerial Council, Environment Protection and Heritage Council, Australian Health Ministers' Conference. Canberra, Australia.

NRMMC-EPHC-NHMRC (2008) Australian guidelines for water recycling: managing health and environmental risks: Phase 2. Augmentation of water drinking supply. National Water Quality Management Strategy. Natural Resource Management Ministerial Council, Environment Protection and Heritage Council, Australian Health Ministers' Conference. Canberra, Australia.

NRMMC-EPHC-NHMRC (2009) Australian guidelines for water recycling: managing health and environmental risks: Phase 2c: Managed aquifer recharge. National Water Quality Management Strategy. NRMMC-EPHC-AHMC, Canberra, Australia.

NHMRC-NRMMC (2011) Australian drinking water guidelines. Natural Resource Management Ministerial Council, National Health and Medical Research Council Canberra, Australia.

Paranychianakis, N.V., Salgot, M., Snyder, S.A., Angelakis, A.N. (2015). Water reuse in EU states: Necessity for uniform criteria to mitigate human and environmental risks (Review). Critical Reviews in Environ. Sci. Technol. 45, 1409-1468

Prosser, R.S., Sibley, P.K. (2015). Human health risk assessment of pharmaceuticals and personal care products in plant tissue due to biosolids and manure amendments, and wastewater irrigation. Environ. Int., 75C, 223–233.

Reemtsma, T., Berger, U., Arp, H. P. H., Gallard, H., Knepper, T. P., Neumann, M., Quintana, J. B., de Voogt, P. (2016). Mind the Gap: Persistent and Mobile Organic Compounds—Water Contaminants That Slip Through. Environ. Sci. Technol. 50, 10308-10315.

Rizzo L. (2011). Bioassays as a tool for evaluating advanced oxidation processes in water and wastewater treatment. Water Research 45, 4311-4340.

Rizzo, L., Manaia, C., Merlin, C., Schwartz, T., Dagot, C., Ploy, M.C., *et al*. (2013). Urban wastewater treatment plants as hotspots for antibiotic resistant bacteria and genes spread into the environment: a review. Sci. Total Environ. 447, 345–360.

Ternes, T.A. (1998). Occurrence of drugs in German sewage treatment plants and rivers. Water Res.32, 3245-3260

Toze, S., Bekele, E., Page, D., Sidhu, J., Shackleton, M. (2010). Use of static Quantitative Microbial Risk Assessment to determine pathogen risks in an unconfined carbonate aquifer used for Managed Aquifer Recharge. Water Res 44(4), 1038-1049.

USEPA (2004) Guidelines for water reuse. EPA/625/R-04/108. United States Environmental Protection Agency, Washington, DC, USA.

USEPA (2006) National Primary Drinking Water Regulations: Groundwater rule. Final Rule. 40 CFR, Federal Register, Vol. 71, n. 216; Washington, DC, USA.

USEPA (2009). National Primary Drinking Water Regulations. EPA 816-F-09-004. United States Environmental Protection Agency, Washington DC, USA.

USEPA (2012) Guidelines for water reuse. (EPA/600/R-12/618) United States Environmental Protection Agency, Washington, DC, USA.

USEPA (2012) Guidelines for water reuse. (EPA/600/R-12/618) United States Environmental Protection Agency, Washington, DC, USA.earch 44, 2010, 1038-1049.

Vaz-Moreira, I., Nunes, O. C., Manaia, C. M. (2014). Bacterial diversity and antibiotic resistance in water habitats: searching the links with the human microbiome. FEMS Microbiol. Rev. 38, 761–778.

WHO (2006). Guidelines for the safe use of wastewater, excreta and greywater. Volume 2: Wastewater use in agriculture. World Health Organization, Geneva, Switzerland.

Zuccato, E., Calamari, D., Natangelo, M., Fanelli, R. (2000). Presence of therapeutic drugs in the environment. The Lancet, 355, 1789-1790.

7. LIST OF ABBREVIATIONS

ARB	Antibiotic resistant bacteria
ARGs	Antibiotic resistant genes
BOD	Biochemical Oxygen Demand
CEC	Compounds of Emerging Concern
DBPs	Disinfection by-products
EFSA	European Food Safety Authority
ESBL	Extended spectrum beta lactamases
FOCUS	FOrum for Co-ordination of pesticide fate models and their USe
IIA	Inception Impact Assessment
JRC	Joint Research Centre
MS	Member State
q(RT)PCR	Quantitative Reverse Transcription Polymerase Chain Reaction
RA	Risk assessment
RSB	Regulatory Scrutiny Board
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
TSS	Total Suspended Solids
TTC	Threshold of Toxicological Concern
USEPA	United States Environmental Protection Agency
UWWTP	Urban Wastewater Treatment Plant
WFD	Water Framework Directive
WHO	World Health Organization