

The Director General

Maisons-Alfort, 31 October 2018

### Scientific and Technical Support NOTE of the French Agency for Food, Environmental and Occupational Health & Safety

on the draft Regulation on the reuse of treated wastewater for agricultural irrigation adopted by the European Commission on 28 May 2018

On 3 September 2018, ANSES received a joint request from the Directorate General for Health (DGS), the Directorate for Water and Biodiversity (DEB) and the Directorate for Economic and Environmental Performance of Enterprises (DGPE)<sup>1</sup> to provide the following scientific and technical support (STS): Request for scientific and technical support on the draft Regulation on the reuse of treated wastewater for agricultural irrigation adopted by the European Commission (EC) on 28 May 2018.

#### 1. BACKGROUND AND PURPOSE OF THE REQUEST

On 28 May 2018, the European Commission (EC) published a draft Regulation on the reuse of treated wastewater for agricultural irrigation (EC, 2018c) together with its Annexes (EC, 2018a)<sup>2</sup>.

Following requests from the Ministries of Health, Environment and Food, ANSES had previously issued opinions setting out recommendations for limiting health risks related to exposure to treated wastewater (AFSSA, 2008; AFSSA, 2010; ANSES, 2012). This work enabled the ministries to draw up regulatory technical requirements on the use of treated wastewater for irrigating crops and watering green spaces<sup>3</sup>.

In addition, ANSES contributed to the EC's work during the preparation of the aforementioned Proposal for a Regulation and provided scientific and technical support in 2016 to assess the relevance to health of the proposals in the interim report of the Joint Research Centre (JRC) following a request from the Ministry of the Environment<sup>4</sup>. The Proposal for a Regulation described in this Scientific and Technical Support Note is based on the final version of the JRC report after taking into account the opinions of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and the European Food Safety Authority (EFSA) published in 2017 (EFSA, 2017).

The ministries intend to provide input for the positions taken by the French authorities based on the response to this request, which is to provide "a detailed analysis, in electronic form, of the abovementioned draft Regulation with regard to the following points:

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<sup>&</sup>lt;sup>1</sup> Of the Ministry of Agriculture and Food

proposal 2 Referenced Brussels. 28.05.2018. COM(2018) 337 final: https://eur-lex.europa.eu/legalcontent/EN/TXT/HTML/?uri=CELEX:52018PC0337&from=EN

<sup>&</sup>lt;sup>3</sup> Ministerial Order of 25 June 2014 (JORF 2014) amending the Ministerial Order of 2 August 2010 (JORF 2010) relating to the use of water resulting from the purification treatment of urban wastewater for irrigation of crops or green spaces <sup>4</sup> Scientific and Technical Support No 2016-SA-0174 of 7 October 2016

- relevance of the proposed quality classes of treated wastewater, including related parameters and thresholds, with regard to environmental protection and the safeguarding of human and animal health;
- relevance of the proposed monitoring conditions for treated wastewater with regard to the various quality classes of treated wastewater;
- relevance of not having a mandatory, regulated monitoring system for soil irrigated with treated wastewater (parameters, thresholds, conditions);
- relevance of the proposed uses with regard to the various quality classes of treated wastewater and irrigation methods".

#### 2. ORGANISATION OF THE WORK

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

It was carried out by the "European RTWW Regulation" Emergency Collective Expert Appraisal Group (GECU). Telephone meetings in sub-groups were organised on 4 and 5 October and the GECU met on 22 October 2018. The work was validated electronically on 30 October 2018.

The Expert Committee (CES) on "Water" was consulted during the meeting of 2 October 2018.

Given the scope of the draft Regulation proposed by the EC and ongoing work at ANSES, the "BioRisk" CES was consulted on 17 October.

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.

The experts' declarations of interests are made public via the website of the Ministry of Solidarity and Health (<u>https://dpi.sante.gouv.fr</u>).

Given the time constraints imposed by the formal request, the GECU was not able to carry out a review of the scientific literature to update its previous work, and therefore essentially relied on the following documentation:

- The documents associated with the draft Regulation and its Annexes on the EC's website, in particular:
  - The JRC report published in 2017 (JRC, 2017), which was used to prepare the Annexes to the draft Regulation;
  - The EFSA report on the draft JRC report (EFSA, 2017);
  - The SCHEER report on the draft JRC report (SCHEER, 2017);
  - The impact assessment carried out by the EC (EC, 2018b).
- The opinions, reports and STS notes produced by the Agency, as well as its ongoing work;
- The European Directives and Regulations cited in the aforementioned draft Regulation, as well as French regulatory texts related to the themes addressed in the draft Regulation.

For some parameters of the draft Regulation, these data were supplemented by an analysis of recent scientific publications.

#### 3. ANALYSIS AND CONCLUSIONS

#### 3.1. General comments regarding the draft Regulation

#### 3.1.1. Reasons for and objectives of the proposal

The reasons given for the proposed Regulation rely on the declining availability of freshwater resources in the European Union from year to year, especially in Southern Europe, due to the growing needs of populations and climate change. This water stress has already had major environmental and economic consequences that are expected to become more severe in the coming years, which is why the management of water resources should be reconsidered.

In particular, the EC's Proposal for a Regulation recommends that water-saving should be a priority and that the use of available resources should be improved. To that end, the use of treated urban wastewater is presented as providing a potential reliable water supply, especially for agricultural irrigation. To prevent potential obstacles to the free movement of agricultural products irrigated with treated wastewater (TWW), the Proposal for a Regulation sets out minimum quality requirements in addition to key tasks. Moreover, the draft Regulation insists on the cost-effectiveness of water reuse compared to other water-production systems. The use of TWW is described as having a lower environmental impact than water transfers or desalination for example, but no arguments are given to support this statement. Regarding the expected benefits, agricultural irrigation via TWW could, in the context of large-scale agricultural irrigation considered in the document, lead to a more than 5% reduction in direct abstraction from water bodies and groundwater and thus reduce overall water stress by the same amount.

#### 3.1.2. The GECU's general comments regarding the reasons for and objectives of the proposal

The GECU notes that while robustness from the standpoint of health and environmental protection is claimed in the draft Regulation, it is not supported by scientific arguments, especially regarding the safety of treated wastewater in terms of chemical contaminants in human food or livestock feed and their impact.

With regard to human health, the requirements and measures associated with TWW irrigation seem only to apply to consumers of irrigated food products and not to other population groups. The GECU considers in particular that the Proposal for a Regulation should clearly define all of the populations potentially exposed to TWW, including workers exposed to TWW, bystanders and residents.

#### With regard to animal health, the GECU notes that:

In general, in this draft Regulation, animal health only seems to be considered through human food since there is only mention of risks to human health via the consumption of milk and meat from animals directly exposed to TWW.

The objective of protecting animal health, in particular that of sports and leisure animals, should be included in the draft Regulation and should be supported by risk management measures. This finding is consistent with the above observation regarding the human population targeted in this draft Regulation.

With regard to the environment, the GECU would like to emphasise that the stated benefits in terms of water stress should be qualified since there could be negative impacts in certain circumstances. For example, TWW used for irrigation will not or will no longer replenish low water levels and/or supply water to wetlands, which will not receive discharge from wastewater treatment plants (WTPs). Furthermore, the issue of evaporation losses during the open storage of TWW for reuse should also be considered. At the same time, the GECU would like to emphasise that discharges of TWW into rivers (and wetlands) suffering from significant water shortages can in some situations cause the water to become severely contaminated. Its use for agricultural irrigation would therefore be a way to limit this contamination and

thus protect downstream areas for sensitive uses such as those for bathing, water recreation, or the harvesting of filter-feeding shellfish (AFSSA, 2008).

The GECU insists that the economic model characterising the water production/distribution/treatment value chain is not clearly defined but should be.

#### 3.1.3. Consultation of interested parties

The GECU notes, as stated on page 6 of the draft Regulation, that 506 contributions were received during the first public consultation which ran from 30 July to 7 November 2014 and that 344 were received during the second public consultation which ran from 28 October 2016 to 27 January 2017.

The GECU therefore wonders what was the basis for the following affirmation: "compared to water from rivers ... nearly 70% of respondents consider reused water as at least as safe". If this statement can be connected to the respondents' profiles, it is likely to be biased.

#### 3.1.4. Recitals of the European draft Regulation

Recital (2): "The Union's ability to respond to the increasing pressure on water resources could be enhanced by wider reuse of treated waste water [...]"

The GECU's opinion of this recital is given in Section 3.1.2 of this document.

Recital (4): "The Communication from the Commission to the European Parliament and the Council 'Addressing the challenge of water scarcity and droughts in the European Union'<sup>18</sup> sets out the hierarchy of measures that Member States should consider in managing water scarcity and droughts [...]"

The GECU suggests that the statement "in regions where all preventive measures have been implemented" should be further developed.

Recital (7): "Health standards in relation to food hygiene for agricultural products irrigated with reclaimed water can be achieved only if quality requirements for reclaimed water destined for agricultural irrigation do not differ significantly in Member States [...]"

The expression "does not differ significantly" is very imprecise.

Recital (16): "In order to adapt the existing minimum requirements and the key risk management tasks to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to amend the minimum requirements and the key risk management tasks [...]"

As indicated above, the second sentence of this paragraph should clearly mention the protection of animal health.

#### 3.1.5. Articles of the draft Regulation

#### Article 3 – "Definitions"

The GECU notes that vague terminology is used for some of the definitions given and considers that this article should include additional or supplementary definitions.

For example, no framework is given for the transport of TWW to its place(s) of use or place(s) of storage if it is meant to be stored prior to use. A number of terms should thus be better defined and clarified, primarily in connection to the definition given for "reclamation" plant.

Indeed, a wide variety of scenarios can be considered based on the definition of this term in the article. It is essential to define the technical characteristics and location of the reclamation plant if it is not an integral part of a WTP. It is then necessary to define the origins, treatments, quality classes and flow rates of the TWW accepted in this plant.

Regarding the collection system, it is necessary to specify how the sewage system works and indicate the origins and characteristics of the collected effluents. Indeed, an assessment dealing only with the performance of the WTP is not sufficient since this can be affected by the seepage of stray water for a separate system or by rainwater for a combined system. Industrial rainwater, runoff from roads, water from industrial processes, and water from service activities (hospitals, automotive repairs, hair salons, drycleaning, etc.) are all potential sources of contaminants (PAHs, trace metal elements (TMEs), hydrophilic compounds, substances specific to industrial processes such as biocides, solvents, drug residues, contrast agents in medical imaging, etc.) that should be taken into consideration.

In the event that the "reclamation plant" is a TWW centralisation system downstream of various WTPs, then this system should be described. It should also be included in the performance validation process.

Experience has shown that with agricultural irrigation, water storage is inevitable in order to be able to respond to variations in water demand. The storage of TWW in open ponds may, among other things, lead to the development of potentially toxic cyanobacteria whose transfer to vegetables has been described (Corbel *et al.*, 2016). With TWW requiring storage, it would be necessary to determine the time spent in the storage pond in order to consider the possible formation of biofilms. Depending on the irrigation period, there could be microbial proliferation in these ponds and in the pipes taking the stored water to its points of use. The GECU therefore considers that the water storage step needs to be described. Moreover, if the reclamation plant does not offer storage, another point of compliance will need to be added.

In addition, definitions should be added relating to the sanitation system, including the collection system and the WTP(s), as well as to TWW storage, the TWW distribution system, and the various irrigation devices used.

- The following expressions should also be introduced and defined:
  - Environmental impact
  - Reference pathogen
  - o Industrial crops
  - Energy crops

Lastly, the GECU notes that definitions 5 and 6 are not consistent. Definition 5 for "reclaimed water" suggests that this water inevitably passes through a reclamation plant, whereas according to definition 6, treated effluent from a WTP and reused effluent can be the same.

#### Article 7 – "Granting of the permit"

In paragraph 3(c), the expression "mitigate any unacceptable risks" is unclear and should be revised. In paragraph 4, it would be advisable to reiterate that in the event of any changes in the sanitation system, the permit will need to be reviewed.

#### Article 8 – "Compliance check"

As indicated above, the second sentence of the third paragraph should clearly mention the protection of animal health.

#### Article 11 – "Information on monitoring of implementation"

Paragraph 2 states that two European agencies have access to the data sets referred to in paragraph 1. The GECU suggests that these should also be accessible to EFSA as well as to national agencies in Member States (MSs) whose missions include monitoring, issuing alerts and assessing risks in the areas of human and animal health and environmental protection.

The GECU also questions the interpretation of the word "thereafter" in paragraph 1(b).

#### Article 13 – "Evaluation"

The GECU reiterates that the protection of animal health should be mentioned in paragraph 2(d).

#### 3.1.6. Annex I to the draft Regulation

The GECU notes that Table 1 from the JRC 2017 report entitled "Examples of monitoring for several treatment processes" has been deleted and is surprised by this choice. In addition, Table 3 in the current draft Regulation is spread out over two pages (2-3), making it difficult to read.

#### Section 2. Minimum requirements

The GECU recommends deleting the sub-section (2.1) since it only contains one item.

• Table 1 – Classes of reclaimed water quality and allowed agriculture use and irrigation method

The GECU notes that the presentation of the various crop categories is not the same as that in Section 1 defining them. Moreover, the GECU wonders whether the notion of root crop is still appropriate in this type of text.

In addition, the GECU suggests removing the words "tiny", "very" and "plastic" from the sentence below the table as these are not necessary for understanding the text.

• Table 2 – Reclaimed water quality requirements for agricultural irrigation

The GECU suggests that the "Indicative technology target" column should be deleted since its content is minimal, meaning that it serves no purpose. It raises several questions and could be interpreted as meaning that questionable technological processes may be appropriate, for example chlorination as a disinfection process. Moreover, the purpose of the Regulation is to lay down requirements in terms of outcomes, which will determine the choice of technology to be used based on the local context. Its purpose is not to agree on the resources available which, with respect to those mentioned in the JRC report, call for the following comments:

• The disinfection of TWW by chlorination as a form of tertiary treatment is, in principle, inexpensive and easy to implement, enabling residual concentrations of disinfectants to be maintained in systems. However, the chlorination of TWW does not appear to be a good solution compared to other physical disinfection processes (UV irradiation, membrane filtration) due to the formation of disinfection by-products (organohalogen compounds of which around 50% are of an unknown nature). These by-products have been identified by the World Health Organization (WHO) as being compounds with human toxicity for which the Guidelines for Drinking-water Quality (WHO, 2017) have set a target to limit their formation during the production of drinking water to limit human exposure. For partially nitrified TWW, the final disinfection step relies on monochloramine formed when chlorine reacts with ammonia.

Monochloramine produces far fewer organohalogen by-products and more nitrosamines and is less effective than chlorine in terms of biocidal activity. The requirements for *E. coli* could therefore be met, but not those for viruses or parasites, especially in the form of cysts or oocysts. The quality of commercial solutions of sodium hypochlorite (levels of chlorate and bromate) as well as chloride levels (increase in salinity and the mobility of metals) may be additional drawbacks of chlorination.

- Ozonation is a very expensive but powerful disinfection technique, in principle leading to a lower rate of formation of hazardous by-products than chlorine when used for the treatment of WW. It is nonetheless necessary to monitor concentrations of bromate ions formed with this type of treatment.
- Membrane filtration techniques provide an alternative for meeting the *E. coli* targets set for quality classes A and B. These treatments are physical disinfection techniques based on the retention of particles and micro-organisms and do not use any chemical reagents. There is therefore no risk of by-products forming that are harmful to human health.
- The performance of UV disinfection is another suitable solution that depends, among other parameters (ANSES, 2010), on the turbidity of the water to be treated, which should be as low as possible. For this reason, if this treatment is implemented, the turbidity quality requirement for quality class A should apply regardless of the microbiological target in order to guarantee disinfection performance.
- As for compliance with the *E. coli* requirement for Class D, a treatment using "activated sludge" can already enable a 1.5 to 2 log reduction to be achieved. If necessary, according to the GECU, adding a sand filtration step, or even lengthening the time spent in the reclamation pond, can enable the target for Class D to be met. However, the table in its current version implicitly suggests that chemical disinfection is also required.
- In light of the possible regrowth or cell repair capacities (especially with UV disinfection) of certain micro-organisms after the disinfection step, there should be a monitoring point at the outlet of the storage pond if such a pond is planned.

# In general, the GECU notes that the risks to human health, animal health and the environment associated with chemical contaminants, regardless of their nature, seem under-estimated in light of the possible contamination.

Regarding column 3 of the table, the statement "or below detection limit" on the second line is not necessary.

• Table 3 – Minimum frequencies for routine monitoring of reclaimed water for agricultural irrigation

The text following Table 3 contains a terminology error as "sulfate-reducing" should be replaced by "sulfite-reducing". The same is true for Table 4.

• Table 4 – Validation monitoring of reclaimed water for agricultural irrigation

The terms *Campylobacter* and *Cryptosporidium* and *Clostridium perfringens* below the table should appear in italics.

#### 3.1.7. Annex II to the draft Regulation – Key risk management tasks

The GECU insists that some of these tasks should be placed in the body of the draft Regulation since they are essential actions in the assessment of risks to human health, animal health and the environment. Moreover, the key tasks described are qualitative but no notion of quantitative limit associated with the parameters mentioned in point 5 of Annex II appears in the document.

In developing the use of TWW, the GECU recommends first identifying water requirements and the measures already taken to alleviate water stress and thus assessing the need to use TWW as an additional tool on a case-by-case basis. This first step requires that the Aarhus Convention be implemented<sup>5</sup> (UNECE, 1998). In a second phase, the key risk management tasks described here could apply and enable the definition, on a case-by-case basis, of all necessary measures aiming to control risks to human and animal health and protect the environment.

#### Key task 1 – "Describe the water reuse system [...]"

As stated above, the GECU considers that this step should appear in the body of the draft Regulation itself; its aims and content are only briefly described here and should be further developed.

If water centralisation and a storage step are planned, these should also be specified. In addition, the distribution system enabling water to be dispatched to its point(s) of use, as well as the irrigation techniques used, should be described and taken into account for the following key tasks.

Information that depends on thresholds or limit values should be quantified in order to clarify the treatment steps. The "secondary treatment" mention is not sufficient.

For the specific treatment system, it is necessary to not only specify the technologies specifically used but also the expected performance in relation to the targets. In addition, conditions of operation in relation to irrigation requirements – seasonal or ongoing production, storage conditions (storage method, storage time, draining, open loop or recirculation) – should be specified for the deployment of the following tasks in Annex II.

#### Key task 2 – "Identify potential hazards [...]"

A detailed Failure Mode, Effects, and Criticality Analysis (FMECA) would be appropriate and would improve the identification of possible hazards, risks and failures. Additional checkpoints could be positioned depending on the sanitation and reclamation system used and whether or not the treated wastewater is stored downstream.

## Key task 3 – "Identify the environments, populations and individuals at risk of direct or indirect exposure to the identified potential hazards [...]"

The populations (farmers, residents, bystanders, consumers, etc.) likely to be directly or indirectly exposed to TWW used for agricultural irrigation should be mentioned. In addition, this paragraph of the draft Regulation, which also includes an animal health target, should mention animals as well.

#### Key task 4 – "Conduct a risk assessment covering both environmental risks and risks to human and animal health [...]"

The GECU notes that the cited Regulation (EC) No 183/2005<sup>6</sup> (EC, 2005) is not very clear regarding the issue of irrigation water except to reiterate the responsibility of the operator and the need to manage pasture grazing in such a way that minimises the contamination of foods of animal origin.

The GECU notes that the expression "shall, as a minimum, be taken into account", found in the sentence on requirements and obligations preceding point (e), seems perfunctory. It is important to remember that compliance with the applicable Directives and Regulations aiming to safeguard health and protect the environment takes precedence over the goal of developing the use of TWW and that these texts should be consulted and enforced when identifying and analysing hazards.

 <sup>&</sup>lt;sup>5</sup> Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters
<sup>6</sup> Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene

The overall impact on biodiversity of TWW use requires that the affected geographic areas be specified and that time-space horizons be taken into account. Furthermore, the indirect effects on human and animal health are not adequately described in the draft Regulation.

#### Key task 5 – "When necessary and appropriate to ensure sufficient protection of the environment and human health, specify requirements for water quality and monitoring that are additional to and/or stricter than those specified in Annex I [...]"

It is necessary to define the notion of substances of concern (carcinogenic, mutagenic and reprotoxic (CMR) substances, persistent, bioaccumulative and toxic (PBT) substances, very persistent and very bioaccumulative (vPvB) substances, persistent organic pollutants (POPs), endocrine disruptors (EDs)) and link it, for example, to the REACH Regulation<sup>7</sup> (EC, 2006b) if that is the meaning intended by the authors of this draft Regulation. The list of substances (Annex XIV) from the REACH Regulation is updated on a regular basis.

Moreover, the notion of "pesticides" mentioned in point (b) should refer to plant protection products as defined in Regulation No 1107/2009<sup>8</sup> (EC, 2009) and to biocidal products as defined in Regulation No 528/2012<sup>9</sup> (EC, 2012).

#### Key task 6 – "Identify preventive measures [...]"

The GECU questions the meaning of point (j), "pathogen die-off support before harvest", which is vague and should be clarified. If this statement means, for example, that a pre-harvest interval is provided for, then this should be specified.

Furthermore, point (k) should also be further developed. Regarding the health of agricultural workers, the main risk is exposure to pathogens via TWW aerosolisation. It thus seems important to characterise the exposure of workers in agricultural facilities as well as in "reclamation" plants, depending on the treatment process used, and describe preventive measures applicable to them.

Regarding Table 1 in Annex II, the GECU questions several of the specific preventive measures listed:

- The choice of the term "dairy cattle" should be explained, as it is too limited. In reality, all livestock animals are concerned.
- The fact that the table of specific measures only mentions pigs is striking and this should also be explained.

The GECU reiterates the importance of analysing activities connected to the WTP during the preliminary study, considering that in its report published in 2008 (AFSSA, 2008), the Agency recommended a 10-day interval before turning animals out to pasture when using Class B water on grazing land, as well as for the distribution of fresh fodder as animal feed, without any slaughterhouse(s) connected to the treatment plant. This interval was increased to 30 days with one or more slaughterhouses.

Admittedly, Class B defined in the European draft Regulation is more demanding than the French regulations in terms of *E. coli* enumeration, but the existence of slaughterhouse and rendering activities connected to the sanitation system deserves special attention with regard to the protection of animal health.

#### Key task 7 – "Ensure that adequate quality control systems and procedures are in place [...]"

The detection of possible anomalies with new data management systems should be included in the requirements requested in this section.

<sup>&</sup>lt;sup>7</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

<sup>&</sup>lt;sup>8</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

<sup>&</sup>lt;sup>9</sup> Regulation (EU) No 528/2012 of the Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

## Key task 8 – "Ensure that environmental monitoring systems are in place that will detect any negative effects [...]"

Regulation (EC) No 1881/2006<sup>10</sup> (EC, 2006a) is the only guideline used. It mainly provides indicators, but these indicators are not necessarily appropriate for contaminants likely to be found in TWW. The risk of soluble contaminants being transferred to plants (Wu *et al.*, 2013) should be further taken into account, for example by monitoring the agricultural foodstuffs produced.

Key task 9 – "Ensure that an appropriate system is in place to manage incidents and emergencies [...]" The GECU has no comments to make regarding key task 9.

## 3.2. The conclusions of the GECU regarding the issues examined in the draft Regulation

# 3.2.1. Relevance of the proposed quality classes of treated wastewater, including related parameters and thresholds, with regard to environmental protection and the safeguarding of human and animal health

Overall, the GECU considers that every project involving the use of TWW for agricultural irrigation is different and that a case-by-case approach is necessary. It is essential to first determine the critical points for each one. To do so, it is necessary to collect, at the very least, a set of data, in accordance with the preliminary studies required by Annex IV of the Ministerial Order of 25 June 2014 (JORF, 2014) amending the Ministerial Order of 2 August 2010 (JORF, 2010).

This essential prerequisite should contain in particular, on a case-by-case basis, a hazard analysis depending on the origin and quality class of the wastewater (homes, slaughterhouses, hospitals, any other facility having industrial activity connected to the wastewater system). In all cases, a description of the characteristics of the sanitation system ("sewage system and WTP" pair) and a diagnosis of its operations will be necessary. For example, for a combined sewage system, the chemical hazards will be different since in this case, they will also be related to runoff harvesting.

The GECU considers that the identification and characterisation of these hazards should be mentioned in the main text of the draft Regulation and not in the Annexes.

In each case, a methodological risk assessment should also be undertaken, as described in the Ministerial Order of 14 December 2013<sup>11</sup> (JORF, 2013), on the basis of the draft Regulation and its Annexes.

The SCHEER's analysis indicated that the version of the JRC report it had examined did not provide a methodology for selecting the parameters used, and there was no quantitative assessment of microbiological risks. This analysis is also valid for the draft Regulation.

The GECU therefore suggests that a guide to the implementation of the minimum requirements and key tasks of the draft Regulation be developed in order to ensure consistency and facilitate its implementation.

Regarding Table 2 of Annex I on reclaimed water quality requirements for agricultural irrigation, the GECU suggests not mentioning the technology targets included in column 2 since they have little added value.

<sup>&</sup>lt;sup>10</sup> Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs <sup>11</sup> Ministerial Order of 14 December 2013 relating to general requirements applicable to installations subject to a prior declaration under section 2921 of the nomenclature of classified installations for the protection of the environment. NOR: DEVP1305345A. Consolidated version of 7 February 2018.

The GECU recommends that Table 4 on "Validation monitoring of reclaimed water for agricultural irrigation" should appear before Table 3 on "Minimum frequencies for routine monitoring of reclaimed water for agricultural irrigation", since validation monitoring has to be performed before the equipment is put into operation.

Regarding this same Table 4, the GECU is surprised that this step is only required for Class A. There is no way of verifying that the microbiological requirements for the other classes, in particular B and C, will be sufficient. It is therefore essential that Classes B, C and D be included in Table 4 and also comply with even more limited performance targets for the treatment chain in order to validate the performance of the reclamation plant.

Furthermore, these performance targets expressed as log reductions in Table 4 should be supplemented by precise rules for performance validation regarding:

- The validation period, including a declining validation frequency, as provided by the experimental period in the French regulations.
- The defined number of samples for validating the performance of the reclamation plant.

As a reminder, the Ministerial Order of 25 June 2014 (JORF, 2014), amending the Ministerial Order of 2 August 2010 (JORF, 2010), recommends measuring log reductions of intestinal enterococci and not those of *E. coli* to validate the performance of WTPs or, where relevant, of the supplementary treatment system producing TWW intended for agricultural irrigation, especially with regards to disinfection. However, the *E. coli* indicator is used for monitoring facilities once their performance has been validated. The GECU recommends adding performance related to log reductions of intestinal enterococci to validate the reclamation plant.

Regarding column 3 of Table 2 in Annex I, the GECU would like to emphasise that the *E. coli* quality requirements for each of these classes with regard to the technology target given in column 2 are unsuitable for Classes B, C and D. They imply that *E. coli* is an indicator of both faecal contamination and treatment performance, which is all the more reason to include a prior performance validation step to control microbiological risks (bacteria, viruses and parasites).

The GECU also has some other comments and remarks in relation to Table 2:

- The document only describes basic parameters biochemical oxygen demand (BOD<sub>5</sub>), total suspended solids (TSS), turbidity and *E. coli* – which alone cannot guarantee the protection of human health, animal health and the environment.
- The GECU questions the choice of BOD<sub>5</sub> and not chemical oxygen demand (COD), which enables concentrations of organic matter in water to be assessed, as well as the potential connection with an inaccurate interpretation of the definition of urban wastewater in the Urban Waste Water Treatment Directive (UWWTD)<sup>12</sup> (EC, 1991), leading the JRC to only consider industrial activities generating biodegradable discharges in its report that served as the basis for the draft Regulation. As a reminder, the French regulations are based on the measurement of COD, with a 60 mg/l limit for Class A. Moreover, COD is likely to be replaced by total organic carbon (TOC), which would enable the operator to have results more quickly, improve the monitoring of the facility, and detect potential anomalies earlier.
- There seems to be some confusion for the thresholds of 1000 and 10,000 *E. coli*, between *E. coli* considered as an indicator of faecal contamination and *E. coli* used to demonstrate the performance of a disinfection process. Such values suggest there are still risks related to the pathogens since they will not have not been reduced to the same extent as the performance indicators for a disinfection process.

<sup>&</sup>lt;sup>12</sup> Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment

- There are some points in Table 2 that are unclear, in particular:
  - The notion of 90% compliance. It appears necessary to define a number of samples to be taken for each of the parameters in Table 2, to be able to validate the level of compliance defined as 90% of all analyses undertaken. This observation also applies to Table 4.
  - The volumes of TWW produced.

Regarding the risk related to *Legionella* spp., the French regulations stipulate that only localised irrigation, as defined in Article 2 of the Ministerial Order of 25 June 2014 (JORF, 2014) amending the Ministerial Order of 2 August 2010 (JORF, 2010), is authorised in greenhouses.

And yet this risk should be taken into consideration for any irrigation generating aerosols. The GECU recommends introducing preventive risk management measures covering the storage step and the distribution system for TWW intended for agricultural irrigation.

Moreover, wind direction and speed should also be taken into account with overhead irrigation in fields, which is likely to expose residents as well as anyone passing near the irrigated plots. A rule for a minimum distance from residents and roads is also appropriate (ANSES, 2012).

The GECU notes that the method for enumerating *Legionella* by crop used, underlying the expression of results in "cfu/l" in the draft Regulation, has drawbacks such as a waiting period of up to 10 days to obtain definitive results, as well as possible under-estimates related in particular to the presence of viable but non-culturable (VBNC) bacteria. Its replacement with a molecular method (q-PCR) or the use of both methods in synergy should be studied (ANSES, 2017).

Regarding parasitic risks, the GECU maintains ANSES's position (AFSSA, 2008), considering that it is not relevant to monitor helminth eggs in TWW: no new evidence likely to refute this position was identified. However, the GECU considers it would be advisable to monitor forms of resistance in protozoa, such as *Cryptosporidium* and *Giardia*, which are good reference pathogens indicative of parasitic risks to humans and animals. Indeed, even if effluents from rendering plants are not permitted at a WTP, the risk of animal epidemics related to WW cannot be ruled out, due for example to animal faeces in the runoff of a combined system, and should be taken into consideration in the draft Regulation.

The choice of rotaviruses as reference viruses is questionable. Noroviruses or adenoviruses would likely be more suitable since larger quantities of them can be found in wastewater (Prevost *et al.*, 2015). In addition, adenoviruses are more resistant to UV disinfection treatments (ANSES, 2010). On this subject, several laboratories have developed an internal control method for monitoring the concentration, extraction and detection of viruses. Regarding rotaviruses, there is no internal control commonly used in scientific publications, making it difficult to use them as indicators. Adenoviruses may therefore be better indicators of viral risk (Verani *et al.*, 2019).

A phage-based performance indicator is used. While the use of phages as performance indicators represents significant progress, the "total phages" parameter is not defined. The receptive strains will need to be specified in particular, as in the available standardised methods ISO 10705-1 and ISO 10705-2, respectively targeting F-specific RNA phages and "somatic" phages. It should be noted that the draft revision of the European Drinking Water Directive, for which the Agency provided STS (ANSES, 2018), targeted somatic phages as treatment indicators, and that some consistency should perhaps be ensured between European Directives and Regulations. While it is not for the regulations that recommend monitoring log reductions to propose volumes for taking measurements, it would nonetheless be desirable, in light of comments and feedback from users of the French regulations on TWW use, to provide a measurement volume (100 millilitres or 1 litre in total) for the "phage" parameter. This would enable the calculation and verification of significant log reductions when there are low concentrations of phages in wastewater before treatment.

Regarding key task 5 in Annex II, the GECU would like to underline several points:

• The purpose of the text is to define "minimum requirements", but no limits are associated with the chemical contaminants listed (points (a) to (f)). That is why the GECU questions the effectiveness of these measures if there are no regulatory references for interpreting their results. An approach

by indicator would be appropriate. However, within the time allotted for this formal request and in the current state of knowledge, ANSES cannot make any detailed proposals.

- It seems inappropriate to place heavy metals, substances of emerging concern (see comment about key task 6 in Section 3.1.7), and disinfection by-products likely to be formed during treatment all on the same level. The phrase "may in particular concern" should be replaced with "should be studied as a priority". It would therefore be advisable to focus on compounds whose physico-chemical characteristics promote their occurrence in the soluble fraction of treated wastewater and their potential accumulation in soil. As a first approach, metals, disinfection by-products (if there is disinfection) or other chemical contaminants such PAHs do indeed seem more appropriate.
- These listed contaminants, in addition to being further developed, should be identified upstream depending on the origin of the effluents and the sanitation system used in order to carry out monitoring only as necessary and not end up having too many analyses. Furthermore, the monitoring of these contaminants should be required for water quality classes B, C and D. This monitoring, if carried out, would enable risks of soil contamination to be controlled. This decision can be left to the discretion of the local health authority in light of the context as determined by the diagnosis of the sanitation system and the origins of the effluents.

The draft Regulation does not take into account recent scientific studies showing the possible absorption, by plants irrigated via their roots (Goldstein *et al.*, 2018) (Herklotz *et al.*, 2010), of emerging chemical contaminants such as plant protection products or disinfection by-products contained in TWW. A programme should be developed to assess their possible accumulation in soil and crops. Even though it is difficult to draw up a positive list of these compounds, it is necessary to take into account the comments made by the SCHEER (SCHEER, 2017) and EFSA (EFSA, 2017) pointing out substances and classes of substances likely to have health impacts.

Taking into account challenges related to antimicrobial resistance, which is an issue both for the use of TWW and for discharge into surface water, requires the definition of one or more relevant indicators. This is not feasible in the current state of knowledge and within the time frame of this STS. ANSES is currently working on the issue of "Antimicrobial resistance and the environment" as part of a formal request.

Regarding occupational exposure to TWW and related preventive measures, the GECU recommends complying with the recommendations issued by ANSES in its report published in 2012 (ANSES, 2012) aimed at professionals during spraying over farmland.

In addition, in the event of greenhouse irrigation, protective measures supplementing those recommended for overhead field irrigation (ANSES, 2012) should be implemented:

- Maintain the recommendation to only use localised irrigation in a greenhouse (as noted in the Ministerial Order of 25 June 2014 (JORF, 2014) amending the Ministerial Order of 2 August 2010 (JORF, 2010))
- Prohibit access to the greenhouse during and for at least one hour after the end of irrigation.

More broadly, regardless of the type of irrigation (localised in a greenhouse or overhead in a field), if intervening exceptionally before the end of watering or within an hour of stopping, the GECU recommends the wearing of:

- An FFP2 (Filtering Facepiece Particles) mask
- Waterproof clothing
- Waterproof boots

• Personal protective equipment for eyes such as glasses with rigid side protection or a splashproof face shield.

## 3.2.2. Relevance of the proposed monitoring conditions for treated wastewater with regard to the various quality classes of treated wastewater

The monitoring frequencies recommended in Table 3 of Annex I are relatively high compared to those of the UWWTD<sup>13</sup> (EC, 1991). That said, no notion of treated wastewater volume appears in the text whereas it would be appropriate to establish monitoring frequencies based on flow rates.

The GECU would also like to emphasise that the proposed frequencies can only apply in ordinary situations. It should therefore be stipulated that if special events occur such as exceptional rainfall or accidental releases into the system, the monitoring frequencies may be increased.

Furthermore, only a few thermotolerant species of the *Campylobacter* genus are pathogenic to humans. It should therefore be specified that testing for *Campylobacter* should focus on the species relevant to human health mentioned in the NF EN ISO 10272-1 standard<sup>14</sup> (ISO, 2017).

The GECU notes that unlike the work undertaken by ANSES (AFSSA, 2008), the JRC report (JRC, 2017) on which the draft Regulation is based does not take into account log reductions in micro-organisms from the washing of fresh fruits and vegetables, or log reductions in micro-organisms once dispersed in the environment.

Moreover, as indicated above in relation to monitoring points, if a storage pond is planned, then the Annex needs to specify that the point of compliance is positioned after this storage step.

## 3.2.3. Relevance of not having a mandatory, regulated monitoring system for soil irrigated with treated wastewater (parameters, thresholds, conditions)

The GECU considers that for all of the natural environments concerned, the authorisation of TWW use should be based on a prior assessment of the project's environmental impact. In this regard, it is of concern that the impacts of TWW use on irrigated soil quality are not given more consideration in key task 5 of the draft Regulation, especially since this fact, which suggests they were under-estimated, is not supported by any arguments. In reality, soil will be exposed to a potential risk of chemical contamination with various forms and physico-chemical characteristics (Kow, solubility), depending on the origin of the reused water.

The GECU observes that the technical requirements applicable to the spreading of sludge on irrigated soil defined in the Ministerial Order of 8 January 1998<sup>15</sup> (JORF, 1998) cannot be fully transposed to TWW use. The health and environmental impacts are similar but not exactly the same. However, the reference to sludge is at least valid for organisation principles relating to monitoring since the potential contaminants have only one origin: the same untreated wastewater. That said, it is not technically possible to adapt the Agency's expert appraisal work from 2008 (AFSSA, 2008) to TWW use within the allotted time frame. Nevertheless, the GECU recommends requiring that irrigated soil quality be monitored as already described in the Ministerial Order of 8 January 1998<sup>15</sup> (JORF, 1998) as well as in Decree No 97-1133 of 8 December 1997 in its repealed version of 23 March 2007<sup>16</sup>, with an initial assessment of soil conditions including:

- soil characteristics (levels of metals, mineral salts, emerging pollutants) and vulnerability
- an assessment of the ability of agronomic systems to receive TWW
- consideration of the following types of information:

<sup>&</sup>lt;sup>13</sup> Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment

<sup>&</sup>lt;sup>14</sup> ISO 10272-1:2017. Microbiology of the food chain -- Horizontal method for detection and enumeration of *Campylobacter spp.* – Part 1: Detection method

<sup>&</sup>lt;sup>15</sup> Ministerial Order of 8 January 1998 laying down the technical requirements applicable to the spreading of sludge on agricultural soil pursuant to Decree No 97-1133 of 8 December 1997 on the spreading of sludge resulting from wastewater treatment

<sup>&</sup>lt;sup>16</sup> Decree No 97-1133 of 8 December 1997 on the spreading of sludge resulting from wastewater treatment

- o characteristics and properties of the crop(s), possible transfers
- o climatic and weather conditions
- o if there are local sensitivities: protected areas, sensitive areas (catchment, etc.).

The GECU recommends that this initial assessment of soil conditions be followed by a first inspection at least after 10 years and then by other assessments at various times. Moreover, the reference to the JRC is not valid since the JRC seems to have essentially based its work on the use of domestic wastewater, leading risks to be under-estimated.

Lastly, if there is a change in the use of the irrigated plot, and if a risk related to the accumulation of chemical contaminants is observed, then the soil monitoring frequency should be increased.

## 3.2.4. Relevance of the proposed uses with regard to the various quality classes of treated wastewater and irrigation methods

The word "treatment" in the definition "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)" could lead to confusion with the notion of water treatment. The GECU therefore recommends using "processing" instead of "a treatment process". In addition, this assertion seems inappropriate and it would be advisable to replace "not to be" with "not intended to be".

In general, the GECU notes that Table 1 in Annex I is not clear and should be further developed. Classes B and C are better described in the JRC report in terms of the two possible types of irrigation.

Moreover, the GECU would like to emphasise that ANSES's work on the reuse of treated wastewater for watering or irrigation (AFSSA, 2008) was more specific regarding the various uses of the different classes of TWW. It therefore suggests further developing Table 1 in Annex I to the draft Regulation to remove certain inconsistencies such as:

- The description of crops irrigated with Class A water suggests, in light of the definitions given in Section 1, that these crops are only intended for human consumption. In reality, nothing prevents crops intended for animal feed from also being irrigated with Class A water. The preventive measure for pigs in Table 1 of Annex II for water quality class A also makes this clear. The definitions in Section 1 thus need to be revised, at least to delete this obvious contradiction.
- The description of crops irrigated with Class B water, in which it is stated that the edible part of food crops is not in contact with reclaimed water, is not consistent with the fact that all irrigation methods can be used for these crops.

Lastly, Table 1 in Annex II also contains some inconsistencies:

- Regarding water class B, as mentioned earlier, the GECU questions the decision to reserve preventive measures for dairy cattle and pigs only. They should, in principle, apply to all livestock animals as well as to sports and leisure and other animals that may be exposed to the same risks.
- The Class C recommendations relating to animals are illogical since drip irrigation is not likely to be used for pastures and forage as stated in Table 1 of Annex I for Class C.

#### 4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The French Agency for Food, Environmental and Occupational Health & Safety endorses the GECU's conclusions.

**Roger GENET** 

#### **K**EYWORDS

Eaux usées traitées, réutilisation, irrigation agricole, exigences minimales, règlement Treated wastewater, reuse, agricultural irrigation, minimum requirements, regulation

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#### ANNEX 1

#### Presentation of the participants

**PREAMBLE:** The expert members of the Expert Committees and Working Groups or designated rapporteurs are all appointed in a personal capacity, *intuitu personae*, and do not represent their parent organisation.

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