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PROPOSAL

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То:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union			
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Delegations will find attached document COM(2018) 337 final - Annexes 1 to 2.

Encl.: COM(2018) 337 final - Annexes 1 to 2



EUROPEAN COMMISSION

> Brussels, 28.5.2018 COM(2018) 337 final

ANNEXES 1 to 2

ANNEXES

to the

Proposal for a Regulation of the European Parliament and of the Council on minimum requirements for water reuse

 $\{SEC(2018) 249 \text{ final}\} - \{SWD(2018) 249 \text{ final}\} - \{SWD(2018) 250 \text{ final}\}$

ANNEX I

USES AND MINIMUM REQUIREMENTS

Section 1. Uses of reclaimed water as referred to in Article 2

(a) Agricultural irrigation

Agricultural irrigation means irrigation of the following types of crops:

- food crops consumed raw, meaning crops which are intended for human consumption to be eaten raw or unprocessed;
- 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);
- non-food crops, meaning crops which are not intended for human consumption (e.g. pastures, forage, fiber, ornamental, seed, energy and turf crops).

Section 2. Minimum requirements

2.1. Minimum requirements applicable to reclaimed water destined to be used for agricultural irrigation

The classes of reclaimed water quality and the allowed use and irrigation methods for each class are set out in Table 1. The minimum requirements for water quality are set out in point (a), Table 2. The minimum frequencies and performance targets for monitoring the reclaimed water are set out in point (b), Table 3 (routine monitoring) and Table 4 (validation monitoring).

Table 1 Classes of reclaimed water quality and allowed agricultural use and irrigation method

Minimum reclaimed water quality class	Crop category	Irrigation method
A	All food crops, including root crops consumed raw and food crops where the edible part is in direct contact with reclaimed water	All irrigation methods
В	Food crops consumed raw where the edible part is produced above ground and is not in direct	All irrigation methods
С	contact with reclaimed water, processed food crops and non-food crops including crops to feed milk- or meat-producing animals	Drip irrigation* only
D	Industrial, energy, and seeded crops	All irrigation methods

(*) Drip irrigation (also called trickle irrigation) is a micro-irrigation system capable of delivering water drops or tiny streams to the plants and involves dripping water onto the soil or directly under its surface at very low rates (2-20 litres/hour) from a system of small diameter plastic pipes fitted with outlets called emitters or drippers.

(a) Minimum requirements for water quality

Reclaimed water	Indicative technology					
quality class	target	E. coli	BOD₅	TSS	Turbidity	Other
Class		(cfu/100 ml)	(mg/l)	(mg/l)	(NTU)	
A	Secondary treatment, filtration, and disinfection	≤10 or below detection limit	≤10	≤10	≤5	<i>Legionella</i> spp.: <1,000 cfu/l where there is risk of aerosolization in greenhouses
В	Secondary treatment, and disinfection	≤100	According to	According to	-	Intestinal nematodes (helminth eggs): ≤1 egg/l for irrigation of pastures or forage
С	Secondary treatment, and disinfection	≤1,000	Council Directive 91/271/EEC ¹ ((Annex I, Table 1)	Directive 91/271/EEC ((Annex I, Table 1)	-	
D	Secondary treatment, and disinfection	≤10,000			-	

Table 2 Reclaimed water quality requirements for agricultural irrigation

The reclaimed water will be considered compliant with the requirements set out in Table 2 if the measurements meet all of the following criteria:

- The indicated values for *E. coli*, *Legionella spp* and Intestinal nematodes are met in 90 % or more of the samples. None of the values of the samples can exceed the maximum deviation limit of 1 log unit from the indicated value for *E. coli* and *Legionella* and 100 % of the indicated value for intestinal nematodes.
- The indicated values for BOD₅, TSS, and turbidity in Class A are met in 90 % or more of the samples. None of the values of the samples can exceed the maximum deviation limit of 100% of the indicated value.
 - (b) Minimum requirements for monitoring

Reclamation plant operators shall perform routine monitoring to verify that the reclaimed water is complying with the minimum water quality requirements set out in point (a). The routine monitoring shall be included in the verification procedures of the water reuse system.

Table 3 Minimum frequencies for routine monitoring of reclaimed water foragricultural irrigation

Minimum monitoring frequencies						
Reclaimed water quality	E. coli	BOD₅	TSS	Turbidity	Legionella	Intestinal

Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ L 135, 30.5.1991, p. 40).

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class					spp. (when applicable)	nematodes (when applicable)
A	Once a week	Once a week	Once a week	Continuous	Once a week	Twice a month or frequency
В	Once a week	Directive 91/271/EEC 9 ((Annex I,	e Directive EC 91/271/EEC I, (Annex I,	-	-	determined by the reclamation plant operator according to the number of eggs in waste water entering the reclamation plant
С	Twice a month			-		
D	Twice a month			-		

Validation monitoring has to be performed before the reclamation plant is put into operation, when equipment is upgraded, and when new equipment or processes are added.

Validation monitoring shall be performed for the most stringent reclaimed water quality class, Class A, to assess that the performance targets (log₁₀ reduction) are complied with. Validation monitoring entails the monitoring of the indicator microorganisms associated to each group of pathogens (bacteria, virus and protozoa). The indicator microorganisms selected are *E. coli* for pathogenic bacteria, F-specific coliphages, somatic coliphages or coliphages for pathogenic viruses, and *Clostridium perfringens* spores or spore-forming sulfate-reducing bacteria for protozoa. Performance targets (log₁₀ reduction) for the validation monitoring for the selected indicator microorganisms are set out in Table 4 and shall be met at the outlet of the reclamation plant (point of compliance), considering the concentrations of the raw waste water effluent entering the urban waste water treatment plant.

Reclaimed water quality class	Indicator microorganisms (*)	Performance targets for the treatment chain (log10 reduction)
Α	E. coli	≥ 5.0
	Total coliphages/ F-specific coliphages/somatic coliphages/coliphages(**)	≥ 6.0
	Clostridium perfringens spores/spore-forming sulfate-reducing bacteria(***)	≥ 5.0

Table 4 Validation monitoring of reclaimed water for agricultural irrigation

(*) The reference pathogens Campylobacter, Rotavirus and Cryptosporidium can also be used for validation monitoring purposes instead of the proposed indicator microorganisms. The following \log_{10} reduction performance targets should then apply: Campylobacter (≥ 5.0), Rotavirus (≥ 6.0) and Cryptosporidium (≥ 5.0).

(**) Total coliphages is selected as the most appropriate viral indicator. However, if analysis of total coliphages is not feasible, at least one of them (F-specific or somatic coliphages) has to be analyzed.

(***) Clostridium perfringens spores is selected as the most appropriate protozoa indicator. However sporeforming sulfate-reducing bacteria is an alternative if the concentration of Clostridium perfringens spores does not allow to validate the requested log10 removal.

Methods of analysis for monitoring shall be validated and documented by the operator in accordance with EN ISO/IEC-17025 or other national or international standards which ensure an equivalent quality.

<u>Annex II</u>

Key risk management tasks

- 1. **Describe the water reuse system**, from the waste water entering the urban waste water treatment plant to the point of use, including the sources of waste water, the treatment steps and technologies at the reclamation plant, the supply and storage infrastructure, the intended use, the place of use, and the quantities of reclaimed water to be supplied. The aim of this task is to provide a detailed description of the entire water reuse system.
- 2. Identify potential hazards, in particular the presence of pollutants and pathogens, and the potential for hazardous events such as treatment failures, accidental leakages or contamination in the described water reuse system.
- 3. **Identify the environments, populations and individuals at risk** of direct or indirect exposure to the identified potential hazards, taking into account specific environmental factors such as local hydrogeology, topology, soil type and ecology, and factors related to the type of crops and farming practices. Possible irreversible or long-term negative effects of the water reclamation operation have to be considered as well.
- 4. **Conduct a risk assessment covering both environmental risks and risks to human and animal health,** taking into account the nature of the identified potential hazards, the identified environments, populations and individuals at risk of exposure to those hazards and the severity of possible effects of the hazards, as well as all relevant Union and national legislation, guidance documents and minimum requirements in relation to food and feed and worker safety. Scientific uncertainty in risk characterisation shall be addressed in accordance with the precautionary principle.

The risk assessment shall consist of the following elements:

- (c) an assessment of **environmental risks**, including all of the following:
 - i. confirmation of the nature of the hazards, including, where relevant, the predicted no-effect level;
 - ii. assessment of the potential range of exposure;
 - iii. characterisation of the risk.
- (d) an assessment of **risks to human health**, including all of the following:
 - i. confirmation of the nature of the hazards, including, where relevant, the dose-response relationship;
 - ii. assessment of the potential range of dose or exposure;
 - iii. characterisation of the risk.

The following requirements and obligations shall, as a minimum, be taken into account in the risk assessment:

- (e) the requirement to reduce and prevent water pollution from nitrates in accordance with Council Directive 91/676/EEC²;
- (f) the obligation for drinking water protected areas to meet the requirements of Council Directive 98/83/EC³;
- (g) the requirement to meet the environmental objectives set out in Directive 2000/60/EC of the European Parliament and of the Council⁴;
- (h) the requirement to prevent groundwater pollution in accordance with Directive 2006/118/EC of the European Parliament and of the Council⁵;
- (i) the requirement to meet the environmental quality standards for priority substances and certain other pollutants laid down in Directive 2008/105/EC of the European Parliament and of the Council⁶;
- (j) the requirement to meet the environmental quality standards for pollutants of national concern (i.e. river basin specific pollutants) laid down in Directive 2000/60/EC;
- (k) the requirement to meet the bathing water quality standards laid down in Directive 2006/7/EC of the European Parliament and of the Council⁷;
- the requirements concerning the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture under Council Directive 86/278/EEC⁸;
- (m) the requirements regarding hygiene of foodstuffs as laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council⁹ and the guidance provided in the Commission Notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene;

² Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p. 1-8).

³ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).

⁴ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

⁵ Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19).

⁶ Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

⁷ Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC (OJ L 64, 4.3.2006, p. 37).

⁸ Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (OJ L 181, 4.7.1986, p. 6).

⁹ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

- (n) the requirements for feed hygiene laid down in Regulation (EC) No 183/2005 of the European Parliament and the Council¹⁰.
- (o) the requirement to comply with the relevant microbiological criteria set out in Commission Regulation (EC) No 2073/2005¹¹;
- (p) the requirements regarding maximum levels for certain contaminants in foodstuffs set out in Commission Regulation (EC) No 1881/2006¹²;
- (q) the requirements regarding maximum residue levels of pesticides in or on food and feed set out in Regulation (EC) No 396/2005 of the European Parliament and of the Council¹³;
- (r) the requirements regarding animal health in Regulation (EC) 1069/2009 of the European Parliament and of the Council¹⁴ and Commission Regulation (EC) 142/2011 of the European Parliament and of the Council¹⁵.
- 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.

Depending on the outcome of the risk assessment referred to in point 4, such additional requirements may in particular concern:

- (a) heavy metals;
- (b) pesticides;
- (c) disinfection by-products;
- (d) pharmaceuticals;
- (e) other substances of emerging concern;
- (f) anti-microbial resistance.
- 6. **Identify preventive measures** that are already in place or that should be taken to limit risks so that all identified risks can be adequately managed.

Such preventive measures may include:

- (g) access control;
- (h) additional disinfection or pollutants removal measures;

¹⁰ Regulation (EC) 183/2005 of the European Parliament and the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

¹¹ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L338 22.12.2005, p.1)

¹² Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5)

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)

¹⁴ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1)

¹⁵ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text with EEA relevance (OJ L 54, 26.2.2011, p. 1)

- (i) specific irrigation technology mitigating the risk of aerosol formation (e.g. drip irrigation);
- (j) pathogen die-off support before harvest;
- (k) establishment of minimum safety distances.

Specific preventive measures that may be relevant are set out in Table 1.

Table 1: Specific preventive measures

Reclaimed water quality class	Specific preventive measures
A	 Pigs must not be exposed to fodder irrigated with reclaimed water unless there is sufficient data to indicate that the risks for a specific case can be managed.
В	 Prohibition of harvesting of wet irrigated or dropped produce. Exclude lactating dairy cattle from pasture until pasture is dry. Fodder has to be dried or ensiled before packaging. Pigs must not be exposed to fodder irrigated with reclaimed water unless there is sufficient data to indicate that the risks for a specific case can be managed.
C	 Prohibition of harvesting of wet irrigated or dropped produce. Exclude grazing animals from pasture for five days after last irrigation. Fodder has to be dried or ensiled before packaging. Pigs must not be exposed to fodder irrigated with reclaimed water unless there is sufficient data to indicate that the risks for a specific case can be managed.
D	- Prohibition of harvesting of wet irrigated or dropped produce.

- 7. Ensure that adequate quality control systems and procedures are in place, including monitoring of the reclaimed water for relevant parameters, and that adequate maintenance programmes for equipment are established.
- 8. Ensure that environmental monitoring systems are in place that will detect any negative effects of the water reuse, as well as ensure that feedback from the monitoring is provided and that all processes and procedures are appropriately validated and documented.

It is recommended that the reclamation plant operator set up and maintain a quality management system certified under ISO 9001 or equivalent.

9. Ensure that an appropriate system is in place to manage incidents and emergencies, including procedures to inform all relevant parties appropriately such event, and keep a regularly updated emergency response plan.