

Case handler: Maxime Baudouin
Tel: (+32)(0)2 286 1875
mba@eftasurv.int

Brussels, 19 April 2016
Case No: 75720
Document No: 800189

EFTA SURVEILLANCE
AUTHORITY

Ministry of Health and Care Services
Postboks 8011 Dep
0030 Oslo
Norway

Dear Sir or Madam,

Subject: Draft Norwegian Regulation on water for human consumption

By an e-mail dated 8 January 2016 (Doc No 787274), the Norwegian Government informed the EFTA Surveillance Authority (“the Authority”) that an updated draft Norwegian regulation on water for human consumption had been submitted to a public consultation with a deadline for reply until 11 April 2016.

The Authority’s Internal Market Affairs Directorate (“the Directorate”) would like to provide the Norwegian Government with its preliminary comments on this draft regulation in the context of the complaint case against Norway regarding the requirements for use of clean seawater in fishery production. This is however without prejudice to further analysis of the draft regulation that the Directorate may make with regard to other aspects of relevant EEA legislation.

1. Relevant provisions of the draft regulation

Article 3 a) point 2 of the draft regulation includes “clean seawater” as a category of “water for human consumption” (“*drikkevann*”). The use of clean seawater is then subject to most of the provisions of the draft regulation, with some specific requirements.

Article 5 of the draft regulation provides that, in cases where the hygiene regulations allow food businesses to use clean seawater, seawater is considered wholesome and clean if:

- it does not contain micro-organisms, harmful substances or toxic plankton in quantities that directly or indirectly affect the foodstuff (which is in essence the requirement set in the hygiene regulations), and
- it complies with the “relevant” limits set in its Annex 1 for microbiological and chemical parameters.

Article 6 also subjects the use of clean seawater to “action limits” set in its Annex 1.

Article 8 foresees different requirements for “limits” and “action limits”. Concerning “limits”, it states that waterworks owners (“vannverkseier”) shall take measures to correct deviations from these “limits” as soon as possible. Concerning “action limits”, Article 8 states that in case of deviations, waterworks owners shall assess whether the deviation can pose a health risk. If the deviation can pose a health risk, the waterworks owner must implement measures to correct the deviation as soon as possible.

For most parameters, Annex 1 does not specify whether they are relevant for seawater (except for *E.Coli* and coliform bacteria, as a specific standard for seawater is mentioned).

The consultation document states that it is for waterworks owners to determine in each case which parameters are relevant. However this is not specified in the draft regulation itself.

Then, the draft regulation foresees a number of requirements that are similar to requirements already imposed by the hygiene regulations to food business operators using seawater, e.g. *inter alia*: hazard analysis (Article 9), internal controls for water supply systems (Article 10), prior approval of the operation plan when establishing a water supply system (Article 13).

Article 14 requires waterworks owners to ensure the necessary protection of the water source, so that there is no danger that water for human consumption becomes contaminated. The Directorate understands that this provision would also apply to seawater.

According to Article 15, waterworks owners shall ensure that the raw water is treated with a sufficient number of hygienic barriers so that the water meets *inter alia* the limits (for seawater, the relevant limits) of Annex 1. Article 15 also provides that a water treatment that removes or inactivates pathogenic microorganisms and parasites, should always be included as part of the hygienic barriers, unless the hazard analysis indicates that it is not necessary.

Finally, according to Article 22, waterworks owners shall prepare a sampling plan for the water supply system, based on the hazard analysis, to ensure that the requirements of Articles 5 and 6 are met. For clean seawater, the requirement is limited to “relevant” parameters.

Article 23 sets the minimum number of samples to be taken for raw water depending on water volume, and states that they should at least be analysed for *E. coli*, and if water is destined to food businesses, also for colony count at 22°C, coliforms, pH, turbidity and color. Article 24 sets the minimum number of samples for water for human consumption depending on water volume and on the sample group as specified in Annex 1.

2. Analysis

The Authority considered in its letter of formal notice of 8 July 2015 (Doc No 759366) that the Norwegian Government’s practice of requiring land-based seafood producing establishments to comply with the requirements for potable water laid down in the Norwegian regulation implementing Directive 98/83/EC when they use clean seawater in accordance with the conditions laid down by Regulations (EC) No 852/2004 and (EC) No 853/2004, was in breach of the said regulations.

The draft regulation subjects the use of seawater by food business operators to most of the requirements applicable to water for human consumption, while introducing some “flexibility” concerning certain provisions. However, the Directorate does not believe that the draft regulation as it stands would be in line with the hygiene regulations, in particular for the following reasons:

- **Mandatory biological and chemical parameters:** the draft regulation would require food business operators using seawater to comply with the limits and action limits for the “relevant” parameters in its Annex 1. First of all, the draft regulation does not specify whether it will be for the operators to determine which parameters are relevant. This could lead to situations where, like with the current guidance, most parameters could be considered relevant by the competent authorities with some exceptions (e.g. sodium and taste). Moreover, for relevant parameters, operators would be subject to mandatory limits, which are not required by the hygiene regulations.
- **Hygienic barriers:** the obligation to have a sufficient number of hygienic barriers will depend to a certain extent on the hazard analysis of the operator. However, as the draft regulation does not specify whether it will be for the operators to determine which parameters of Annex 1 are relevant, the application of this requirement may result in practice in a more stringent obligation for operators than the requirements of the hygiene regulations.
- **Sampling requirements:** the draft regulation would require food business operators using seawater to comply with minimum sampling frequencies and requirements for raw water and for water for human consumption, which are not required by the hygiene regulations. In addition, while the sampling plan would be based on the hazard analysis, the extent of this requirement would here also depend on the determination of the relevant parameters.
- **Hazard analysis/internal controls/additional requirements:** several requirements of the draft regulation, in particular the obligations to carry out a hazard analysis, to obtain approvals and to have internal controls for the water supply system, would likely overlap with similar requirements already imposed by the hygiene regulations, and would possibly also impose additional requirements to primary producers.

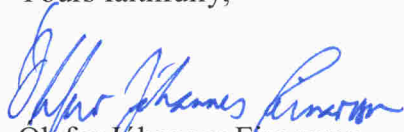
Finally, it should be underlined that Article 13(3) and (4) of Regulation (EC) No 852/2004 and Article 10(3) and (4) of Regulation (EC) No 853/2004 as adapted provide that EEA States may adopt national measures adapting the requirements laid down respectively in their Annexes II and III, only in limited situations listed by the regulations:

- enabling the continued use of traditional methods; or
- accommodating the needs of food businesses situated in regions that are subject to special geographical constraints;
- in other cases, the measures shall apply only to the construction, layout and equipment of establishments.

The Directorate considers that the additional requirements of the draft regulation concerning the use of seawater would not find a legal basis in these provisions.

In view of the above, the Directorate's preliminary view is that the draft regulation would be in breach of the provisions of the hygiene regulations concerning the use of clean seawater. The Directorate invites the Norwegian Government to take note of the observations put forward in this letter. Should the Norwegian Government find it useful, the Directorate is also willing to set up a meeting in order to discuss the provisions of the draft regulation in more detail.

Yours faithfully,



Olafur Johannes Einarsson

Director

Internal Market Affairs Directorate