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To the attention of:

Sandra Gallina

Director General
Directorate General for Health and Food Safety (DG SANTE)
Rue Breydel 4, 1000 Brussels

Brussels, 13 October 2022

Subject: Discussions of DG SANTE's Working Group about a regulation concerning norovirus in shellfish

Dear Ms Sandra Gallina,

Following the resumption of DG SANTE's Working Group on Shellfish concerning the possibility of introducing a "norovirus" criterion into the Hygiene Package regulation, the Aquaculture Advisory Council (AAC)¹'s Working Group on shellfish would like to share its position with you on the new proposals discussed.

First, we welcome the proposal to withdraw the analyses of 10% of the batches of live oysters, which, in the case of marketing from November to April, should not exceed the viral limit of 500 copies of the norovirus genome. These analyses would not have ensured optimal protection for consumers since, to date, no link has been established between the presence of the norovirus genome and infectious norovirus in food. Moreover, as demonstrated in the AAC recommendation on the proposal for a delegated act to amend Annex III of Regulation 853/2004 (June 2020), the financial cost of such an analytical volume could not have been borne by the European oyster industry.

We also welcome the proposal to include norovirus as a risk in the health control plan for oyster farming companies. Nevertheless, in order to develop a relevant HACCP approach and effectively protect consumers, it seems essential to us to integrate the water purification actors in the needs for

¹ The AAC is a stakeholder body created by the Common Fisheries Policy to provide recommendations to the European Commission and the Member States on any matter related to aquaculture. More information: www.aac-europe.org



action in this area. Indeed, as mentioned in the EFSA report² (2019), noroviruses are associated with human faecal pollution, mainly from waste water discharges from sewage plants. Consequently, we recommend, as did EFSA (2012³, 2019), that the control measures relating to noroviruses include efforts to reduce faecal contamination of human origin upstream of shellfish production areas.

The AAC's WG on shellfish cannot accept that the responsibility for the degradation of the quality of coastal waters lies solely with shellfish farmers through corrective actions within their companies and through, as has also been proposed during your discussions, the monitoring of norovirus in shellfish production areas. We would remind you that shellfish farmers, the last users of water from the catchment area, are the victims and are not responsible for this pollution.

In addition, we would like to remind you that the monitoring of the areas will face the same problems as the monitoring of batches leaving dispatch centres:

- Lack of valid, functional and reproducible detection and analysis methods characterising norovirus infectivity;
- No relationship between the prevalence of norovirus food-borne CAI and the amount of viral infectious particles in foodstuffs to determine the human infectious dose of norovirus.

It is therefore appropriate to focus attention on the core of the problem, namely the sources of pollution that cause contamination with enteric viruses and namely noroviruses in shellfish production areas. Taking norovirus into account in area health studies is a first step, as it will ensure the acquisition of knowledge about the sources of pollution. However, this action must be coupled with additional measures, such as the establishment at European level of a threshold for enteric viruses in waste water treatment plant discharges, for example by using specific F-RNA bacteriophages as indicators, along the lines of the bacterial indicators of faecal contamination that already exist. It is also imperative to connect individual sanitation systems to collective sanitation systems, to separate rainwater networks from waste water networks and to resize waste water treatment plants, which in heavy rainfall - an event that is tending to increase with climate change - frequently discharge volumes of untreated waste water into the environment.

These measures, associated with the integration of the "norovirus" risk into the health control plans and the area health studies, will accelerate the creation of local alert strategies based on the

² <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5762>

³ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2500>





communication of information in real time during episodes of environmental contamination, especially during periods of gastroenteritis and on the sheltering of batches during these episodes. We therefore insist on the need for real communication and cooperation, spontaneous or even compulsory, between waste water treatment managers and those in the shellfish industry.

The AAC's working group on shellfish considers that the norovirus risk, which represents a public health issue, must be treated with the utmost seriousness while considering the economic viability of a future industry such as shellfish farming, which contributes to guaranteeing food safety in Europe.

Yours respectfully,

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