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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis Preparedness in Food, Animals and Plants
Food Hygiene, Feed and Fraud

Brussels
SANTE.G.5/PC/acg(2022)8102054

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

Dear Mr Angeri,

I refer to your letter of 13 October 2022 addressed to Ms Gallina, Director General for Health and Food Safety, on the above subject, who asked me to reply on her behalf.

In the period between January 2020 and October 2022, there were 94 notifications in the RASFF for Norovirus in bivalve molluscs, most of which concerned oysters. Noroviral contamination of bivalve molluscs, in particular oysters, represents one of the most serious concerns for public health. This is why this issue has been discussed on several occasions both with Member States and stakeholders since 2019, following the publication by EFSA of the “Analysis of the European Baseline Survey of norovirus in oysters”.

Regarding the analytical method used for the detection of Norovirus, the above-mentioned survey followed the technical specifications set out by EFSA, notably applying the real-time RT-PCR-based ISO (15216-1:2017) method to detect and quantify Norovirus. EFSA in its survey affirms indeed that “... *notwithstanding the potential for non-infectious viruses to contribute to the results, Norovirus quantity in live oysters as determined by PCR methods has been shown to correlate with the likelihood of association with human illness, so the PCR result is relevant to public health (Le Guyader et al., 2010; Lowther et al., 2010, 2012a; Polo et al., 2016)*”. ⁽¹⁾

Furthermore EFSA concluded that the prevalence in production areas was significantly lower in Class A areas than in Class B or C areas, supporting a conclusion that the current existing bacteria-based classification system is useful. However, Class A areas were not free from Norovirus and thus additional criteria should be considered when managing the Norovirus risk.

⁽¹⁾ Chapter 4.2, page 49-50

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The approach you propose cannot be adopted for solving the recurrent problem of contamination of oysters by Norovirus and the consequent outbreaks that regularly appear during the winter season around the EU.

Yours sincerely,

[e- signed]

Eric Thévenard
Head of Unit

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