27 November 2020

National Food Safety Agency

Status: Confidential

Dear EU regulatory team,

We need your urgent advice! We are Seastar, the producer of the Seaweed Salad, and we have reason to suspect that there is norovirus (GI & GII /25g) in our frozen seaweed salad that has been shipped and distributed to retailers across Europe at the beginning of November. What should we do? (Question 1)



More generally, it seems that we find it much harder to deal with viruses rather than bacterial contamination in our food. Is that something you can support when you look at the legal framework, and perhaps also the coronavirus? (Question 2)

Thank you very much for your valuable help on this!

The executive unit

**Question 1**

*GFL Regulation (EC) No 178/2002*

*EU COM guidelines on GFL* <https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf>

**Article 1(3)** – Scope: Regulation applies to all stages of production, processing and distribution of food

**Article 2** – “frozen seaweed salad” falls under the definition of food

**Article 14** – Food safety requirements

Food must be safe. Food is unsafe if: injurious to health OR unfit for human consumption:

14.4. In determining whether any food is *injurious to health*, regard shall be had:

1. not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
2. to the probable cumulative toxic effects;
3. to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers

14.5. In determining whether any food is *unfit for human consumption*, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

Is our frozen seaweed salad injurious to health? Based on the following notification we can say it is:

* RASFF portal

<https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchByKeyword&NewSearch=1&Keywords=norovirus>

* Notification details - 2019.2938; foodborne outbreak caused by norovirus (GI & GII /25g) in frozen seaweed salad from China, via Germany 🡪 Risk decision: serious/Notification type: food - alert - food poisoning

**Article 17** – FBO responsibilities: FOBs must ensure food complies with food law.

**Article 18** – Traceability

* Article 3 Point 15 ‘Traceability’ means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.
* Why is it relevant? The focus of Regulation 178/2002 is on food safety and the removal of unsafe food from the market. It facilitates targeted withdrawal and recall of food, thereby avoiding unnecessary disruption of trade.
* Article 18 requires food business operators:
	+ To be able to identify from whom and to whom a product has been supplied; “one step back” - “one step forward” approach
	+ To have systems and procedures in place that allow for this information to be made available to the Competent Authorities upon request.
* Article 18 does not specify what type of information should be kept by the food and feed business operators. However, to fulfil the objective of Article 18, the following information should be kept at least: Name, address of supplier, and identification of products supplied; Name, address of customer, and identification of products delivered; Date and, where necessary, time of transaction / delivery; Volume, where appropriate, or quantity.

**Article 19** – responsibilities of FOBs when suspecting food might not be safe: Withdrawal, recall and notification

* Article 19 (1) imposes the specific obligation on food business operators to *withdraw from the market* a food which has *left their immediate control* and that *does not meet the food safety requirements* and *inform the competent authorities* thereof.
* The obligation to withdraw, recall or notify unsafe food under Article 19 arises when the food is or may be unsafe under Article 14.
* The withdrawal from the market may take place at any step along the food chain and not only at time of delivering to the end consumer;
	+ Withdrawal is not defined in Regulation (EC) 178/2002, but is commonly understood to be the process by which a product is removed from the supply chain, with the exception of a product that is in the possession of consumers. The definition in Directive 2001/95/EC on General Product Safety is useful, as it indicates that withdrawal is aimed at preventing the distribution, display or offer of a product.
* A food is considered to have left the immediate control of a food business operator when it has been sold or supplied free of charge or otherwise transferred so that the initial operator no longer has the legal right to the food, for example when they have sent it to a wholesaler or it is with any other operators later in the distribution chain.
* The obligation to notify a withdrawal to the competent Authorities is a consequence of the obligation to withdraw
	+ The FBO shall notify this withdrawal to the competent authority, which has enforcement responsibility for the operator’s establishment, and the national authority 🡪 It is up to the national authority to issue the RASFF

In our case the food has left the immediate control of a food business operator – our client needs to withdraw it and inform the competent authorities.

* When a withdrawal is necessary and the product may have reached the consumer, Article 19 requires the food business operators:
	+ to inform the consumer accurately and effectively of the reason for withdrawal
	+ if necessary to recall from consumers products already supplied to them - i.e. to take “any measure aimed at achieving the return of an unsafe product that has already been supplied or made available to consumers by a food business operator”.
	+ A recall will mean asking consumers to take the product back to the place of purchase or to destroy it. The recall is necessary when other measures are not sufficient to achieve a high level of health protection.

They need to contact the retailers to verify this.

* Article 19 (3) places a specific, stronger requirement on food business operators when they consider or have reason to believe that a food that they have ‘placed on the market’ may be ‘injurious to health’. In this case, they must immediately inform the competent Authorities and detail the action taken to prevent the risk.
	+ The objective of this Article is to ensure that the competent authorities are informed in case of a potential risk for health for a product which is placed on the market, even if the product is under the immediate control of the operator.

**Question 2**

EU Rules regarding Food Hygiene cover all stages of the production, processing, distribution and placing on the market of food intended for human consumption 🡪 [Regulation (EC) 852/2004](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02004R0852-20090420) on the hygiene of foodstuffs

* + From a policy perspective, it has been identified for some time that the 2004 EU food hygiene regulations are largely adequate to tackle bacterial, but not viral contamination (see WHO 2008).
	+ In 2011, EFSA gave a more honest opinion: “Viruses do not multiply in foods, but may persist for extended periods of time as infectious particles in the environment, or in foods.”.
	+ Also good to remember that and why existing food hygiene regulations do not tackle viral – as opposed to bacterial - contamination well (see WHO 2008).

Microbiological criteria give guidance on the acceptability of foodstuffs and their manufacturing processes – provide objectives and reference points to assist food businesses and competent authorities in their activities to manage and monitor the safety of foodstuffs respectively.

Bacteria are regulated much more than viruses: COMMISSION REGULATION (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

* lays down food safety criteria for relevant foodborne bacteria, their toxins and metabolites, such as Salmonella, Listeria monocytogenes, Enterobacter sakazakii, staphylococcal enterotoxins and histamine in specific foods.
* These criteria define the acceptability of a product or a batch of food applicable to products placed on the market. In addition, this Regulation lays down certain process hygiene criteria to indicate the correct functioning of the production process.
* Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs, ‘viruses’ are only mentioned in the definition (Art. 2(a)“‘micro-organisms’ means bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites;”), while bacteria are elaborated upon in all the Annexes.
* “The most common viruses implicated in foodborne disease are enteric viruses, which are found in the human gastrointestinal tract”. “Emerging viruses should be monitored, particularly when new problems arise, in an effort to assess the potential for foodborne transmission. The specific research needs to address this question should be defined at the early stages of their emergence.” (WHO, 2008). The WHO defined the following agenda: “To adequately control foodborne viral infections it will be necessary to: heighten awareness of the potential for transmission by infected food handlers; optimize and standardize methods for detection of foodborne viruses and foodborne disease outbreaks; enhance laboratory-based surveillance to detect large common-source outbreaks at an early stage; develop quality control measures specifically for virus control; take into consideration the role of viruses as foodborne pathogens in the development of HACCP plans; inform consumers of the risks presented by foodborne viruses; and better understand transmission and risk through the application of risk assessment.”
* EFSA put out a Summary Report of Joint Scientific Workshop on Foodborne Viruses, in which it stated that: “In the area of foodborne viruses there is a need to move beyond presence/absence methods to quantification and infectivity assays in order to better understand the potential risks to the consumer and the burden of disease this represents so that appropriate controls in the food chain can be applied.” and “Viruses were found to have overtaken Salmonella as a cause of foodborne outbreaks in the EU, causing 20.4% of all foodborne outbreaks”
* Issues to be considered: viral persistence and stability in different environments/transfer rates 🡪 “there are current data gaps in the understanding of foodborne viruses and their behavior”.
* Regarding difficulties handling the norovirus, the European Union published a commission notice on guidance document on addressing microbiological risks in fresh fruits at primary production through good hygiene (2017/C 163/01). It covers norovirus in food of leafy greens eaten raw as salads. The purpose of this guidance document is to assist growers (regardless of size) at primary production to apply in a correct and uniform way hygiene requirements related to production and handling of fresh fruits and vegetables. It provides guidance to growers on how to address microbiological food safety hazards through good agricultural practices (GAP) and good hygiene practices (GHP) in primary production (i.e. growing, harvest and post-harvest) of fresh fruits and vegetables sold to consumers raw (unprocessed) or minimally processed (i.e. washed, sorted, packed), including during transportation provided that these activities do not substantially alter their nature as laid down in the definition of Annex I of Regulation (EC) No 852/2004.

Coronavirus is just another virus and can be relevant for food safety

* As of 31 March 2020, the EU Reference Laboratory for Foodborne viruses, the Swedish Food Agency, has not posted a Coronavirus update.
* Emerging data on coronavirus viability unanimously point to the possibility of additional transmission routes (Yeo et al, Lancet, 2020; Kampf et al, JoHI, 2020; N van Doremalen et al, NEJM, 2020).
* Data on virus viability; although it has been shown that SARS/MERS-CoV are viable under various conditions. “Although direct droplet transmission is an important route of transmission, faecal excretion, environmental contamination, and fomites might contribute to viral transmission” (Yeo et al in Lancet 2020)
* Hand hygiene had a clear protective effect in SARS (see Yen et al, 2010), indicating contact transmissions as significant transmission factor.
* The missing data are ‘known unknowns’ in the literature, such as transfer efficiencies, and it would be urgent to find these out. Partial data indicate the following -worrying - findings:
	+ A meta review (Kampf et al, JoHI, 2020) concluded that touch surfaces are a potential source of transmission, and that data on transmissability is unavailable.
	+ Lab and practical studies confirm that contact transmissions
* It is clear that there are a number of ‘known unknowns’ relating to the behavior of foodborne viruses in general, including the coronaviruses. However, several studies have partial findings which support the conclusion that coronaviruses may be a hazard in the food supply chain.

EFSA, Scientific opinion on an update on the present knowledge on the occurrence and control of foodborne viruses, EFSA J., 9 (2011), p. 2190

Albert Bosch, Elissavet Gkogka, Françoise S. Le Guyader, Fabienne Loisy-Hamon, Alvin Lee, Lilou van Lieshout, Balkumar Marthi, Mette Myrmel, Annette Sansom, Anna Charlotte Schultz, Anett Winkler, Sophie Zuber, Trevor Phister, Foodborne viruses: Detection, risk assessment, and control options in food processing, International Journal of Food Microbiology, Volume 285, 2018, Pages 110-128, ISSN 0168-1605, <https://doi.org/10.1016/j.ijfoodmicro.2018.06.001>