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AAC recommendation “Norovirus 2” on the proposal for a delegated act to amend Annex III to Regulation 853/2004

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AAC recommendation on the proposal for a delegated act to amend Annex III to Regulation 853/2004	
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Working Group **Rapporteur** **Internal Legal Basis** **Internal ID**	Working Group on Shellfish Bruno Guillaumie, Audrey Lainé art. 3 of the AAC Statutes
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Follow-up and comments received	

Content

1. Context and explanatory memorandum

DG SANTE has published a working document numbered 10432/2020 of March 2020 laying the first bases for a legislative revision of Regulation (EU) No 853/2004 by means of a delegated act amending Annex III to that regulation (see annex I).

This proposed modification particularly details the possibilities of introducing a "norovirus" criterion. The AAC published a first recommendation on norovirus in November 2019 after EFSA published its report on noroviral prevalence in areas of production and shipping of oysters in the European Union.

Recently, a UK study undertaken by the Food Standards Agency investigated norovirus in the community and discovered that very little of it was attributable to shellfish. The vast majority was transmission from person to person, and of the small proportion which came from food, the vast majority of that came from salad and fruit.

This recommendation therefore supplements that of November 2019 with regard to norovirus surveillance.

The AAC agrees that the viral risk assessment should be based on a sound scientific basis and is relevant when:

- it is based on the detection of infectious particles and not on the detection of RNA genomes (the genetic material of norovirus), using the current ISO 15216 standard, and
- it demonstrates the link between the prevalence and amount of viral infectious particles in the foodstuff and the prevalence of gastroenteritis among consumers.

This new recommendation aims to establish recommendations as to other criteria that the draft delegated act proposes to modify in terms of food safety of live bivalve molluscs (LBM):

- The registration document;
- Phycotoxins;
- Noroviruses;
- Labelling and traceability.

Particular attention is paid to additions concerning noroviruses and traceability. The AAC considers that the norovirus risk must be treated with the utmost seriousness because it represents a public health issue for consumers of bivalves.

2. Specific objectives for shellfish farming

2.1 NOROVIRUS

Text of the draft delegated act :

3. Food business operators operating in dispatch centres and in purification centres shall identify NoV as a hazard within the HACCP plan.
4. 10% of the batches of live bivalve molluscs destined to, or intended to be, eaten raw shall be tested, if placed on the market in the period from November to April, for the presence of enteric viruses as Norovirus, before leaving the dispatch centre [in production and relaying areas where live are cultivated];
Those molluscs must not exceed the viral limit of 500 copies per gram (cpg) measured in the whole body

The AAC is stunned by the criteria proposed on noroviruses because it had been clearly mentioned, following the implementation of the EFSA prevalence study (2019) and at the meeting of 25/11/2019 of the working group "Live Bivalve Molluscs" from the European Commission, that at the end of this study, no threshold would be proposed because no link is established between the presence of norovirus genome and that of infectious norovirus in food and only an analysis on health risks for the consumer is therefore necessary. Indeed, the ESFA report mentions on page 63: "This study only considered the implementation of a threshold from an analytical point of view. No risk analysis for human health was carried out and integrated into the study."

The AAC recalls that this study only looked at the prevalence of norovirus in European oysters. We therefore have no data for the other shellfish (mussels, cockles, clams, ...) although they are included in the draft delegated act by the mention "live bivalve molluscs". These shells however have a different physiology and do not react in the same way to contaminants, pathogens, viruses, ...

Analysis of the presence of enteric viruses

The AAC wonders about the drafting of the proposal, which is confusing, since it is proposed to analyze 10% of the batches from November to April for the presence of enteric viruses and not exclusively for the presence of norovirus.

Threshold at 500 cpg of total flesh

In addition, the AAC questions the scientific arguments and foundations leading to the establishment of a proposed threshold of 500 copies of genome per gram (cpg) of total flesh of live bivalve molluscs, knowing that for noroviruses, as demonstrated for poliovirus in 2003 (another enteric virus structurally close to noroviruses: naked RNA virus), no link is established between the viral genome and its infectious nature in mineral water (Gassilloud and Gantzer, 2003). It is widely accepted by the scientific community that the viral genome quantified by RT-PCR may reflect the presence of infectious viral particles, but also of non-infectious viral particles (altered capsids, not with integrity) and / or of free viral genome . Thus in prospective analyzes (self-checks, HACCP surveillance plans), a positive result in the norovirus genome cannot, in any case, testify to the integrity of the capsid, or even that of the genome and therefore does not provide information on the infectiousness of the virus. The establishment of such a threshold is therefore purely empirical. In addition, contrary to what is described in the ISO 15216 standard, the results must be expressed in copies of the genome per gram of digestive glands. However here, the proposed threshold is expressed in "copies per gram of total flesh". Thus, it is appropriate to wonder about what justifies this change and about the conversion factor between these two units.

In addition, it should be recalled, for norovirus, that it is certainly possible to quantify 500 copies of the genome per gram of digestive glands if the faecal pollution is "old" because the genome can still be detected even if the noroviruses could have been inactivated in the environment (UV and

temperature). However, it is just as possible to quantify 100 copies of genomes per gram of digestive glands and translate the presence of infectious virus if the faecal pollution is "recent". In addition, it is equally important to remember that the number of norovirus genome copies quantified in live bivalve molluscs using ISO 15216-1 (2017) can be very heterogeneous from one batch to another, given i) of the test sample (10 individuals) and, ii) the significant variability observed in the virus extraction yields and the inhibition of the RT-PCR reaction.

The establishment of this empirical threshold, in the light of current scientific data, will raise the following questioning: how to justify itself with regard to the consumer in the event of declaration of collective foodborne toxi-infections to norovirus in shellfish despite the establishment of this threshold? It is necessary to obtain additional quantitative data before the establishment of such a threshold, such as:

- The proportion of collective foodborne toxi-infections to norovirus confirmed or the direct link between the presence of the norovirus genome in the faeces of infected people and in leftover meals has been established;
- Norovirus genome contents quantified in shellfish, when a norovirus collective foodborne toxi-infections is confirmed.

Genome detection method: limits, cost and analysis time

In addition, no reference method for the detection of the genome is specified or, if the ISO 15216 standard is adopted for noroviruses, its recognized limits, concerning its inability to discriminate infectious noroviruses from non-infectious noroviruses when the genome is detected, will result in the potentially unjustified withdrawal of lots from the market by application of the precautionary principle as soon as the norovirus genome is detected above 500 copies, even though the health risk for the consumer is not proven. As a reminder, it was recommended by the EFSA prevalence study (2019) that the European reference laboratory for food viruses work on the harmonization of this method and in particular on the limits of detection and quantification.

More concretely, within Member States, a norovirus analysis costs on average 250 euros and the results can be obtained within a period of between 5 and 10 days. There seems to be a fairly high variance between Member States in the costs of the analysis, without it being possible to specify whether, for example, this is due to a lack of standardization as regards the primers or the kit to be used for each analysis. This delay is incompatible with the operation of a business and the needs of the market. In addition, as mentioned above, the result of this analysis is in no way representative of the batch (low test intake, variability and sensitivity of the method, sometimes insufficient reproducibility between different laboratories). Given these elements, it seems difficult to know whether this test of 10 individuals is statistically robust enough to have a 95% chance of detecting the norovirus genome in a batch.

Analysis on 10% of the lots (November-April)

In the same way, one can wonder about the scientific foundations which make it possible to act the establishment of a genome research of enteric viruses on 10% of the batches leaving a dispatch center from November to April? What would then be the measures taken when a threshold is exceeded for a lot?

HACCP approach

Regarding the HACCP approach, it only works if its implementation is rigorous with identification of critical points and measures taken and verification that the measures put in place are sufficient

to control the health risk. However, not knowing precisely the infectious dose of norovirus for humans, the very principle of the HACCP approach is called into question.

Request for an economic impact study for the sector

In Chapter 2, entitled "Consultations preceding the adoption of the act", the Commission indicates that it has consulted the Member States, experts and certain private or professional organizations. It specifies that certain amendments suggested by these stakeholders have been retained by DG SANTE in this draft delegated act. Finally, she added that these consultations showed broad support from those consulted. The AAC in its November 2009 recommendation expressed doubts about its merits in the state of science. The HACCP approach and the self-monitoring, by Bivalve Molluscs dispatch centers during a period from November to April, of 10% of the batches marketed in which a sample of Bivalve Molluscs will be taken pushes the AAC to formulate the following economic arguments:

1st hypothesis: shipping lots as a basis for sampling

The literal application of the Commission proposal should be able to be interpreted as follows: the sanitary lot is defined in Article 2, paragraph e) of Regulation (EU) No 2073/2005, each lot corresponds to a homogeneous set of livestock products in size and quality, purified together at the same time to which corresponds a unique number which appears on the sanitary label affixed on each of the unit packages which makes up the shipping lot. In this literal interpretative hypothesis, a shipment lot every ten lots should therefore be subject to a random sampling of an unspecified number of unit packages, unit lots from which should be extracted, at random, ten molluscs for analysis. Again the text does not specify whether it is the producer who makes these choices or whether it is an approved laboratory which proceeds according to a standardized protocol.

It therefore seems relevant to simulate, on this basis, the economic impact of such a sampling for the series of norovirus analyzes envisaged by the Commission throughout the period considered "at risk" (November to April).

AAC members, questioned for this purpose, declare that they do not have statistics on the number of shipping lots, by type of bivalve mollusk, for the period envisaged. Otherwise, the two simulations below are based on data from companies of members of the Aquaculture Advisory Council who have agreed to provide them for prospective purposes. Each of these companies was invited to communicate, for each of the months from November to April: the number of shipping days and the number of lots shipped in the month, making it possible to make an average.

Shipping to France of live oysters intended for human consumption

Month	November	December	January	February	Mach	April
Shipping days	19	19	22	20	22	20
Lots shipped	145	213	176	155	180	155
10% to analyze	15	21	18	16	18	16

Shipping to France of live mussels intended for human consumption

Month	November	December	January	February	March	April
Shipping days	24	24	24	20	20	20
Lots shipped	143	145	100	100	100	100
10% to analyze	14	15	10	10	10	10

The monthly average is therefore 17 batches of oyster to be analyzed per month over the period, while it is 12 batches for mussels (the "batch commas" are necessarily rounded to the nearest whole value).
The monthly cost of the analyzes would therefore be, at the average unit cost using a “turnkey” kit supplied by a pharmaceutical laboratory, of 17 x 250 = € 4,250 per oyster company and of 12 x 250 = € 3,000 per mussel company.

Added to this cost is the oyster basket to be sacrificed so that the laboratory can extract the 10 oysters on which the actual analysis will be carried out, knowing that the most classic basket is that of 12 kg, at the price released shipping cost of 4.5 € / kg, i.e. a monthly product cost of 17 x 12 x 4.5 = € 918 for an oyster business. Mussels are more conventionally packaged in trays of 1.4 kg at the outgoing shipping price of 2.5 € / kg, i.e. a monthly product cost of 12 x 1.4 x 2.5 = 42 € for a mussel farming company.

The average monthly financial charge per business would therefore be 4,250 + 918 = € 5,168 for an oyster shipper and 3,000 + 42 = € 3,042 for a mussel shipper. Shippers specializing in mussels alone are around 400 in France.

For France, which currently has 3,168 companies benefiting from an approval for the shipment of live bivalve molluscs, this would entail a monthly financial charge of (3,168 - 400) x 5,168 = € 14,305,024 for oyster and 400 x 3,042 = € 1,216,800 for mussel shipments.

The total bivalve shipment over the six-month period envisaged by the legislative proposal would thus amount to (14,305,024 + 1,216,800) x 6 = € 93,130,944 which we will round to € 93M. With regard to the turnover of the profession of around 1 billion Euros, these 93 million Euros therefore represent 9.3% of the turnover of the French LBM expedition.

It should be noted that clams and cockles should also be included in the base of this calculation. Representing only 3,000 T of annual production in France, these were not taken into account in the approximate calculation of the financial charges induced by the proposed sampling. It is obvious that the calculation should be adapted to each Member State, in particular in Italy where these LBM represent a significant part of the shellfish production.

In addition, the analysis relates to only one batch out of 10, each of these dispatch batches being able to be the fruit of the assembly of breeding bags for oysters or “bouchots” for mussels coming from various plots each potentially located in quite different geographical areas, (and all the more frequently as the shipping company handles many large shipping lots), it is to be feared that the sampling of a hamper at the inside the shipping lot to be sampled is not representative of the risk of contamination of products from several farming areas in the same company. Finally, as the collection from the hamper for analysis concerns only 10 oysters within this batch, the AAC suggests that a statistical calculation be carried out to assess the probability that such a sampling is representative of the norovirus risk in the all the molluscs marketed.
Therefore, the only way to sample with certainty the expedition lots coming from several farming areas would be to apply the rate of 10% to the **unit** lots constituting the expedition lot. The following paragraph considers this second hypothesis.

2nd hypothesis: unit lots as a basis for sampling

The period from November to April corresponds to the marketing of an average of 70% of the French national annual production of oysters and 30% of the production of mussels, products notably covered by this new provision. Wanting to control 10% of the lots therefore amounts to

taking, for analysis, 7% of French production of oysters and 3% of French production of mussels, production becoming, therefore, unsellable and corresponding to a deadweight loss.

The AAC cannot imagine that the Commission really envisages such an hypothesis and recommends that, in the event of a scenario based on the unit lot, the percentage to be sampled be revised on statistically robust bases representative of the risk, while remaining economically bearable and does not affect the sustainability of companies in the European shellfish sector.

Finally, it should be noted that these products are all marketed with the shortest circuit that can be imagined: from producer / shipper to point of sale to consumer (very rarely a wholesaler), or even shorter: from producer / shipper to consumer direct sales. A product placed on the market is therefore consumed within 2 to 3 days following this date. Knowing that the average time for return of norovirus analysis is one week, it must be concluded that the preventive measure for consumer health is null and void. If, on the other hand, it was appropriate to store the products pending the return of analysis, then dead and damaged products should be considered for marketing. In both cases, the proposed measure is ineffective and does not correspond to the societal reality of the production and consumption cycle of the product.

The AAC therefore calls for a socio-economic impact study to be carried out on all the proposed provisions before going any further. If this analysis were to confirm these hypotheses, then the AAC could only consider that this choice of the European Commission very seriously endangers the very existence of European oyster farming, a sector with zero carbon footprint, providing an immense ecosystem service in nitrogen sink and surplus trade balance with Third Countries. It should then answer for it and justify this incomprehensible political decision.

Pollution sources in shellfish growing areas

It is also necessary to bring back the debate on the real problem, namely the sources of pollution at the origin of contaminations with enteric viruses and in particular with noroviruses from shellfish growing areas. It is known that enteric viruses are excreted in the faeces of its host (animal or human) and are released into the environment by various sources of contamination: discharges from treatment plants, individual discharges not connected, leaching, floods,. .. As mentioned in the EFSA report (2019), the case of noroviruses is associated with human faecal pollution from, inter alia, discharges of wastewater from treatment plants. EFSA has repeatedly recommended (2012, 2019) that control measures for noroviruses include efforts to reduce faecal contamination of human origin in shellfish-growing areas.

Also, to develop a relevant HACCP approach and effectively protect consumers, it is essential to have information in real time on the episodes of contamination and especially during the period of winter gastroenteritis. The establishment, at European level, of limits for enteric viruses in discharges from treatment plants should also be assessed and proposed. Water treatment managers should have the obligation to analyze their effluents for enteric viruses and immediately warn those involved in the shellfish sector as soon as the limits set are exceeded in order to maximize consumer protection measures. Thus, while it is essential to improve the efficiency of wastewater treatment plants with regard to the “enteric virus and infectivity” criterion, it is also essential to connect individual sanitation to collective sanitation and to separate rainwater networks from wastewater networks and / or resizing wastewater treatment plants which, due to heavy rain - a phenomenon which tends to increase with climate change -, cause frequent discharges of wastewater into the environment.

Scientific research on norovirus infectivity

Finally, it is important to remember that the shellfish farming sector is aware of the health risk of norovirus for the consumer, although it is not responsible for this pollution and, faced with all these missing elements to ensure optimal health security, it accentuates its research efforts on controlling the danger of norovirus in shellfish. For example, it strongly supports the OXYVIR project (French project funded by the EMFF between 2017-2020) which aims to develop a method for assaying infectious noroviruses in live bivalve shells through the use of F-specific RNA bacteriophages as indicators of norovirus pollution in oysters. Failing to be able to carry out a clinical study, consisting in the consumption of marketable oysters by healthy volunteers to demonstrate the correlation between the presence of these infectious phages and that of infectious noroviruses in oysters via a randomized controlled trial, to validate as soon as possible the indicator "infectious phages" for the management of the danger of infectious norovirus in oysters, the partners of the OXYVIR project and the French shellfish industry have launched the NOROZONE project. Thus, from January to April 2020, the levels of these phages (infectious and genome) and noroviruses (genome) were monitored in several shellfish growing areas and in particular during administrative closings due to norovirus contamination. The results are being analyzed. Finally, the research avenues of the OXYVIR project, already well argued, should be validated during the next OXYVIR 2 project, which should start in early 2021.

The European shellfish farming profession is also organizing to adapt its practices by creating local alert strategies and sheltering lots in situations of contamination episodes, but these strategies can only be effective if real communication and collaboration, spontaneous or compulsory, takes place between the managers of wastewater treatment and those involved in the shellfish sector.

SEAFOODtomorrow partners have also published a norovirus purification protocol for shellfish intended for businesses. Laboratory tests have shown encouraging results with a reduction of 46% of the noroviruses of the GII group after 2 days of purification at 18 ° C and 60% after 5 days of purification. The AAC, strongly interested in these tools, wishes to experiment with different purification conditions on a company scale according to protocols established in conjunction with the health authorities of the Member States. This method, coupled with local alert strategies, would make it possible to reduce the risk to norovirus without setting up a threshold and binding norovirus analyzes, both technically and financially for shellfish companies.

2.2 TRACEABILITY

Draft delegated act

c) For bivalve molluscs not destined to or not intended to be eaten raw the sentence "to be cooked before consumption".

The AAC does not understand the need to add the words "to be cooked before consumption" on batches of live bivalve molluscs not intended to be eaten raw. This addition will only cause confusion and mistrust in the consumer who will not find this mention on other products such as pieces of meat, eggs or flour…

3. Recommendations

As introductory remarks, the AAC states that, as soon as a reliable, rapid "Norovirus" test, discriminating between infectious noroviruses and non-infectious noroviruses as well as being inexpensive, will be available, it will request the addition of a microbiological criterion relating to noroviruses, measurable by such a new test.
Pending such a test, the AAC notes that none of these criteria have been met to date, even if immense progress has been made and the day is near when the consumer will be effectively protected against norovirus risk in a sustainable manner.
The AAC recommends that, by the means of a study by EFSA, the following elements be scientifically specified:

- What is the behaviour of live bivalve molluscs **other than oysters** (mussels, cockles, clams, etc.) with regard to contamination by enteric viruses;
- What are the **enteric viruses targeted** by the proposed addition of thresholds and analysis;
- What are the valid, functional and reproducible methods of detection and analysis characterizing **the infectivity** of enteric viruses;
- What are the arguments motivating the setting of **a threshold at 500 cpg and this, per gram of total flesh** of living bivalve mollusc and not per gram of digestive gland;
- What are the arguments **for fixing analysis on 10% of the shipment lots** from November to April;
- What is the robustness and the statistical representativeness of the noroviral risk of a sample of 10 bivalve molluscs in such a sample of 10% of the lots shipped.

More specifically, in the case of noroviruses, the AAC recommends that additional quantitative data be collected before the introduction of such a threshold, in particular:

- The proportion of collective foodborne toxi-infections to norovirus confirmed (establishment of the direct link between the presence of the norovirus genome in the stools of infected people and in leftover meals);
- In the hypothesis of a confirmed norovirus collective foodborne toxi-infections, the levels of norovirus genome quantified in shellfish.

The AAC recommends, as mentioned by EFSA in its report (2019), failing to be able to use a test on infectivity, to work on harmonizing the precision, accuracy and sensitivity of the RT-PCR method (ISO 15216).

The provisions of the draft delegated act would cause significant upheavals within the European shellfish sector which should be, above all, quantified from an economic point of view. The AAC therefore recommends that a socio-economic impact study be carried out by a neutral consultant as soon as possible.
In view of the lack of scientific and economic elements, the AAC recommends awaiting the results of the NOROZONE study and of the future OXYVIR 2 project before establishing an unsuitable threshold and reference method.
In addition, it is also possible to reduce the risk to norovirus by other methods and in particular by tackling the cause of the problem: the sources of contamination located upstream of shellfish production areas. Thus, the AAC recommends the establishment, by the Member States of a real communication between actors of wastewater treatment and the shellfish sector with the

addition of criteria “enteric virus and infectivity” in the stations of purification. This communication must be reinforced when there are outbreaks of winter gastroenteritis.
In the same spirit, the AAC recommends that Member States encourage the connection of individual sanitation to collective sanitation and the separation of rainwater networks from wastewater networks and / or the resizing of treatment plants.
These processes will allow the creation of local predictive alert systems which, together with the sheltering of batches and the purification in the event of detection of norovirus, will make it possible to control the norovirus risk and protect consumers.
Furthermore, regarding the Commission's proposal to authorize deconditioning and reconditioning, the AAC considers it imperative that this proposal be accompanied by the transfer of responsibility from the dispatch center to the reconditioning center when this practice is implemented. The AAC also recommends that consumers be more clearly informed.
Finally, with regard to the LBM traceability proposal, the AAC recommends that the drafting of the proposed model be reviewed to establish more clearly that the document records the plot(s) from which the lot was harvested with a view to put it on the market.

4. Annex I: DG SANTE working document 10432/2020

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council[1] lays down specific hygiene rules for different food of animal origin. In order to maintain a high level of food safety to the consumers, these rules need to kept up to date taking into account the experience gained from the implementation, technological developments and their practical consequences and changes in patterns of consumption.

The following amendments are therefore proposed by this Delegated Regulation:

- introduction of more flexibility for slaughter of bovine and equine animals at the holding of provenance for animal welfare reasons and to avoid risks for the handler (e.g. in case of free range animals), under strict conditions of hygiene and official controls. This action is part of Commissions Green Deal, since it contribute to animal welfare (avoiding transport of liven difficult to handle animals) as part of the Farm to Fork strategy.
- sorting out practical difficulties/inconsistencies in the handling of stomachs for rennet production, the handling of heads and feet, including temperature conditions for storage.
- aligning the role of the official veterinarian in case of emergency slaughter with the new requirements in Delegated Regulation (EU) 2019/624.
- introduction of specific hygiene conditions in collection centres for wild game.
- extension of hygiene requirements for farmed game, snails and frogs' legs to new species/families placed on the market for human consumption (e.g. lama)
- adaptation of storage conditions for grease and animal fat to new technologies such as vacuum packaging
- deletion of pectenotoxins from the list of marine biotoxins to be analysed in live bivalve molluscs as it interferes with the detection of other analogues.
- establishing a specific model of the registration document that must accompany movements of live bivalve molluscs after harvesting and until their placing on the market
- aligning the rules for echinoderms fixed in … to the limitations in derogation established by the Parliament and the Council in Regulation 2017/625
- fixing specific temperature requirements for fishery products handled on board of fishing vessels, specific hygiene requirements for reefer vessels as regards transport temperature and cold store maintenance, obligation on board vessels that containers used for fishery products are not used for other purposes.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Several of the proposed amendments were requested by competent authorities of a Member States and certain private stakeholders' organisations. They have been discussed during several meetings of the relevant expert group, representing competent authorities of all Member States, and are largely supported by these experts.

[1] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)

In addition, private stakeholders' organisations were consulted within the framework of the Advisory Group on the Food Chain and Animal and Plant Health.
Before adopting this Delegated Regulation the Commission conducted public consultations in an open and transparent way in accordance with the procedures laid down in the Interinstitutional Agreement on Better Law-Making.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Amendments to the Annex III of Regulation (EC) No 853/2004 should be made by introducing a Delegated Regulation in accordance with Article 10.1 of Regulation (EC) No 853/2004.

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,
Having regard to Regulation, (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[2], and in particular Article 10.1(b), (c) and (f) thereof,
Whereas:

(1) Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council lays down specific hygiene rules for different food of animal origin. The Commission is allowed to amend these rules in Annex III by the adoption of a Delegated Regulation when it deemed necessary in order to maintain a high level of food safety to the consumers, taking into account the experience gained from the implementation, technological developments and their practical consequences and changes in patterns of consumption.

(2) Rennet is a complex of enzymes used for the production of certain cheeses. Rennet is collected from the stomachs of young ruminants. In order to optimise the collection of rennet from young sheep and goats, it is appropriate to allow that such stomachs can leave the slaughterhouse without being emptied or cleaned.

(3) There is an increased demand for heads and feet to be skinned or scalded and depilated outside the slaughterhouse in specialised approved establishments for further processed for food. Heads and feet should therefore be allowed for transport to these establishments under certain conditions that ensure that the safety of the food.

(4) In accordance with Article 18(7)(c) of Regulation (EU) 2017/625 of the European Parliament and of the Council[3] and Article 4 of Commission Delegated Regulation (EU) 2019/624[4], ante-mortem inspection must be carried out by an official veterinarian in case of emergency slaughter. Requirements on emergency slaughter in Regulation (EC) No 853/2004 should be made consistent with the requirements in Regulation (EU) 2017/625.

(5) Improving animal welfare is one of the actions proposed in the draft Farm to Fork Strategy on Sustainable Food System, being part of the Commissions' Green Deal. There is in particular an increasing demand of farmers and consumers to avoid possible animal welfare constrains during catching and transport of large domesticated animals intended for slaughter.

(6) Regulation (EC) 853/2004 already allows killing and slaughter on the farm of otherwise healthy animals such as by approved mobile slaughterhouses, slaughtering several animals at

2 OJ L 139, 30.4.2004, p. 55

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the same time. Additional possibilities should be introduced to allow killing and bleeding on the farm of an individual large domestic animal when live transport of such animal would create a risk for the handler or welfare of the animal. Such practice should be subject to strict conditions to maintain a high level of food safety of the meat derived from such animal.

(7) Specific hygiene requirements for the production and placing on the market of meat from even-toed farmed game mammals are only laid down in Section III of Annex III to Regulation (EC) No 853/2004 when derived from Cervidae or Suidae. Similar requirements should also be applied to meat derived from other even-toed farmed game mammals such as lama's to avoid a possible food safety risk from the increasing consumption of such meat.

(8) The bodies and viscera of hunted wild game might be brought together and stored in a collection centre before transport to a game-handling establishment. Specific hygiene rules on the handling and storage of these bodies and viscera in such collection centres to ensure the safety of their meat.

(9) Live bivalve molluscs when moving from a production or relaying area or between establishments must be accompanied by a registration document. Batches of bivalve molluscs can be sent also to an intermediate operator. The registration document should also include this possibility. Moreover, in order to harmonise the information contained in the registration document, a common model should be established.

(10) Bivalve molluscs placed on the market must not contain marine biotoxins. Pectenotoxins (PTX) in shellfish are always accompanied by toxins from the Okadaic acid (OA) group. EFSA in its opinion[5] concluded that because PTX-group toxins do not share the same mechanism of action as OA- group toxins they should not be included in the regulatory limit for OA-group toxins. EFSA moreover concluded that there are no reports on adverse effects in humans associated with PTX-group toxins. It is opportune to remove PTX from the list of marine biotoxins that should be tested in bivalve molluscs.

(11) The presence of Norovirus in oysters represents, especially during the winter months, a serious risk for public health. In order to minimise the risk for the consumers related to the consumption of raw oysters, specific control measures, including microbiological criteria, should be established in raw oysters.

(12) Article 11 of Commission Delegated Regulation 2019/624 establishes that the classification of production and relaying areas is not required in relation to the harvesting of Holothuroidea. Chapter IX of Section VII should be amended accordingly.

(13) Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. Also holds , tanks, or containers used for storing, cooling or freezing fishery products shall not be are used for other purposes than the production and or storage of fishery products

(14) Freezer vessels and reefer vessels should be equipped with freezing equipment fit for the purpose and storage holds should not be used for freezing products if freezer equipment is not in compliance with those rules. The same requirements shall be applied to cold stores on land.

(15) Specific hygiene rules in Section XI of Annex III to Regulation (EC) No 853/2004 are limited to frogs' legs of the species RNA (family Ranidae). Specific hygiene rules for snails in that Section are limited to terrestrial gastropods of the species *Helix pomatiaLinné*, *Helix aspersaMuller*, *Helix lucorum* and species of the family Achatinidae. Due to changes eating habbits, frogs' legs and snails of other species are also produced and placed on the market for

[5] https://doi.org/10.2903/j.efsa.2009.1109

human consumption. The specific hygiene rules should be extended to these species to ensure the safety of food derived from these species.

(16) Specific temperature requirements for the storage of greaves intended for human consumption are laid down in Section XII of Annex III to Regulation (EC) No 853/2004. These requirements prevent innovation and are not relevant in case of certain packaging techniques e.g. vacuum-packaging. These temperature conditions should therefore be deleted while the food business operator must ensure the safety of food derived from the greaves by good hygiene practices and procedures bases on the Hazard Analysis and Critical Control Point (HACCP) principles in accordance with Regulation (EC) No 852/2004 of the European Parliament and of the Council[6].

(17) Since the requirements in Regulation (EC) No 853/2004 allowing the slaughter of bovine and equine animals on the holding of provenance will only apply from 21 April 2021 on, the amendment of the criteria and conditions for ante-mortem inspection on the holding of provenance should only apply from that date on.

HAS ADOPTED THIS REGULATION:

Article 1

Annex III is amended as follows:

1) In Chapter IV of Section I, point 18 is replaced by the following:

''18. When destined for further handling:

(a) stomachs must be scalded or cleaned; however, when intended for rennet production, the stomachs:

(i) only need to be emptied in case of young bovine animals

(ii) do not need to undergo any handling in case of young ovine and caprine animals;

(b) intestines must be emptied and cleaned;

(c) heads and feet must be skinned or scalded and depilated; however, when authorised by the competent authority, visibly clean heads, **not containing specified risk materials in accordance with Article 8 of Regulation (EC) No 999/2001 of the European Parliament and of the Council***, and visibly clean feet, intended for processing into food, may be transported to and skinned or scalded and depilated in an approved establishment.

* Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1)'

2) In Section I, Chapter VI is amended as follows:

(a) the word "veterinarian" is replaced by "official veterinarian" in points 2 and 3;

(b) point 6 is replaced by the following:

'The official certificate laid down in Annex V of Commission Regulation (EU) 2019/628** shall accompany the slaughtered animal to the slaughterhouse.

** Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101)'.

3) The following Chapter VIa is inserted after Chapter VI in Section I:

6

''CHAPTER VIa: SLAUGHTER ON THE FARM OTHER THAN EMERGENCY SLAUGHTER
Food business operators may slaughter one domestic bovine animals or one domestic solipeds on the farm only with the authorisation of the competent authority for each individual animal and in compliance with the following requirements.

a) The animal cannot be transported, to avoid any risk for the handler or to protect the welfare of the animal.

b) The farm shall undergo regularly veterinary inspection.

c) The owner of the animal shall submit a request and inform the competent authority in advance of the date and time of slaughter if the animal.

d) An official veterinarian carrying out an ante-mortem inspection of the animal intended for slaughter shall be present at the time of killing.

e) The farm or vehicle for transport to the slaughterhouse has facilities suitable for the hygienic handle, slaughter, bleeding of the animal, and the proper disposal of blood.

f) The slaughtered and bled animal shall be transported to the slaughterhouse hygienically and without undue delay. Removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal.

g) If more than two hours elapse between slaughter and arrival at the slaughterhouse, the animal shall be refrigerated. Where climatic conditions so permit, active chilling is not necessary.

h) The slaughterhouse shall be informed in advance on the arrival of the slaughtered animal and further handle it without undue delay after arrival.

i) During the transport to the slaughterhouse, the certificate laid down in [Part III of Annex IV to Commission Implementing Regulation (EU) 2019/628]* shall accompany the slaughtered animal.

* ……..'

4) In Section III, point 1 is replaced by the following:
' The provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game mammals ~~(Cervidae and Suidae)~~, unless the competent authority considers them inappropriate.'

5) The following point 10 is at the end of Chapter II to Section IV:
'10. The bodies and viscera of large wild game may be transport and stored in a collection centre before transport to a game handling establishment if:

(a) the collection centre is

(i) registered as an food business carrying out primary production when located in the area where the large wild game was hunted, or

(ii) approved as a food business operator when collecting bodies and viscera of large wild game from different hunting areas;

(b) the temperature conditions in point 5 are complied with;

(c) storage time is kept to the minimum possible;

(d) no other handling takes place on the bodies and viscera of the large wild game; however the initial examination by a trained person and the removal of viscera may take place under the conditions laid down in points 2 to 4.'

6) The following point 8 is inserted at the end of Chapter III to Section IV:

'8. The bodies, including viscera, of small wild game may be transported and stored in a collection centre before transport to a game handling establishment if:

(a) the collection centre is:

(i) registered as a food business carrying out primary production when located in the area where the small wild game was hunted, or

(ii) approved as a food business operator when collecting bodies, including viscera of small wild game from different hunting areas;

(b) the temperature conditions in point 4 are complied with;

(c) storage time is kept to the minimum possible;

(d) no other handling takes place on the bodies, including viscera, of the large wild game; however the initial examination by a trained person may take place.'

(e)

7) Section VII Chapter I is amended as follows:

CHAPTER I: GENERAL REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than via a dispatch centre, where an identification mark must be applied in accordance with Chapter VII.

2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements set out in points 3 to 7 have been complied with.

3. Whenever a food business operator moves a batch of live bivalve molluscs **from a production or relaying area or** between establishments, up to and including the arrival of the batch at a dispatch centre or processing establishment, a registration document must accompany the batch.

4. The registration document must be in at least one official language of the Member State in which the receiving establishment is located and contain at least the information specified below.

(a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:

(i) the gatherer's identity and address;

(ii) the date of harvesting;

(iii) the location of the production area described in as precise detail as is practicable or by a code number;

(iv) the health status of the production area;

(v) the shellfish species and quantity;

and

(vi) the destination of the batch.

(b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:

(i) the location of the relaying area;

and

(ii) the duration of relaying.

(c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:

(i) the address of the purification centre;

(ii) the duration of purification;

and

(iii) the dates on which the batch entered and left the purification centre.

(d) In the case of a batch is sent to an intermediate operator for splitting or for conditioning as defined in Annex I point 2.3 of this Regulation, a registration document must accompany the batch after splitting or conditioning. The registration document must contain at least the information referred to in (a) and the following information:

(i) the intermediary identity and address

(ii) in case of conditioning the duration of conditioning, the status of the area where the conditioning took place, the date when the conditioning started and the date of the end of the conditioning

5. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.

6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify).

7. However, if:

(a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs;

and

(b) a single competent authority supervises all the establishments concerned,

registration documents are not necessary if that competent authority so permits.

8) Section VII Chapter V is amended as follows:

CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.

2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:

(a) for paralytic shellfish poison (PSP), 800 micrograms per kilogram;

(b) for amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;

(c) for okadaic acid, and dinophysistoxins ~~**pectenotoxins**~~ together, 160 micrograms of okadaic acid equivalents per kilogram;

(d) for yessotoxins, 3,75 milligrams of yessotoxin equivalent per kilogram;

and

(e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

3. Food business operators operating in dispatch centres and in purification centres shall identify NoV as a hazard within the HACCP plan.

4. 10% of the batches of live bivalve molluscs destined to, or intended to be, eaten raw shall be tested, if placed on the market in the period from November to April, for the presence of enteric viruses as Norovirus, before leaving the dispatch centre [in production and relaying areas where live are cultivated];

those molluscs must not exceed the viral limit of 500 copies per gram (cpg) measured in the whole body

9) Section VII Chapter VII is amended as follows:

CHAPTER VII: IDENTIFICATION MARKING AND LABELLING

1. The label, including the identification mark, must be waterproof.

2. In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label:

(a) the species of bivalve mollusc (common name and scientific name);

and

(b) the date of packaging, comprising at least the day and the month.

By way of derogation from Directive 2000/13/EC, the date of minimum durability may be replaced by the entry ‘these animals must be alive when sold’.

(c) For bivalve molluscs not destined to or not intended to be eaten raw the sentence "to be cooked before consumption".

3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumer-size packages for at least 60 days after splitting up the contents

10) Section VII Chapter IX is amended as follows:
CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE, MARINE GASTROPODS AND **HOLOTHUROIDEA** WHICH ARE NOT FILTER FEEDERS HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae, marine gastropods and **Holothuroidea** which are not filter feeders, outside classified production areas or handling such pectinidae, and/or such marine gastropods and/or **Holothuroidea** must comply with the following requirements:

1. Pectinidae, marine gastropods and **Holothuroidea** which are not filter feeders, must not be placed on the market unless they are harvested and handled in accordance with Chapter II, Part B, and meet the standards laid down in Chapter V, as demonstrated by a system of own-checks;

2. In addition to point 1, where data from official monitoring programmes enable the competent authority to classify fishing grounds — where appropriate, in cooperation with food business operators — the provisions of Chapter II, Part A, apply by analogy to pectinidae;

3. Pectinidae, marine gastropods and **Holothuroidea** which are not filter feeders, must not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae and/or such marine gastropods, and/or **Holothuroidea** food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV;

4. Food business operators handling pectinidae, live marine gastropods and live **Holothuroidea** which are not filter feeders, must comply with the following requirements:

(a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area where the pectinidae and/or live marine gastropods and/or live **Holothuroidea** were harvested; or

(b) with the requirements of Chapter VI, point 2 concerning the closing of all packages of live pectinidae, live marine gastropods and live **Holothuroidea** dispatched for retail sale and Chapter VII concerning identification marking and labelling.

11° CHAPTER X

MODEL OF REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS

<table>
<tr><td colspan="3">REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS</td></tr>
<tr><td rowspan="6">Part I – Supplier</td><td>I.1 IMSOC Reference number</td><td>I.2 Internal reference number (dispatching)</td></tr>
<tr><td>I.3 Supplier

Name
Address
Registration or Approval No
Country ISO Country code</td><td>I.4 Receiving operator

Name
Address
Registration or Approval No
Country ISO Country code</td></tr>
<tr><td colspan="2">I.5 Description of goods

• CN code | species | quantity | package | date of harvesting | production area | health status
• CN code | species | quantity | package | date of harvesting | production area | health status
• CN code | species | quantity | package | date of harvesting | production area | health status</td></tr>
<tr><td>I.6 From relaying area Yes☐ No☐
Relaying area
Duration of relaying</td><td>I.7 From purification centre Yes☐ No☐
Purification centre
Date of entry Date of exit
Duration of purification</td></tr>
<tr><td>1.8 Intermediary operator

Name
Address
Registration or Approval No
Country ISO Country code</td><td>1.9 Receiving operator

Name
Address
Registration or Approval No
Country ISO Country code</td></tr>
<tr><td colspan="2">1.10 Origin of goods

Supplier

Name
Address
Registration or Approval No
Country ISO Country code

• CN code | species | quantity | package | date of harvesting | production area | health status
• CN code | species | quantity | package | date of harvesting | production area | health status
• CN code | species | quantity | package | date of harvesting | production area | health status</td></tr>
</table>

	1.11 Description of goods • CN code | species | quantity | package | date of starting of conditioning | date of end of conditioning | production area | health status
	I.12 Declaration of the dispatching operator I, the undersigned operator responsible for dispatching the consignment declare that, to the best of my knowledge and belief, the information provided in Part I of this document is true and complete. Date Name of signatory Signature
Part II – Receiving operator	**II.1 Internal reference number (receiving)**
	II.2 Declaration of the receiving operator I, the undersigned operator responsible for receiving the consignment declare that the consignment has arrived on [DATE] in my premises. Name of signatory Signature

Explanatory notes

Box	Description
Part I – Dispatching operator This part of the document shall be filled by the food business operator dispatching a batch of live bivalve molluscs.	
I.1	**IMSOC reference number** This is the unique alpha-numeric code assigned by the IMSOC
I.2	**Local reference number (dispatching)** This box may be used by the dispatching operator to indicate an internal reference number.
I.3	**Supplier** Indicate the name and address street, city and region/province/state, as appropriate), country and ISO country code of the establishment of origin. In case of production or relaying areas please indicate the area as authorised by the CAs. Where applicable, indicate the registration or approval number. Indicate the activity (gatherer, purification centre, dispatch centre or intermediary activities)
I.4	**Receiving operator** Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of destination. In case of production or relaying areas please indicate the area as authorised by the CAs. Where applicable, indicate the registration or approval number. Indicate the activity (gatherer, purification centre, dispatch centre or intermediary activities)
I.5	**Description of goods** Indicate as required, the Common Nomenclature code, species, quantity, type of packaging(bags, bulk, etc)date of harvesting, production area and its health status (classification of the production area).
I.6	**From relaying area** In case the batch of live bivalve molluscs is dispatched from a relaying area, indicate the location of the relaying area, , as authorised by the CAs, and the duration of the relaying.
I.7	**From purification centre** In case the batch of live bivalve molluscs is dispatched from a purification centre, indicate the address of the purification centre, the duration of the purification and the dates on which the batch entered and left the purification centre.
I.8	**Intermediary operator**

	Indicate the name and address street, city and region/province/state, as appropriate), country and ISO country code of the operator. Where applicable, indicate the registration or approval number.
1.9	**Receiving operator** Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of destination. Where applicable, indicate the registration or approval number. Indicate the activity (gatherer, purification centre, dispatch centre or intermediary activities). This Section must be filled in only in the case that the receiving operator receives the batch from an intermediary
1.10	**Origin of goods** Indicate the name and address street, city and region/province/state, as appropriate), country and ISO country code of the production area of origin. Please indicate the area as authorised by the CAs.
1.11	**Description of goods** **In case of splitting indicate only CN code | species | quantity | package**
1.12	**Declaration of the dispatching operator** Include the date, name of the signatory and the signature.

Part II – Receiving operator

This part of the document shall be filled by the food business operator receiving a batch of live bivalve molluscs.

II.1	**Local reference number (receiving)** This box may be used by the food business operator receiving the batch to indicate an internal reference number.
II.2	**Declaration of the receiving operator** Indicate the date of arrival of the batch of live bivalve molluscs at the premises of the receiving operator. Include the name of the signatory and the signature.

12) Section VIII, Chapter I is amended as follows:
1. STRUCTURAL REQUIREMENTS
A. requirements for all vessels
1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. **Holds , tanks, or containers used for storing, cooling or freezing fishery products shall not be used for other purposes than the production and or storage of fishery products.**
C. Requirements for freezer vessels
Freezer vessels must:
1. have freezing equipment with sufficient capacity to **freeze quickly, with a thermal arrest period as short as possible,** so as to achieve a core temperature of not more than -18 °C;
2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18 °C. Storage holds **shall not be used for freezing unless they respect the conditions of point 1, and** must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest.
E. Requirements for reefer vessels
Reefer vessels transporting and/or storing fishery products in bulk must have equipment meeting the requirements for freezer vessels laid down in part C, point 2.
II. HYGIENE REQUIREMENTS
6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice~~, at a temperature approaching that of melting ice as close as possible to 0°C,~~ or be frozen.
13) Section VIII, Chapter III is amended as follows:A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS
4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water **is drained out** and does not remain in contact with **any** products.
B. REQUIREMENTS FOR FROZEN PRODUCTS
Establishments on land that freeze **and store** frozen fishery products must have equipment that satisfies the requirements laid down for freezer vessels in Section VIII, Chapter I, part I. C, points 1 and 2.

14) The following points 7 and 8 are inserted at the end of Section XI:
'7. The requirements in points 1, 3, 4 and 6, also apply to any other snails of the Family of *Helicidae, Hygromiidae* or *Sphincterochilidae*, when intended for human consumption.
8.
The requirements in points 1 to 5 also apply to frogs' legs of the species *Pelophylax* from the Family of *Ranidae*, and the species *Limnonectes* and *Hoplobatrachus* from the Family of *Dicroglossidae*, when intended for human consumption.'
15) Point 5 in Chapter II to Section XII is deleted.

Article […]

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.
It shall apply immediately, however Article 1(3) shall only apply from 21 April 2021 on.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
[…]

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