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Icelandic Ministry of Food, Agriculture and Fisheries
Skúlagötu 4
101 Reykjavík
Iceland

Dear Sir or Madam,

Subject: Letter of formal notice to Iceland regarding incorrect implementation of EEA food hygiene requirements, and failure to undertake official controls, concerning fish oil

1 Introduction

The EFTA Surveillance Authority ('the Authority') undertook a veterinary mission to Iceland between 8 to 17 May 2017 to evaluate official controls of European Economic Area ('EEA') feed safety requirements ('the 2017 mission').

During the 2017 mission, the Authority identified shortcomings (described in the Authority's final report on the mission dated 12 September 2017¹ (Doc No 873155) ('the 2017 mission report') relating to official controls of EEA requirements concerning production of fish oil ('the identified shortcomings'). The identified shortcomings included official controls of the use and handling of raw materials by establishments approved for production of both fish oil for human consumption ('HC fish oil') and fish oil and/or fish meal not intended for human consumption ('NHC fish oil') ('dual approved establishments').²

In the light of correspondence and discussions with the Icelandic Government since the 2017 mission, the Authority has concluded, as further described at Section 6 of this letter of formal notice, that the Icelandic Government has failed to:

- correctly implement the EEA law requirement that raw materials used in the preparation of HC fish oil and in the preparation of NHC fish meal at dual approved establishments must derive from raw materials fit for human consumption; and
- undertake certain official controls required under EEA law to ensure that EEA law requirements relating to the raw materials and production process used to produce NHC fish oil at dual approved establishments are complied with.

¹ Final report EFTA Surveillance Authority mission to Iceland regarding feed safety from 8 May to 17 May 2017

² Recommendation 6 of the 2017 mission report:

"The competent authority should ensure that establishments producing both fish oil for human consumption and fish oil/fish meal for feed receive and handle the raw materials in line with the requirements of Annex III, Section VIII, Chapter IV, Point B of Regulation (EC) No 853/2004."

2 Principal Correspondence

Initial requests for information of the Authority and responses of Icelandic Government

By letter dated 8 June 2017 (Doc No 859618) ('the Authority's letter dated 8 June 2017'), the Authority invited the Icelandic Government to provide it with certain information relating to the identified shortcomings.

By letter dated 30 June 2017, the Icelandic Food and Veterinary Authority ('MAST') (reference 1706446, Doc No 882604) ('MAST's letter dated 30 June 2017'), not received by the Authority until 14 November 2017 due to a delay in submission, MAST responded to the Authority's letter dated 8 June 2017 with details of five dual approved establishments, procedures for official controls of production of HC fish oil at those establishments, the results of such controls undertaken, non-compliance detected and related follow up actions taken by MAST.

By letter dated 1 December 2017 (Doc No 882696) ('the Authority's letter dated 1 December 2017'), the Authority invited the Icelandic Government to provide further information concerning official controls on the production of fish oil in the light of the information provided in MAST's letter dated 30 June 2017. The requested information included further details of official controls of EEA requirements concerning raw materials and the production process used for production of both HC and NHC fish oil at dual approved establishments.

By letter dated 30 January 2018 (MAST reference 1712177, Doc No 895788) ('MAST's letter dated 30 January 2018'), MAST responded to the Authority's letter dated 1 December 2017 with, *inter alia*, further details of official controls carried out at dual approved establishments, an explanation of the differences between official controls undertaken at dual approved establishments and at establishments approved solely for production of HC fish oil ('sole HC fish oil producing establishments') and details of production volumes of HC fish oil at dual approved establishments during 2015, 2016 and 2017. In the letter, MAST noted that it required that at dual approved establishments "*the fish oil pipes are flushed for 60 minutes with HC-quality fish oil before the production of HC-fish oil starts.*"³

By letter dated 17 April 2018 (Doc No 906591) ('the Authority's letter dated 17 April 2018'), the Authority invited the Icelandic Government to provide further details of official controls undertaken to verify compliance of dual approved establishments with the hygiene requirements for HC fish oil under Part B. of Chapter IV of Section VIII of Annex III 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 origin⁴ ('Regulation (EC) No 853/2004').⁵

³ Second paragraph, page 2 of MAST's letter dated 30 January 2018.

⁴ The Act incorporated at Point 17 of Part 6.1 of Chapter 1 of Annex I to the Agreement on the European Economic Area ('EEA Agreement') by Decision of the EEA Joint Committee No 137/2007 of 26 October 2007, *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*, as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement, which entered into force in the EEA EFTA States on 1 May 2010.

⁵ Annex III to Regulation (EC) 853/2004 was amended by Annex II to the Act incorporated at Point 17. of Part 6.1 of Chapter I of Annex I to the EEA Agreement by Decision of the EEA Joint Committee No 18/2010 of 1 March 2010, *Regulation (EC) No 1020/2008 of 17 October 2008 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products*, as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement ('Regulation (EC) No 1020/2008'), which entered into force in the EEA EFTA States on 1 May 2010 and which added Part B. to Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004.

At the package meeting in Iceland on 6 June 2018 ('the 2018 package meeting'), the Authority expressed concern that checks on food business operator ('FBO') records undertaken by MAST to ensure that the TVB-N value of whole fish used as raw material to produce HC fish oil did not exceed the limit laid down (at that time)⁶ at Point 1.d of Chapter I of Section II of Annex II to Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004⁷ ('Regulation (EC) No 2074/2005') were not alone sufficient to ensure compliance with the various requirements of Part B.1. of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004 ('Part B.1.'). The Authority further stated that flushing of a system used for production of both HC and NHC fish oil with HC fish oil before commencing production of HC fish oil in that system could not be considered a substitute for meeting the requirements of Part B.1 and Part B.3.⁸ of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004 ('Part B.3.').

Following two requests for extension of the deadline for responding to the Authority's letter dated 17 April 2018 (Doc Nos 913048 and 917937),⁹ the Authority invited the Icelandic Government, by follow-up letter to the 2018 package meeting dated 4 July 2018 (Doc No 918168), to respond to the Authority's letter dated 17 April 2018 by 30 June 2018.

By letter dated 27 June 2018 (MAST reference 1712177, Doc No 920435) ('MAST's letter dated 27 June 2018'), MAST responded to the Authority's letter dated 17 April 2018 by providing, *inter alia*, the following information:

- Official controls (in the form of official checks of the FBO's own records) to ensure that raw materials used for production of fish oil at dual approved establishments were derived from fishery products fit for human consumption, pursuant to Part B.1.(b) of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004 ('Part B.1.(b)'), were undertaken by MAST only where the relevant establishment had produced HC fish oil since the last inspection.¹⁰

⁶ Section II of Annex II to Regulation (EC) No 2074/2005 has since been deleted by Regulation (EU) 2019/627. See page 7 and 8 of this letter of formal notice.

⁷ The Act incorporated at Point 134. of Part 1.2 of Chapter 1 of Annex I to the EEA Agreement by Decision of the EEA Joint Committee No 137/2007 of 26 October 2007, Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004, as amended and as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex I to that Agreement, which entered into force in the EEA EFTA States on 1 May 2010.

⁸ "Provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption a food business operator may produce and store both fish oil for human consumption and fish oil and fish meal not intended for human consumption in the same establishment."

⁹ See the letter from the Ministry of Industries and Innovation ('Ministry') dated 11 May 2018 (Ministry Reference: ANR 18010713/15.02.02; Doc No 913048), the letter from MAST dated 12 June 2018 (MAST reference 1712177; Doc No 917937) and the Authority's email response dated 12 June 2018 (Doc No 918686).

¹⁰ Section 1.i., page 1 and Section 1.v.b., page 2 of MAST's letter dated 27 June 2018:

i...As part of regular inspections MAST checks the records of dual approved factories to establish if they have produced any HC fish oil from last inspection. In such cases MAST verifies via inspection of documents and records that the production of HC fish oil is in line with requirements, including verification that the vessel and factory are registered and/or approved, inspection of records/measurements concerning the quality of the raw material i.e. TVB-N value and temperature.

- MAST did not interpret Part B.3. as prohibiting production of HC fish oil and NHC in the same dual approved establishment (even in the absence of compliance with Part B.) where the separation in time of production processes and appropriate cleaning procedures between such processes precluded cross-contamination.¹¹
- Official controls to ensure fitness for human consumption of raw materials used to prepare HC fish oil or NHC fish oil in dual approved establishments, pursuant to Parts B.1. and B.3., did not include physical examination of raw materials, rather only verification of the FBO's own records.¹²
- With the exception of checking that raw material used to produce HC fish oil originated from registered vessels (described in the quality manual of each factory), MAST's official controls, which were limited to desk top monitoring of records of fish oil producing establishments, did not include ensuring that the requirements of Part B.1. concerning raw materials used in the production of both HC and (pursuant to Part B.3.) NHC fish oil at dual approved establishments were met by the upstream supply chain prior to arrival of those materials at such establishments.¹³

MAST provided no specific information concerning official controls undertaken to ensure that raw materials used for the production of NHC fish oil at dual approved establishments complied with the raw material requirements applying to HC fish oil, pursuant to Parts B.1 and B.3., notwithstanding specific requests that the Icelandic Government provide such information in the Authority's letter dated 17 April 2018.¹⁴

By email dated 15 May 2019 (Doc No 1071136) ('the Authority's email dated 15 May 2019'), the Authority requested the Ministry of Industries and Innovation ('the Ministry') to clarify, in the light of previous contradictory statements by MAST on the point (cited in the email), whether or not MAST undertook official controls of the production process of NHC fish oil at dual approved establishments (to verify compliance with the requirements under Part B.2. of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004 ('Part B.2.'), pursuant to Part B.3.) and, if so, in what circumstances such controls were carried out.

At the package meeting on 4 June 2019, the Authority explained that it had identified a number of deficiencies in official controls of fish oil production at dual approved establishments. In particular, production of NHC and HC fish oil on the same production line was not permitted in the absence of compliance with the Part B.3. requirement, notwithstanding separation in time of HC and NHC production and cleaning and disinfection of the line in between. The Authority informed the Icelandic Government that they were in the process of preparing a formal letter setting out these findings.

The fish meal factories are regularly inspected in accordance with MAST risk-based inspection plan for feed producers...If records provide evidence that HC fish oil has been produced since the last inspection MAST checks the relevant records in line with para ii and iv above and the quality manual is inspected to verify that procedures and instructions for HC fish oil are in place and compliant." (our emphasis).

¹¹ Section 2., page 2 and last paragraph, page 3 of MAST's letter dated 27 June 2018 responding to Section 2., page 5 of the Authority's letter dated 17 April 2018. See also Section 2.i., page 2 of MAST's letter dated 30 January 2018 and Inspection Report A616 (Doc No 882598) attached to MAST's letter dated 30 June 2017:

"Eftirfarandi eru reglugerðarkröfur vegna hráefnis og vinnslu þessa lýsis, en að auki þess sem fram kemur er ætlast til að frátaka lýsis til manneldisvinnslu hefjist ekki fyrr en 60 mín eftir að vinnsla hefst, þannig að rásin nái að hreinsast tryggilega af öðrum afurðum."

¹² Section 1.iv., page 2 of MAST's letter dated 27 June 2018, responding to Section 1.(iv), page 3 of the Authority's letter dated 17 April 2018: "MAST does not carry out any physical examination of raw materials since the Authority is normally not present during landing. Records kept by the fish meal factories are checked and need to be sufficient."

¹³ Section 1.i., page 1 and Section 1.iii., page 2 of MAST's letter dated 27 June 2018, in response to Section 1.(iii), page 3 of the Authority's letter dated 17 April 2018.

¹⁴ Section 1., page 2 and Section 1.(v)(b), page 4 of the Authority's letter dated 17 April 2018.

On 27 June 2019, the Authority received a copy of a letter from MAST to the Ministry dated 3 June 2019 (MAST reference 1712177, Doc No 1078036) ('MAST's letter dated 3 June 2019'), responding to an earlier letter from the Ministry to MAST (apparently dated 27 May 2019)¹⁵ concerning the Authority's email dated 15 May 2019. The letter contained no information concerning official controls of the production process of NHC fish oil at dual approved establishments,¹⁶ notwithstanding the Authority's specific request in its email dated 15 May 2019 that the Ministry provide such information. Rather, MAST noted that inspections concerning production of HC fish oil at dual approved establishments were undertaken at the same time as those for NHC fish oil, were based on the inspection manual for feed and that a new control system was being implemented enabling the food and feed activities of dual approved establishments to each be inspected separately.

The Authority's pre-Article 31 letter and the Icelandic Government's response

By letter dated 30 July 2019 (Doc No 881497) ('the Authority's pre-Article 31 letter'), the Authority noted, *inter alia*, the following:

- Statements in MAST's letter dated 27 June 2018 implied an understanding by MAST that raw materials used for production of NHC fish oil in dual approved establishments were not required to be derived from fishery products fit for human consumption, pursuant to Parts B.1.(b) and B.3., and that related official controls were not therefore required. TVB-N controls of raw materials used to produce NHC fish oil were undertaken in order to assess the quality grade of the NHC fish oil, rather than to assess whether raw materials were fit for human consumption.¹⁷
- In addition to being undertaken by MAST only where the relevant dual approved establishment had produced HC fish oil since the previous inspection,¹⁸ the Authority's understanding was that official controls undertaken to ensure that raw materials and the production process used for production of fish oil at dual approved establishments met the requirements of, respectively, Part B.1. and Part

¹⁵ MAST's letter dated 3 June 2019 is entitled "An answer [sic] to letter dated 27. May 2019".

¹⁶ The only information provided in MAST's letter dated 3 June 2019 concerning official controls of NHC fish oil was the following (in footnote 1 of that letter) which did not comment on the production process:

"Inspections on NHC fish oil are carried out in accordance with the applicable MAST working procedures based on classification and performance indicators, as well as inspections of HC fish oil."

MAST also noted that its answers in previous correspondence quoted in the Authority's email dated 15 May 2019 were "only to answer questions regarding official control regarding HC fish oil not NHC fish oil".

¹⁷ Section 3.1.1.1, page 10 of the Authority's pre-Article 31 letter, which refers to the following statements from, respectively, the second paragraph, page 1 and Section 1.v.a., page 2 of MAST's letter dated 27 June 2018:

"During the ESA inspection in May 2017 no production of fish oil for HC was undergoing and thus any raw material located in the establishments was solely intended for production of NHC products".

"...the two [dual approved establishments] also produce fish meal from trimmings of herring, mackerel and capelin but the oil from these species is not used in HC fish oil production, only for feed purposes."

Re TVB-N controls, see the last paragraph of Section 3.1.1.1, page 10 of the Authority's pre-Article 31 letter.

¹⁸ Section 3.1.1.2, pages 11 and 12 of the Authority's pre-Article 31 letter. Concerning official controls of raw materials, see the citation at footnote 10 of this letter of formal notice. Concerning official controls of raw materials and the production process, see also Section 1., page 1 of MAST's letter dated 30 June 2017:

"During official control, the inspector checks if the establishment has produced fish oil for human consumption since the last inspection. If this is the case, the documentation of the quality of the raw material is checked. If the documentation fulfils all requirements, inspection item 6.24.1[Work procedures: Description of the procedure of production of fish oil]-2 is marked 'in order'. The procedure is also checked and recorded under the same item."

MAST will in the next inspection of establishments check if they are still producing fish oil for human consumption. If that is the case their procedures, controls and documentation of the checks on the raw material will be checked." (our emphasis).

B.2. were limited to production of HC fish oil and did not extend to the production of NHC fish oil at such establishments.¹⁹

- Where the Part B.3. requirement was not met, production and storage of HC fish oil and NHC fish oil in the same dual approved establishment was prohibited, irrespective of the fact that:
 - production of HC fish oil and NHC fish oil was separated in time, with cleaning and disinfection/flushing of the system in the interval;²⁰
 - HC fish oil had not been produced at the relevant establishment since the last official control of that establishment;
 - no HC fish oil was being produced at the time of an official control;
 - raw materials received were used solely for production of NHC fish oil;
 - production of HC fish oil at dual approved establishments constituted only a fraction of total HC fish oil production in Iceland; or
 - HC fish oil produced in a dual approved establishment was subsequently further refined and purified prior to being placed on the market for consumers.²¹
- The absence of:
 - physical examination of raw materials used to prepare HC fish oil or NHC fish oil in dual approved establishments; and
 - official controls (other than verifying that raw materials used to produce HC fish oil come from registered vessels) to ensure that the Part B.1. requirements relating to raw materials used in the production of both HC and (pursuant to Part B.3.) NHC fish oil at dual approved establishments were met by the upstream supply chain

applied equally to raw materials used by sole HC fish oil producing establishments.²²

The Authority therefore informed the Icelandic Government of its preliminary conclusion that the Icelandic Government had failed to implement:

¹⁹ Section 3.1.1.2, pages 11 and 12 of the Authority's pre-Article 31 letter. Concerning official controls of raw materials, see footnote 17 of this letter of formal notice and the paragraph in this letter of formal notice to which that footnote relates as well as footnote 10 of this letter of formal notice. Concerning the production process, in addition to footnotes 10 and 18 of this letter of formal notice (read together), MAST's description of the control procedure for dual approved establishments in Section 1., page 1 of its letter dated 30 January 2018 mentions only checks on production of HC fish oil:

"The control procedure is outlined the handbook for feed control and is linked to the control system called ÍsLeyfur. The control procedure involves the following items:

...

d) 6.24.1 Work procedures: Description of the procedure of production of HC fish oil." (our emphasis).

²⁰ For example, see paragraph 60 of the Final report of the European Commission, Directorate-General for Health and Safety's audit carried out in Peru from 30 April 2018 to 11 May 2018 in order to evaluate the control systems in place governing the production of fishery products intended for export to the European Union (http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_inspection_ref=2018-6390).

"As the raw materials with TVB-N values in excess of 60 mg of nitrogen/100 g are unfit for human consumption, the condition referred to in point B.3 is not met. Should therefore, the conditions of this provision not be met, production and storage of CHD fish oil and CHI fish oil in the same establishment is not permitted under EU legislation irrespective of any separation in time of production and cleaning and disinfection of the lines."

²¹ Section 3.1.2, pages 13 to 15 of the Authority's pre-Article 31 letter.

²² See the statements concerning sole HC fish oil producing establishments on page 16 in Section 3.2.1 and on page 18 in 3.3.1 of the pre-Article 31 letter.

- (i) official controls required under Article 10(2) of Regulation (EC) No 882/2004,²³ Chapters I and II of Annex III to Regulation (EC) No 854/2004²⁴ and Section II of Annex II to Regulation (EC) No 2074/2005 to ensure that both the raw materials and production process used to produce NHC fish oil at dual approved establishments complied with the requirements of Part B.1. and Part B.2. applying to HC fish oil, pursuant to Part B.3. ('the Section 4(i) infringement');
- (ii) with the exception of verifying that raw materials used to produce HC fish oil came from registered vessels, official controls required under Article 10(2) of Regulation (EC) No 882/2004 and Chapters I and II of Annex III to Regulation (EC) No 854/2004 to ensure that requirements applying to raw materials used to produce both HC and NHC fish oil at dual approved establishments, pursuant to Parts B.1. and B.3., or used to produce HC fish oil at sole HC fish oil producing establishments, pursuant to Part B.1., were met by the upstream supply chain prior to arrival of such materials at the respective establishments ('official upstream controls of requirements relating to raw materials') ('the Section 4(ii) infringement'); and
- (iii) organoleptic checks, random testing and sampling required under Chapter II of Annex III to Regulation (EC) No 854/2004 and chemical checks regarding TVB-N values under Section II of Annex II to Regulation (EC) No 2074/2005 in order to ensure fitness for human consumption of raw materials used to produce both HC fish oil and NHC fish oil at dual approved establishments, pursuant to Parts B.1.(b) and B.3., or used to produce HC fish oil at establishments licensed solely to produce HC fish oil, pursuant to Part B.1.(b) ('official physical examination of raw materials') ('the Section 4(iii) infringement').

The above-mentioned Section 4 (i), (ii) and (iii) infringements are referred to collectively below as 'the Section 4 infringements'.

Regulations (EC) Nos 882/2004 and 854/2004 have since been repealed by Article 146(1) of *Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC²⁵ ('Regulation (EU)*

²³ The Act previously incorporated at Point 11. of Part 1.1 of Chapter 1 of Annex I to the EEA Agreement by Decision of the EEA Joint Committee No 137/2007 of 26 October 2007, *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement, which entered into force in the EEA EFTA States on 1 May 2010.

²⁴ The Act previously incorporated at Point 12. of Part 1.1 of Chapter 1 of Annex I to the EEA Agreement by Decision of the EEA Joint Committee No 137/2007 of 26 October 2007, *Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption*, as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement, which entered into force in the EEA EFTA States on 1 May 2010.

²⁵ The Act incorporated at Point 11b. of Part 1.1 of Chapter 1 of Annex I to the EEA Agreement by Decision of the EEA Joint Committee No 210/2019 of 27 September 2019, *Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European*

2017/625'). The relevant parts of Regulation (EC) No 2074/2005 have since been deleted by Article 74(3) of *Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls*²⁶ ('Regulation (EU) 2019/627'). References in this letter of formal notice to the Section 4 infringements should therefore be construed as meaning those infringements with the references to the relevant provisions of Regulations (EC) Nos 882/2004, 854/2004 and 2074/2005 replaced by the corresponding provisions of Regulation (EU) 2017/625 and Regulation (EU) 2019/627 which are materially the same.²⁷

By letter dated 25 September 2019 (Ministry reference ANR18010713/15.02.02, Doc No 1122315) ('the Ministry's response to the pre-Article 31 letter'), not received by the Authority until 20 March 2020,²⁸ the Ministry responded to the Authority's pre-Article 31 letter. The Ministry expressly acknowledged that "*the control of raw materials used for the production of HC fish oil ha[d] been lacking, i.e. organoleptic checks, random testing and sampling*"²⁹ because "*MAST's supervision and official control of fish oil producers...ha[d] hitherto comprised of inspections of buildings, equipment, procedures and internal control of the companies, including recording temperature, organoleptic checks, TVB-N measurements, important control points, cleaning amongst other things that fall under internal control.*"³⁰ Given that MAST's official controls on the production of dual approved establishments were "*in the opinion of the Authority inadequate*", the Ministry informed the Authority that it would by formal letter request MAST to "*review the supervisors official control in line with*" the EEA official control requirements referred to in the Section 4 infringements.³¹ The Ministry further committed to request MAST to explain clearly to dual approved establishments the provisions concerning fish oil production to which they were subject and that such establishments not capable of fulfilling those requirements would have their approval licence reviewed.³² The Ministry noted, however, that the Authority's finding (reflected in the Section 4(ii) and (iii) infringements) that no official upstream controls of requirements relating to raw materials or official physical examination of raw materials were undertaken in relation to HC fish oil produced at sole HC fish oil producing

Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC, as amended and as adapted to the EEA Agreement by the sectoral and the specific adaptations referred to in Annex I to that Agreement, which entered into force in the EEA EFTA States on 7 March 2020.

²⁶ The Act incorporated at Point 11bk. of Part 1.1 of Chapter 1 of Annex I to the EEA Agreement by Decision of the EEA Joint Committee No 3/2020 of 7 February 2020, Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 *laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls*, as amended and as adapted to the EEA Agreement by the sectoral and the specific adaptations referred to in Annex I to that Agreement, which entered into force in the EEA EFTA States on 7 March 2020.

²⁷ More specifically, Article 10(2) of Regulation (EC) No 882/2004 has been replaced by Article 14 of Regulation (EU) 2017/625. Point 1. of Chapter I of Annex III to Regulation (EC) No 854/2004 has been replaced by Article 67 of Regulation (EU) 2019/627. Chapter II of Annex III to Regulation (EC) No 854/2004 has been replaced by Article 70 and Chapter I of Annex VI to Regulation (EU) 2019/627. Chapter 1 of Section II of Annex II to Regulation (EC) No 2074/2005 has been replaced by Point 1. of Section A. of Chapter II of Annex VI to Regulation (EU) 2019/627.

²⁸ See email from the Authority to the Icelandic Government dated 19 March 2020 (Doc 1122966).

²⁹ Second paragraph, page 2 of the Ministry's response to the pre-Article 31 letter.

³⁰ Third paragraph, page 2 of the Ministry's response to the pre-Article 31 letter.

³¹ Fourth paragraph, page 2 of the Ministry's response to the pre-Article 31 letter. For the sake of completeness, it should be noted that the Ministry's description in that paragraph of the Section 4(ii) infringement omits the reference in the Section 4(ii) infringement in the Authority's pre-Article 31 letter to Chapters I and II of Annex III to Regulation (EC) No 854/2004. The Authority assumes that this omission is simply a typographical error.

³² Pages 2 and 3 of the Ministry's response to the pre-Article 31 letter.

establishments ('the Authority's understanding concerning sole HC fish oil producing establishments') was incorrect.³³

Further requests for information of the Authority following the Icelandic Government's response to the pre-Article 31 letter

By letter dated 20 May 2020 (Doc No 1129984) ('the Authority's letter dated 20 May 2020'), the Authority requested the Icelandic Government to provide certain further information in light of the Ministry's response to the pre-Article 31 letter. References to specific information requested by the Authority are included in the descriptions of the Ministry's letter dated 3 November 2020 and the Authority's letter dated 29 March 2021 referred to below.

At the package meeting on 27 May 2020, the Authority noted that the Icelandic Government's position concerning the Section 4 infringements, as set out in the Ministry's response to the pre-Article 31 letter, remained unclear. Certain statements in the Ministry's response to the pre-Article 31 letter recognised only the Authority's findings relating to production of HC fish oil, not those relating to NHC fish oil. The Ministry expressly acknowledged the absence of official physical examination of raw materials used for production of HC fish oil in dual approved establishments but not the other Section 4 infringements. The Ministry had not explained why the Authority's understanding concerning sole HC fish oil producing establishments was incorrect. The Authority further noted that the recently adopted Icelandic Regulation No 1081 of 2 December 2019 amending Icelandic Regulation No 104/2010 on the entry into force of Regulation (EU) No 853/2004 laying down specific hygiene rules concerning foodstuffs of animal origin ('Icelandic Regulation No 1081/2019') appeared to contradict the Part B.1.(b) requirement that raw materials used to produce both HC and (through Part B.3.) NHC fish oil in dual approved establishments "*derive from fishery products which are fit for human consumption*".

By follow-up letter to the package meeting dated 24 June 2020 (Doc No 1133598) ('the follow-up letter to the 2020 package meeting'), the Authority invited the Icelandic Government to respond to the Authority's letter dated 20 May 2020 by 20 July 2020 at the latest and to inform the Authority by the same date of how, and on what legal basis, Icelandic Regulation No 1081/2019 was consistent with Parts B.1.(b) and B.3..

There followed two requests from the Ministry for extension of the deadline for responding to the Authority's letter dated 20 May 2020 (Doc Nos 1142720 and 1150048) (the second of which the Authority refused) and two written reminders from the Authority to the Ministry concerning the Authority's request that the Icelandic Government inform the Authority of how, and on what legal basis, Icelandic Regulation No 1081/2019 was consistent with Parts B.1.(b) and B.3..³⁴

By letter dated 3 November 2020 (Ministry reference ANR18010713/15.02.02, Doc No 1161219) ('the Ministry's letter dated 3 November 2020') attaching a letter from the Ministry to MAST dated 30 June 2020 (Ministry reference ANR18010713/15.02.02, Doc No 1161221) ('the Ministry's letter to MAST dated 30 June 2020'), the Ministry responded to the Authority's letter dated 20 May 2020. The Ministry acknowledged the Section 4(ii) and (iii) infringements concerning, respectively, official upstream controls of requirements relating to raw materials and official physical examination of raw materials in relation to both HC and NHC fish oil produced at dual approved establishments³⁵ and that each of

³³ Final paragraph, page 3 of the Ministry's response to the pre-Article 31 letter.

³⁴ See the Ministry's letters dated 3 July 2020 (Ministry reference ANR18010713/15.02.02, Doc No 1142720) and 1 September 2020 (Ministry reference ANR18010713/15.02.02, Doc No 1150048) and the Authority's emails in response dated 14 July 2020 (Doc No 1144269) and 4 September 2020 (Doc No 1150846).

³⁵ Section 3.(i), page 2 of the Ministry's letter dated 3 November 2020:

"The Ministry acknowledges the Authority's findings regarding official control of raw materials and upstream activities. MAST is currently reviewing the methods used in official control of raw material and upstream

the Section 4 infringements concerned NHC fish oil (rather than only HC fish oil).³⁶ It further acknowledged the absence of official physical examination of raw materials used for producing HC fish oil at sole HC fish oil producing establishments³⁷ but confirmed, contrary to the Authority's understanding reflected in the Section 4(ii) infringement, that official upstream controls of requirements relating to raw materials used for producing HC fish oil at such establishments were already undertaken.³⁸ The Ministry further confirmed that MAST would present "*the requirements of Part B.1. and Part B.2...., pursuant to Part B.3.*" to licensees of dual approved establishments, notwithstanding that such requirements were already a condition for grant and maintenance of dual approved licences,³⁹ "*to sharpen the requirements for the production in dual approved establishments and the license on which it is based so that there is no doubt for the parties concerned as to what these licenses entail.*"⁴⁰ The Ministry stated that dual approved establishments which thereafter did not fulfil raw material and production process requirements applying to HC fish oil would have their licences reviewed.⁴¹ The Ministry further committed to follow up on MAST's review of relevant official controls and dual approved establishment licences and to assess whether there was a need for further

activities. The review is scheduled to be finished in November this year and if necessary, changes in the methods used for official control will be implemented in December.

Plan of review and possible corrective actions foreseen:..."

Section 4(ii)(a), page 4 of the Ministry's letter dated 3 November 2020:

"The reason why physical checks of raw materials and upstream controls are undertaken in relation to raw materials used by sole HC fish oil producing establishments but not in relation to raw materials used to produce HC fish or NHC fish oil at dual approved establishments, is that there is a difference in nature of these establishments." (our emphasis).

³⁶ Section 2., page 1 of the Ministry's letter dated 3 November 2020, in response to Section 2.(i) and (ii), page 2 of the Authority's letter dated 20 May 2020.

³⁷ Section 4.(iii), page 5 of the Ministry's letter dated 3 November 2020, in response to Section 4, pages 5 and 6 of the Authority's letter dated 20 May 2020:

"The Ministry believes that this was somewhat a misunderstanding on its own behalf and MAST as well, in the sense that the Authority meant that there was no official control with HC oil production and therefore thought the Authority's conclusion [relating to official physical examination of raw materials used to produce HC fish oil at sole HC fish oil producing establishments] was unfounded. To clarify, MAST undertakes official control with HC oil production as is explained above and as has been described in this letter official control with fish oil production in general is now under review, physical examination of raw materials included." (our emphasis).

³⁸ Section 4.(i), page 4 of the Ministry's letter dated 3 November 2020:

"The Icelandic Government can affirm that physical checks on raw materials and upstream controls are in fact undertaken in relation to raw materials used by sole HC fish oil producing establishments. In short, there is inspection of the handling of raw material during fishing, landing, transport, reception and storage in the processing establishments." (our emphasis).

Section 4.(ii)(b), page 5 of the Ministry's letter dated 3 November 2020: "*The stages of production, processing and distribution of the raw materials used by sole HC fish oil producing establishments at which physical checks on raw materials and/or upstream controls are undertaken are the following:*

Handling of the catch is examined and the origin of the raw material, as regards the rendering it is examined through the HACCP system,..." (our emphasis).

³⁹ Section 3.1.2, page 14 of the Authority's pre-Article 31 letter:

"The Directorate understands that MAST requires as a condition for grant and maintenance of a dual approval licence that relevant establishments receive only raw material fit for human consumption and that they establish working procedures in their quality manual for the production process ('the approval condition')."

See the 2017 mission report, Section 5.2.2, page 8:

"The mission team noted that several operators had been granted approvals for the production of both fish oil for human consumption (under the Hygiene regulations) and fish oil and fish meal for animal feed (under the Animal by product (ABP) Regulation). In order to maintain such approvals, MAST requires that the operators receive only raw material fit for human consumption."

See Section 1., page 1 of MAST's letter dated 30 June 2017:

"When these establishments were approved, it was reiterated by the Competent Authority (MAST) that the relevant requirements in Regulation (EC) No 853/2004 regarding the raw material used in the processing had to be fulfilled. The establishments were requested to define procedures on handling of the raw material and the criteria used for assessing if the raw material is fit for human consumption."

⁴⁰ Section 5.(i), page 6 of the of the Ministry's letter dated 3 November 2020, in response to Section 5.(i), page 7 of the Authority's letter dated 20 May 2020.

⁴¹ Section 5.(ii), page 6 of the Ministry's letter dated 3 November 2020, in response to Section 5.(ii), page 7 of the Authority's letter dated 20 May 2020.

risk assessment of fish oil production.⁴² Further statements from the Ministry's letter dated 3 November 2020 are referred to in the description of the Authority's letter dated 29 March 2021 referred to below.

In the Ministry's letter to MAST dated 30 June 2020, the Ministry described in detail the relevant correspondence between the Authority and the Icelandic Government in the case and requested MAST to:

- re-evaluate official controls of dual approved establishments in the light of the relevant requirements of EEA legislation; and
- review current dual approval establishment licence conditions with the operators of such establishments and revert to the Ministry on the same.⁴³

By letter dated 29 March 2021 (Doc No 1186531 or 1190073) ('the Authority's letter dated 29 March 2021'), the Authority noted that the Ministry's statement in its letter dated 3 November 2020 stated "*the emphasis [in previous case correspondence between the Authority and the Icelandic Government] ha[d] been on describing the official control of production of HC fish oil in establishments that have a dual approval licence rather than official control of production of NHC fish oil/meal which MAST also carries out*"⁴⁴ was incorrect.⁴⁵ The Authority stated that, on the contrary, it had repeatedly requested information from the Icelandic Government relating to production of NHC fish oil at dual approved establishments from an early stage in the case⁴⁶ and that, as expressly acknowledged in the Ministry's letter dated 3 November 2020,⁴⁷ the Section 4. infringements referred to failure by the Icelandic Government to undertake official controls relating to NHC fish oil, as well as HC fish oil, produced at dual approved establishments.

For the purposes of clarification, the Authority listed in the Annex to the Authority's letter dated 29 March 2021,⁴⁸ *inter alia*, the following aspects of the case which the Authority understood as acknowledged by the Icelandic Government:

- All of the Section 4 infringements concerned production of NHC fish oil at dual approved establishments (in addition to production of HC fish oil at both dual approved and sole HC fish oil producing establishments in the case of the Section 4(ii) and (iii) infringements).⁴⁹
- The Icelandic Government had failed to undertake official upstream controls of requirements relating to raw materials and official physical examination of raw materials used to produce HC fish oil and NHC fish oil at dual approved establishments⁵⁰ as noted in the Sections 4(ii) and (iii) infringements.
- Irrespective of practical challenges which may arise (from rapid deterioration of the quality of fish or otherwise), official physical examination of raw materials should be carried out at all stages of production, processing and distribution including (although not limited to) landing.⁵¹

⁴² Section 5.(iii), page 6 of the Ministry's letter dated 3 November 2020, in response to Section 5.(iii), page 7 of the Authority's letter dated 20 May 2020.

⁴³ Last two paragraphs, page 3 of the Ministry's letter to MAST dated 30 June 2020.

⁴⁴ Section 3(i), page 1 of the Ministry's letter dated 3 November 2020.

⁴⁵ Section I., pages 1 and 2 of the Authority's letter dated 29 March 2021.

⁴⁶ See, for example, Section 2., page 1 of the Authority's letter dated 1 December 2017

⁴⁷ See footnote 36 of this letter of formal notice.

⁴⁸ Pages 10 to 12 of the Authority's letter dated 29 March 2021.

⁴⁹ See footnote 36 of this letter of formal notice.

⁵⁰ See footnote 35 of this letter of formal notice.

⁵¹ Section 3.(ii), page 3 of the Ministry's letter dated 3 November 2020, in response to Section 3.(ii), page 4 of the Authority's letter dated 20 May 2020.

- The requirement to undertake the official controls mentioned in the Section 4 infringements:
 - (i) applied irrespective of the quantity of HC fish oil produced at dual approved establishments;
 - (ii) was not met where official controls were limited to inspections of buildings, equipment, procedures and internal controls of fish oil producers.⁵²
- Where the Part B.3. requirement was not met, production and storage of HC and NHC fish oil in the same dual approved establishment was prohibited, irrespective of whether production of HC and NHC fish oil at that establishment was separated in time, with cleaning and disinfection/flushing of the system in the interval.⁵³
- Official upstream controls of requirements relating to raw materials (handling, origin) were undertaken in the case of raw materials used by sole HC fish oil producing establishments but not in relation to raw materials used to produce HC fish or NHC fish oil at dual approved establishments. This was due to differences in production arrangements at the two types of establishments. In the case of HC fish oil produced (from fish liver) at sole HC fish oil establishments, establishments or trawlers gutted the fish before supplying the raw materials to the sole HC fish oil establishment and the upstream supply chain was the subject of official controls by MAST. In the case of production of HC and NHC fish oil at dual approved establishments, however, whole fish (which had not been gutted) were landed directly at such establishments from vessels, except where fish trimmings from food processing establishments were used to produce NHC fish oil.⁵⁴ The opportunities for upstream official controls by MAST where raw materials are directly landed were reduced and such controls were not undertaken.⁵⁵

The Authority invited the Icelandic Government to inform it if it disagreed with any of the above-mentioned statements in the Annex and, if so, to explain the reason.⁵⁶

The Authority also informed the Icelandic Government of its understanding that MAST's "*physical checks on raw materials...used by sole HC fish oil producing establishments*" mentioned in the Ministry's letter dated 3 November 2020 did not include official physical examination of such raw materials, only official upstream controls of requirements relating to such raw materials (handling, origin).⁵⁷ The Authority requested the Icelandic Government to inform it if this was incorrect.⁵⁸

The Icelandic Government did not subsequently inform the Authority that the above-mentioned understanding was incorrect or that it disagreed with any of the statements in the Annex to the Authority's letter dated 29 March 2021.

⁵² Section 3.(iii), page 3 of the Ministry's letter dated 3 November 2020, in response to Section 3.(iii), page 4 of the Authority's letter dated 20 May 2020.

⁵³ Section 3.(iv), page 3 of the Ministry's letter dated 3 November 2020, in response to Section 3.(iv), page 4 of the Authority's letter dated 20 May 2020:

"In the licenses that MAST has issued to the dual licensees the requirements of Parts B.1 and B.3 are listed and as the Authority is aware of it was previously considered satisfactory that production processes are separated in space or time and cleaning undertaken between production processes. It is now clear that that does not fulfil the requirement of the legislation and parties concerned are aware of that."

⁵⁴ Section 4.(i) and (ii), page 4 of the Ministry's letter dated 3 November 2020

⁵⁵ As stated (translated) in the Ministry's letter to MAST dated 30 June 2020, page 4: "...the condition of the raw material [for production of fish oil at dual approved establishments] is evaluated during landing and therefore it is not possible to wait for an inspector from MAST to evaluate the quality of the raw material". See similarly, second paragraph, page 2 of the Ministry's response to the pre-Article 31 letter.

⁵⁶ Section II., page 2 of the Authority's letter dated 29 March 2021.

⁵⁷ See footnotes 37 and 38 of this letter of formal notice.

⁵⁸ Section III.2.(ii)(a), page 6 of the Authority's letter dated 29 March 2021.

In the Authority's letter dated 29 March 2021, the Authority also requested the Icelandic Government to provide further information on already undertaken or anticipated official controls in light of, and since, the Ministry's letter dated 3 November 2020. The information requested included details of official physical examination of raw materials (including relevant official controls under Article 70 and Annex VI to Regulation (EU) 2019/627) and official upstream controls of requirements relating to raw materials in relation to production of both HC and NHC fish oil at dual approved establishments and production of HC fish oil at sole HC fish oil producing establishments ('all relevant types of fish oil production'), including verification of compliance with relevant requirements of Section VIII of Annex III to Regulation (EC) No 853/2004 ('Section VIII').^{59 60} The Authority specifically requested information on already undertaken or anticipated official controls of NHC fish oil produced at dual approved establishments (including in the case where no HC fish oil was currently being produced at the establishment in question)⁶¹ and clarification of whether the "*random organoleptic checks*" mentioned as a possible corrective action in the Ministry's letter dated 3 November 2020⁶² referred to official verification of FBOs own records of organoleptic checks⁶³ or to official physical examination of raw materials.⁶⁴ The Authority further requested the Icelandic Government to provide, without further delay, an explanation of how, and on what legal basis, Icelandic Regulation No 1081/2019 is consistent with the requirement of Parts B.1.(b) and B.3..⁶⁵

By letter dated 26 May 2021 (Ministry reference ANR18010713/15.02.02, Doc No 1203348) ('the Ministry's letter dated 26 May 2021'), the Ministry responded to the Authority's request for an explanation of how, and on what legal basis, Icelandic Regulation No 1081/2019 was consistent with the requirement of Parts B.1.(b) and B.3.. In that letter, the Ministry explained that the purpose of Icelandic Regulation No 1081/2019 was "*that both vessels and businesses on land could produce...HC fish oil...and as well...NHC fish oil*" and that "*it would be possible to produce HC fish oil and NHC fish oil/meal from a whole fish, and that the raw material could also come from guts, among heads, back bones and bycatch.*" It further stated that Icelandic Regulation No 1081/2019 was consistent with the requirement of Parts B.1.(b) and B.3. "*under certain conditions. Firstly, the NHC fish oil/meal has to be produced in the same way it would be if the fish oil was meant for human consumption. Secondly, the relevant establishments and vessels may produce HC fish oil and NHC fish oil/meal with raw material using the guts, head, back bones and other bycatch, under the condition that the production meets the requirements that are stated in Regulation (EC) No 853/2004 and the Icelandic Act no. 93/1995.*"⁶⁶

Attached to the same letter was:

- an example of a letter sent by MAST to operators of dual approved establishments (MAST reference 2105313, Doc No 1203346) ('the letter to Ísfélag Vestmannaeyja hf dated 12 May 2021');

⁵⁹ Part B.1.(b) of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004 requires that "*raw materials used in the preparation of fish oil for human consumption must...derive from fishery products which...comply with the provisions set out in [Section VIII]*".

Article 67 of Regulation (EU) 2019/627 requires that:

"*Official controls on the production and placing on the market of fishery products shall include verification of compliance with the requirements set out in Section VIII of Annex III to Regulation (EC) No 853/2004...*"

⁶⁰ Section III. 2.(i) and (ii), page 5 of the Authority's letter dated 29 March 2021

⁶¹ Section III.1. (i) and (ii), pages 2 to 4, Section III.2.(iii)(c), page 8 and Section III.3(ii), page 8 of the Authority's letter dated 29 March 2021.

⁶² See Section 3(i), pages 2 and 3 and Section 4(i), page 4 of the Ministry's letter dated 3 November 2020.

⁶³ Point A. of Chapter V of Section VIII of Annex III to Regulation (EC) No 853/2004 states that:

"*Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.*"

⁶⁴ Section III. 2.(ii)(c), page 7 of the Authority's letter dated 29 March 2021.

⁶⁵ Section III.5., page 9 of the Authority's letter dated 29 March 2021.

⁶⁶ Page 1 of the Ministry's letter dated 26 May 2021.

- a letter from MAST to the Authority dated 21 May 2021 (MAST reference 1712177, Doc No 1203350) ('MAST's letter dated 21 May 2021') responding to the Authority's letter dated 29 March 2021; and
- MAST's check list for official controls of compliance of fishing vessels and landing sites with requirements of, *inter alia*, Section VIII (Doc No 1203352) ('the relevant official controls check list').

In the letter to Ísfélag Vestmannaeyja hf. dated 12 May 2021, MAST informed the FBO that it had noted during an audit of the relevant dual approved establishment that "*fish oil [for human consumption] is produced in the same process as fish oil made from raw materials unfit for human consumption.*" MAST explained that the relevant establishment therefore had two choices. Firstly, "*if fish oil is to be produced for human consumption, all the raw materials used by the company for processing must be suitable human consumption in accordance with [Part B.]*" Alternatively, "*if non-food grade [raw materials] (ABP) [are] to be used, the company may only produce fishmeal and fish oil as animal by-products.*" The operator was requested to inform MAST by 31 May 2021 whether it intended to continue producing HC fish oil in which case "*the company's license will be converted into a food processing license following an audit.*" If, on the other hand, "*the company intends to produce fish oil from raw materials that are not suitable for human consumption... processing of fish oil for human consumption is abolished.*"

In MAST's letter dated 21 May 2021, MAST provided the following information:

- (i) The approval of all dual approved establishments would be withdrawn by 30 June 2021. Thereafter, fishmeal establishments intending to continue to produce HC fish oil would need to apply for approval as a food business (as well as a feed establishment) and all raw material used would need to fulfil the Part B. requirements.⁶⁷ An audit verifying compliance with all relevant requirements of the hygiene regulations would be undertaken by MAST before issuing such approval. Meanwhile, the frequency of official controls in relation to fish oil produced at such approved establishments ('future dual approved establishments') would be revised. Such official controls would be undertaken by MAST's division of Consumer Protection responsible for approval and official control of FBOs producing food of animal origin. They would entail official upstream controls of requirements relating to herring (pelagic species) used as raw materials (fishing vessels, landing of fish, control of raw materials and transport of raw materials to the establishments) in the next June – July 2021 fishing season as well as control of raw material used for production of HC fish oil. This would include relevant official controls under Articles 67 (including verifying FBOs' own controls) and 70 of Regulation (EU) 2019/627, the latter including undertaking random official organoleptic checks at all stages of production as well as the official controls specified in Parts B., C. (histamine in scombroid species), D. and F.⁶⁸ of Chapter I of Annex VI to Regulation (EU) 2019/627.⁶⁹ A sampling plan in relation to the relevant areas of Article 70 in the upstream supply chain of pelagic species and in production establishments would be devised in June 2021 once it was clear how many

⁶⁷ Reference was made in that context to the letter to Ísfélag Vestmannaeyja hf. dated 12 May 2021.

⁶⁸ Part B. Freshness indicators, Part C. Histamine, Part D. Residues and contaminants and Part F. Parasites.

⁶⁹ Section III.1., page 1, first two paragraphs of Section III.1.(i), page 2, final paragraph of Section III.(2).(i), page 2, Section III.2.(ii)(c), page 3, Section III.(iii)(a) and (b), page 3 and Section III.4.(i-ii), page 4 of MAST's letter dated 21 May 2021 (References in this letter of formal notice to Section numbers and pages of MAST's letter dated 21 May 2021 are to those of the revised version of MAST's letter dated 21 May 2021 (revised on 21 February 2022, MAST reference 1712177, Doc No 1271275) received by the Authority from the Icelandic Government on 22 February 2022).

fishmeal establishments would obtain dual approval as a food business producing HC fish oil.⁷⁰

- (ii) The handling of fish and liver as a raw material would be checked at sole HC fish oil producing establishments, on fishing vessels gutting fish, at landing sites, fish markets and during transport. Random organoleptic checks on raw materials as well as other official controls under Article 70 of Regulation (EU) 2019/627 would also be checked at all stages of production, processing and distribution.⁷¹
- (iii) Official controls of future dual approved establishments would “*cover all the relevant [Part B.1.] requirements...and all other relevant requirements in regulations EC/852/2004 and EC/853/2004*”.⁷²
- (iv) Although official controls of fishing vessels included verification of compliance with relevant requirements of Section VIII, there was “*room for improvement in organoleptic examination on board the fishing vessels and at landing sites*” and the relevant official controls check list would be updated accordingly and a revised version issued on 1 June 2021.⁷³

MAST’s letter dated 21 May 2021 provided no specific, unambiguous⁷⁴ confirmation that the official controls concerning production of NHC fish oil at dual approved establishments listed in the Section 4 infringements had been, or would be, undertaken, notwithstanding numerous specific requests in the Authority’s letter dated 29 March 2021 that the Icelandic Government provide such information.⁷⁵

The only comments specifically referring to NHC fish oil in the letter were that:

- “MAST is not planning big changes in the control of establishments which produce NHC fish oil from animal by-products from fish. However, MAST is in the process of reviewing the official control in general and some changes can be made soon in the organisation and responsibility of official control performed by MAST.”⁷⁶ (our emphasis)
- in response to the Authority’s request for information on official controls to ensure compliance with Part B.2. in the case of all relevant types of fish oil production:⁷⁷
“*The fish oil establishment must make a hazard analysis of the production steps. The [production] process includes heating, pressing, separation, centrifugation, and processing when producing crude HC fish oil. Purification and refining HC fish oil is normally done in other establishments. The process*

⁷⁰ Third paragraph, Section III.2.(ii)(a), page 3 of MAST’s letter dated 21 May 2021.

⁷¹ Final paragraph, Section III.1.(i), page 2 and first paragraph, Section III.2.(i), page 2 of MAST’s letter dated 21 May 2021.

⁷² First paragraph, Section III.2.(ii)(a), page 2 of MAST’s letter dated 21 May 2021.

⁷³ Second paragraph, Section III.2.(ii)(a), pages 2 and 3 of MAST’s letter dated 21 May 2021. See also Section III.(iii)(a), page 3 of MAST’s letter dated 21 May 2021:

“*Reference is made to part III.2 (ii) (a). The official control will cover: Control of fishing vessels to verify the relevant requirements of section VIII in annex III of regulation 853/2004. Checklist is in annex 2.*”

⁷⁴ Statements in the letter (including those in response to questions in the Authority’s letter dated 29 March 2021 specifically requesting information on NHC fish oil) either referred specifically to HC fish oil (for example, Section III.1., page 1 of MAST’s letter dated 21 May 2021: “*The official control will cover control of the fishing vessels, landing of fish, control of raw material, transport to the establishments and control of raw material used for production of HC fish oil*”), referred generically to fish oil without specifying if they applied to NHC fish oil (for example, see first paragraph, Section III.1.(i), page 2 of MAST’s letter dated 21 May 2021) or confirmed that no changes to official controls of production of NHC fish oil were planned (see footnote 76 of this letter of formal notice).

⁷⁵ See footnote 61 of this letter of formal notice.

⁷⁶ Section III.1.(ii), page 2 of MAST’s letter dated 21 May 2021. See, similarly, Section III.(iii)(c), page 3.

⁷⁷ Section III. 3., page 8 of the Authority’s letter dated 29 March 2021.

*is the same in establishments producing NHC fish oil. The hazard analysis and HACCP plan are audited during official control at least once a year.*⁷⁸ (our emphasis)

It is not clear whether the Icelandic Government meant by this statement that (i) the production process for HC fish oil is the same whether or not it is undertaken in a dual approved establishment (i.e. “*in establishments producing NHC fish oil*”) or in a sole HC fish oil producing establishment (with the mentioned annual official controls being limited to HC fish oil); or (ii) the production process for NHC fish oil in a dual approved establishment is the same as that for HC fish oil at such establishments.

Neither did MAST’s letter dated 21 May 2021 include any comment in response to the request in the Authority’s letter dated 29 March 2021 (and previously in the Authority’s follow-up letter to the 2020 package meeting) for an explanation of how, and on what legal basis, Icelandic Regulation No 1081/2019 is consistent with the requirement of Parts B.1.(b) and B.3.

At the package meeting on 1 June 2021, the Authority noted that MAST had in its letter dated 21 May 2021 expressly acknowledged the Section 4 infringements concerning HC fish oil – namely, the absence of official physical examination of raw materials and official upstream controls of requirements relating to raw materials. As regards these infringements, the Authority’s focus would now be on ensuring that the remedial actions proposed in MAST’s letter were implemented. The Authority further noted, however, that it remained unclear from MAST’s letter dated 21 May 2021 whether official controls of future dual approved establishments would extend to checking relevant raw material and production process requirements in relation to production of NHC fish oil at such establishments. The Authority stated that it required confirmation from the Icelandic Government that such official controls would be undertaken before it could consider closing the case.

The Authority also invited the Icelandic Government to provide the Authority with a revised version of MAST’s letter dated 21 May 2021, with section numbering corrected to correspond to that in the Authority’s letter dated 29 March 2021 (‘the revised version of MAST’s letter dated 21 May 2021’), in order to clarify which responses in MAST’s letter related to which questions in the Authority’s letter.

The Authority further noted that nothing in the Ministry’s letter dated 26 May 2021 detracted from the fact that Icelandic Regulation No 1081/2019 contravened the requirement of Parts B.1.(b) and B.3. that raw materials used to produce HC and NHC fish oil in dual approved establishments “*derive from fishery products which are fit for human consumption*”.

By follow-up letter to the 2021 package meeting dated 1 July 2021 (Doc No 1204495) (‘the Authority’s 2021 package meeting follow-up letter’), the Authority invited the Icelandic Government to address those questions (and parts of questions) in the Authority’s letter dated 29 March 2021 (Doc No 1186531 or 1190073) concerning official controls to verify production of NHC fish oil at dual approved establishments in accordance with Part B.3.⁷⁹ and to provide the Authority with the revised version of MAST’s letter dated 21 May 2021. The Authority noted that it would consider next steps in the case as regards Icelandic Regulation No 1081/2019.

By letter dated 30 August 2021 (Ministry reference ANR21080292/15.02.02, Doc No 1223536), the Ministry responded to the request in the Authority’s 2021 package meeting for confirmation of whether official controls of future dual approved establishments would

⁷⁸ Section III.3. (i)-(iii), page 4 of MAST’s letter dated 21 May 2021.

⁷⁹ See footnote 61 of this letter of formal notice.

extend to production of NHC fish oil at such establishments by providing information on dioxin testing of fish oil produced at fish meal factories and related official controls pursuant to feed hygiene legislation.⁸⁰ The Ministry's response did not address, in relation to future dual approved establishments, those questions (and parts of questions) in the Authority's letter dated 29 March 2021 concerning official controls to verify production of NHC fish oil at dual approved establishments in accordance with Part B.3., notwithstanding the Authority's specific request to this effect in the Authority's 2021 package meeting follow-up letter.

By email to the Ministry dated 9 February 2022 (Doc No 1268983), the Authority noted that it had still not received from the Icelandic Government the revised version of MAST's letter dated 21 May 2021 and requested that the Icelandic Government provide it to the Authority without further delay.

The Authority received the revised version of MAST's letter dated 21 May 2021 (revised on 21 February 2022, MAST reference 1712177, Doc No 1271275) from the Icelandic Government on 22 February 2022.

By letter dated 28 March 2022 (MAST reference 1712177, Doc Nos 1280478 and 1286556) ('MAST's letter dated 28 March 2022'), MAST provided an update of actions taken pursuant to MAST's letter dated 21 May 2021. The letter contained details of recent and ongoing official controls of vessels fishing pelagic species and in the relevant areas of Article 70 of Regulation (EU) 2019/627 regarding fish on board the fishing vessels, at landing, during transport and at dual approved establishments.⁸¹ MAST explained that it had extended the deadline for withdrawal of existing dual approval of relevant establishments until 1 September 2022 at the request of the Icelandic Association of Fish Meal Manufacturers.⁸² A decision to change the responsibility for relevant official controls within MAST to MAST's division of Consumer Protection had not yet been taken pending relevant establishments' decisions as to whether or not they would continue to produce HC fish oil as future dual approved establishments.⁸³ Neither had the frequency of official controls in relation to fish oil produced at future dual approved establishments yet been revised.⁸⁴ The letter contained no specific confirmation that official controls concerning production of NHC fish oil at dual approved establishments listed in the Section 4 infringements had been, or would be, undertaken and a number of statements suggesting that official controls would be undertaken in relation to production of HC fish oil only.⁸⁵

⁸⁰ Section 1., page 1 of the Ministry's letter dated 30 August 2021.

⁸¹ Final paragraph, page 1 and first paragraph, page 2 of MAST's letter dated 28 March 2022.

⁸² Second paragraph, page 1 of MAST's letter dated 28 March 2022.

⁸³ Third paragraph from end of letter, page 2 of MAST's letter dated 28 March 2022.

⁸⁴ Final paragraph, page 2 of MAST's letter dated 28 March 2022.

⁸⁵ Second paragraph, page 1 of MAST's letter dated 28 March 2022: "*The producers were required to notify to MAST when production of fish oil for human consumption was planned.*" First paragraph, page 2 of MAST's letter dated 28 March 2022: "*...the TVB-N value is used to determine if the raw material can be used for production of fish oil for human consumption in establishments with dual approval. MAST received one notification from FBO which were planning production of fish oil for human consumption. An inspector performed control of the processing soon after the processing. Non-compliances were made regarding the frequency of monitoring of TVB-N, procedure of cleaning the pipelines before HC fish oil is pumped into HC fish oil tank and TVB-N value was over the limit for some time before decision was taken to pump it into a tank with non-HC fish oil.*" Second paragraph, page 2 of MAST's letter dated 28 March 2022: "*Sampling of HC fish oil if the establishments will be approved for processing of HC fish oil.*" Final paragraph, page 2 of MAST's letter dated 28 March 2022: "*MAST has required the establishment to notify when they plan to produce fish oil for human consumption, to be able to perform additional control [sic] while producing or shortly after production.*"

3 Relevant national law

Incorporation of Regulation (EC) No 853/2004

Regulation (EC) No 853/2004 is incorporated into Icelandic legislation by the reference method through *Regulation No. 104/2010 on the entry into force of Regulation (EC) No. 853/2004 on special rules on hygiene of food of animal origin (Reglugerð nr. 104/2010 um gildistöku reglugerðar Evrópupingsins og ráðsins (EB) nr. 853/2004 um sérstakar reglur um hollustuhætti sem varða matvæli úr dýraríkinu, auk áorðinna breytinga)*⁸⁶ ('Icelandic Regulation No 104/2010') which entered into force on 12 February 2010.

Icelandic Regulation No 104/2010 has been amended by, amongst other national amending regulations, Icelandic Regulation No 1005/2011 which incorporated Regulation (EC) No 1020/2008 amending Annex III to Regulation 853/2004 to include Part B. in Chapter IV of Section VIII to Annex III to Regulation (EC) No 853/2004.⁸⁷

Icelandic Regulation No 1081/2019

Icelandic Regulation No 1081/2019 entered into force on 2 December 2019 as provided in its Article 2.⁸⁸ This Regulation is not presented as incorporating any EEA Act.

Article 1 of Icelandic Regulation No 1081/2019 provides that:

"The following paragraph shall be added to Article 7 of Regulation No 104/2010:

For the production of fishmeal and fish oil intended for human consumption, fish and fish aquaculture products may be used, including: whole fish, cuts, viscera and other raw materials resulting from the treatment and processing of fish and aquaculture products, provided that the treatment of the raw material meets food hygiene requirements."

Incorporation of Regulation (EU) 2017/625

Regulation (EU) 2017/625 is incorporated into Icelandic law by the reference method through *Regulation No. 234/2020 on the entry into force of Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities in the field of food, feed, etc. (Reglugerð nr. 234/2020 um gildistöku reglugerðar Evrópupingsins og ráðsins (ESB) 2017/625 um opinbert eftirlit og aðra opinbera starfsemi með matvælum, fóðri o.fl.)*⁸⁹ which entered into force on 20 March 2020.

Incorporation of Regulation (EU) 2019/627

⁸⁶ Article 1(a) of Regulation No. 104/2010, dated 25 January 2010

<https://www.reglugerd.is/reglugerdir/allar/nr/0104-2010> states:

"The provisions of the EEA Agreement which are referred to in Chapter I, Annex I, shall be enforced with later amendments and additions under Annex I, protocol 1 to the Agreement and other provisions of the Agreement. Based on Joint Committee Decision no. 137/2007, dated 27 October 2007, the following EC legislation shall be enforced in Iceland:

a) Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for on the hygiene of foodstuffs..."

⁸⁷ See footnote 5 of this letter of formal notice and

<https://www.reglugerd.is/reglugerdir/eftir-raduneytum/sjavaroglandbunadar/nr/17962>.

⁸⁸ See link <https://www.reglugerd.is/reglugerdir/allar/nr/1081-2019>.

⁸⁹ Article 1 of Regulation No. 234/2020, dated 17 March 2020

<https://www.reglugerd.is/reglugerdir/allar/nr/0234-2020> states:

"Article 1

Implementation.

The provisions of the Agreement on the European Economic Area referred to in Chapter I, Annex I, shall enter into force with amendments and additions resulting from Annex I, Protocol 1 to the Agreement and other provisions thereof. On the basis of the Decision of the EEA Joint Committee no. 210/2019, from 27 September 2019, the following EU acts enter into force in this country: Regulation (EU) 2017/625..."

Regulation (EU) 2019/627 is incorporated into Icelandic law by the reference method through *Regulation No. 518/2020 on (21st) amendment to Regulation no. 104/2010 on the entry into force of Regulation (EC) No. 853/2004 on special rules on hygiene on food of animal origin (Reglugerð nr. 518/2020 um (21.) breytingu á reglugerð nr. 104/2010 um gildistöku reglugerðar Evrópuþingsins og ráðsins (EB) nr. 853/2004 um sérstakar reglur um hollustuhætti sem varða matvæli úr dýraríkinu)*⁹⁰ which entered into force on 29 May 2020.

4 Relevant EEA law

4.1.1 Hygiene requirements for fish oil

Specific hygiene rules for HC fish oil are laid down in Regulation (EC) No 853/2004.

Part B. of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004⁹¹ (entitled “Requirements for fish oil intended for human consumption”) states:

“CHAPTER IV: REQUIREMENTS FOR CERTAIN PROCESSED FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements in establishments handling certain processed fishery products.

...

B. REQUIREMENTS FOR FISH OIL INTENDED FOR HUMAN CONSUMPTION

1. *Raw materials used in the preparation of fish oil for human consumption must:*

(a) *come from establishments, including vessels, registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation;*

(b) *derive from fishery products which are fit for human consumption and which comply with the provisions set out in this Section;*

(c) *be transported and stored in hygienic conditions;*

(d) *be chilled as soon as possible and remain at the temperatures set out in Chapter VII.*

By way of derogation from point 1(d), the food business operator may refrain from chilling the fishery products when whole fishery products are used directly in the preparation of fish oil for human consumption, and the raw material is processed within 36 hours after loading, provided that the freshness criteria are met and the total volatile basic nitrogen (TVB- N) value of the unprocessed fishery products do not exceed the limits set out in point 1 of Chapter I of Section II of Annex II to Commission Regulation (EC) No 2074/2005.

2. *The production process for fish oil must ensure that all raw material intended for the production of crude fish oil is subject to a treatment including, where relevant, heating,*

⁹⁰ Article 1 of Regulation No. 518/2020, dated 20 May 2020.

<https://www.reglugerd.is/reglugerdir/allar/nr/0518-2020> states:

“Article 1

The provisions of the Agreement on the European Economic Area referred to in Chapter I of Annex I shall enter into force with amendments and additions resulting from Annex I, Protocol 1 to the Agreement and other provisions thereof. On the basis of the Decision of the EEA Joint Committee no. 3/2020, from 7 February 2020, the following EU acts enter into force in this country:

Commission Implementing Regulation (EU) 2019/627...”.

⁹¹ This part of Annex III to Regulation (EC) No 853/2004 was added to that Annex by Regulation (EC) No 1020/2008. See link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1020> .

pressing, separation, centrifugation, processing, refining and purification steps before being placed on the market for the final consumer.

3. Provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption a food business operator may produce and store both fish oil for human consumption and fish oil and fish meal not intended for human consumption in the same establishment.”

4.1.2 Hygiene requirements for viscera

Point 6. of Part II of Chapter I of Section VIII of Annex III to Regulation (EC) No 853/2004 states:

“Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the fishery products must be washed immediately. The viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from fishery products intended for human consumption.”.

4.1.3 Official controls to ensure compliance with food and feed law

General rules on official controls to ensure compliance with food and feed law (including fish oil production) are regulated by Regulation (EU) 2017/625.

Article 9(1) of Regulation (EU) 2017/625 (Article 9 being entitled “*General rules on official controls*”) states:

“1. Competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency, taking account of:

(a) identified risks associated with:

- (i) animals and goods;*
- (ii) the activities under the control of operators;*
- ...*
- (v) the use of products, processes, materials or substances that may influence food safety, integrity and wholesomeness, or feed safety,...*

Article 10(1) of Regulation (EU) 2017/625 (Article 10 being entitled “*Operators, processes and activities subject to official controls*”) states:

“1. To the extent necessary to ascertain compliance with the rules referred to in Article 1(2), competent authorities shall perform official controls on:

...

(b) substances, materials or other objects which may influence the characteristics or health of animals and goods and their compliance with applicable requirements, at any stage of production, processing, distribution and use;...

Article 14 of Regulation (EU) 2017/625 (entitled “*Methods and techniques for official controls*”) states that:

“Official control methods and techniques shall include the following as appropriate:

(a) an examination of the controls that operators have put in place and of the results obtained;

(b) an inspection of:

- (i) equipment, means of transport, premises and other places under their control and their surroundings;*
- (ii) animals and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals;*

...

(c) controls on the hygiene conditions in the operators' premises;

(d) an assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of procedures based on the principles of hazard analysis critical control points (HACCP);

(e) an examination of documents, traceability records and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2), including, where appropriate, documents accompanying food, feed and any substance or material entering or leaving an establishment;

(f) interviews with operators and with their staff;

(g) the verification of measurements taken by the operator and other test results;

(h) sampling, analysis, diagnosis and tests;

(i) audits of operators;

(j) any other activity required to identify cases of non-compliance.”.

4.1.4 Official controls of fishery products for human consumption

Specific rules for the organisation of official controls of fishery products for human consumption (including HC fish oil) are provided in Regulation (EU) 2019/627.

Title VI of Regulation (EU) 2019/627 (Articles 67 to 72) establishes specific requirements and uniform minimum frequency of official controls with respect to fishery products.

Article 67 of Regulation (EU) 2019/627 (entitled “Official controls on production and placing on the market”) states:

“Official controls on the production and placing on the market of fishery products shall include verification of compliance with the requirements set out in Section VIII of Annex III to Regulation (EC) No 853/2004, in particular:

(a) a regular check on the hygiene conditions of landing and first sale;

(b) regular inspections of vessels and establishments on land, including fish auctions and wholesale markets, in particular to check:

- (i) whether the conditions for approval are still fulfilled;*
- (ii) whether the fishery products are handled correctly;*
- (iii) compliance with hygiene and temperature requirements;*

- (iv) *the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene;*

(c) checks on storage and transport conditions.”

Article 70 of Regulation (EU) 2019/627 (entitled “Official controls of fishery products”) states:

“Official controls of fishery products shall include at least the practical arrangements laid down in Annex VI as regards:

(a) organoleptic examinations;

(b) freshness indicators;

(c) histamine;

(d) residues and contaminants;

(e) microbiological checks;

(f) parasites;

(g) poisonous fishery products.”.

Chapter I of Annex VI to Regulation (EU) 2019/627 (Annex VI being entitled “Practical arrangements or official controls on fishery products in accordance with Article 70”) states:

“CHAPTER I

GENERAL PROVISIONS

A. Organoleptic examinations

Random organoleptic controls shall be carried out at all stages of production, processing and distribution. One aim of the controls is to verify compliance with the freshness criteria established in accordance with this Regulation. In particular, this includes verifying, at all stages of production, processing and distribution, that fishery products at least meet the baselines of freshness criteria established in accordance with Council Regulation (EC) No 2406/96.

B. Freshness indicators

When the organoleptic examination gives rise to any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N) in accordance with the technical arrangements in Chapter II.

The competent authorities shall use the criteria laid down in this Regulation.

When the organoleptic examination gives cause to suspect the presence of other conditions that may affect human health, appropriate samples shall be taken for verification purposes.

C. Histamine

Random testing for histamine shall be carried out to verify compliance with the permitted levels laid down in Regulation (EC) No 2073/2005.

D. Residues and contaminants

Monitoring arrangements shall be established in accordance with Directive 96/23/EC and Decision 97/747/EC to control compliance with the EU legislation on:

— maximum residue limits for pharmacologically active substances, in accordance with Regulations (EU) No 37/2010 and (EU) No 2018/470;

— prohibited and non-authorised substances, in accordance with Regulation (EU) No 37/2010, Directive 96/22/EC and Decision 2005/34/EC;

— contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food; and

— pesticide residues, in accordance with Regulation (EC) No 396/2005.

For wild caught fishery products monitoring arrangements shall be established to control compliance with the EU legislation on contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food.

E. Microbiological checks

Where necessary, microbiological controls shall be performed in accordance with the relevant rules and criteria laid down in Regulation (EC) No 2073/2005.

F. Parasites

Risk-based testing shall take place to verify compliance with Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 and Section I of Annex II to Regulation (EC) No 2074/2005.

G. Poisonous fishery products

Controls shall take place to ensure that:

1. fishery products derived from poisonous fish of the following families are not placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae;

*2. fresh, prepared, frozen and processed fishery products belonging to the family Gempylidae, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may be placed on the market only in wrapped/packaged form and are appropriately labelled to inform the consumer about preparation/ cooking methods and the risk related to the presence of substances with adverse gastrointestinal effects. The scientific names of the fishery products and the common names shall appear on the label;*

3. fishery products containing biotoxins such as ciguatera or other toxins dangerous to human health are not placed on the market. However, fishery products derived from live bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No 853/2004 and comply with the standards laid down in point 2 of Chapter V of that Section.”

Annex I to the EEA Agreement states: “*Point A of Chapter I of Annex VI shall not apply to the EFTA States.*”⁹² The requirement for such organoleptic examinations is, however, implicit in Annex VI to Regulation (EC) 2019/627 (particularly in Part B. *Freshness indicators* of Chapter I and in Point 1. of Part A. of Chapter II) and in Article 71 of Regulation (EU) 2019/627 and freshness criteria equivalent to those laid down in Council Regulation (EC) 2406/96 (not incorporated into the EEA Agreement) are incorporated in Icelandic law.⁹³ Article 10(1)(b) of Regulation (EU) 2017/625 also requires competent authorities to perform official controls on “*materials... which may influence the characteristics or health of...goods and their compliance with applicable requirements, at any stage of production, processing, distribution and use*” to the extent necessary to ascertain compliance with EEA food and feed law the rules and Part B. necessitates official controls at different stages of the supply chain.

Article 71 of Regulation (EU) 2019/627 (entitled “*Decisions after controls*”) states:

“*The competent authorities shall declare fishery products unfit for human consumption if:*

(a) official controls carried out in accordance with Article 70 reveal they are not in compliance with organoleptic, chemical, physical or microbiological requirements or requirements for parasites as established in Section VII of Annex III of Regulation (EC) No 853/2004 and/or Regulation (EC) No 2073/2005;...”.

4.1.5 Chemical checks of fitness for human consumption of unprocessed fishery products through analysis of TVB-N limits

Point 1. of Part A. of Chapter II of Annex VI to Regulation (EU) 2019/627 requires that competent authorities must in certain circumstances assess whether unprocessed fishery products (including raw materials used to produce fish oil) are fit for human consumption by carrying out chemical checks to analyse whether TVB-N values in those products exceed specified limits. It states:

“*CHAPTER II*

CONTROLS ON TOTAL VOLATILE BASIC NITROGEN (TVB-N)

A. TVB-N limit values for certain categories of fishery products and analysis methods to be used

1. Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:

(a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Part B of this Chapter;

(b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Part B of this Chapter;

(c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Part B of this Chapter;

⁹² Adaptation (c) at Point 11bk. of Part 1.1 of Chapter I and Point 31qk. of Chapter II of Annex I to the EEA Agreement.

⁹³ Article 7 of Icelandic Regulation No 104/2010:

“*Sensory evaluation properties of fish products.*

The freshness criteria for sensory evaluation research on legal products shall be in accordance with Annex A.”

(d) 60 mg of nitrogen/100 g of whole fishery product used directly for the preparation of fish oil for human consumption, as referred to in the second paragraph of point 1 of Chapter IV.B of Section VIII of Annex III to Regulation (EC) No 853/2004; however, where the raw material complies with points (a), (b) and (c) of the first paragraph of that point, Member States may set limits at a higher level for certain species pending the establishment of specific Union legislation...”.

5 The Authority’s assessment

The Authority assesses below:

- (i) whether Icelandic Regulation No 1081/2019 is consistent with the requirement of Parts B.1.(b) and B.3.; and
- (ii) the extent to which the Icelandic Government continues to fail to undertake the official controls listed in the Section 4 infringements.

Icelandic Regulation No 1081/2019

The Authority notes that Article 1 of Icelandic Regulation No 1081/2019,⁹⁴ insofar as it permits use of any fish and fish aquaculture products in all relevant types of fish oil production, is contrary to the Part B.1.(b) requirement, made part of the Icelandic legal order through Icelandic Regulation No. 104/2010, that raw materials used in all relevant types of fish oil production “*derive from fishery products which are fit for human consumption*”. In particular, and as the Ministry has previously recognised, EEA law provides that fish viscera “*may constitute a danger to public health*” and “*must be...kept apart from fishery products intended for human consumption.*”⁹⁵

Nothing in the Ministry’s letter dated 26 May 2021 responding to the Authority’s request for an explanation of how, and on what legal basis, Icelandic Regulation No 1081/2019 is consistent with the requirement of Parts B.1.(b) and B.3. detracts from this conclusion.

The Authority cannot agree with the Icelandic Government’s contention that “*relevant establishments and vessels may produce HC fish oil and NHC fish oil...with raw material using the guts, head, back bones and other bycatch, under the condition that the production meets the requirements that are stated in Regulation (EC) No 853/2004.*”

Regulation (EC) No 853/2004 requires all relevant types of fish oil production to comply with both Part B.1.(b) (raw materials to be derived from fishery product which are fit for human consumption) and Part B.2. (prescribed production process treatment steps), each being a separate and distinct legal requirement. In contrast, Article 1 of Icelandic Regulation No 1081/2019 expressly permits non-compliance of all relevant types of fish oil production with Part B.1.(b), provided that Part B.2. is adhered to (in the words of Article 1 of Icelandic Regulation No 1081/2019, “*provided that the treatment of the raw material meets food hygiene requirements*” (our emphasis)). It is not open to the Icelandic Government to adopt national legislation permitting such non-compliance, thereby enabling relevant FBOs to depart from the high level of consumer protection with regard to food safety which Regulation (EC) No 853/2004 seeks to establish.⁹⁶ The Authority

⁹⁴ Article 1 of Icelandic Regulation No 1081/2019 provides that:

“*The following paragraph shall be added to Article 7 of Regulation No 104/2010:*

For the production of fishmeal and fish oil intended for human consumption, fish and fish aquaculture products may be used, including: whole fish, cuts, viscera and other raw materials resulting from the treatment and processing of fish and aquaculture products, provided that the treatment of the raw material meets food hygiene requirements.”.

⁹⁵ Section 6. of Part II of Chapter I of Section VIII of Annex III to Regulation (EC) 853/2004. See the third paragraph of Section 3., page 2 of MAST’s letter dated 30 June 2017 and MAST’s decision letter dated 28 November 2014 (MAST reference 13070218/5.5.2, Doc No 882596) referred to therein.

⁹⁶ Recital (9) of Regulation (EC) No 853/2004 states:

further notes that if Article 1 of Icelandic Regulation No 1081/2019 were a correct interpretation of Part B.1.(b) then Part B.1.(b) would serve no purpose, given the requirement in all relevant types of fish oil production to comply with Part B.2.

Neither does the fact that a purpose of Icelandic Regulation No 1081/2019 is “*that both vessels and businesses on land could produce...HC fish oil...and as well...NHC fish oil*” alter its contravention of Parts B.1.(b) and B.3.. For the avoidance of doubt, Part B. applies to “*establishments, including vessels...*”.⁹⁷

The Section 4 infringements

Contrary to the Authority’s related finding in the Authority’s pre-Article 31 letter,⁹⁸ the Icelandic Government has confirmed that official upstream controls of requirements relating to raw materials (referenced in the Section 4(ii) infringement) are undertaken in relation to HC fish oil produced at sole HC fish oil producing establishments.⁹⁹

The Icelandic Government has acknowledged, either expressly¹⁰⁰ or implicitly¹⁰¹, all of the other Section 4 infringements in relation to all relevant types of fish oil production, as relevant. It has also conceded that where the Part B.3. requirement is not met, production and storage of HC and NHC fish oil in the same dual approved establishment is prohibited, irrespective of whether production of HC and NHC fish oil at that establishment is separated in time, with cleaning and disinfection/flushing of the system in the interval.¹⁰²

Notwithstanding Article 1 of Icelandic Regulation No 1081/2019 to the contrary, the Icelandic Government has recently informed prospective future dual approved establishments of the need to “*convert*” their approval licences into food processing licences on condition that (pursuant to Parts B.1.(b) and B.3.) all raw materials used to produce both NHC and HC fish oil at such establishments “*derive from fishery products which are fit for human consumption*”¹⁰³ (‘the food processing licence conversion process’).

The Icelandic Government has confirmed to the Authority that it has either undertaken, or plans to undertake (notwithstanding delays¹⁰⁴), the official controls referred to in:

- the Section 4(ii) and (iii) infringements concerning, respectively, official upstream controls relating to raw materials and official physical examination of

“*The principal objectives of the recasting are to secure a high level of consumer protection with regard to food safety, in particular by making food business operators throughout the Community subject to the same rules...*”

⁹⁷ Part B.1.(a) of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004.

⁹⁸ See footnote 22 of this letter of formal notice.

⁹⁹ See footnote 38 of this letter of formal notice.

¹⁰⁰ Concerning official physical examination of raw materials (under the Section 4(iii) infringement) and official upstream controls of requirements relating to raw materials (under the Section 4(ii) infringement) in relation to both HC and NHC fish oil produced at dual approved establishments, see footnote 35 of this letter of formal notice. Neither has the Icelandic Government expressed any disagreement with the Authority’s statement in the Annex to its letter dated 29 March 2021 that the Icelandic Government had committed these infringements. Concerning failure to undertake official physical examination of raw materials used to produce HC fish oil at sole HC fish producing establishments, see footnote 37 of this letter of formal notice.

¹⁰¹ Concerning official checks to ensure that both the raw materials and production process used to produce NHC fish oil at dual approved establishments comply with the requirements of Part B.1. and Part B.2., pursuant to Part B.3. (under the Section 4(i) infringement), the Ministry informed the Authority in the Ministry’s response to the pre-Article 31 letter that it would request MAST to review official controls in the light of the EEA official control requirements referred to in the Section 4(i) infringement (see footnote 31 of this letter of formal notice).

¹⁰² See footnotes 20 and 53 of this letter of formal notice.

¹⁰³ See the letter to Ísfélag Vestmannaeyja hf dated 12 May 2021 described on page 14 of this letter of formal notice and Section III.1., page 1 of MAST’s letter dated 21 May 2021.

¹⁰⁴ See the description of MAST’s letter dated 28 March 2022 on page 17 of this letter of formal notice.

raw materials in relation to HC fish oil produced at dual approved establishments,¹⁰⁵ and

- the Section 4(iii) infringement concerning official physical examination of raw materials in relation to HC fish oil produced at sole HC fish oil producing establishments.¹⁰⁶

Again, notwithstanding the provision of Article 1 of Icelandic Regulation No 1081/2019 to the contrary, the Icelandic Government has confirmed that such official controls will include verifying compliance with the Part B.1.(b) requirement.¹⁰⁷ The Authority will continue to monitor the situation to ensure that such official controls are undertaken in practice.

The Icelandic Government has, however, from an early stage in this case, both before and after acknowledging the Section 4 infringements and despite numerous specific requests from the Authority,¹⁰⁸ repeatedly failed to confirm in specific and unambiguous terms that it has undertaken, or plans to undertake, the official controls referred to in the Section 4 infringements concerning production of NHC fish oil at dual approved establishments in order to verify compliance with the Part B. requirements mentioned in those infringements ('the relevant official controls concerning NHC fish oil').¹⁰⁹ The Authority has, at the time of writing, received no information from the Icelandic Government enabling it to conclude with certainty that the relevant official controls concerning NHC fish oil have, or will be, undertaken. The Authority notes, in this connection, that merely informing relevant FBOs (during the food processing licensing conversion process or previously¹¹⁰) of their obligation to comply with specific Part B. requirements when producing NHC fish oil at dual approved establishments does not constitute, and is not a substitute for, undertaking on a regular basis¹¹¹ the relevant

¹⁰⁵ Section III.1., page 1 of MAST's letter dated 21 May 2021:

"If a fishmeal factory wants to produce fish oil for human consumption (HC fish oil), all of the raw material must fulfil the requirements of part B of chapter IV of section VIII of Annex III of regulation (EC) No 853/2004... The official control will cover control of the fishing vessels, landing of fish, control of raw material, transport to the establishments and control of raw material used for production of HC fish oil." (our emphasis)
 See further the citations at footnotes 69 and 70 of this letter of formal notice.

¹⁰⁶ First paragraph, Section III.2.(i), page 2 of MAST's letter dated 21 May 2021.

¹⁰⁷ See the mention of official controls in accordance with relevant requirements of Article 70 of Regulation (EU) 2019/627 in the references given in footnotes 105 and 106 of this letter of formal notice.

¹⁰⁸ The Authority has specifically requested the Icelandic Government to provide information on official controls undertaken to verify compliance of production of NHC fish oil at dual approved establishments with the Part B. requirements on at least six different occasions. See Section 2., page 1 and 2(ii) page 2 of the Authority's letter dated 1 December 2017, Section 1., page 2 and Section 1.(v)(b), page 4 of the Authority's letter dated 17 April 2018, the Authority's email dated 15 May 2019, Sections III.1.(i) and (ii), pages 2 to 4, III.2.(iii)(c), page 8 and III.3.(ii), page 8 of the Authority's letter dated 29 March 2021, the 2021 package meeting and the Authority's 2021 package meeting follow-up letter.

¹⁰⁹ Statements in the Icelandic Government's correspondence (including in response to specific requests for information on the relevant official controls concerning NHC fish oil) refer rather to corresponding controls for HC fish oil, official controls of NHC fish oil other than the relevant official controls concerning NHC fish oil or merely assessing the need for further official controls or requesting MAST to review its official controls in this area (as opposed to confirming that relevant official controls concerning NHC fish oil are, or will be, undertaken in practice). See especially Sections 1. and 2., pages 1 and 2 of MAST's letter dated 30 January 2018, Section 1., pages 1 and 2 of MAST's letter dated 27 June 2018, footnote 1 of MAST's letter dated 3 June 2019 and the description of that letter on pages 4 and 5 of this letter of formal notice, last paragraph of page 2 and the paragraph on pages 2 and 3 of the Ministry's response to the pre-Article 31 letter, Section 3(i) and (iv), pages 1 to 3, Section 4(i) on page 4 and Section 5.(iii) on page 6 of the Ministry's letter dated 3 November 2020, MAST's letter dated 21 May 2021 (see the description at footnote 74 of this letter of formal notice), Section 1. of the Ministry's letter dated 30 August 2021 and MAST's letter dated 28 March 2022 (see descriptions of each of the last two mentioned letters on pages 16 and 17 of this letter of formal notice).

¹¹⁰ See footnote 39 of this letter of formal notice.

¹¹¹ Article 9(1) of Regulation (EU) 2017/625 provides that "*competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency*". (our emphasis)
 Article 67 under Title VI of Regulation (EU) 2019/627 (entitled "*Specific requirements and uniform minimum frequency of official controls with respect to fishery products*") (our emphasis) requires that:

official controls concerning NHC fish oil in order to ensure compliance with the Part B. requirements in practice. Whilst MAST has informed the Authority that an audit of relevant establishments will be undertaken as part of the food processing licence conversion process,¹¹² it is not clear to the Authority, in the light of correspondence to date, that this will include the relevant official controls of NHC fish oil.¹¹³

6 Conclusion

Accordingly, on the basis of the above assessment and as its information presently stands, the Authority must conclude that Iceland has:

1. by adopting and maintaining in force Icelandic Regulation No 1081/2019 permitting the use of any fish or aquaculture products in the production of HC fish oil or NHC fish meal, failed to fulfil its obligation to correctly implement the requirement at Part B.1.(b) of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004 that both raw materials used in the preparation of HC fish oil (whether at dual approved or sole HC fish oil producing establishments) or, pursuant to Part B.3. of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004, used in the preparation of NHC fish meal at dual approved establishments must derive from raw materials fit for human consumption; and
2. failed to undertake the relevant official controls required under Article 14 of Regulation (EU) 2017/625 and under Articles 67 and 70 and Chapter I and Point 1. of Part A. of Chapter II of Annex VI to Regulation (EU) 2019/627 in relation to production of NHC fish oil or meal at dual approved establishments to ensure that:
 - (i) both the raw materials and production process used comply with the requirements of Parts B.1. and Part B.2. of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004, pursuant to Part B.3. of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004;
 - (ii) requirements relating to raw materials used, pursuant to Parts B.1. and B.3. of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004, are met by the upstream supply chain prior to arrival of such materials at such establishments; and
 - (iii) raw materials used are subject to official physical examination (including organoleptic examination, random testing, sampling and chemical checks) in order to ensure, pursuant to Parts B.1.(b) and B.3. of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004, their fitness for human consumption.

“Official controls on the production and placing on the market of fishery products shall include verification of compliance with the requirements set out in Section VIII of Annex III to Regulation (EC) No 853/2004, in particular:

- (a) *a regular check on the hygiene conditions of landing and first sale;*
- (b) *regular inspections of vessels and establishments on land, including fish auctions and wholesale markets, in particular to check:*
 - (i) *whether the conditions for approval are still fulfilled;*
 - (ii) *whether the fishery products are handled correctly;*
 - (iii) *compliance with hygiene and temperature requirements;*
 - (iv) *the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene;...*

(c) *checks on storage and transport conditions.”* (our emphasis).

¹¹² See Section III.1., page 1 of MAST’s letter dated 21 May 2021:

“Before issuing the approval, MAST will verify with an audit if all the relevant requirements of the hygiene regulations are fulfilled.”

¹¹³ See footnote 109 of this letter of formal notice.

In these circumstances, and acting under Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, the Authority requests that the Icelandic Government submits its observations on the content of this letter of formal notice *within two months* of its receipt.

After the time limit has expired, the Authority will consider, in the light of any observations received from the Icelandic Government, whether to deliver a reasoned opinion in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice.

Done at Brussels,

For the EFTA Surveillance Authority

Arne Røksund
President

Stefan Barriga
College Member

Árni Páll Árnason
Responsible College Member

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This document has been electronically authenticated by Arne Roeksund, Mel-po-Menie Josephides.