EXPLANATORY MEMORANDUM TO

THE NOVEL FOODS REGULATIONS (NORTHERN IRELAND) 2017

SR no – 233

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency in Northern Ireland to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under Articles 15(1)(a), (e) and (f), 16(2), 17(1)(a), 25(1)(a) and (3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991.

1.3 The rule is due to come into operation on 1st January 2018.

2. Purpose of the Rule

2.1 This Rule will revoke and replace the Novel Foods and Novel Food Ingredients Regulations (Northern Ireland) 2004 (S.R. 2004 No.33) and The Food Enzymes Regulations (Northern Ireland) 2009 (S.R. 2009 No.415). The proposed Regulations will enable the execution and enforcement in Northern Ireland of the Novel Food Regulation (EU) 2015/2283 (which amends Regulation (EU) No 1169/2011 and repeals Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001). The regulations also introduce a more proportionate enforcement regime, introducing the use of Improvement Notices for non-compliance.

3. Background

3.1 Following a review, EU legislation on novel foods has been replaced by a new directly applicable EU regulation which comes into effect on 1 January 2018. Domestic regulations are required to provide powers to enforce the new EU regulation in Northern Ireland from that date. Until EU exit we are required to implement EU law and provide for its enforcement. These legislative changes will establish the regulatory framework for novel foods which will be repatriated into UK law on EU exit.

3.2 Novel foods are foods that do not have a significant history of consumption in the EU before May 1997. Under EU law, they must be shown to be safe by means of a scientific assessment, and be authorised, before they can be placed on the market.

3.3 The new Novel Food Regulation (EU) No 2015/2283 provides revised legislative requirements for placing novel foods on the market. The EU

requirements have been updated in line with technical and scientific progress and introduce:

- an updated definition of what constitutes a 'Novel food';
- a clear duty on operators to verify whether the food they intend to place on the market falls within the scope of the legislation. If unsure a food business operator should consult the Member State in which they first intend to market the product providing all necessary information to enable a determination of the novel food status to be made;
- a Union list of authorised novel foods, including any conditions of use that may apply;
- a consistent, time-limited and streamlined authorisation process for food businesses;
- centralised risk assessments to be carried out by the European Food Safety Authority;
- generic authorisations that will enable all operators to benefit from an authorisation unless any proprietary data protection provisions apply; this removes the need to demonstrate substantial equivalence with an already authorised novel food;
- a simpler notification procedure for traditional foods consumed to a significant degree in third countries but not in the EU prior to 1997, facilitating free trade; and
- a 5-year period (from the date of authorisation) of intellectual property protection for scientific evidence and data produced in support of applications.

3.4 The new NI regulations will revoke the Novel Foods and Novel Food Ingredients Regulations (NI) 2004 and the Food Enzymes Regulations (NI) 2009.

4. Matters of Special Interest to the Health Committee

N/A

5. Consultation

5.1 A consultation was conducted from 4 April to 27 June seeking comments on the draft SR. No responses were received to the consultation in Northern Ireland.

6. Position in Great Britain

6.1 Separate legislation is being made in England, Scotland and Wales within the EU deadline on the same timetable as Northern Ireland.

7. Equality Impact

7.1 These regulations will apply in equal measure to all Section 75 groups. It is not expected that any of these changes will impact differentially across any of the section 75 groups.

8. Regulatory Impact

8.1 A UK Regulatory Impact Assessment was prepared and accompanied the consultation, which identified sectors affected, benefits and costs of the options.

9. Financial Implications

9.1 N/A

10. Section 24 of the Northern Ireland Act 1998

10.1 These regulations will apply in equal measure to all groups. It is not expected that any of these changes will impact differentially across any as determined by Section 24.

11 EU Implications

11.1 N/A