STATUTORY INSTRUMENTS

2019 No. 702

The Novel Food (Amendment) (EU Exit) Regulations 2019

PART 3

Amendment of retained direct EU legislation

Amendment of Regulation 2015/2283

17. For Article 11, substitute—

"Opinion of the Food Safety Authority

- 1. Where the appropriate authority requests an opinion from the Food Safety Authority, it must forward the valid application to the Food Safety Authority without delay, and not later than one month after having verified its validity. The Food Safety Authority must adopt its opinion within nine months from the date of receipt of a valid application.
- **2.** In assessing the safety of novel foods, the Food Safety Authority must, where appropriate, consider whether—
 - (a) the novel food concerned is as safe as food from a comparable food category already placed on the market within the United Kingdom;
 - (b) the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the United Kingdom;
 - (c) a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.
- **3.** The Food Safety Authority must forward its opinion to the appropriate authority and, where applicable, to the applicant.
- **4.** In duly justified cases, where the Food Safety Authority requests additional information from the applicant, the nine month period provided for in paragraph 1 may be extended. After consulting the applicant, the Food Safety Authority must specify a period within which that additional information is to be provided.
- **5.** Where the additional information referred to in paragraph 4 is not provided to the Food Safety Authority within the additional period referred to in that paragraph, the Food Safety Authority must draw up its opinion on the basis of the available information.
- **6.** Where an applicant submits additional information on its own initiative, it must send that information to the Food Safety Authority. In such cases, the Food Safety Authority must give its opinion within the nine month period provided for in paragraph 1.
- 7. The Food Safety Authority must make the additional information provided in accordance with paragraphs 4 and 6 available to the appropriate authority.".