
DRAFT STATUTORY INSTRUMENTS

2019 No.

**The Materials and Articles in Contact with
Food (Amendment) (EU Exit) Regulations 2019**

PART 3

Amendment of retained direct EU legislation

Amendment of Regulation 1935/2004

20. In Article 11—

(a) in the heading, omit “Community”;

(b) for paragraph 1, substitute—

“1. The authorisation of a substance must be prescribed by the appropriate authority and may contain such restrictions or conditions as the appropriate authority may specify in light of the opinion of the Food Safety Authority.”;

(c) for paragraph 2, substitute—

“2. In determining whether to authorise a substance, and what restrictions or conditions, if any, to specify, the appropriate authority must take account of relevant provisions of retained EU law and other legitimate factors relevant to the matter under consideration. Where the determination is not in accordance with the opinion of the Food Safety Authority, the appropriate authority must provide without delay an explanation of the reasons for the differences. If the appropriate authority does not intend to authorise a substance after a favourable opinion by the Food Safety Authority, it must inform the applicant without delay and provide the applicant with an explanation.”;

(d) omit paragraph 3;

(e) for paragraph 4, substitute—

“4. After the authorisation of a substance in accordance with this Regulation, any business operator using the authorised substance or materials or articles containing the authorised substance must comply with any condition or restriction attached to such authorisation.”;

(f) for paragraphs 5, substitute—

“5. The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance must immediately inform the Food Safety Authority of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Food Safety Authority must then review the assessment.”;

(g) omit paragraph 6.