

**EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION
WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND
WINDSOR FRAMEWORK**

C(2023)6632:

COMMISSION REGULATION (EU) / amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards food additives nitrites (E 249-250) and nitrates (E 251-252)

Submitted by Food Standards Agency December 2023

SUBJECT MATTER

Nitrates and Nitrites (E 249 – E 252) are used in certain cheeses and processed meats such as bacon, ham, corned beef and other cured meats to perform a range of technological functions including as a preservative / to inhibit microbial growth, in particular *Clostridium botulinum*. Nitrites and nitrates have been linked with the formation of nitrosamines, which have been linked with colorectal cancer.

Over the last number of years there have been many studies conducted on the safety of nitrites and nitrates, including EFSA's (The European Food Safety Authority) re-evaluation of the safety of nitrites and nitrates as food additives in 2017, which concluded nitrites and nitrates intentionally added at permitted levels to meat and other foods were safe. In 2023, a further EFSA scientific opinion was published on the risks to public health related to the presence of nitrosamines. Following this, the European Commission has now concluded it is appropriate to amend the current conditions of use of nitrites and nitrates as food additives and lower the existing maximum limits for the presence of lead, mercury and arsenic in nitrites (E 249 and E 250) and nitrates (E 251 and E 252), laid down in the Union specifications.

The new regulation includes both changes to the specifications of the four additives (E 249 – E 252) in Regulation 231/2012 which come into force on the 29th April 2024, setting new purity criteria in regards lead, arsenic and mercury; as well as changes to the additive provisions in Annex II of Regulation 1333/2008, which reduce the levels of these additives that can be used in various food commodities, such as cured meats, cheeses and processed fish/fishery products. These changes have transition periods ranging from 9th October 2025 (24 months), 9th October 2026 (36 months) to 9th October 2027 (48 months). In all cases food can be placed on the market up until the end of the transition period and can then remain on the market, until they reach the end of their durability.

The Food Standards Agency (FSA) considers that existing levels of nitrites and nitrates, as laid down in retained Regulation 1333/2008 and retained Regulation 231/2012, are sufficiently protective for consumers. However, as for all food additives this position will be kept under review and as such, four-nation discussions will continue to assess whether similar regulatory changes may be adopted in GB. Any

future proposals will be subject to public consultation. Once a policy position has been agreed between the four nations, the FSA will provide an update to the Committee.

SCRUTINY HISTORY

No relevant recent scrutiny history.

MINISTERIAL RESPONSIBILITY

The Secretary of State for Health and Social Care has responsibility for this area of food law in England.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

This is a devolved area of policy. The responsible Government department is the Food Standards Agency in England, Northern Ireland and Wales, and Food Standards Scotland (FSS) in Scotland. This area sits within scope of the Food and Feed Safety and Hygiene provisional Common Framework. FSA colleagues in Northern Ireland and Wales, and FSS colleagues in Scotland, have been consulted in the preparation of this explanatory memorandum (EM) and confirm there is expected to be no significant impact on the trading relationship between Great Britain and Northern Ireland.

Scottish Government Ministers, Welsh Government Ministers and Northern Ireland Executive Ministers/Permanent Secretaries have an interest in food and feed safety and hygiene law. The devolved administrations have been consulted in the preparation of this EM. They confirm that there is expected to be no impact on the trading relationship between Great Britain and Northern Ireland.

LEGAL AND PROCEDURAL ISSUES

i. Legal Base

COMMISSION REGULATION (EU) / amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards food additives nitrites (E 249-250) and nitrates (E 251-252)

ii. Voting procedure

Qualified majority voting.

iii. Timetable for adoption and implementation

Commission Regulation (EU) 2023/2108 was adopted by the Commission on 6 October 2023, published in the Official Journal of the European Union on 9th October and will come into force twenty days later on 29 October 2023.

iv.

Foods that were lawfully placed on the EU and Northern Ireland market before the end of the various transition periods detailed in the measure (these range from 24 months to 48 months after the regulation comes into force), may remain on the market until their date of minimum durability or use-by date.

POLICY AND LEGAL IMPLICATIONS

These measures will apply directly in Northern Ireland, under the terms of the Windsor Framework. Businesses in Northern Ireland producing ham, bacon and other cured meats and cheeses where their production uses nitrites or nitrates will have a substantial amount of time to apply any necessary changes, and business impact will depend on the extent to which they need to reformulate their products. The FSA is engaging with stakeholders across the UK, but especially in Northern Ireland to better understand these impacts and provide support. This engagement is informing policy considerations for GB.

However, since 1 October 2023, pre-packed retail goods, moved from GB to Northern Ireland via the new Northern Ireland retail movement scheme (NIRMS) and intended for the final consumer in Northern Ireland, can meet GB standards in public health, marketing (including labelling) and organics.

GB standards means the public health and consumer protection standards as set out in legislation that applies in England, Wales and Scotland. Therefore, pre-packed agri-food goods containing GB-authorized additives may be moved from GB-NI under the Northern Ireland Retail Movement Scheme, for supply to Northern Ireland consumers.

In line with the Government's commitment to ensuring Northern Ireland traders have unfettered access to the rest of the UK internal market, these measures will in no way impede the movement of qualifying Northern Ireland goods from Northern Ireland to Great Britain. Such qualifying Northern Ireland goods will also continue to benefit from the market access principles set out in the United Kingdom Internal Market Act 2020. Accordingly, so long as those goods meet Northern Ireland standards, they can be sold anywhere in the UK internal market.

As such, these changes will not impede the movement of relevant goods from Great Britain to Northern Ireland, or from Northern Ireland to Great Britain.

CONSULTATION

No formal public consultation has taken place. The FSA have conducted a review of the new EU additive provisions, comparing with those in retained legislation (1333/2008) to identify the scope of the EU changes, as well as seeking views from limited key stakeholders on the practicalities of reformulation to ensure compliance by the respective transition periods.

However, as above, the FSA is engaging with stakeholders in the United Kingdom to both better understand the impact and support them through any required changes.

FINANCIAL IMPLICATIONS

Due to the long-term nature of the transition periods, whilst business may need to reformulate to meet the new EU requirements, we are not aware of any significant immediate financial implications. As above, we will work with industry to signpost and support them through any such changes.

MINISTERIAL NAME AND SIGNATURE



Min Rt Hon Dame Andrea Leadsom

Parliamentary Under Secretary of State

Department of Health and Social Care