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Conventional smoking processes

06/11/2024

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Conventional smoking processes

Details of the Deep Dive

Topic: NA
Thematic area(s): Chemical contaminants, Food ingredients and packaging
Keyword(s):

- Conventional smoking techniques
  Generic keywords:
    Smoked food products (including meat and meat products, fish and fisheries products, cheese and dairy products, smoked spices and salt).
  Technical keywords:
    Polycyclic aromatic hydrocarbons
    Styrene
    Benzofuran
    Furan-2(5H)-one
    Benzene-1,2-diol (catechol)
- Smoke flavourings

Query: (smoke OR smoking OR smoked) AND (meat OR fish OR cheese OR dairy OR spice OR salt OR food) AND (flavour OR flavouring OR additive OR preservative OR stocking OR stoked OR conventional)
Timeframe: 2023-present

A. Deep dive general introduction

In response to recent risk management discussions, EFSA has been assigned the responsibility of providing a comprehensive scientific opinion on the safety of smoked meat, smoked meat products, smoked fish and fishery products, and smoked cheese. The focus will be on products that are produced through the conventional smoking process as compared to the use of smoke flavouring. EFSA's previous evaluations, which raised genotoxicity and safety concerns regarding eight smoke flavouring primary products, prompted risk managers to evaluate the viability and safety of conventional smoking as an alternative to these flavourings.

The objective of this deep dive is to offer a thorough comprehension of the positions and concerns of EFSA's partners and stakeholders regarding the use of the conventional smoking process as compared to the use of smoke flavouring.

B. Distilled information

B.1 Articles that mainly concern the conventional smoking sector

Temperature control and food safety: Several articles emphasise the significance of preserving the cold chain during the transport, storage, and processing of smoked products to prevent the growth of bacteria. The Ministry for Primary Industries and World Health Organisation (WHO) illustrate the necessity of consistent temperature regulation to guarantee product safety by illustrating a recent instance in which cold chain disruption resulted in consumer-level recalls of smoked meats and fish in France (1) (2). In addition to this, the Ministry provides a detailed explanation of hot smoking practices and the application of the "2-hour/4-hour" rule for temperature control. It explains that smoking can be securely conducted within the danger zone if these guidelines are followed (3) (4). The ministry delineates the safety requirements for both hot and cold smoking. It emphasises that products that are smoked exclusively for flavour necessitate the management of time in the danger zone, but not formal validation. This underscores the practical considerations that food businesses must make when managing pathogen control (5).

Chemical contaminants and health risks associated with smoked foods: Focusing on the production of polycyclic aromatic hydrocarbons (PAHs) and nitrosamines, which are carcinogenic and are the result of high-temperature processes like frying, barbecuing, and smoking. The Norwegian Scientific Committee for Food Safety and Environment and Finnish Food Authority examines the most recent discoveries of the European Food Safety Authority concerning the population's exposure to nitrosamines, which are a cause for interest due to their

genotoxicity and carcinogenicity. The article also explores PAH contamination, where it is noted that smoked foods, like other high-temperature processed foods, frequently contain PAHs, which pose long-term health risks. The theme is further elaborated upon by references to testing methodologies for PAHs, as precise quantification is crucial for regulatory compliance and consumer protection. This is demonstrated by previous interlaboratory studies that addressed analytical accuracy (6) (7) (8) (9) (10).

Preservation of traditional smoking practices: Food and Agriculture Organization of the United Nations (FAO) investigates the regulatory exemptions that are granted to traditionally smoked meats and fish in order to prevent the closure of small and medium-sized enterprises in specific EU Member States. These exemptions allow for higher PAH levels. This text underscores the conflict between the preservation of the distinctive sensory attributes of these foods, which are a critical component of their market appeal, and the adherence to contemporary health standards. The objective of this regulatory flexibility is to encourage the production of traditional foods while simultaneously mandating that producers monitor PAH levels and adhere to safe smoking practices whenever practicable. These texts collectively offer a comprehensive perspective on the intricate regulatory landscape and safety challenges in the conventional smoking and smoke flavouring sectors. They involve a variety of stakeholders, including traditional producers and regulatory authorities, who are all striving to balance health risks with product quality and cultural preservation (11).

Regulatory: Regulation (EC) No 1333/2008 categorises smoked meat and fish products, defining the permissible amounts of food additives, particularly nitrites and nitrates, that are necessary in traditional smoking methods to preserve the safety of the product and extend its shelf life. This regulatory approach recognises the distinctive requirements of traditionally smoked products by allowing the use of specific additives within controlled limits. This enables producers to maintain traditional methods without compromising safety standards. It is important to note that producers are encouraged to implement appropriate smoking practices in order to reduce the levels of polycyclic aromatic hydrocarbons in traditionally smoked meats and fish, which may contain higher levels of PAHs as a result of the nature of these processes (12). The U.S. Environmental Protection Agency (EPA) in particular, are instrumental in the enforcement of effluent limitations that address biochemical oxygen demand (BOD), total suspended solids (TSS), and specific contaminants associated with conventional smoking procedures. These standards not only ensure that food safety is maintained by restricting the presence of potential carcinogenic and genotoxic substances in effluents, but also assist facilities in the implementation of best practices to minimise environmental impact (13).

B.2 Articles that mainly concern the smoke flavouring sector

Registered Stakeholders: The European Flavour Association (EFFA) has responded to recent EU amendments that have removed several Smoke Flavouring Primary Products (SFPPs) from the authorised list, emphasising the importance of regulatory compliance and industry adaptation. This change has an impact on food categories such as meat, fish, and cheese, and requires industry adaptation to be implemented over a period of time (14). The advocacy for New Approach Methodologies (NAMs) in risk assessments for flavourings, including smoke flavourings, is a reflection of a push from scientific stakeholders for EFSA to incorporate alternative testing methods that reduce reliance on animal studies, in addition to regulatory concerns. This underscores the significance of integrating innovation into safety evaluations (15). In addition, the European Food and Fermentation Cultures Association (EFFCA) promotes consumer transparency and labelling. The organisation suggests that clear labelling practices be implemented to inform consumers about fermentation-related processes without imposing undue regulatory burdens. This consideration is also pertinent to the labelling of smoke-flavoured products (16). Finally, methodological critiques of health risk assessments in processed foods, including ultra-processed foods (UPFs), emphasise the limitations of observational studies in establishing causative links between processing methods and health outcomes. This underscores the necessity of more rigorous assessment frameworks to mitigate confounding factors and reverse causality (17).
Guidelines have been established by Food Supplements Europe, which state that importers and manufacturers of smoke flavouring products are required to comply with EU regulations regarding safety, quality, and labelling. This includes ensuring that any animal-origin components contained in smoke flavourings meet rigorous hygiene standards. In order to mitigate health risks, it is necessary to comply with these regulations by employing approved establishments, obtaining appropriate certification, and adhering to EU directives that regulate products of animal origin. Regulatory bodies are instrumental in the supervision of these standards, providing manufacturers and importers with guidance on how to comply with legal obligations in order to safeguard public health (18).

Regulatory requirements and safety assessments: The Food Safety Authority of Ireland (FSAI) mandates that all smoke flavourings receive EFSA approval before market entry. Following a review, EFSA raised genotoxicity concerns for eight primary smoke flavourings (SF-001 to SF-009), leading to their removal from the Union list and the introduction of a transitional period, as per Regulation (EU) 2024/2067, allowing continued sales until set use-by dates to aid industry adaptation. Affected stakeholders are responsible for navigating this transition and sourcing alternatives. Additionally, FSAI emphasizes the need for adherence to quality and labelling standards under Regulations (EU) No 1169/2011 and (EC) No 2065/2003, specifying that only approved smoke flavourings should be labelled as such, while products imitating smoky Flavors should use the general term "flavourings" to prevent consumer misrepresentation and ensure transparency (19) (20) (21).
Austrian Agency for Health and Food Safety (AGES) explains the controlled production process of smoke flavourings, which involves burning wood to create primary smoke condensates and tar fractions, monitored for PAH levels to ensure safety (22). Building on this, the Food Standards Agency details the criteria for product authorization, such as purity standards and specific food applications, reinforcing the regulatory obligations for smoke flavouring manufacturers (23). The United States Department of Agriculture (USDA) emphasizes transparency in consumer labelling, requiring that products be clearly labelled as “natural smoke flavouring” rather than a more general “natural flavour,” a guideline aimed at informing consumers while supporting accurate labelling practices (24). Safety assessments are highlighted by the Ministry of Agriculture of the Czech Republic and the PAFF Committees, which discuss EFSA’s decision to withhold authorization for Prosmoke BW 01 based on its genotoxicity potential, signalling EFSA's caution with products that exceed safety thresholds (25) (26). PAFF Committees references also the Regulation (EU) No 1321/2013, which sets out the authorized list of smoke flavouring products and prescribes purity and usage conditions, providing a standardized regulatory foundation (27). Lastly, The Organisation for Economic Co-operation and Development (OECD) touches on data protection, where Article 16 of Regulation (EC) No 2065/2003 ensures that proprietary data from original applicants is protected, thus maintaining an incentive for innovation in compliance (28) (29).

B.3 Articles that concern both conventional smoking and smoke flavouring sectors

Food and Agriculture Organization of the United Nations references Codex standards for smoked fish and smoke-flavoured fish, which establish guidelines on allowable acidity regulators and preservatives. This demonstrates the compliance responsibilities of producers in accordance with international food safety benchmarks (30). Food Safety Authority of Ireland investigates the carcinogenic risks associated with processed meats, particularly with compounds such as nitrites and PAHs, which are associated with colorectal and potentially stomach cancer. This reinforces concerns regarding the health effects of both smoked and processed meats (31).
The Ministry for Primary Industries has established microbiological safety standards for ready-to-eat smoked and smoke-flavoured fish. These standards include a minimum salt content of 3.4% and stringent bacterial contamination thresholds, such as aerobic plate count limits and non-detection requirements for Listeria monocytogenes, which are essential for ensuring food safety in both the EU and international markets (32) (33). In the guidance, is underscored the importance of operational safety and quality control in seafood processing facilities, providing a comprehensive overview of the hygiene, handling, and contamination management protocols that are unique to fish smoking practices. This guidance emphasises the necessity of rigorous adherence to both domestic and export standards in the aquaculture industry (34). On the other hand, the Ministry elaborates on these regulatory requirements by addressing the preparation and storage of smoked fish, as well as the use of additives such as smoke flavourings. This document elucidates that smoke flavourings are subject to distinct regulations from conventional smoking, with distinct compliance requirements for flavour purity and labelling to guarantee consumer transparency (35).

C. Monitoring timelines

The time period covered by the following deepening is from 1 January 2023 to 30 October 2024.

D. Key actors and roles

Organization	Tag	Sector	Reference to paragraph and subsection
Austrian Agency for Health and Food Safety	EU Member State Organisation	smoke flavouring	See section B2: Regulatory requirements and safety assessments

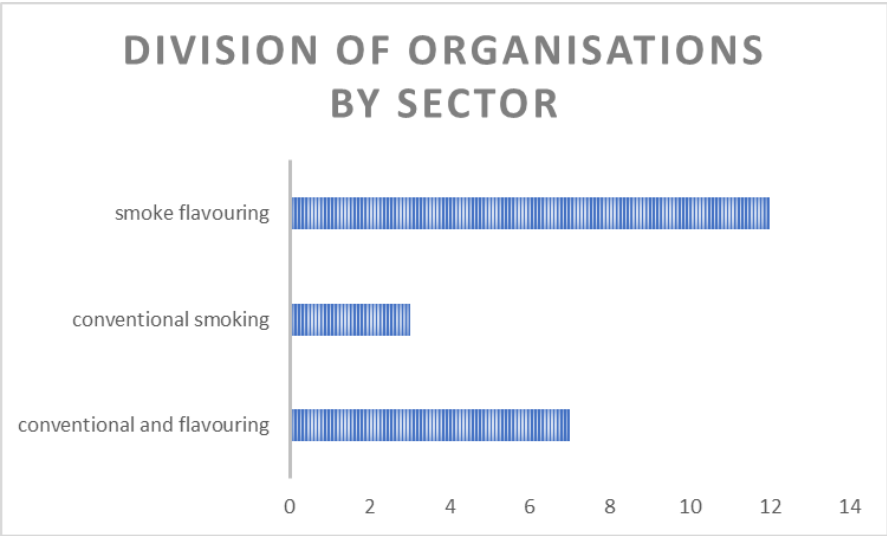
European Flavour Association	Registered stakeholders	smoke flavouring	See section B2: Registered Stakeholders
European Food & Feed Cultures Association	Registered stakeholders	smoke flavouring	See section B2: Registered Stakeholders
Federation of European Specialty Food Ingredients Industries	Registered stakeholders	smoke flavouring	See section B2: Registered Stakeholders
Finnish Food Authority	EU Member State Organisation	conventional and flavouring	See section B1: Chemical contaminants and health risks associated with smoked foods
Food and Agriculture Organization of the United Nations	International Organisation	conventional and flavouring	See section B1: Preservation of traditional smoking practices and section B3
Food Safety Authority of Ireland	EU Member State Organisation	conventional and flavouring	See section B1: Chemical contaminants and health risks associated with smoked foods and section B2: Regulatory requirements and safety assessments and section B3
Food Standards Agency	Non-EU Organisation	smoke flavouring	See section B2: Regulatory requirements and safety assessments
Food Supplements Europe	Registered stakeholders	smoke flavouring	See section B2: Registered Stakeholders
FoodDrinkEurope	Registered stakeholders	smoke flavouring	See section B2: Registered Stakeholders
Health Canada	Non-EU Organisation	smoke flavouring	See section B2: Regulatory requirements and safety assessments
United States Agency for International Development	Non-EU Organisation	conventional smoking	See section B1: Chemical contaminants and health risks associated with smoked foods
United States Department of Agriculture	Non-EU Organisation	smoke flavouring	See section B2: Regulatory requirements and safety assessments
World Health Organisation	International Organisation	conventional and flavouring	See section B1: Temperature control and food safety
Ministry for Primary Industries	Non-EU Organisation	conventional and flavouring	See section B1: Temperature control and food safety and section B3
Ministry of Agriculture of the Czech Republic	EU Member State Organisation	smoke flavouring	See section B2: Regulatory requirements and safety assessments
Norwegian Scientific Committee for Food Safety and Environment	Non-EU Organisation	conventional smoking	See section B1: Chemical contaminants and health risks associated with smoked foods
PAFF committees	EU institution	conventional and flavouring	See section B1: Regulatory and section B2: Regulatory requirements and safety assessments
Saudi Food and Drug Authority	Non-EU Organisation	conventional and flavouring	See section B1: Chemical contaminants and health risks associated with smoked foods
The Organisation for Economic Co-operation and Development	International Organisation	smoke flavouring	See section B2: Regulatory requirements and safety assessments
The United States Environmental Protection Agency	Non-EU Organisation	conventional smoking	See section B1: Regulatory

E. Key insights and recommendations

The following key insights and recommendations are the result of an in-depth investigation of regulatory standards, safety assessments, and stakeholder perspectives in the conventional smoking and smoke flavouring sectors. They are aimed at guiding EFSA and associated stakeholders, including regulatory authorities, food producers, and industry representatives, in addressing safety, compliance, and transparency concerns while balancing cultural preservation with public health objectives.

- **Temperature control and food safety**: Provide tailored support to smaller producers who are responsible for managing pathogen control requirements, ensuring that smoking processes are equipped with robust cold chain and time control measures to prevent bacterial growth.
- **Chemical contaminants and health risks**: Prioritise the monitoring and testing of PAHs and nitrosamines in smoked foods, utilising precise methodologies to comply with safety regulations and mitigate long-term health risks.
- **Preservation of traditional smoking practices**: Through extensive surveillance of PAHs, ensure that regulatory exemptions for traditional smoked products are maintained, thereby harmonising health standards with cultural heritage.
- **Regulatory framework**: Encourage the implementation of practices that reduce PAHs, despite the higher levels of PAHs that are inherently present in conventional smoking, by promoting adherence to additive limits in traditionally smoked products.
- **Compliance and adaptation in smoke flavouring**: Encourage the use of NAMs for safety assessments to support industry adaptation to recent EU smoke flavouring restrictions.
- **Consumer transparency and labelling**: Implement explicit guidelines that differentiate flavourings from conventionally smoked products to prevent consumer confusion in the labelling of smoke-flavoured products.
- **Cross-sectoral engagement**: Enable stakeholder engagement across both sectors, with a focus on shared safety and regulatory objectives to safeguard consumer health and ensure industry adherence to the most recent standards.

F. Document analytics



Based on the analysis carried out and the relevance of the articles reported, most organisations only talk about smoke flavouring, and only a few address the topic of conventional smoking.

On the other hand, it can be observed from the table in section D, that all registered stakeholders speak exclusively of smoke flavouring and that they all belong to the sub-category "*Business and food industry*".

G. Concise summary

In response to safety concerns regarding genotoxicity in eight smoke flavouring products, the European Food Safety Authority has been assigned the responsibility of evaluating the safety of smoked food produced through conventional smoking processes as a potential alternative to smoke flavouring primary products. The objective of this evaluation is to collect perspectives from stakeholders in both the traditional smoking and smoke flavouring sectors, with an emphasis on consumer transparency, regulatory compliance, and safety.

Regulatory authorities, such as the Food Safety Authority of Ireland (FSAI), highlight the need for stringent monitoring of carcinogenic compounds like PAHs and nitrosamines to ensure compliance and consumer safety. Industry representatives and traditional producers underscore the importance of maintaining exemptions for traditional smoking practices under close PAH surveillance in order to balance cultural preservation with modern health standards. Scientific organisations promote the implementation of New Approach Methodologies (NAMs) to improve safety assessments and decrease dependence on conventional animal testing. Small producers, particularly those in the conventional smoking sector, stress the importance of tailored support for maintaining cold chain integrity and pathogen control during smoking processes.

Meanwhile, compliance experts and consumer advocacy groups underline the necessity of unambiguous labelling guidelines to differentiate between conventionally smoked and smoke-flavoured products, reducing consumer confusion and promoting transparency. Recent findings suggest that the majority of registered stakeholders provide insights focused on the smoke flavouring sector, particularly from the "Business and Food Industry" category, with fewer contributions addressing the conventional smoking sector. This highlights the importance of broadening stakeholder engagement to ensure balanced representation in EFSA's assessments.

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