

| Basic information | |
|---|---------------------|
| 2002/0163(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation | Procedure completed |
| Food safety: smoke flavourings used on foods, authorisation procedure (Directive 88/388/EEC, Regulation (EC) No 178/2002) Amended by 2018/0088(COD) Subject 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety | |

| Key players | | | | |
|-------------------------------|---|--|---|------------------|
| European Parliament | Committee responsible | | Rapporteur | Appointed |
| | ENVI Environment, Public Health, Consumer Policy | | MALLIORI Minerva Melpomeni (PSE) | 02/10/2002 |
| | Committee for opinion | | Rapporteur for opinion | Appointed |
| | JURI Legal Affairs and Internal Market | | The committee decided not to give an opinion. | |
| | ITRE Industry, External Trade, Research, Energy | | The committee decided not to give an opinion. | |
| | | | | |
| Council of the European Union | Council configuration | | Meetings | Date |
| | Transport, Telecommunications and Energy | | 2531 | 2003-10-09 |
| European Commission | Commission DG | | Commissioner | |
| | Health and Food Safety | | | |

| Key events | | | |
|------------|---|--|---------|
| Date | Event | Reference | Summary |
| 15/07/2002 | Legislative proposal published | COM(2002)0400  | Summary |
| 02/09/2002 | Committee referral announced in Parliament, 1st reading | | |
| | | | |

| | | | |
|------------|---|--|-------------------------|
| 23/04/2003 | Vote in committee, 1st reading | | Summary |
| 23/04/2003 | Committee report tabled for plenary, 1st reading | A5-0122/2003 | |
| 05/06/2003 | Decision by Parliament, 1st reading | T5-0255/2003 | Summary |
| 04/07/2003 | Modified legislative proposal published | COM(2003)0407  | Summary |
| 09/10/2003 | Act adopted by Council after Parliament's 1st reading | | |
| 10/11/2003 | Final act signed | | |
| 10/11/2003 | End of procedure in Parliament | | |
| 26/11/2003 | Final act published in Official Journal | | |

| Technical information | |
|-----------------------------------|--|
| Procedure reference | 2002/0163(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Legislation |
| Legislative instrument | Regulation |
| Amendments and repeals | Amended by 2018/0088(COD) |
| Legal basis | EC Treaty (after Amsterdam) EC 095 |
| Stage reached in procedure | Procedure completed |

| Documentation gateway | | | | |
|---|--|---|-------------------------|-------------------------|
| European Parliament | | | | |
| Document type | Committee | Reference | Date | Summary |
| Committee report tabled for plenary, 1st reading/single reading | | A5-0122/2003 | 23/04/2003 | |
| Text adopted by Parliament, 1st reading/single reading | | T5-0255/2003 OJ C 068 18.03.2004, p. 0330-0477 E | 05/06/2003 | Summary |
| European Commission | | | | |
| Document type | Reference | Date | Summary | |
| Legislative proposal | COM(2002)0400  OJ C 262 29.10.2002, p. 0523 E | 15/07/2002 | Summary | |
| Modified legislative proposal | COM(2003)0407  | 04/07/2003 | Summary | |
| Other institutions and bodies | | | | |
| Institution/body | Document type | Reference | Date | Summary |
| | Economic and Social Committee: | CES1355/2002 | | |

| | | | | |
|------|------------------------------|---|------------|-------------------------|
| EESC | opinion, report | OJ C 085 08.04.2003, p. 0032-0033 | 11/12/2002 | |
| EU | Implementing legislative act | 32006R0627 OJ L 109 22.04.2006, p. 0003-0006 | 21/04/2006 | Summary |

| Additional information | | |
|------------------------|-------------------------|------|
| Source | Document | Date |
| European Commission | EUR-Lex | |

| Final act | |
|---|-------------------------|
| Regulation 2003/2065 OJ L 309 26.11.2003, p. 0001-0008 | Summary |

Food safety: smoke flavourings used on foods, authorisation procedure (Directive 88/388/EEC, Regulation (EC) No 178/2002)

2002/0163(COD) - 21/04/2006 - Implementing legislative act

Food safety: smoke flavourings used on foods, authorisation procedure (Directive 88/388/EEC, Regulation (EC) No 178/2002)

2002/0163(COD) - 05/06/2003 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Minerva Melpomeni MALLIORI (PES, Greece) making some amendments to the commission's proposal. (Please see the document dated 23/04/03.) In addition: - the national competent authority must send receipt of the application to the applicant within 14 days of its receipt; - the time limit for supplementary particulars must not exceed 12 months; - authorisations are renewable on application to the Commission; - if no decision is taken on the renewal of an authorisation until one month before its expiry date, the period of authorisation of the product will automatically be extended by 6 months.

Food safety: smoke flavourings used on foods, authorisation procedure (Directive 88/388/EEC, Regulation (EC) No 178/2002)

2002/0163(COD) - 10/11/2003 - Final act

PURPOSE : to harmonise national rules on the authorisation and use of smoke flavourings. **LEGISLATIVE ACT** : Regulation 2065/2003/EC of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods. **CONTENT** : the Council adopted by a qualified majority - the United-Kingdom delegation abstained - a Regulation on smoke flavourings used or intended for use in or on foods. The European Parliament adopted amendments corresponding to the changes proposed by the Council. They include the deletion of the Annex to the Regulation regarding the traditional smoking methods and natural reserves of woods for the production of smoke and provisions on public access to documents regarding the European Food Safety Authority (EFSA). In order to ensure a high level of protection of human health and protection of consumers' interests and to ensure fair trading practices, this Regulation establishes a safety assessment and authorisation procedure for primary smoke condensates and primary tar fractions which can be used as such in and on foods and/or for the production of derived smoke flavourings. The primary products for which no health concern is expressed during evaluation and their conditions of use will be included in a positive list of products authorised to the exclusion of all others in the Community. Authorisations shall be restricted to a period of 10 years after which they will have to be renewed. This provision ensures that products are regularly re-assessed in the light of the latest scientific and technical knowledge and that authorised products that are no longer used are removed from the Community positive list. Anyone applying for authorisation of a primary product, must provide detailed information on production methods and on the further steps to be taken in the production of derived smoke flavourings, the intended uses in or on specific food or food categories, chemical specifications, toxicological studies and recognised methods for sampling and detecting primary products

and derived smoke flavourings. The evaluation will be carried out by the European Food Safety Authority according to a specific time-limit and on the basis of transparent procedures. The regulation stipulates that the Authority must inform the Commission and the Member States of the receipt of an application and provide a summary or the full dossier. If requested by the applicant, sensitive data must remain confidential. The United Kingdom delegation issued a statement expressing its concerns about the legal basis for the Regulation - qualified majority based on the approximation of laws (Article 95) rather than unanimity (Article 308) - concerning the authorisation procedure. ENTRY INTO FORCE : 16/12/2003. Article 4 (2) shall apply from 16 June 2005. Until this date, national provisions in force concerning smoke flavourings and their use in and on foods continue to apply in the Member States.

Food safety: smoke flavourings used on foods, authorisation procedure (Directive 88/388/EEC, Regulation (EC) No 178/2002)

2002/0163(COD) - 15/07/2002 - Legislative proposal

PURPOSE : to establish Community procedures for the safety assessment and the authorisation of smoke flavourings intended for use in or on foods in order to ensure a high level of protection of human health and protection of consumers' interest, as well as to ensure fair trade practices. **CONTENT** : the current situation in the Member States concerning the authorisation of smoke flavourings is diverse. Some Member States have a very strict authorisation procedure, others have none at all. Thus, there is a need for harmonisation at Community level. The objective of the present proposal is to establish Community procedures for the safety assessment and the authorisation of smoke flavourings intended for use in or on foods in order to ensure a high level of protection of human health and protection of consumers' interests, as well as to ensure fair trade practices. The present draft proposes to establish a safety assessment and authorisation procedure for primary smoke condensates and primary tar fractions which can be used as such in and on foods and/or for the production of derived smoke flavourings. The primary products for which no health concern is revealed during evaluation and their conditions of use will be included in a positive list of products authorised to the exclusion of all others in the Community. It is proposed to restrict the authorisations to a period of 10 years after which the authorisations will need to be renewed. This provision ensures that products are regularly reevaluated according to the latest scientific and technical knowledge and ensures also that authorised products which are no longer used will disappear from the Community positive list. For an application for authorisation of a primary product, detailed information on the production method of this product as well as on the further steps in the production of derived smoke flavourings, the intended uses in or on specific food or food categories, chemical specifications, toxicological studies and validated methods for sampling and detection of the primary product and derived smoke flavourings have to be provided by the applicant. The evaluation will be done by the European Food Safety Authority according to a defined time limited and transparent procedure. The Authority has to inform the Commission and the Member States about the receipt of an application and has to provide a summary thereof or the whole dossier. Confidentiality for sensitive data is provided if requested by the applicant. After the European Food Safety Authority has completed its scientific evaluation, the Commission will propose a risk management decision to be adopted by the regulatory procedure laid down by Council Decision 1999/468/EC. Since many smoke flavourings are already on the market in the Community, the transition to a Community positive list should be smooth and should not lead to unfair conditions for smoke flavouring producers. Therefore, the proposal foresees an initial period of 18 months during which applications for existing and new products can be submitted to the European Food Safety Authority. The establishment of the Community list will take place in a single step procedure after the European Food Safety Authority has expressed opinions on all products for which applications have been submitted during the 18-month period.

Food safety: smoke flavourings used on foods, authorisation procedure (Directive 88/388/EEC, Regulation (EC) No 178/2002)

2002/0163(COD) - 04/07/2003 - Modified legislative proposal

The Commission can accept all the amendments adopted by the European Parliament.