



# Procedure file

| Basic information  |                                       |
|--|---------------------------------------|
| COD - Ordinary legislative procedure (ex-codecision procedure)<br>Regulation | 2000/0286(COD)<br>Procedure completed |
| Food law, European Food Authority, and food safety                           |                                       |
| Amended by <a href="#">2002/0179(COD)</a>                                    |                                       |
| Amended by <a href="#">2012/0266(COD)</a>                                    |                                       |
| Amended by <a href="#">2013/0169(COD)</a>                                    |                                       |
| Amended by <a href="#">2018/0088(COD)</a>                                    |                                       |
| Subject  |                                       |
| 3.10.10 Foodstuffs, foodstuffs legislation                                   |                                       |
| 4.60.04.04 Food safety   |                                       |
| 8.40.08 Agencies and bodies of the EU  |                                       |

| Key players         |   |   |            |
|---------------------|---|---|------------|
| European Parliament | Committee responsible                                   | Rapporteur                                    | Appointed  |
|                     | <b>ENVI</b> Environment, Public Health, Consumer Policy | PSE <a href="#">WHITEHEAD Phillip</a>         | 09/01/2001 |
|                     | Former committee responsible                            |   |            |
|                     | <b>ENVI</b> Environment, Public Health, Consumer Policy | PSE <a href="#">WHITEHEAD Phillip</a>         | 09/01/2001 |
|                     | Former committee for opinion                            |   |            |
|                     | <b>BUDG</b> Budgets                                     | PSE <a href="#">KUCKELKORN Wilfried</a>       | 29/11/2000 |
|                     | <b>CONT</b> Budgetary Control                           | PPE-DE <a href="#">POMÉS RUIZ José Javier</a> | 24/01/2001 |
|                     | <b>JURI</b> Legal Affairs and Internal Market           | PSE <a href="#">GEBHARDT Evelyne</a>          | 25/01/2001 |
|                     | <b>ITRE</b> Industry, External Trade, Research, Energy  | PPE-DE <a href="#">FOLIAS Christos</a>        | 24/01/2001 |
|                     | <b>AGRI</b> Agriculture and Rural Development           | ELDR <a href="#">PESÄLÄ Mikko</a>             | 24/01/2001 |
|                     | <b>PECH</b> Fisheries                                   | V/ALE <a href="#">HUDGHTON Ian</a>            | 23/01/2001 |
|                     | Council of the European Union                           | Council configuration                         | Meeting    |
|                     | <a href="#">Agriculture and Fisheries</a>               | <a href="#">2404</a>                          | 21/01/2002 |

|                     |   |                      |            |
|---------------------|---|----------------------|------------|
| European Commission | <a href="#">Competitiveness (Internal Market, Industry, Research and Space)</a> | <a href="#">2389</a> | 26/11/2001 |
|                     | Health  | <a href="#">2384</a> | 15/11/2001 |
|                     | <a href="#">Competitiveness (Internal Market, Industry, Research and Space)</a> | <a href="#">2371</a> | 27/09/2001 |
|                     | <a href="#">Transport, Telecommunications and Energy</a>                        | <a href="#">2364</a> | 27/06/2001 |
|                     | <a href="#">Competitiveness (Internal Market, Industry, Research and Space)</a> | <a href="#">2351</a> | 30/05/2001 |
|                     | <a href="#">Agriculture and Fisheries</a>                                       | <a href="#">2343</a> | 24/04/2001 |
|                     | <a href="#">Competitiveness (Internal Market, Industry, Research and Space)</a> | <a href="#">2336</a> | 12/03/2001 |
|                     | <a href="#">Agriculture and Fisheries</a>                                       | <a href="#">2332</a> | 26/02/2001 |
|                     | <a href="#">Agriculture and Fisheries</a>                                       | <a href="#">2322</a> | 19/12/2000 |
|                     | Commission DG   | Commissioner         |            |
|                     | <a href="#">Health and Food Safety</a>  |                      |            |

| Key events |  |   |         |
|------------|--|---|---------|
| 08/11/2000 | Legislative proposal published                           | COM(2000)0716   | Summary |
| 11/12/2000 | Committee referral announced in Parliament, 1st reading  |   |         |
| 19/12/2000 | Debate in Council  | <a href="#">2322</a>  | Summary |
| 26/02/2001 | Debate in Council  | <a href="#">2332</a>  | Summary |
| 12/03/2001 | Debate in Council  | <a href="#">2336</a>  | Summary |
| 24/04/2001 | Debate in Council  | <a href="#">2343</a>  |         |
| 29/05/2001 | Vote in committee, 1st reading                           |   | Summary |
| 29/05/2001 | Committee report tabled for plenary, 1st reading         | <a href="#">A5-0198/2001</a>  |         |
| 30/05/2001 | Debate in Council  | <a href="#">2351</a>  |         |
| 12/06/2001 | Debate in Parliament                                     |  |         |
| 12/06/2001 | Decision by Parliament, 1st reading                      | <a href="#">T5-0310/2001</a>  | Summary |
| 17/09/2001 | Council position published                               | <a href="#">10880/1/2001</a>  | Summary |
| 19/09/2001 | Committee referral announced in Parliament, 2nd reading  |   |         |
| 27/09/2001 | Debate in Council  | <a href="#">2371</a>  |         |
| 15/11/2001 | Debate in Council  | <a href="#">2384</a>  |         |
| 21/11/2001 | Vote in committee, 2nd reading                           |   | Summary |
| 21/11/2001 | Committee recommendation tabled for plenary, 2nd reading | <a href="#">A5-0416/2001</a>  |         |
| 26/11/2001 | Debate in Council  | <a href="#">2389</a>  |         |
| 10/12/2001 | Debate in Parliament                                     |  |         |
| 11/12/2001 | Decision by Parliament, 2nd reading                      | <a href="#">T5-0664/2001</a>  | Summary |

|            |   |  |  |
|------------|---|--|--|
| 21/01/2002 | Act approved by Council, 2nd reading    |  |  |
| 28/01/2002 | Final act signed                        |  |  |
| 28/01/2002 | End of procedure in Parliament          |  |  |
| 01/02/2002 | Final act published in Official Journal |  |  |

### Technical information

|                            |  |
|----------------------------|--|
| Procedure reference        | 2000/0286(COD)   |
| Procedure type             | COD - Ordinary legislative procedure (ex-codecision procedure)   |
| Procedure subtype          | Legislation  |
| Legislative instrument     | Regulation   |
|                            | Amended by <a href="#">2002/0179(COD)</a><br>Amended by <a href="#">2012/0266(COD)</a><br>Amended by <a href="#">2013/0169(COD)</a><br>Amended by <a href="#">2018/0088(COD)</a> |
| Legal basis                | EC Treaty (after Amsterdam) EC 037; EC Treaty (after Amsterdam) EC 152-p4; EC Treaty (after Amsterdam) EC 133; EC Treaty (after Amsterdam) EC 095                                |
| Stage reached in procedure | Procedure completed  |
| Committee dossier          | ENVI/5/14831   |

### Documentation gateway

|   |   |            |      |         |
|---|---|------------|------|---------|
| Legislative proposal  | COM(2000)0716<br>OJ C 096 27.03.2001, p. 0247 E                                     | 08/11/2000 | EC   | Summary |
| Economic and Social Committee: opinion, report                  | <a href="#">CES0404/2001</a><br><a href="#">OJ C 155 29.05.2001, p. 0032</a>        | 28/03/2001 | ESC  |         |
| Committee report tabled for plenary, 1st reading/single reading | <a href="#">A5-0198/2001</a>  | 29/05/2001 | EP   |         |
| Text adopted by Parliament, 1st reading/single reading          | <a href="#">T5-0310/2001</a><br>OJ C 053 28.02.2002, p. 0021-0047 E                 | 12/06/2001 | EP   | Summary |
| Committee of the Regions: opinion                               | <a href="#">CDR0064/2001</a><br><a href="#">OJ C 357 14.12.2001, p. 0022</a>        | 14/06/2001 | CofR |         |
| Commission opinion on Parliament's position at 2nd reading      | COM(2001)0475<br><a href="#">OJ C 304 30.10.2001, p. 0273 E</a>                     | 07/08/2001 | EC   | Summary |
| Council position  | <a href="#">10880/1/2001</a><br><a href="#">OJ C 004 07.01.2002, p. 0018-0051</a>   | 17/09/2001 | CSL  | Summary |
| Commission communication on Council's position                  | SEC(2001)1406   | 18/09/2001 | EC   | Summary |
| Committee recommendation tabled for plenary, 2nd reading        | <a href="#">A5-0416/2001</a>  | 21/11/2001 | EP   |         |
| Text adopted by Parliament, 2nd reading                         | <a href="#">T5-0664/2001</a><br><a href="#">OJ C 177 25.07.2002, p. 0033-0065 E</a> | 11/12/2001 | EP   | Summary |
| Commission opinion on Parliament's position at 2nd reading      | COM(2001)0821   | 10/01/2002 | EC   | Summary |

|                              |  |   |            |    |         |
|------------------------------|--|---|------------|----|---------|
| Implementing legislative act |  | <a href="#">32004R2230</a><br><a href="#">OJ L 379 24.12.2004, p. 0064-0067</a> | 23/12/2004 | EU | Summary |
| Follow-up document           |  | <a href="#">COM(2010)0496</a>   | 23/09/2010 | EC | Summary |
| Follow-up document           |  | SWD(2013)0045   | 11/02/2013 | EC |         |
| Follow-up document           |  | SWD(2018)0037   | 15/01/2018 | EC |         |
| Follow-up document           |  | SWD(2018)0038   | 15/01/2018 | EC |         |

#### Additional information

European Commission

[EUR-Lex](#)

#### Final act

[Regulation 2002/178](#)  
[OJ L 031 01.02.2002, p. 0001-0024](#) Summary

## Food law, European Food Authority, and food safety

**PURPOSE:** to lay down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food. **CONTENT:** The White Paper on Food Safety outlined the Commission's strategic objectives, priorities and work programme in relation to food safety in particular, and food law in general. It elaborated the Commission's commitment to develop a comprehensive integrated approach to regulating the food supply chain. In particular, it proposed the establishment of a European Food Authority and an overarching set of definitions, principles and measures to ensure a high level of protection and the effective functioning of the internal market in food. Against this background, this proposal for a European Regulation responds to this commitment by laying down the general principles and requirements of food law, establishing procedures in matters of food safety and establishing a rapid alert system for food and feeds. It creates a European Food Authority defining its scope, tasks and responsibilities. One of the objectives of this Regulation is to establish common definitions, including a definition of food, and to lay down the overarching guiding principles and legitimate objectives for food law in order to ensure a high level of health protection and the effective functioning of the internal market. Moreover, this Regulation seeks to harmonise at Community level existing national requirements, placing them in the European context. A further objective of this proposal is not only to harmonise national requirements, but also to provide the basic framework of principles and definitions for future European food law. Where measures are revised in the future or where proposals are drafted in new areas, this Regulation will provide the basic principles, definitions and orientation for doing so. Although some specific requirements are proposed in this Regulation, others are more generally applicable and will provide the basis for more specific provisions. The following are the main provisions of this proposed Regulation: - principles, responsibilities and obligations on businesses to address the causes of food safety problems in a broad manner; - provisions addressing the organisational changes needed in relation to the provision of scientific opinions and the increased collaboration with the Member States that must be fostered in order for the best use of expertise to be made; - provisions responding to the commitment in the White Paper and providing the concrete basis for the functioning of the European Food Authority, detailing its mission, tasks, organisational arrangements and scope; - provisions relating to the most logical and effective arrangements for the collection and analysis of scientific and other data, the identification of emerging risks to health and the role of the Food Authority in a food safety crisis. It also establishes a rapid alert system for foods and feeds, which will integrate and improve the system; - finally, provisions aligning procedures and responsibilities where a serious risk to health has been identified in the European food supply whether the product originates within the Community or a third country.?

## Food law, European Food Authority, and food safety

The Council held an open debate on the subject of food safety and the future European Food Authority on the basis of the proposal on the matter submitted by the Commission. From the debate it emerged that in general the delegations felt there was an urgent need to act on this proposal, the overall approach of which they endorsed. In particular they shared the view that implementation of the general principles of food law advocated by the Commission (scientific basis, precautionary principle, traceability, transparency) at every point in the food chain, on the basis of a new, "integrated" approach, ought to result in a clear, consistent legal framework with the highest health standards. The greatest possible health protection would thus be guaranteed at Community level, which is where decisions should preferably be taken. The debate also showed broad agreement on the fact that high-level, independent, transparent assessment of risks to health is vital to effective risk management and hence to ensuring that the responsible authorities take the right decisions at the right time. The Food Authority ought therefore to make a useful contribution to the safety of the food supply and consequently to crisis prevention. It was felt that in crisis situations it would be for the Food Authority - by means of its scientific opinions - to advise the Commission and the Member States as fully and as swiftly as possible on the emergency measures to be taken. Concluding the debate, the President made a point of stressing that food safety in Europe had progressed, on the one hand driven by the need to improve the Community response to the BSE crisis, and on the other carried forward by the groundwork done by the Commission since its White Paper in January. ?

## Food law, European Food Authority, and food safety

The Council took note of a progress report concerning the establishment of a European Food Authority and on questions pertaining to food safety. The report focuses on the question of the establishment of the Authority. The Presidency stated that progress had been made in the negotiations on the Authority and drew the conclusion that the Authority should be in place early next year in accordance with the task assigned by the European Council in Nice. It also stated that the Agriculture Council will remain closely associated with the work concerning the establishment of the European Food Authority and that the aim is to achieve a political decision by June 2001.?

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## Food law, European Food Authority, and food safety

The Council took note of the progress made on this dossier since the beginning of the year and had a brief exchange of views on some of the main issues raised by the proposal, in particular concerning: - the remit to be given to the Authority; - the administration of the early warning system. Some delegations also mentioned the question of the seat of the Authority. In concluding this item, the Council stressed the importance of respecting the conclusion of the Nice European Council that the Authority should be operational as from the beginning of 2002.?

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## Food law, European Food Authority, and food safety

The committee adopted the report by Phillip WHITEHEAD (PES, UK) substantially amending the Commission proposal under the codecision procedure (1st reading). First and foremost, the word "safety" was added to the name of the Authority on the grounds that this was its purpose. It would thus be called the European Food Safety Authority (EFSA). The committee also differed from the Commission on the role of the Authority and questions of risk assessment and risk management, transparency, the composition of the Management Board, the financing of the EFSA and the location of its headquarters. It argued that the members of the Management Board should be no more than 12 in number, including 2 from the food industry and 2 consumers' representatives. They should be proposed by the Commission following a process of open application. Not every Member State should have a representative on the Board. All appointments should be made on merit and be individually subject to confirmatory hearings by Parliament. Although risk assessment, risk communication and risk management could not be separated as easily as the Commission's proposal suggested, the committee saw risk assessment as being the duty of the EFSA and risk management as ultimately the province of the Commission. It was therefore at odds with the Commission over the Rapid Alert System (RAS) for food and animal feed, and wanted the day-to-day management of the system to be a task for the Commission rather than for the EFSA, as the Commission had proposed. The committee also set out its views on where the Authority should be located, saying the location should have a long-standing tradition in food safety, enhance the Authority's independence and integrity, provide a good scientific infrastructure and facilities in the field of food safety and also be easily accessible. Regarding the mission of EFSA, the report said it should include animal health and welfare, plant health, nutrition and matters relating to genetically modified organisms and the labelling of foodstuffs. The committee also adopted a number of more technical amendments. ?

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## Food law, European Food Authority, and food safety

In adopting the report presented by Philip WHITEHEAD (PES, UK), by 491 votes to 5 with 21 abstentions, the European Parliament has made a large number of amendments to the Commission's proposal (please refer to the previous document). The European Parliament stressed that the Food Authority must be able to monitor the whole food chain, including inputs used in agriculture. MEPs added that the draft regulation should also cover food and animal feed imported from third countries. For example, in the interests of consumer protection, the precautionary principle should apply not only to goods produced in the EU but also to food and feed imported from third countries. A further amendment tightens up the ban on exporting risky poor-quality food and animal feed to third countries. In light of the recent food safety scandals, illegal practices that could endanger consumer safety must be reported. Employees and internal inspectors must therefore be assured that in so doing, they will not jeopardise their own position. MEPs also agreed that food hygiene was the other key requirement for food and should therefore be one of the important tasks of the Authority. Processing must be considered part of the food chain and the directive should also cover food supplements. Although the entire food chain 'from farm to fork' was supposed to be covered by the new regulation, there was no specific article dealing with the responsibilities of farmers. The European Parliament therefore stipulates that food producers must ensure, at all stages of production under their control, that their produce complies with food and agricultural law, in particular on food safety. MEPs also called for a better definition of the Authority's mission, so that it also covers cases where food or feed may become harmful, food safety matters relating to GMOs and food labelling. As regards financing, the European Parliament says the Authority should be entirely funded from the Community budget in order to ensure its independence. But the financing for the Authority should only be transferred from the reserve once a satisfactory solution for both its location and effective operation has been agreed. As regards, its location, MEPs want the European Parliament to be consulted when the decision is taken on where the Authority should be located. However, replying to the debate Commission David BYRNE could not accept the amendments related to the location of the authority, amendments regarding the word 'safety' and the composition of the board of the Authority. On balance however, he could accept half of the amendments and emphasised that he welcomes the European Parliament's support in general for the new Food Authority, seeing the amendments more of a textual nature. ?

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## Food law, European Food Authority, and food safety

Having received the amendments of the European Parliament's first reading as well as political agreement in the Council, the European Commission has presented its revised draft for the proposed Regulation on Food Safety. Of the 189 amendments proposed by the European Parliament, the Commission accepted in full 43 amendments, in part or in principle 55 amendments and rejected 88 amendments. (186 in total as some were merged). Whilst the European Commission accepted most of the Council's position parts of it were not approved. The new text has been revised taking into account the views of both institutions. Concerning Chapter I and II relating to General Food Law, the text remains largely unchanged. There has however been a significant re-ordering of some of the articles with some being placed in a more logical order. For example, principles are separated from requirements. The definition of stages of production, processing and distribution has been significantly redrafted so that the scope of Chapter II which covers these stages is clearer. An additional definition "final consumer" is included and the definition "official control" deleted for inclusion in a more specific text on controls. A further change by which food law principles and

procedures should be adopted has also been agreed. There are some minor changes in emphasis in relation to the import and export of food. Importantly, food that may be injurious to health or unsafe feed shall not be exported from the Community. A requirement for food and feed businesses to enable employees to co-operate with the competent authorities to prevent, reduce or avoid risk has been added. Concerning Chapter III relating to the Food Authority the following changes have been made. The mission of the Authority has been amended in such a way that whilst it retains a wide scope its main mission will be to focus on food and feed safety. Importantly, the mission of the Authority in relation to animal health, animal welfare and plant health issues, which are not linked to food and feed safety, will now be limited to scientific opinions only. There has also been a rewording of Article 22 (5) which now underlines co-operation between the Authority, the Commission and the Member States in order to ensure a sound coherence between risk assessment, risk management and risk communication. Moreover, it has now been agreed that the Commission will monitor and manage the rapid alert system, whilst the Authority will remain a member of the network. Feed will be covered by the rapid alert emergency procedures. Conditions of referral to the Authority of a request for scientific opinions have been completed and the situation in which a request may be amended or refused specified. Chapter V dealing with the Final Provisions has seen few major changes. The exception being the deletion of the Article on the seat of the Food Authority. Further, the 1 January 2002 has now been fixed as the starting date for the Food Authority. The Commission was unable to agree to the Council's common position regarding the composition of the Management Board. Nor could, the Commission agree to the date proposed by the Council whereby certain articles need only be applicable as from January 2005. The Commission foresees an earlier starting date of January 2004.

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## Food law, European Food Authority, and food safety

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The Council's common position reflects the main thrust of the initial Commission proposal, as well as incorporating a number of Parliamentary amendments into the revised text. The Council has agreed to retain the legal form of a Regulation for this piece of legislation, despite the problems of implementation a Regulation implies. In return, the Council felt it necessary to amend the provisions on the timetable for its application. This should help reduce the difficulties of implementation as much as possible as well as ensuring an effective and non-discriminatory introduction of the provisions of food law. The main amendments to the Commission proposals are as follows: - A general framework of obligations imposed on operators will apply from 1 January 2005. - Principles and procedures already in force should be adapted by 1 January 2007 at the latest so that existing legislation can be made compatible with the principles and procedures set out in the Regulation. - On 'food law', the Council has amended the definition of 'food or foodstuff'. The new definition will only cover water once it has left the tap, as well as bottled water and water used in the manufacture, preparation or treatment of food. Municipal water is regulated by existing Directives. Furthermore, residues and contaminants have been added to the list of substances and products which are not covered by the definition of 'food'. - Provisions have been made to strengthen safety requirements. - Concerning the mission and tasks of the Food Authority, the common position explicitly awards the Food Authority responsibility for animal feedingstuffs. This equips it with an overall view of the food chain, considered essential if emerging risks are to be managed effectively. Significantly, the common position confirms that food safety will be the primary responsibility of the Food Authority. - The operational separation between the tasks of risk assessment and risk management is confirmed by the common position. - Concerning the composition of the Management Board, the Council has sided with the European Parliament and adopted a position contrary to that of the Commission. The modified text proposes a system whereby the Management Board will be composed of 16 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission. It will include a Commission representative. A quarter will stem from consumer organisations. - An open and transparent procedure for the appointment of the Executive Director has been agreed to. - Concerning the Advisory Forum, the common position has made substantial amendments largely in line with Parliamentary suggestions. The aim of the Forum is, inter alia, to advise the Executive Director, exchange information and ensure solid co-operation amongst interested parties. - Concerning the scientific committees and scientific panels the Council decided to allow Parliament and Member States the right, under certain conditions, to request an opinion from the Authority. - Concerning the seat of the authority, the Council has decided not to include such a provision in the Regulation. - Lastly, the Commission will retain responsibility for the rapid alert system.?

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## Food law, European Food Authority, and food safety

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The Commission broadly welcomes the Council's common position remarking that it is in line with the general thrust of the aims and principles of the new Regulation. There are nevertheless certain changes to the substance of the text which the Commission rejects. Firstly, the composition of the Management Board. The Commission considers that further consideration needs to be given to the relationship between the different criteria for the Board's constitution including size, balance and nomination process. Secondly, the location of the Food Authority. The Commission considers it necessary to establish a seat as soon as possible. Thirdly, the Commission expresses reservation over the dates of application. The Commission believes a delay of three years is too long and would prefer to see the application of provisions within a two year time-frame. The Commission however signals that the second reading in Parliament may now proceed and hopes that the process will be completed as soon as possible to allow for the establishment of the Food Authority by 2002 as requested by the Council meeting in Nice.?

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## Food law, European Food Authority, and food safety

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The committee adopted the report by Philip WHITEHEAD (PES, UK) amending the Council's common position under the codecision procedure (2nd reading). Although the Council had taken on board a number of Parliament's amendments from 1st reading, the committee retabled other amendments - which had been rejected by Council - aimed at improving the Authority's efficiency, democratic accountability and transparency. The committee wanted the Management Board to be streamlined by having just 12 members rather than 16. Appointments to the Board and the post of Executive Director should be made on merit and be subject to individual confirmatory hearings by Parliament. Meetings of the Authority should be held in public and its opinions should be published immediately. The committee also retabled an amendment calling for the Authority to be located in a place which would enable it to be seen as independent of the Commission and other EU institutions. This place should have a longstanding tradition in food safety, good scientific infrastructure and facilities and good transport connections. Another amendment retabled in the report added the word "safety" to the name of the new body, which would thus be called the European Food Safety Authority. On the question of food safety procedures, the committee wanted food operators, food businesses and animal feed businesses to be required to inform the competent authorities if they had reason to believe a suspect product had been placed on the market. They should

also not prevent or discourage anyone from cooperating with the authorities when a food risk was suspected. Lastly, the committee retabled in slightly modified form a first reading amendment calling for a consignment containing animal feed which is deemed not to satisfy feed safety requirements to be destroyed, unless the relevant control authority states that it can be used for other purposes.?

## Food law, European Food Authority, and food safety

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The European Parliament adopted the recommendation by Mr Philip WHITEHEAD (PES, UK). It supports the wish of the Commission and Council for a start date in early 2002 for the new Authority but MEPs felt this imminent deadline must not prevent Parliament from playing its full role as co-legislator on a crucial issue such as food safety. An amendment retabled from first-reading adding the word 'safety' to the name was adopted almost unanimously, as were amendments on the streamlining of the Authority's Management Board (14 instead of 16), its efficiency, its democratic accountability (public meetings and documents) and its seat. Important amendments were also adopted with regard to food safety procedures. The Management Board should be appointed in such a way as to secure the highest standard of competence, a broad range of relevant expertise, for instance in management and in public administration. This should be facilitated by a rotation of the different countries of origin of the members of the Management Board without any post being reserved for nationals of any specific Member State. An amendment was adopted demanding that 4 of the 14 members of the Management Board should have their background in organisations representing consumers and other interests in the food chain. The Parliament suggests that the Members' term of office shall be four years, and may be renewed once. Before appointment the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and answer questions put by members of this institution. Although there is general agreement between the three institutions on the European Food Safety Authority, this is not the case for its seat. The Parliament called on the Council to apply the following criteria in its decision-making procedure on the location of the EFSA: - it should be, and be seen physically to be, independent of the Commission and their institutions; - it should have a long-standing tradition in food safety in order to lend credibility to the Authority in the eyes of EU citizens; - it should enhance the Authority's independence and integrity; - it should provide good scientific infrastructure and facilities in the field of food safety; - it should be easily accessible in terms of communications and have good rapid transport connections.?

## Food law, European Food Authority, and food safety

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The Commission is able to accept all amendments to the common position from the Parliament. The main differences of opinion that have been resolved relate to the composition and selection procedures for the Management Board and the selection of Executive Director. Parliament's amendments clarify the selection process for the appointments. Amendments relating to the transparency of the Authority and those concerning greater legal clarity for its procedures are acceptable. Amendments on the fees and budget are acceptable as they take into account the provision for EEA/EFTA countries financial contributions and the fact that if fees for authorisations are established in the future this will be done on the basis of a further report. The change to the name is acceptable. Other amendments concerning international obligations, the overall risk analysis procedure, and the responsibilities of food or feed businesses are also acceptable. The Commission agrees with the reformulation on whistle blowing. It should be added that no amendments are rejected.?

## Food law, European Food Authority, and food safety

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**PURPOSE :** to lay down the general principles and requirement of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. **COMMUNITY MEASURE :** Regulation 178/2002/EC of the European Parliament and of the Council laying down the general principles and requirement of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. **CONTENT :** this Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisation arrangements and procedures to underpin decision-making in matters of food safety. The Authority established by this Regulation will be able to begin carrying out its activities immediately. In accordance with the Laeken European Council's Conclusions, these will begin in Brussels pending a general agreement on where the agencies' headquarters will be located. The creation of this new authority is one of the main political measures appearing in the White Paper on Food Safety published by the Commission in January 2000 and approved subsequently by the European Council. The mission of the Food Authority is to provide the Community with the independent scientific and technical advice it needs to support policy and legislation in all areas of food safety. It will contribute to providing a high level of public health protection while not neglecting animal health, plant preservation and environmental protection matters. The Authority's bodies (Management Board, Executive Director, Advisory Forum, Scientific Committee and scientific working parties) are designed to ensure its independence, its transparency and the scientific excellence of its opinions. They also provide for close cooperation with the competent bodies of Member States in the food safety field. The Authority's other tasks will be: - to identify and reconcile divergent scientific opinions at Community and Member State levels; - to ensure the public dissemination of reliable, objective and comprehensible information in all areas; - covered by its mission; - to collect and analyse data and identify emerging risks; - to establish a system of networks of bodies working in the food safety area. Besides creating the European Food Safety Authority, the Regulation defines the general principles and requirements of food law, the essential objectives of which are to ensure a high level of protection of human health, of the safety and interests of consumers and to ensure that the common market functions effectively. A rapid alert system for the allocation of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States-, the Commission and the Authority. The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation. Lastly, before 1 January 2005 and every 6 years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. **ENTRY INTO FORCE :** 21/02/2002. The Authority shall commence its operations on 1 January 2002.?

## Food law, European Food Authority, and food safety

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ACT : Commission Regulation 2230/2004/EC laying down detailed rules for the implementation of European Parliament and Council Regulation 178/2002/EC with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission.

CONTENT : networking between the European Food Safety Authority and the Member States? organisations operating in the fields within the Authority?s mission is one of the basic principles of the Authority?s operation. It is therefore necessary to stipulate how this principle should be implemented, in accordance with Regulation 178/2002/EC in order to ensure efficiency.

Certain bodies in the Member States carry out tasks at national level which are similar to those of the Authority. Networking must make it possible to foster a framework for scientific cooperation allowing information and knowledge to be shared, common tasks to be identified, and optimum use to be made of resources and expertise. It is also important to facilitate the compilation of a Community-level summary of the data on food and feed safety collected by these bodies. As these bodies are to be entrusted with certain tasks with a view to assisting the Authority with its general mission as defined by Regulation 178/2002/EC it is essential for them to be designated by the Member States on the basis of criteria covering scientific and technical competence, efficiency and independence.

In accordance with the provisions of Regulation 178/2002/EC, it is important for the Advisory Forum to be able to ensure close cooperation with the Authority and the competent bodies of the Member States by promoting the European networking of organisations operating within the fields of the Authority?s mission.

It is important to ensure on a general basis that the tasks entrusted by the Authority to the network?s member organisations are performed to high scientific and technical standards, efficiently (also with regard to deadlines) and independently. However, the Authority must remain responsible for allocating tasks to the competent bodies and for monitoring performance.

The tasks entrusted to the competent bodies on the list must involve providing the Authority with assistance with its mission to provide scientific and technical support in relation to Community policy and legislation, without prejudice to the Authority?s responsibility for performing its tasks pursuant to Regulation 178/2002/EC.

Lastly, the Authority may decide to allocate financial support for tasks entrusted to the organisations on the list where they are of particular interest as regards contributing to the performance of the Authority?s tasks or addressing the priorities laid down in its work programmes, or where the Authority?s assistance is urgently needed by the Commission, particularly in order to deal with crisis situations.

ENTRY INTO FORCE : 13/01/2005.

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According to Regulation (EC) N° 178/2002, the Commission is to publish a report stating its position on the advisability and feasibility of presenting a legislative proposal establishing fees for European Food Safety Authority (EFSA) three years after its creation.

The report looks at EFSA?s experience in managing its workload since its creation and takes into account the views expressed by the Member States and other stakeholders.

The processing of applications has significantly increased in EFSA?s overall workload since the end of 2006. The share of budget required for handling applications in 2010 represents 31% of EFSA's budget, compared to 20% in 2007. These developments should be taken into account when envisaging the establishment of fees for EFSA.

Although the majority of Member States are not, in principle, against a fee system designed to pay for a service provided to those who require it, and most of them consider it is a public responsibility. They point out, however, that in the specific case of the EFSA, the introduction of a fee system is complex because of: i) the difficulty of identifying the beneficiaries of generic authorisations and ii) the instability of EFSA?s budget and the risk of inefficiency of a fee system.

Most representatives of the actors of the food chain expressed reservations regarding the advisability of establishing fees. These concerns relate in particular to: i) the need to guarantee EFSA?s independence; the need for public funding of the EFSA, iii) the need for consistency with the better regulation approach.

EFSA's Management Board did not express a position in favour of or against the establishment of fees. The source of the funding may not be an issue provided that a certain number of conditions, particularly in relation to the independence and accountability of EFSA are covered by the legislators.

Most of the comments provided by Member States and stakeholders acknowledged that, in principle, fees are a useful tool for good governance. Four options emerge from stakeholders' contributions:

- 1) flat-rate fee for all applicants for authorisation;
- 2) graduated fees for all applicants for authorisation;
- 3) graduated fees for applicants who are authorisation holders;
- 4) maintain the existing system without fees.

In view of these considerations, the Commission considers that more reflection is needed on the range of options to be considered and that it is not possible to draw any definitive conclusions at this stage. This will be done in the course of an impact assessment.

Without pre-empting the outcome of such an assessment, the option of graduated fees for applicants who are authorisation holders (option 3) should in any cases be given further consideration. In this context, the issue of enhanced services for applicants will also have to be explored.

The introduction of fees for EFSA could, in particular, be considered in the following sectors where the authorisation in all cases, or in some specific cases, is issued to a specific holder and is not generic:

- authorisation of genetically modified organisms (cultivation);
- authorisation of genetically modified food and feed;



- authorisation of feed additives issued to a specific holder;
- authorisation of claims issued to a specific holder;
- authorisation of novel foods issued to a specific holder;
- positive listing of active substances eligible for authorisation as plant protection products;
- authorisation of smoke flavourings.

The assessment will also look at other EU policy areas as well as practices of other EU regulatory agencies. Each potential candidate sector will have to be assessed in detail in order to identify the economic and budgetary impact of the various scenarios of fees on enterprises (including SMEs).

The Commission considers that it is also essential to assess the impact that a fee-system would have on EFSA's overall functioning and efficiency, in particular: i) the various options for providing a more professional service to applicants, ii) the impact on the sharing of work with national agencies/bodies, iii) the balance between the interests of a more efficient service and the preservation of general interest objectives, iv) the perception of EFSA's independence, and v) the impact on the overall sustainability of EFSA's functioning.