

# Evaluation on the legislation on additives for use in animal nutrition (Regulation (EC) No 1831/2003).

Fields marked with \* are mandatory.

## Introduction

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The Feed Additives Regulation, adopted in 2003 and applying since October 2004, sets out rules for authorising feed additives and placing them on the market in the EU. It aims to deliver high standards of public and animal health and ensure environmental safety through predictable, science-based authorisations. After 14 years of applying the Regulation, and several hundred assessments of existing feed additives, it is now time to evaluate whether the Regulation has achieved its objectives and to what extent it is necessary to update and modernise it.

The main changes from the pre-2003 rules (former Directive 70/524/EEC) were:

- introduction of time-limited authorisation of feed additives at EU level, taking account of societal, economic and environmental factors;
- a harmonised safety assessment of feed additives at EU level by the European Food Safety Authority (EFSA);
- new categories of additives (silage additives, amino acids, zootechnical additives) and new forms of administration (via drinking water);
- harmonised rules on labelling and the use of feed additives;
- the post-marketing monitoring of certain additives to identify unforeseen effects;
- the setting up of a register of authorised feed additives held by the Commission;
- creation of an EU reference laboratory evaluating the method used to analyse feed additives;
- the phasing out of the use of antibiotics as feed additives.

In the EU, feed additives are authorised via a centralised procedure after an assessment carried out by EFSA to ensure that they are safe for human health, animal health and the environment. EFSA is an EU agency that provides scientific advice based on the expertise of scientists using methods that are grounded in internationally recognised standards.

The questionnaire is divided into four sections as follows:

The first section asks for some important background information about you to better understand your perspective.

The second section contains general questions for the general public.

The third section contains specific technical questions for experts or stakeholders who are familiar with the EU legislation on feed additives.

The final section gives respondents the chance to raise other issues and to upload a position paper or other relevant information to better explain their choices and position.

## About you

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\* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- Gaelic
- German
- Greek
- Hungarian
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

\* I am giving my contribution as

- Academic/research institution
- Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

\* Please indicate if your company is involved in manufacturing and/or distributing and trading any of the following products:

- Manufacturing feed additives
- Manufacturing premixtures of feed additives
- Manufacturing compound feed for food-producing animals (including farmers using feed additives directly to produce compound feed)
- Manufacturing compound feed for non-food producing animals (e.g. pets or animals for fur production)

- Importer of feed
- Distributor of feed
- Applicant for an authorisation of a feed additive
- Farmer (for activities other than those under bullet point 3)
- Other (please specify below)

-

\* First name

\* Surname

\* Email (this won't be published)

\* Scope

- International
- Local
- National
- Regional

Does your company have subsidiaries in more than one country?

- Yes
- No
- Don't know

If yes, please specify where they are located:

- EU countries
- Non-EU countries

\* Organisation name

*255 character(s) maximum*

\* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

## Transparency register number

255 character(s) maximum

Check if your organisation is on the [transparency register](#). It's a voluntary database for organisations seeking to influence EU decision-making.

### \*Country of origin

Please add your country of origin, or that of your organisation.

- |   |   |  |  |
|---|---|--|--|
| <input type="radio"/> Afghanistan         | <input type="radio"/> Djibouti                              | <input type="radio"/> Libya            | <input type="radio"/> Saint Pierre and Miquelon                    |
| <input type="radio"/> Åland Islands       | <input type="radio"/> Dominica                              | <input type="radio"/> Liechtenstein    | <input type="radio"/> Saint Vincent and the Grenadines             |
| <input type="radio"/> Albania             | <input type="radio"/> Dominican Republic                    | <input type="radio"/> Lithuania        | <input type="radio"/> Samoa  |
| <input type="radio"/> Algeria             | <input type="radio"/> Ecuador                               | <input type="radio"/> Luxembourg       | <input type="radio"/> San Marino                                   |
| <input type="radio"/> American Samoa      | <input type="radio"/> Egypt                                 | <input type="radio"/> Macau            | <input type="radio"/> São Tomé and Príncipe                        |
| <input type="radio"/> Andorra             | <input type="radio"/> El Salvador                           | <input type="radio"/> Madagascar       | <input type="radio"/> Saudi Arabia                                 |
| <input type="radio"/> Angola              | <input type="radio"/> Equatorial Guinea                     | <input type="radio"/> Malawi           | <input type="radio"/> Senegal                                      |
| <input type="radio"/> Anguilla            | <input type="radio"/> Eritrea                               | <input type="radio"/> Malaysia         | <input type="radio"/> Serbia                                       |
| <input type="radio"/> Antarctica          | <input type="radio"/> Estonia                               | <input type="radio"/> Maldives         | <input type="radio"/> Seychelles                                   |
| <input type="radio"/> Antigua and Barbuda | <input type="radio"/> Ethiopia                              | <input type="radio"/> Mali             | <input type="radio"/> Sierra Leone                                 |
| <input type="radio"/> Argentina           | <input type="radio"/> Falkland Islands                      | <input type="radio"/> Malta            | <input type="radio"/> Singapore                                    |
| <input type="radio"/> Armenia             | <input type="radio"/> Faroe Islands                         | <input type="radio"/> Marshall Islands | <input type="radio"/> Sint Maarten                                 |
| <input type="radio"/> Aruba               | <input type="radio"/> Fiji                                  | <input type="radio"/> Martinique       | <input type="radio"/> Slovakia                                     |
| <input type="radio"/> Australia           | <input type="radio"/> Finland                               | <input type="radio"/> Mauritania       | <input type="radio"/> Slovenia                                     |
| <input type="radio"/> Austria             | <input type="radio"/> Former Yugoslav Republic of Macedonia | <input type="radio"/> Mauritius        | <input type="radio"/> Solomon Islands                              |
| <input type="radio"/> Azerbaijan          | <input type="radio"/> France                                | <input type="radio"/> Mayotte          | <input type="radio"/> Somalia                                      |
| <input type="radio"/> Bahamas             | <input type="radio"/> French Guiana                         | <input type="radio"/> Mexico           | <input type="radio"/> South Africa                                 |
| <input type="radio"/> Bahrain             | <input type="radio"/> French Polynesia                      | <input type="radio"/> Micronesia       | <input type="radio"/> South Georgia and the South Sandwich Islands |
| <input type="radio"/> Bangladesh          | <input type="radio"/> French Southern and Antarctic Lands   | <input type="radio"/> Moldova          | <input type="radio"/> South Korea                                  |
| <input type="radio"/> Barbados            | <input type="radio"/> Gabon                                 | <input type="radio"/> Monaco           | <input type="radio"/> South Sudan                                  |
| <input type="radio"/> Belarus             | <input type="radio"/> Georgia                               | <input type="radio"/> Mongolia         | <input type="radio"/> Spain  |
| <input type="radio"/> Belgium             | <input type="radio"/> Germany                               | <input type="radio"/> Montenegro       | <input type="radio"/> Sri Lanka                                    |
| <input type="radio"/> Belize              | <input type="radio"/> Ghana                                 | <input type="radio"/> Montserrat       | <input type="radio"/> Sudan  |

- Benin
- Bermuda
  
- Bhutan
  
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
  
- Burkina Faso
- Burundi
- Cambodia
  
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
  
- Central African Republic
- Chad
- Chile
  
- China
  
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
  
- Colombia
- Comoros
  
- Congo
- Gibraltar
- Greece
  
- Greenland
  
- Grenada
- Guadeloupe
  
- Guam
  
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
  
- Guyana
  
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
  
- Iceland
- India
- Indonesia
- Iran
  
- Iraq
  
- Ireland
- Isle of Man
  
- Israel
  
- Italy
  
- Jamaica
- Japan
  
- Jersey
- Jordan
  
- Kazakhstan
- Morocco
- Mozambique
  
- Myanmar /Burma
- Namibia
- Nauru
  
- Nepal
  
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
  
- Niger
  
- Nigeria
- Niue
  
- Norfolk Island
- North Korea
- Northern Mariana Islands
- Norway
- Oman
- Pakistan
- Palau
  
- Palestine
  
- Panama
- Papua New Guinea
- Paraguay
  
- Peru
- Philippines
- Pitcairn Islands
  
- Poland
- Portugal
- Puerto Rico
- Suriname
- Svalbard and Jan Mayen
- Swaziland
- Sweden
- Switzerland
  
- Syria
  
- Taiwan
- Tajikistan
- Tanzania
- Thailand
  
- The Gambia
  
- Timor-Leste
- Togo
  
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
  
- Uganda
- Ukraine
  
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan

- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czech Republic
- Democratic Republic of the Congo
- Denmark
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Saint Martin
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

**\* Publication privacy settings**

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- Anonymous**  
Only your type, country of origin and contribution will be published. All other personal details (name, organisation name and size, transparency register number) will not be published.
- Public**  
Your personal details (name, organisation name and size, transparency register number, country of origin) will be published with your contribution.

\* I agree with the [personal data protection provisions](#)

## 1.- GENERAL QUESTIONS

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1.1 To what extent do you agree with the following statements on the safety and efficacy of feed additives?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
* Feed additives authorised in the EU are safe for animals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Feed additives authorised in the EU are safe for the environment.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* Feed additives help improve animal welfare.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Meat, milk, eggs or other products of animal origin are safe when feed additives are used to prepare feed.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Feed additives are efficacious, for example, in preventing the deterioration of feed.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* The ban of antibiotics in feed introduced by the Regulation plays an important role in preventing antimicrobial resistance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Please develop your response**

*5000 character(s) maximum*

\* 1.2 Do you think that the safety assessment of feed additives carried out by the European Food Safety Authority (EFSA) has helped make feed additives safe for human health, animal health and the environment?

- Yes
- No
- Don't know

**Please develop your response**

*5000 character(s) maximum*

1.3. In addition to safety and efficacy, does the authorisation of feed additives sufficiently consider the following aspects?

	Yes	No	Don't know
* Societal needs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Economic aspects	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Please develop your response**

*5000 character(s) maximum*

\* 1.4 Do you think that other aspects should also be considered?

- Yes
- No
- Don't know

Please develop your response

*5000 character(s) maximum*

\* 1.5 Do you think that the Regulation makes it easier, compared with the former Directive 70/524/EEC (pre-2003 rules), to place new innovative additives on the market (e.g. additives facilitating better absorption of nutrients, increasing production, increasing feed durability, increasing acceptance of feed by animals, etc.)?

- Yes
- No
- Don't know

Please develop your response

*5000 character(s) maximum*

\* 1.6 There is added value in having a harmonised, centralised authorisation procedure for feed additives at EU level.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

Please develop your response

*5000 character(s) maximum*

\* 1.7 The information made available in the publicly accessible Register of Feed Additives ([https://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register\\_en](https://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register_en)) provides the public, stakeholders and competent authorities with sufficient information on feed additives.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

Please develop your response

5000 character(s) maximum

## 2.-SPECIFIC TECHNICAL QUESTIONS

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2.1 The definitions in the Regulation are clear, relevant and up to date.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

2.2 Which parts of the procedure for authorising feed additives are key to its effectiveness and which parts hinder its effectiveness?

Please develop your response

5000 character(s) maximum

2.3. To what extent do you agree with the following statements on the different procedures set out in the Regulation?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
The procedures for granting, modifying, suspending and revoking an authorisation are fit for purpose.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The data requirements for renewing an authorisation are fit for purpose.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The procedure for submitting an application is clear and fit for purpose.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The procedure for sharing data is fit for purpose.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<p>Having a centralised authorisation procedure ensures equal treatment for all applicants and common requirements for applications.</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Please develop your response

*5000 character(s) maximum*

2.4 Do you think that the procedure for authorisation set out in the Regulation involving EFSA for the risk assessment and the Commission for the risk management is still fit for purpose?

- Yes
- No
- Don't know

Please develop your response

*5000 character(s) maximum*

2.5 Do you think that the risk assessment carried out by EFSA allows for sound decision-making?

- Yes
- No
- Don't know

Please develop your response

*5000 character(s) maximum*

2.6 To what extent does the assessment of efficacy provided for in the Regulation ensure that feed additives are effective? Are the scientific parameters used to demonstrate efficacy appropriate for all additive categories and for all animal categories?

*5000 character(s) maximum*

2.7 The EU reference laboratory (EURL) must evaluate the method of analysis provided by the applicant for detecting and quantifying the additive. Do you think that in addition to this evaluation, the EURL should be involved in the method for detecting/quantifying certain impurities of concern or in characterising certain feed additives?

*5000 character(s) maximum*

2.8 For the renewal of authorisations, do you think that the method of analysis should be updated by the applicant according to the latest technical knowledge, if appropriate, and evaluated by the EURL?

*5000 character(s) maximum*

2.9. Are the data protection rules effective in relation to the cost of preparing dossiers and the benefits provided by the 10-year protection?

- Yes
- No
- Don't know

Please develop your response

*5000 character(s) maximum*

2.10 Are data-sharing rules effective in reducing costs and animal testing?

- Yes
- No
- Don't know

Please develop your response

*5000 character(s) maximum*

2.11 The Regulation is sufficiently flexible to adapt to new scientific and technical developments.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

Please develop your response

*5000 character(s) maximum*

2.12 Are there new categories of feed additives and/or functional groups that need to be considered? If yes, please specify.

- Yes

- No
- Don't know

Please develop your response

*5000 character(s) maximum*

2.13 Are there aspects of the use of additives in drinking water that need to be clarified? If yes, please specify.

- Yes
- No
- Don't know

Please develop your response

*5000 character(s) maximum*

2.14 To what extent do you agree with the following statements on the suitability of labelling rules?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
The current labelling of feed additives and premixtures is informative along the feed chain.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The labelling of feed additives and premixtures helps prevent misuse along the feed chain, e.g. the maximum doses and the species concerned are observed.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In addition to the label attached to the feed additive or premixture, the Regulation should allow for other information channels, e.g. internet or notices.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The information on safe use included on the labelling of feed additives and premixtures is clear and enables measures necessary for worker protection to be applied effectively.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Please develop your response

5000 character(s) maximum

2.15 To what extent do you agree with the following statements on placing feed additives on the market?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
Having EU-wide harmonised conditions for placing feed additives on the market facilitates trade.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having EU-wide harmonised conditions for placing feed additives on the market ensures fair competition within the EU.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Please develop your response

5000 character(s) maximum

2.16 To what extent do you agree with the following statements on the cost and benefits of implementing the Regulation?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
The cost of getting a feed additive authorised on the EU market is proportionate to the benefits.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The duration of authorisations (10 years) is proportionate to the cost of applying for the authorisation.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The cost of labelling feed additives and premixtures is justified by the value of the information provided to the user (e.g. preventing misuse).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The Regulation has been effective in preventing food/feed crises, thus avoiding major economic loss from the withdrawal or the destruction of additives and premixtures.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Please develop your response**

*5000 character(s) maximum*

**2.17 Are the Regulation's provisions coherent with other EU feed legislation: feed hygiene, feed marketing, feed materials, medicated feed?**

*5000 character(s) maximum*

**2.18 In your view are the Regulation's provisions consistent with other EU legislation: food additives; genetically modified food and feed; classification, labelling and packaging of chemicals (CLP); registration, evaluation, authorisation and restriction of chemicals (REACH); worker safety; and general provisions laid down in the General Food Law?**

*5000 character(s) maximum*

**2.19 To what extent do you agree with the following statements?**

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
The Regulation positively affects the competitiveness of the feed additives sector.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU-level intervention in feed additives is still warranted.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**3.-FINAL REMARKS**

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Would you like to raise other issues that need to be addressed in this evaluation?  
If so, please specify.

*5000 character(s) maximum*

If you wish to provide additional information (for example a position paper) or raise specific points not covered by this questionnaire, you can upload your additional document here. The maximum file size is 1 MB.

The document is optional and serves as additional background reading to help us understand your position better.

### Please upload your file

The maximum file size is 1 MB

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed