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Impact assessment of feed additives Regulation

Fields marked with * are mandatory.

Introduction

Target group

All EU as well as non-EU citizens are welcome to contribute to this consultation.

Objective of the consultation

The public consultation aims to collect the views of citizens about the EU legislation on the authorisation, labelling and use of feed additives as well as the views of professional and non-professional stakeholders. It seeks to receive information on how citizens view the strengths and weaknesses of the current legislation and the perceived contribution of feed additives to improve sustainability of livestock farming and to keep the current high level of protection of human health, animal health and the environment.

What is a feed additive?

Feed additives are products such as vitamins, anti-oxidants, microorganisms, amino acids, enzymes, used in animal nutrition to keep animals in good health, to improve their welfare, to develop productivity (eggs, meat etc.), to reduce environmental impacts of animal farming and to preserve the quality of feed. Feed additives can exert positive effects on animals' health and well-being by stabilising their intestinal flora and reducing the need for medicinal treatments. This in turn helps reducing the use of antimicrobials, thus decreasing antimicrobial resistance and manure contamination. Feed additives are also added to feed for a technological purpose, for example to preserve the feed from microbiological deterioration or to prevent oxidisation. Other additives may have a nutritional purpose, e.g. vitamins or amino acids. There are also additives having a flavouring effect or colouring the feed.
Premixtures are mixtures of feed additives that can contain also feed materials as support. The premixtures are intermediate products prepared to facilitate the incorporation of additives in feedingstuffs but cannot be ingested directly by animals.

What are the requirements for feed additives to be placed on the market and used?

The Feed Additives Regulation (Regulation (EC) No 1831/2003) lays down provisions for use, placing on the market and labelling of feed additives and premixtures to ensure the highest standards of food safety in the EU.
Before an additive can be placed on the EU market, it requires an authorisation. This authorisation is valid for 10 years and it can be renewed.

To obtain an authorisation the European Food Safety Authority (EFSA) must perform an independent safety and efficacy assessment. A dedicated panel of independent scientific and highly qualified experts assesses that the additive does not have any negative effects on human health, animal health and the environment and that it is efficient. Once the assessment is concluded, the additive is authorised or denied by the Commission by a legal act (Implementing Regulation) that applies to all Member States and to all operators. The authorisation includes all the details: animal species for which the additive is authorised, composition of the additive, levels of use, special directions of use or handling etc.
The Feed Additives Regulation also contains labelling provisions and conditions for use that need to be respected.

Where are we in the process of revising the Feed Additives Regulation?

The revision of the feed additives legislation is part of the Farm to Fork Strategy. This strategy has been adopted by the Directorate-General in charge of Health and Food Safety (DG SANTE) and is framed within an ambitious Commission initiative called "The European Green Deal".

The Farm to Fork strategy's goals are to reduce the environmental and climate footprint of the EU food system and strengthen its resilience, ensure food security in the face of climate change and biodiversity loss and lead a global transition towards competitive sustainability from farm to fork by tapping into new opportunities. The revision of the Feed Additives Regulation will contribute to these aims by reducing the environmental impact of livestock farming. Feed additives can for instance modify characteristics of manure and thus contribute to the reduction of methane and ammonia emissions. They can also contribute to reduce phosphorous excretion and thus the risk of excess fertilisation of the soil and of waters' eutrophication. Some feed additives can improve the nutrient uptake from feed, thus reducing the quantities of feed required.

This consultation will inform the revision of the Feed Additives Regulation.

The revision aims to modernise the legislation, without compromising health and food safety, to improve its effectiveness and efficiency and to align it with the goals of the Farm to Fork Strategy and the European Green Deal.

In order to support this revision, the Commission has started an evaluation of the Feed Additives Regulation. This evaluation is ongoing and some preliminary results showed some areas for improvement that can be summarised as follows:

- The current authorisation system does not sufficiently promote the authorisation of feed additives that may be innovative and may have positive effects on the environment, animal welfare or sustainability of livestock farming.
- Animal welfare is not sufficiently considered. The use of animals (vertebrates) in tests to demonstrate that feed additives are safe and effective can be reduced.
- The use of claims - for example, to raise awareness of the last scientific/technical innovation - is not permitted which limits information about certain aspects of the additive.
- The duration of the authorisation is too short for certain additives which have already a long history of safe use.
- The requirements to demonstrate efficacy are too onerous and can be reduced in certain cases.
- There is a risk of lacking important additives such a vitamins or additives intended for species of low economic value (minor species).

- The administrative burden is disproportionate and not justified for some requirements.
- Some provisions of the Regulation are not sufficiently clear or consistent.
- The information provided through the Feed Additives Register can be more comprehensive and user-friendly.

The Commission proposes in the questionnaire below some possible measures to address a number of these shortcomings.

The Commission will base its revision of the Regulation on a back-to-back evaluation and impact assessment. This Public Consultation is part of a broader consultation strategy, which includes stakeholder surveys designed to collect the views of stakeholder organisations and Member State Authorities.

How can you contribute?

Your views are important. Please tell us what you think and fill in the online questionnaire.
The questionnaire for citizens is accessible in all official EU languages. As there may be delays in translating replies submitted in some languages, contributions in English are welcome as they will help to process the survey more swiftly.

You can pause at any time and continue later. Once you have submitted your answers, you will be able to download a copy of your completed questionnaire. Questions marked with an asterisk (*) are compulsory. Those that are interested have the option to develop their responses in a more detailed manner.

Please note that in this questionnaire, we do not intend to obtain data relating to identifiable persons. Therefore, in case you will describe a particular experience or situation, please do it in a way that will not allow linking to a particular individual, whether it is you or somebody else.

Received contributions may be published on the Internet. It is important that you read the specific privacy statement attached to this consultation for information on how your personal data and contribution will be dealt with.

Related links

The information on the evaluation and impact assessment of the Feed Additives Regulation can be found in: https://ec.europa.eu/food/safety/animal-feed/evaluation-eu-legislation_en

About you

* I am giving my contribution as:

- ○ Manufacturers of feed additives and feed premixtures
- ○ Traders of feed additives (importers/exporters/distributors)
- ○ Applicants for feed additive authorisations and professional consultancy for feed additives applications
- ○ Compound feed and pet food producers
- ○ Users and workers of feed additives.
- ○ Farmers
- ○

- Business and professional associations representing: (a menu will be displayed)
- (●) EU non-governmental organisations or other organisations representing: (a menu will be displayed)
- EU non-governmental organisations or other organisations representing consumers
- Academia and research
- National competent authorities (relevant national public authorities or agencies responsible for feed additives legislation).
- Pet owner
- Citizen
- Other. Please specify

Business and professional associations representing

- Farmers
- Feed additives
- Compound feed
- Pet food
- Feed materials
- Veterinary medicinal products
- Veterinarians
- Other: please specify

EU non-governmental organisations or other organisations representing:

- Animal welfare organisations
- Pet owners' organisations
- Environment
- Trade unions
- (●) Other: please specify

Please specify

Public Health

* Language of my contribution

- Bulgarian
- Croatian

- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- 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

* First name

Tifenn

* Surname

Piolot Doco

* Email (this won't be published)

tifenn@epha.org

* Organisation name

255 character(s) maximum

European Public Health Alliance

* 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.

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* Country of origin

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

( ) Afghanistan	( ) Djibouti	( ) Libya	( ) Saint Martin
( ) Åland Islands	( ) Dominica	( ) Liechtenstein	( ) Saint Pierre and Miquelon
( ) Albania	( ) Dominican Republic	( ) Lithuania	( ) Saint Vincent and the Grenadines
( ) Algeria	( ) Ecuador	( ) Luxembourg	( ) Samoa
( )	( ) Egypt	( ) Macau	( ) San Marino

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- Antarctica
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- Armenia
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- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Nauru
- São Tomé and Príncipe
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- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland

- 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
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- Chile
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- Guinea
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- Haiti
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- Indonesia
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- Ireland
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- Niger
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- Niue
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- North Korea
- North Macedonia
- Norway
- Oman
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- Palestine
- Panama
- Papua New Guinea
- Paraguay
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- Taiwan
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- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
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- Tuvalu
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- United Arab Emirates
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Clipperton	Jamaica	Peru	United States
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Costa Rica	Kiribati	Qatar	Vatican City
Côte d'Ivoire	Kosovo	Réunion	Venezuela
Croatia	Kuwait	Romania	Vietnam
Cuba	Kyrgyzstan	Russia	Wallis and Futuna
Curaçao	Laos	Rwanda	Western Sahara
Cyprus	Latvia	Saint Barthélemy	Yemen
Czechia	Lebanon	Saint Helena Ascension and Tristan da Cunha	Zambia
Democratic Republic of the Congo	Lesotho	Saint Kitts and Nevis	Zimbabwe
Denmark	Liberia	Saint Lucia	

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **Fo r the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

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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 organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

Public

Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

☑ I agree with the personal data protection provisions

Contact
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Unit E5.-. Animal nutrition, veterinary medicines

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SECTION I OBJECTIVES

Sustainability of livestock farming is one of the objectives of the revision of the Feed Additives Regulation. Currently, the 'sustainability' concept is not yet defined, nor the criteria determining to what extent a food /feed is 'sustainable'. However, it encompasses various elements of environmental, social and economic nature, such as climate change mitigation (reduction of greenhouse gases as methane), limiting the contamination of soils and waters (e.g. reduction of excess of phosphorous excretion), animal welfare, use of resources, reduction of waste, healthy diets and food/feed affordability.

* **Q.1 To what extent do you consider that feed additives (FA) currently placed on the EU market meet the needs of sustainable farming.** Please justify your answer

5000 character(s) maximum

In the context of the implementation of the Farm to Fork and Biodiversity Strategies, EPHA welcomes the revision of Regulation 1831/2003 on Feed Additives and the ambition to improve animal health and welfare to open the way towards more sustainable animal farming.
According to Regulation 1831/2003, there exist different types of feed additives, including coccidiostats and histomonostats, which are the only antibiotics allowed as feed additives and are not managed under Regulation (EU) 2019/6 on veterinary medicinal products. Article 11 « Phasing Out » of Regulation 1831 specifies that "with a view to a decision on the phasing out of the use of coccidiostats and histomonostats as

feed additives by 31 December 2012, the Commission shall submit to the European Parliament and the Council before 1 January 2008 a report on the use of these substances as feed additives and available alternatives, accompanied, where appropriate, by legislative proposals." This report was duly published by the Commission in 2008. However it concluded the current regulatory framework established by Regulation 1831/2003 was working and no change was required.
In light of the current sustainability challenges posed by food systems and the health threats of antimicrobial resistance (AMR), with the overuse of antibiotics in animal husbandry as an important contributing factor; EPHA expresses its concerns about the continued widespread use of coccidiostats and histomonostats as feed additives.
These substances could be used in a way to compensate for poor animal husbandry conditions, may also contribute to pharmaceutical pollution in the environment and could be associated with horizontal transfer of resistance. Moreover, recent research suggests ionophores (coccidiostats) could become adapted for use in humans, possibly making them medically important in the future. [https://www.nature.com/articles/s41557-020-00601-1]
This state of affairs is not coherent with the EU ambition to be a global leader in the fight against AMR and in the transition towards sustainable food systems as presented in the Farm to Fork Strategy and in the spirit of the Veterinary Medicines and Medicated Feed Regulations.
Thus, EPHA recommends to introduce rules under this Directive to restrict the mass routine preventive use of coccidiostats and histomonostats, equivalent to those rules covering other antibiotics under the Veterinary Medicines and Medicated Feed Regulations. In due time, it should consider adding coccidiostats and histomonostats to scope of the latter Regulations.
Moreover EPHA would like to emphasis that actions to reduce antibiotics use in animal agriculture should be achieved through a primary focus on improving animal health and welfare, guided by a One Health approach.

Q.2: How do you assess the effects of FA on the following aspects?

	Very positive	Fairly positive	Fairly negative	Very negative	I don't know
* On the environment (e.g. phosphorous excretion by animals)	○	○	○	○	◉
* Climate change (e.g. methane emissions)	○	○	○	○	◉
* Carbon footprint of feedingstuffs	○	○	○	○	◉
* Animal welfare	○	○	○	○	◉
* Use of antimicrobials in animals	○	○	○	○	◉
* Other sustainable effects (waste of livestock production or use of local resources)	○	○	○	○	◉
* Animal performance	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

* **Q.3 Are there other aspects (positive or negative aspects) related to the effects of FA etc. that you want to address?**

- ○ Yes
- ◉ No
- ○ I don't know

Please develop your response

5000 character(s) maximum

Q.4 To what extent do you agree with the following statements?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know
* FA should contribute to reduce the environmental impact in livestock production	○	○	○	○	◉
* FA should improve animal welfare	○	○	○	○	◉
* FA should be available for all types of animals including those of lower economic interest	○	○	○	○	◉
* FA should be affordable for operators	○	○	○	○	◉
* Operators should promote the use of FA having a positive effect on the environment and climate, independently of their price	○	○	○	○	◉
* Operators should promote the use of additives having a positive effect on animal welfare, independently of their price	○	○	○	○	◉
* Operators should promote the use of additives having a positive effect on animal health, and thus contributing to reduce the use of antimicrobials, independently of their price	○	○	○	○	◉
* Operators should promote the use of additives having a positive effect on better utilisation of resources/ reduction of waste, independently of their price	○	○	○	○	◉
* Operators should promote the use of additives having a positive effect on performance (e.g. increase of egg production), independently of its price.	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

Q.5 To what extent do you agree with the following statement?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know
* As a consumer I am willing to pay more for food that has been produced under sustainable livestock farming	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

Q.6 If yes, please respond

	Less than 5%	5-10%	>10-15%	>15%
As a consumer I will pay an increase for the price of:	○	○	○	○

Please develop your response

5000 character(s) maximum

Q.7 How do you assess the importance of the following topics, taking into account that the current level of food safety will be maintained?

	Very important	Fairly important	Rather unimportant	Not important at all	I don't know
* Facilitate the placing on the market of FA reducing the effects of animal farming on the environment and climate	○	○	○	○	◉
* Facilitate the placing on the market of FA having positive effects on animal health, and thus contributing to reduce the use of antimicrobials.	○	○	○	○	◉
* Facilitate the placing on the market of FA having positive effects on animal welfare	○	○	○	○	◉
* Facilitate the placing on the market of FA having positive effects on better utilisation of resources/ reduction of waste	○	○	○	○	◉

* Facilitate the placing on the market of innovative FA.	○	○	○	○	◉
* Streamline the authorisation process	○	○	○	○	◉
* Encourage a better functioning of the Single Market so FA may circulate smoothly within the EU	○	○	○	○	◉
* Reduction of unnecessary burden for operators	○	○	○	○	◉
* Improve the information along the food chain	○	○	○	○	◉
* Prevent the shortage of important FA, e.g. vitamins	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

SECTION II INNOVATION AND SUSTAINABILITY

1- Structure of the Regulation

The current Regulation does not allow for the authorisation of FA on the grounds that they were beneficial for the environment or animal welfare as they can only be included in the category “zootechnical additives”. In this category, applicants need to demonstrate performance enhancement (e.g. more production of meat or eggs) in addition to the demonstration of actions having benefits for the environment or animal welfare.

*** Q.8 Do you think that additives intended to reduce the environmental impact or to have beneficial effects for animal welfare also need to increase animal performance?**

- ○ Yes
- ○ No
- ◉ I don't know

Please develop your response

5000 character(s) maximum

2- Data sharing

For the assessment of FA, in particular to ensure that FA are safe, it is necessary to perform toxicological tests on animals (vertebrates). The FA Regulation has few provisions to prevent duplication of those tests by promoting the sharing of data between applicants. According to the results of the evaluation, no cases of data sharing have occurred.

Q.9 To what extent do you agree with the following statements?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know
* Data sharing should be better promoted to reduce toxicological tests on vertebrates for animal welfare reasons	○	○	○	○	◉
* Data sharing must be mandatory to reduce toxicological tests on vertebrates for animal welfare reasons	○	○	○	○	◉
* Clear rules for data sharing must be set up for animal welfare reasons.	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

3.-Claims

Operators may not make claims in the labelling beyond the effects assessed by EFSA. For example, if we authorise a phytase (enzyme) that increases the assimilation of phosphorous by the animal, a claim may state that “this enzyme reduces the phosphorous emission”. The claims may also be related to the way in which the additive is produced, e.g. from renewable feed materials or produced by a new manufacturing method that increases the purity of the additive. This restriction in claims may limit information about other secondary effects intrinsic to the substance, the characteristics of the additive or the latest scientific or technical innovation.

Q.10 To what extent do you agree with the following statements?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know
* Additional claims beyond the effects assessed by EFSA should be made possible for FA	○	○	○	○	◉
* Claims are an important tool to raise awareness of scientific/technical innovations in FA	○	○	○	○	◉
* Claims may help to raise awareness of the effects on sustainability of FA in livestock farming.	○	○	○	○	◉
* Claims may improve the information conveyed to users of FA by adding additional particulars	○	○	○	○	◉
* Claims must be approved according to specific and detailed provisions	○	○	○	○	◉
*					

Claims do not need to be approved but must be substantiated and developed by operators. They must be subject to control by the National Competent Authorities of the Member States.	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

4- Duration of the authorisation

The current duration of the authorisation is 10 years for all additives. One year before the authorisation expires the applicant can submit an application for renewal. On one hand, this involves costs. On the other hand, the renewal is necessary to update the safety assessment and to exclude those additives that are no longer marketed. During the evaluation the duration of the authorisation of some additives having a safe record of use was perceived as too short. Considering the recent Farm to Fork Strategy, the Commission is considering the possibility to extend that period for those additives having positive effects on sustainability. Any extension of the authorisation period must not undermine the current safety level.

Q.11 To what extent do you agree with the following statements?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know
* The current authorisation period for all additives works well	○	○	○	○	◉
* The current system needs to be revised by extending the authorisation period, while keeping a high level of food safety	○	○	○	○	◉
* The extension of the authorisation period will reduce unnecessary burden and costs	○	○	○	○	◉
* The authorisation period can be extended for those additives with high safety profile, e.g. some vitamins	○	○	○	○	◉
* The authorisation period can be extended for those additives aiming at promoting sustainable livestock farming	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

SECTION III AUTHORISATION PROCESS

An issue identified during the evaluation is that there are not sufficient additives intended for minor species. Those species are species not relevant from the economic point of view but help to diversify animal production. During the evaluation it has been identified that the measures to incentivise applications for authorisations in minor species were not enough to encourage applicants to apply for those species.

* Q.12 How can operators be incentivised to request authorisation for minor species?

Please develop your response

5000 character(s) maximum

NA.

SECTION IV ADMINISTRATIVE BURDEN

Reduction of administrative burden for Regulations linked to an authorisation holder.

The authorisation of some additives is linked to an authorisation holder who has the exclusive right to place the additive on the market. Those rights are often transferred to other companies during business mergers or acquisitions. A Commission Regulation must be adopted every time a change of an authorisation holder occurs.

Q.13 To what extent do you agree with the following statement?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know
* The change of the authorisation holder should be processed by a simple administrative procedure and the information on the new authorisation holder should be available to the public.	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

Labelling of FA and premixtures

All information required for labelling about additives and premixtures must be included in a physical label. The revision of the FA Regulation seeks to contribute to a greater use of information and communication technologies amongst operators when passing on information about additives/premixtures.

Q.14 To what extent do you agree with the following statements?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know
* The current system (all the information on a physical label) works well.	○	○	○	○	◉
* The most important information must be kept in the physical label and the rest of the information					

may be communicated more efficiently through other means e.g. through the use of digital tools.	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

Q.15 To your view, which of the following information must be kept on the physical label and what information- if any- may be transmitted by other means?

	PHYSICAL LABEL	OTHER MEANS
* Name of the additive	○	◉
* Identification number of the additive	○	◉
* Functional group	○	◉
* Species for which it is intended for	○	◉
* The person responsible for the labelling (name and address)	○	◉
* Weight or volume	○	◉
* Approval number of the establishment required for certain additives	○	◉
* Directions for use	○	◉
* Safety recommendations	○	◉
* Specific information laid down in the authorising Regulation of the additive	○	◉
* Batch reference and date of manufacture	○	◉

Please develop your response

5000 character(s) maximum

SECTION V IMPORTS, IDENTIFICATION AND CIRCULATION OF FA ONLY INTENDED FOR EXPORT

Imports

FA and premixtures are not identified as such when imported. They are often imported as chemical substances intended for different purposes.

Q.16 To what extent do you agree with the following statements?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know

* Identification of FA and premixtures at import stage will improve the capacity to control imports.	○	○	○	○	◉
The reduced capacity to control imports creates unfair competition for EU operators versus non-EU operators	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

* Q.17 To your view what measures may improve the control and traceability of feed additives and premixtures?

Please develop your response

5000 character(s) maximum

NA

Identification and restrictions on the circulation of FA only intended for export

This concerns FA and premixtures for which an authorisation in the EU has not been requested/granted but which are manufactured within the EU. These FA can only be exported if they are considered safe and under the condition that the importing country expressly agrees to the export (Article 12 of the GFL). They cannot circulate within the EU and must be directly exported from the producing establishment. This issue should be addressed to fulfil the GFL safety requirements while avoiding unnecessary restrictions to the circulation of those FA/premixtures within the EU or at MS level for commercial purposes. In the FA Regulation there is no mandatory labelling indicating that those additives and premixtures are only intended for export. This type of production is an important business activity for many small and medium size enterprises.

Q.18 To what extent do you agree with the following statements?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know
* Additives/premixtures only intended for export must bear an indication on the labelling to inform that they are intended for export and cannot be placed on the EU market	○	○	○	○	◉
* Conditions must be set up for additives only intended for export.	○	○	○	○	◉
* These additives/ premixtures should be allowed to circulate for export purposes only within the producing Member State provided that they bear an appropriate labelling.	○	○	○	○	◉
*					

These additives/ premixtures should be allowed to circulate for export purposes within the EU provided that they bear an appropriate labelling	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

SECTION VI. INSUFFICIENT LEGAL CLARITY AND CONSISTENCY

This public consultation will not enter into the details of all the aspects that would need to be modified to provide clarity and consistency as many of them are simple technical adjustments. For some of them it is important to have feedback as they may entail a change compared to the current situation.

Recommended levels

For some additives there are recommended levels. Those levels are set up in the authorising Regulation to provide users with an orientation on the optimal dose of use.

* Q.19 Do you think that recommend levels of use have an added value?

- ○ Yes
- ○ No
- ◉ I don't know

Please develop your response

5000 character(s) maximum

Additives for which the applicant withdraws the application for renewal

The FA Regulation provides for the renewal of authorisation of additives. If the application for renewal is presented in due time, the feed additive remains on the market until a decision on the renewal is taken. Sometimes the applicant withdraws the application for renewal during the process. In this case, the additive is not permitted anymore. This creates uncertainties for operators who are not informed immediately of that withdrawal. The concerned additive may be present in some compound feed or feed materials as it was incorporated before the withdrawal happened, and in consequence these too suddenly need to be withdrawn from the market.

Q.20 To what extent do you agree with the following statements?

	Fully agree	Rather agree	Rather disagree	Fully disagree	Don't know
* Additives for which the applicant withdraws the application for renewal should be withdrawn from the market following some transitional period that allows operators to take the necessary measures, if there are no safety reasons that justify an immediate withdrawal.	○	○	○	○	◉

* Operators must be informed immediately of any withdrawal that happens during the renewal of an additive.	○	○	○	○	◉

Please develop your response

5000 character(s) maximum

Register of FA

The register of FA is an important tool to inform operators and the general public on the FA that are authorised. The Register is publicly available in https://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register_en

During the evaluation, the need to make this Register more friendly-user and increase the level of information were highlighted.

Q.21 What changes could be introduced in the Register in order to improve its format and presentation?

Please develop your response

5000 character(s) maximum

NA

* **Q. 22 What information do you expect to find in the register of FA? For example, information about additives that have not been requested for renewal and within one year will not be authorised, or information on special precautions for handling due to safety reasons.**

Please develop your response

5000 character(s) maximum

NA

* **Q. 23 Do you think that the Register of FA should send automatic notifications to subscribers alerting them each time the register is modified, if a renewal for an additive has not been processed, a change of an authorisation holder has occurred or an additive under renewal has been withdrawn by the applicant?**

Please develop your response

5000 character(s) maximum

NA

SECTION VII –ADDITIONAL CONTRIBUTION

Q 24 Would you like to raise other issues that need to be addressed in this impact assessment? If so, please specify.

Please develop your response

4500 character(s) maximum

Do you want to upload a position paper or document?

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.

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

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