Respondent report

PPP REFIT Stakeholder survey

1 You are replying:

On behalf of an organisation or as an academic

2 Please report on the nature of your organisation. Is it ...

An industry / business association (including agriculture and retail)

3 Please indicate the major field of activity or interest of your organisation:

Agriculture, forestry and fishing

5 At what level is your organisation primarily active?

Outside the EU

6 Please indicate in which country/countries you are (primarily) active (multiple choices possible):

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Netherlands
Poland
Portugal
Romania
Slovak Republic
Slovenia
Spain
Sweden
United Kingdom
Norway

Switzerland

7 Please provide the name of your organisation:

Gafta - The Grain and Feed Trade Association

8 Is your organisation included in the Transparency Register? For your answer to be properly considered as the contribution of an organisation, your organisation needs to be registered with the Transparency Register. If your organisation is not registered, we invite you to register here. What is the Transparency Register?

Yes

9 Please add your Transparency Register Number below:

288900120

10 In addition to this survey, we will perform interviews to complement the findings from this survey and to explore issues related to the two Regulations in greater depth. Would you be willing to be interviewed?

tradepolicy@gafta.com

11 How familiar are you with the two Regulations?

a MRL Regulation - Regulation (EC) No 396/2005

Very familiar (1 - 4)

b PPP Regulation - Regulation (EC) No 1107/2009

Very familiar (1 - 4)

Overall performance of the regulatory system

The following questions explore if the procedures specified in the two Regulations work in practice.

13 Overall, how well are the provisions of the PPP Regulation working in practice? Please specify with regards to:

a Approval of new active substances

To a small extent only (1 - 6)

b Renewal of approvals of active substances

To a small extent only (1 - 6)

c Authorisation of new plant protection products

To a small extent only (1 - 6)

d Renewal of authorisations of plant protection products

To a small extent only (1 - 6)

e Authorisation of PPPs for minor uses

To a small extent only (1 - 6)

f Authorisation of low-risk substances

Don't know (1 - 6)

g Authorisation of plant protection products in emergency situations

To a small extent only (1 - 6)

h Zonal authorisations of plant protection products

To a small extent only (1 - 6)

i Mutual recognition within one zone

To a small extent only (1 - 6)

j Mutual recognition across zones

To a small extent only (1 - 6)

k Parallel trade

Don't know (1 - 6)

l Labelling of plant protection products

Moderately (1 - 6)

14 Overall, how well are the provisions of the MRL Regulation working in practice? Please specify with regards to:

a Setting / amending MRLs

To a small extent only (1 - 6)

b Reviewing MRLs

To a small extent only (1 - 6)

c Setting import tolerances

To a small extent only (1 - 6)

Click here to view your responses

General objectives

The PPP and MRL Regulations aim to protect human, consumer and animal health, and the environment, while at the same time improving the functioning of the internal market, safeguarding EU agricultural production, and facilitating trade.

15 To what extent do you consider the PPP and MRL Regulations to be reaching the following objectives?

a Protection of the health of users of pesticides, affected bystanders, and residents

To a large extent (1 - 6)

b Protection of the health of consumers

To a large extent (1 - 6)

c Protection of animal health

To a large extent (1 - 6)

d Protection of the environment, incl. wildlife

To a large extent (1 - 6)

e Improving the functioning of the EU internal market

To a small extent only (1 - 6)

f Improving agricultural production and safeguarding the competitiveness of EU agriculture

To a small extent only (1 - 6)

g Facilitating the smooth running of international trade

Not at all (1 - 6)

16 Please explain your reasoning below: (400 characters max.)

EU pesticide legislation meets objectives on health and environment. Improvements are needed on competitiveness and facilitation of international trade. Currently, legislation is leading to a reduced availability of substances for EU agriculture and the lowering of MRLs creates additional trade risk, which are not necessary to meet safety objectives of legislation.

17 In addition to the general objectives mentioned above, the Regulations include more specific objectives. To what extent do you consider the PPP and MRL Regulations to be reaching the following specific objectives?

a Ensuring coherence of the rules and procedures between the placing on the market of PPPs and the setting of MRLs

To a small extent only (1 - 6)

b Ensuring the safety of users, consumers, including vulnerable groups of consumers, affected bystanders, animals, and the environment

To a large extent (1 - 6)

c Allowing an efficient use of resources for risk assessment and risk management in the policy area of pesticides

To a small extent only (1 - 6)

d Reducing the time for new products to enter the market

To a small extent only (1 - 6)

e Making relevant information available for applicants, importers, users, public authorities, and consumers

To a small extent only (1 - 6)

Click here to view your responses

Functioning and coherence of the PPP and the MRL Regulations

The provisions of the PPP and MRL Regulations are interlinked. The following questions explore these linkages. We

want to know if the rules for bringing plant protection products to the market and setting maximum residue levels complement each other or if they are contradictory (internal coherence). The questions also explore if the provisions of the two Regulations are conflicting with other EU legislation (external coherence).

18 Have the PPP and MRL Regulations created a coherent policy in the field of pesticides? In other words, are the provisions within the Regulations complementary or contradictory? The PPP and MRL Regulations...

Complement one another to some extent only

19 Please explain your reasoning below: (400 characters max.)

Improvements could be made to achieve more coherence between PPP and MRL regs. particularly around timelines. Hazardous based criteria are present in PPP reg but MRL regulation is and should remain risk based.

20 Are the provisions of the PPP and MRL Regulations coherent with other EU legislation in the following fields? Please provide your answer for those policy fields that directly affect your interest or field of activity.

a Agriculture

No (1 - 3)

b Baby food

Don't know (1 - 3)

c Biocides

No (1 - 3)

d Chemicals

Don't know (1 - 3)

e Climate Change

Don't know (1 - 3)

f Consumer protection

Don't know (1 - 3)

g Energy / Bio-energy

Don't know (1 - 3)

h Environment

Don't know (1 - 3)

i Feed

No (1 - 3)

j Fertilisers

No (1 - 3)

k Food

No (1 - 3)

l Food security

Don't know (1 - 3)

m Public Health

Don't know (1 - 3)

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21 If you selected ‘No”, please highlight any relevant inconsistencies that directly affect your interests or field of activity: (400 characters max.)

Hazard based criteria will remove important active substances for agriculture where their use is safe using a robust risk assessment. Challenges with residues from mutilple sources: when MRL applies to substances formerly used for Plant protection while main source is different (eg from fertilising products or naturally occuring substances).

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22 Are the existing provisions flexible enough to take new scientific information into account (e.g. new toxicological information)?

a PPP Regulation

To a large extent (1 - 6)

b MRL Regulation

To a large extent (1 - 6)

23 Are the existing provisions flexible enough to allow for quick reactions by risk managers to address unforeseen situations or exceptional circumstances?

a PPP Regulation

To a large extent (1 - 6)

b MRL Regulation

To a large extent (1 - 6)

Click here to view your responses

Implementation and enforcement

The first questions will explore how the Regulation has been implemented and to what extents its provisions have been enforced.

25 To what extent have the provisions of the PPP Regulation been implemented since 2011?

a Approval of active substances

To a large extent (1 - 6)

b Authorisation of plant protection products

To a large extent (1 - 6)

c Comparative assessment

Moderately (1 - 6)

d Zonal authorisation

Don't know (1 - 6)

e Hazard-based 'cut-off criteria'

Moderately (1 - 6)

f Mutual recognition

Moderately (1 - 6)

26 In your opinion, is the PPP Regulation adequately enforced with regard to the approval of active substances?

No

27 In your opinion, is the PPP Regulation adequately enforced with regard to the authorisation of PPPs?

Don't know

28 If you think that the PPP Regulation is not adequately enforced, please explain below why: (400 characters max.)

View is that more controls are need on enforcing illegal and counterfit plant protection products on the market.

Click here to view your responses

Definitions

The PPP regulation provides definitions for a number of different terms relevant for the policy field. The following question seeks to explore whether these definitions are still relevant or need to be modified.

In your opinion, are the definitions for the following terms in the PPP Regulation still relevant for the situation today or would they need modification?

29 'Substances' (Art 3):"chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process"

Still relevant

30 'Active substances' (Art 2):"substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products"

Still relevant

31 'Residues' (Art 3):"one or more substances present in or on plants or plant products, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites, breakdown or reaction products"

Still relevant

32 'Metabolite' (Art 3):"any metabolite or a degradation product of an active substance, safener or synergist, formed either in organisms or in the environment"

Still relevant

33 'Plant protection product' (Art 2):"products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses: a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products; b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives; d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants; e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants."

Still relevant

'Preparations' (Art 3):"mixtures or solutions composed of two or more substances intended for use as a plant

34 protection product or as an adjuvant”

Still relevant

35 ‘Placing on the market’ (Art 3):“the holding for the purpose of sale within the Community, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, but not the return to the previous seller. Release for free circulation into the territory of the Community shall constitute placing on the market for the purposes of this Regulation”

Still relevant

Click here to view your responses

Approval of active substances

An active substance is either a chemical or a biological product that is used as the key component in a plant protection product to achieve the intended goal. Every active substance is evaluated for safety before it reaches the market in a product. Substances, including their residues in food, must demonstrate no risk of unacceptable effect on human health, animal health, and the environment.

The PPP Regulation categorises active substances at the EU level according to certain properties: (1) basic substances have unlimited time approvals, (2) low-risk substances are subject to longer approval periods and longer data protection. 3) "Candidates for Substitution" are substances that Member States should substitute whenever possible.

The approval criteria in the PPP Regulation are based on both hazard and risk. The hazard based ”cut-off” criteria refer to substances that are mutagenic, carcinogenic, toxic for reproduction or with endocrine disrupting properties, or with a combination of persistent, bioaccumulative and toxic properties.

37 In your opinion, how do hazard-based 'cut-off' criteria for decision making on active substances contribute to the following objectives?

a The protection of human health, including operators (users of pesticides), affected bystanders, and residents

No effect (1 - 6)

b The protection of animal health

No effect (1 - 6)

c The protection of the environment, incl. wildlife

No effect (1 - 6)

d Functioning of the internal market

Very negatively (1 - 6)

e Competitiveness of EU agriculture

Very negatively (1 - 6)

38 In your opinion, do the approval criteria (except the hazard-based 'cut-off' criteria) for decision making on active substances contribute to the following objectives?

a The protection of human health, including operators (users of pesticides), affected bystanders, and residents

Positively (1 - 6)

b The protection of animal health

Positively (1 - 6)

c The protection of the environment, incl. wildlife

Positively (1 - 6)

d Functioning of the internal market

No effect (1 - 6)

e Competitiveness of EU agriculture

No effect (1 - 6)

39 Are the criteria for the approval of an active substance appropriate, or should they be more or less strict?

a Hazard-based “cut-off” criteria

Less strict (1 - 4)

b Other criteria

Appropriate (1 - 4)

40 Are the criteria applied appropriately by the authorities (Member State competent authorities, EFSA, the European Commission)?

No

41 If they are not applied appropriately, please explain your reasoning below: (400 characters max.)

Challenges remain when substances are not authorised simply due to unfinalised, inconclusive or

lack of additional data required to carry out risk assessments or need for further consideration by risk managers.

42 Are other factors such as social, economic, or agronomic factors, sufficiently taken into consideration in the decision making for the approval of active substances?

a Social factors

Don't know (1 - 6)

b Economic factors

Insufficiently (1 - 6)

c Agronomic factors

Insufficiently (1 - 6)

d Other factors, please specify risk benefit considerations

Insufficiently (1 - 6)

[section continues on the next page]

43 The PPP Regulation categorises active substances into different groups, i.e. basic substances, low-risk substances, and Candidates for Substitution. How does this categorisation contribute to the following objectives?

a The protection of human health, including operators (users of pesticides), affected bystanders, and residents

No effect (1 - 6)

b The protection of animal health

No effect (1 - 6)

c The protection of the environment, incl. wildlife

No effect (1 - 6)

d The availability of plant protection products

Negatively (1 - 6)

44 The risk assessment process for the approval of active substances involves authorities at the national and EU level, i.e. the European Commission, the European Food Safety Authority, and Member States. Is the current work sharing between EU and national authorities necessary and beneficial for the approval of active substances?

No, both EU and national authorities should be involved, but the work should be shared differently

45 If you selected 'No', please briefly explain your reasoning below: (400 characters max.)

The trade supports one central evaluation of active substances and PPPs including more harmonisation and mutual recognition

Click here to view your responses

Authorisation of plant protection products

With the implementation of the PPP Regulation, Member States were divided into three geographical zones (the southern, central, and northern zone). Authorisations of plant protection products are supposed to be facilitated within these zones. An applicant (i.e. the company filing for the authorisation of a plant protection product) can indicate a number of countries within the same zone (the 'concerned Member States') where the plant protection product should eventually be authorised. A zonal rapporteur Member State assesses the application on behalf of these concerned Member States. The concerned Member States must justify any rejection of authorisation.

46 Overall and per zone, how well is the zonal system working?

a Overall (considering all three zones)

To a small extent only (1 - 6)

b Northern zone

Don't know (1 - 6)

c Central zone

Don't know (1 - 6)

d Southern zone

Don't know (1 - 6)

e Interzonally

To a small extent only (1 - 6)

47 More specifically, how well is the zonal system working with respect to:

a Harmonising the authorisation of plant protection products?

To a small extent only (1 - 6)

b Improving the efficiency of authorisation processes?

To a small extent only (1 - 6)

c Facilitating mutual recognition?

To a small extent only (1 - 6)

d Availability of plant protection products for minor uses (Article 51)?

To a small extent only (1 - 6)

48 Please explain your reasoning below: (400 characters max.)

Zonal system is not working in practice, one zone would be more helpful particularly for minor uses.

49 Plant protection products are currently authorised and placed on the market at the national level. Member State competent authorities are in charge of assessing individual products (Art 36). Is this procedure necessary and beneficial?

Yes, the current procedure is necessary and beneficial

Click here to view your responses

Comparative assessment of Candidates for Substitution

One category of active substances are so-called Candidates for Substitution (CfS). These are active substances that meet one or more of the criteria provided in Annex II Point 4 of the PPP Regulation. Whenever a plant protection product containing a CfS is assessed for re-authorisation, it is subject to a comparative assessment (Art 50). The European Commission published a list of CfS in August 2015.

Member States shall assess plant protection products containing such substances with the aim of substituting them, whenever possible, with non-chemical control or prevention methods, or with products containing substances that require fewer risk-mitigation measures.

50 The PPP Regulation aims to facilitate the substitution of hazardous substances with other substances or by alternative methods. How well do you think this is working?

To a small extent only

51 Does the comparative assessment result – on average – in higher costs for the preparation of a dossier?

Don't know

52 Does the comparative assessment contribute to:

a The protection of human health, including operators (users of pesticides), affected bystanders, and residents

No (1 - 3)

b The protection of animal health

No (1 - 3)

c The protection of the environment, incl. wildlife

No (1 - 3)

53 Please feel free to share any additional comments or thoughts on Candidates for Substitution: (400 characters max.)

Substitution could lead to the removal of key substances due to the hazard based cut off approach, not based on risk assessment and limiting options for integrated pest management programmes.

Click here to view your responses

Availability of plant protection products

The following questions address the availability of plant protection products on the market. We are interested in

potential impacts that the implementation of the PPP Regulation might have had. We also ask more generally for your input on which types of plant protection products are commercially available.

54 How would you characterise the availability of plant protection products on the market?

a Plant protection products in general

Somewhat sufficient (1 - 6)

b Plant protection products for minor uses

Insufficient (1 - 6)

c Low risk active substances

Insufficient (1 - 6)

d Plant protection products that contain new or innovative active substances(Innovative active substances are understood as substances which have never been approved in the EU before and have not been approved in other jurisdictions (e.g. the USA or Canada) for more than 5 years.)

Insufficient (1 - 6)

e Basic substances

Insufficient (1 - 6)

55 The PPP Regulation contains several provisions for low-risk substances and products, such as a longer approval period, longer data protection period, and an authorisation procedure with shorter timelines. How effective are these provisions in facilitating the placing on the market of low-risk PPPs?

Don't know

56 How has the availability of plant protection products on the market developed over the last ten years (2007 until today)?

a Plant protection products in general

Decline in availability (1 - 4)

b Plant protection products for minor uses

Don't know (1 - 4)

57 How would you characterise the availability of alternatives within groups of pesticides?

a Herbicides

Insufficient (1 - 6)

b Insecticides

Highly insufficient (1 - 6)

c Fungicides

Insufficient (1 - 6)

d Other alternatives, please specify Molluscicides

Insufficient (1 - 6)

58 Please feel free to share any additional thoughts on the availability of plant protection products: (400 characters max.)

While some crops have suffecient alternatives for specific pests, there are many crop/pest combiantions where alternatives are clearly insuffecient impacting on farmers ability to protect crops. Availability of storage insecticides is at critical level across the EU and a major concern for those operators storing grains.

Click here to view your responses

Timelines and time-limited approval periods

The PPP Regulation specifies how much time each step of the risk assessment and decision-making process is supposed to take for both the approval of active substances and the authorisation of plant protection products. The purpose of the timelines is to make the procedures more transparent and easier to predict.

59 From application to decision, how much time do the different procedures take in practice? Please provide – if possible – a minimum, maximum, and average in months/ days.

a Approval of a new active substance (months)

Don't know

b Renewal of an approval of an active substance (months)

Don't know

c Authorisation of a plant protection product for the zonal rapporteur (months)

Don't know

d Authorisation of a plant protection product for the concerned Member State (months)

Don't know

e Renewal of an authorisation of a plant protection product (months)

Don't know

f Re-authorisation of a plant protection product containing a Candidate for Substitution (months)

Don't know

g Authorisation of a plant protection product for minor uses (months)

Don't know

h Mutual recognition (days)

Don't know

i Parallel trade (days)

Don't know

61 How do you perceive the timelines as set out in the PPP Regulation? Are they adequate with regard to:

a Approval of a new active substance (Art 7 ff.)

Legal timeline is adequate (1 - 4)

b Renewal of an approval of an active substance (Art 14ff.)

Legal timeline is adequate (1 - 4)

c Authorisation of a plant protection product as the zonal rapporteur (Art 33ff.)

Legal timeline is adequate (1 - 4)

d Renewal of an authorisation of a plant protection product (Art 43)

More time would be adequate (1 - 4)

e Re-authorisation of a plant protection product containing a Candidate for Substitution (Art 50)

More time would be adequate (1 - 4)

f Authorisation of a plant protection product for minor uses (Art 51)

Don't know (1 - 4)

g Mutual recognition (Art 40ff.)

Don't know (1 - 4)

h Parallel trade (Art 52)

Don't know (1 - 4)

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62 Do you think that the requirement to renew the approval of active substances after a limited amount of time is instrumental to ensure the protection of the health of humans and animals and the environment?

a “Regular” active substances (10 / 15 years)

To a small extent only (1 - 6)

b Low-risk active substances (15 years)

To a small extent only (1 - 6)

c Candidates for substitution (7 years)

To a small extent only (1 - 6)

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63 If you selected “Not at all, “To a small extent only”, or “Moderately”, do you think a longer or shorter time period would be appropriate?

a “Regular” active substances (10/ 15 years)

Longer (1 - 3)

b Low-risk active substances (15 years)

Longer (1 - 3)

c Candidates for substitution (7 years)

Longer (1 - 3)

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64 From your experience, how often are approvals of active substances and authorisations of plant protection products delayed beyond the legal timelines?

a Approval of a new active substance

More than 75% of cases (1 - 6)

b Renewal of an approval of an active substance

More than 75% of cases (1 - 6)

c Authorisation of a plant protection product

More than 75% of cases (1 - 6)

d Renewal of an authorisation of a plant protection product

More than 75% of cases (1 - 6)

e Re-authorisation of a plant protection product containing a candidate for substitution

More than 75% of cases (1 - 6)

f Authorisation of a plant protection product for minor uses (Article 51)

50% to 75% (1 - 6)

g Mutual recognition / authorisation as a concerned Member State

Don't know (1 - 6)

h Parallel trade

Don't know (1 - 6)

Click here to view your responses

Costs and benefits

The following questions collect information on potential costs and benefits of the PPP Regulation. In particular, the questions explore if benefits and costs are balanced. The question also address administrative costs.

65 Do the benefits of the approval and authorisation procedures (for the protection of human and animal health and the environment) outweigh their costs (in terms of time and resources)?

a The approval of an active substance

Benefits outweigh costs (1 - 6)

b The re-approval of an active substance

Costs outweigh benefits (1 - 6)

c The (re-)authorisation of a plant protection product

Benefits outweigh costs (1 - 6)

d The (re-)authorisation of a plant protection product for minor uses

Benefits outweigh costs (1 - 6)

e The (re-)authorisation of a plant protection product containing low-risk substances

Benefits outweigh costs (1 - 6)

f The (re-)authorisation of a plant protection product containing a candidate for substitution

Costs outweigh benefits (1 - 6)

g Parallel trade

Benefits outweigh costs (1 - 6)

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66 Compared to the situation before the entry into force of the PPP Regulation, do you think that the procedures today are more efficient than in the past (before 2011)?

a Approval of an active substance

Don't know (1 - 4)

b Authorisation of a plant protection product

Don't know (1 - 4)

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67 What are - on average - the typical costs (in €) that a business faces for the different processes listed below?

a New active substance approval (Art 7-13)

Don't know

b Renewal of active substance approval (Art 14-17)

Don't know

c Authorisation of PPPs (Art 33-37) and Mutual Recognition (Art 40-43)

Don't know

d Renewal of Authorisation of PPPs (Art 43)

Don't know

e Extension of Authorisation to minor uses (Art 51)

Don't know

f Authorisation of Parallel Trade Permit (Art 52)

Don't know

g Authorisation of Emergency Approvals (Art 53)

Don't know

h Renewal of a plant protection product containing a candidate for substitution (Art 50)

Don't know

68 On average, what is the share of administrative costs stemming from the Regulation on pesticides as a percentage of all administrative costs for businesses? Administrative costs arise e.g. from record-keeping and reporting requirements for producers, suppliers, distributors, importers- and exporters, and professional users of pesticides.

Don't know

69 What has been the impact of the PPP Regulation on the sector you represent?

a Investment in research

Don't know (1 - 6)

b Profits

Don't know (1 - 6)

c Productivity

Don't know (1 - 6)

d International trade

Negative (1 - 6)

e Marketing

Don't know (1 - 6)

f Other, please specify

Don't know (1 - 6)

Click here to view your responses

Submission of data, transparency, and public consultation

For the approval and authorisation of plant protection products, a dossier of documents and studies has to be submitted for evaluation. Third parties, the scientific community, and civil society have the opportunity to comment on ongoing assessment processes. The following questions explore your opinions on these topics, if stakeholders are aware of and using these opportunities.

70 For the approval of an active substance and the authorisation of a plant protection product, applicants have to provide a dossier of documents and studies that provide evidence on the hazards and risks. Do you think that this procedure may negatively affect the objectivity of the dossier?

No

71 Third parties, including the scientific community and civil society, have the opportunity to comment on ongoing assessment processes. For example, EFSA publishes all draft assessment reports for the approval of active substances within two weeks of receiving them. Have you ever made use of the opportunity to comment or are you aware of this opportunity to comment?

I am aware of this opportunity but have not contributed

72 If you have ever contributed to one of these public consultations, do you have the perception that your contribution was valued and appreciated?

Don't know

73 In general, do you believe there are sufficient opportunities for the scientific community and civil society to contribute during the decision-making process?

Sufficient

74 Do you think that scientific and other third parties' input (e.g. from civil society), such as peer-reviewed open literature and reports, is sufficiently taken into consideration during the authorisation or approval processes?

Sufficiently considered

75 In your opinion, how relevant is input from third parties (e.g. from civil society) in the context of evaluating and assessing active substances in the EU?

Relevant

76 In your view, how transparent are the decision making processes for the approval of active substances?

a Risk assessment by rapporteur Member State

Moderately (1 - 6)

b Risk assessment by EFSA

Moderately (1 - 6)

c Risk management by European Commission

Moderately (1 - 6)

77 In your view, how transparent are the decision making processes for the authorisation of plant protection products?

a Assessment by zonal rapporteur Member State

Don't know (1 - 6)

b Assessment by concerned Member State

Don't know (1 - 6)

Click here to view your responses

Testing and data sharing

One of the specific objectives of the PPP Regulation is to reduce the number of vertebrate animals used in tests for the approval of active substances and authorisation of plant protection products. To achieve this, rules on data sharing and alternative methods substituting the use of animals have been modified. This section explores the impact of these changes on animal testing.

79 In your opinion, how has the PPP Regulation impacted the development of studies involving vertebrate animal testing (Art 62) since its implementation in 2011? The number of studies involving vertebrate animal testing has:

Don't know

80 How has the number of forced shared studies involving vertebrate animal testing evolved since the PPP Regulation came into force in 2011?

Don't know

Click here to view your responses

Implementation

The first questions will explore how the Regulation has been implemented and whether the Regulation is achieving its objectives.

83 What has been the impact of the MRL setting procedures as set out in the MRL Regulation, with regard to its objectives?

a Ensuring consumer protection

Positive (1 - 6)

b Safeguarding the competitiveness of European agriculture

Negative (1 - 6)

c Improving the functioning of the internal market

Positive (1 - 6)

d Smooth running of international trade

Very negative (1 - 6)

84 In general, do you think that MRLs in the European Union are:

Too low (i.e. the European Union is too strict)

85 Overall, do you consider MRLs today to be more or less strict than before the implementation of the MRL Regulation in 2008?

Stricter

86 In your opinion, is the MRL Regulation adequately enforced?

Yes

89 How has the MRL Regulation impacted the sector you represent?

a Investment in research

Don't know (1 - 6)

b Profits

Don't know (1 - 6)

c Productivity

Don't know (1 - 6)

d International trade

Negatively (1 - 6)

e Marketing

Don't know (1 - 6)

Click here to view your responses

Balance of objectives

The MRL Regulation aims to address the two objectives of protecting consumer health and improving the functioning of the internal market. The two following questions explore in greater detail whether certain aspects of the Regulation contribute to achieving these two objectives.

90 To what extent have the provisions on the setting of MRLs been effective in achieving the objective to ensure a high level of consumer protection?

a MRL provisions in general

To a large extent (1 - 6)

b Establishing MRLs for each substance-commodity combination, including the concept of using default values where no specific MRL is set

To a large extent (1 - 6)

c Dual and multiple use substances

Don't know (1 - 6)

d Naturally occurring substances

Don't know (1 - 6)

e Raw, processed and composite foods

Don't know (1 - 6)

f Setting import tolerances

Moderately (1 - 6)

g Temporary MRLs, in general, and the procedures for MRL setting in case of emergency uses in

particular

Moderately (1 - 6)

91 To what extent have the provisions on the setting of MRLs been effective in achieving the objective to ensure a smooth functioning of the internal market?

a MRL provisions in general

To a large extent (1 - 6)

b Establishing MRLs for each substance-commodity combination, including the concept of using default values where no specific MRL is set

To a large extent (1 - 6)

c Dual and multiple use substances

Not at all (1 - 6)

d Naturally occurring substances

Not at all (1 - 6)

e Raw, processed and composite foods

Not at all (1 - 6)

f Setting import tolerances

To a small extent only (1 - 6)

g Temporary MRLs, in general, and the procedures for MRL setting in case of emergency uses in particular

To a small extent only (1 - 6)

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Scope of the MRL Regulation

The MRL Regulation included provisions to harmonise MRLs for feedingstuff, fish, and defined processed products at the EU level. For defined processed products, currently the MRL for raw products plus an appropriate processing factor are applicable, but processing factors can be variable. Many harmonised processing factors have not yet been established. Until today, MRLs for feedingstuff, fish, and defined processed products are not harmonised. The following questions explore if this non-implementation has had any effect. Some questions also ask if the scope of the MRL Reguation needs to be modified.

92 Does the described non-implementation of the harmonisation have any impact on the protection of human health?

a MRLs for feedstuff

No impact (1 - 6)

b MRLs for fish

Don't know (1 - 6)

c Specific MRLs for defined processed products

No impact (1 - 6)

93 Does the described non-implementation of the harmonisation have any impact on the functioning of the internal market?

a MRLs for feedstuff

Negative (1 - 6)

b MRLs for fish

Don't know (1 - 6)

c Specific MRLs for defined processed products

Negative (1 - 6)

94 Do the existing provisions ensure that pesticide residues do not pose a risk to animal health?

To a large extent

95 In your opinion, is there a need to further narrow down or clarify the scope of the MRL Regulation with regard to dual and multiple use substances?

Yes

96 In your opinion, is there a need to further narrow down or clarify the scope of the MRL Regulation with regard to naturally occurring substances?

Yes

97 Please explain your reasoning regarding the scope of the MRL Regulation below: (400 characters max.)

MRLs should apply to residues from PPP sources, not from other sources (eg contaminants)

[section continues on the next page]

98 Do you see a need to widen the scope of the MRL Regulation to also cover adjuvants, unacceptable co-formulants in the sense of Article 27 of the PPP Regulation, safeners, and/or synergists?

a Unacceptable co-formulants

No (1 - 3)

b Adjuvants

No (1 - 3)

c Safeners

No (1 - 3)

d Synergists

No (1 - 3)

99 Is the MRL Regulation sufficiently aligned with the Regulation on genetically modified organisms (GMOs) in

food to derive MRLs for herbicides used on tolerant crops?

Yes

100 Do you see a need to introduce specific rules on data protection into the MRL Regulation?

Don't know

101 Is it necessary to increase the transparency of the MRL setting process by defining which documents should be made publicly available?

Don't know

102 Are the following needed at the EU level?

a A list of harmonised processing factors

Yes (1 - 3)

b EU MRLs for feedstuff

Yes (1 - 3)

c EU MRLs for fish

Don't know (1 - 3)

d EU MRLs for processed products

Don't know (1 - 3)

e EU MRLs for cut flowers

Don't know (1 - 3)

f Guideline levels for tobacco

Don't know (1 - 3)

g Guideline levels for herbal medicinal products

Don't know (1 - 3)

h EU MRLs for biocides used in food industry

Don't know (1 - 3)

103 Please explain your reasoning below: (400 characters max.)

The non implementation of provisions related to processing factors and MRLs for feed are detrimental to the functioning of the internal market.

Click here to view your responses

Definitions

The MRL regulation provides definitions for a number of different terms relevant for the policy field. The following question seeks to explore whether these definitions are still relevant or need to be modified

In your opinion, are the definitions for the following terms in the MRL Regulation still relevant for the situation today or would they need modification?

105 'Import tolerance' (Art 3):"an MRL set for imported products to meet the needs of international trade where: - the use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use; or - a different level is appropriate because the existing Community MRL was set for reasons other than public health reasons for the specific product and specific use"

address issue of multiple uses and naturally occuring substances

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Trade impacts

The setting of maximum residue levels at EU level may have an impact on the trade with countries outside the EU. The following questions ask about potential effects on international trade, either negative or positive.

107 What has been the impact of the MRL Regulation on international trade (i.e. trading with non-EU countries)? What has been the effect with regards to:

a Exports to third countries

No impact (1 - 4)

b Imports from third countries

Negative impact (1 - 4)

108 Are the needs of trading partners sufficiently taken into account when setting MRLs in the EU?

No

109 Is it necessary to change the procedures for the setting of MRLs in order to take the needs of trading partners into account?

Necessary

[section continues on the next page]

110 If you are answering on behalf of a government or organisation outside the EU, has your country or organisation experienced any trade impacts with regards to the EU MRL Regulation?

(Mostly) negative

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Procedures for MRL setting and revision

With the introduction of the MRL Regulation on the setting of maximum residue levels, MRLs are fully harmonised and set at the EU level. Earlier, European Directives were transposed by Member States but provided only partial harmonisation as Member States defined MRLs at the national level. Since 2008, the application to set an MRL is submitted to a Member State, however also EFSA, as well as the European Commission, are involved in the process.

113 In your opinion, are the existing procedures for MRL setting clearly formulated?

a Setting / amending MRLs (Art. 6-10)

To a large extent (1 - 6)

b Reviewing MRLs (Art. 12)

To a large extent (1 - 6)

c Setting Import Tolerances (Art. 6(4))

To a large extent (1 - 6)

115 Does the MRL Regulation contain sufficiently clear rules concerning the circumstances under which an MRL can be rejected?

Yes

116 Is it necessary to define more clear rules for reviewing MRLs after the renewal of approvals?

Yes

117 Does the MRL Regulation provide sufficiently clear procedures for MRLs for substances that are used in other food domains, e.g. biocides, contaminants, undesirable substances in feed, etc.?

Don't know

118 Are the provisions for microorganisms sufficiently clear as regards the setting of legal limits in food?

Don't know

119 Do you think that the decision to set MRLs at the EU rather than national level has been beneficial to reaching the following objectives?

a Ensuring consumer protection

Fully (1 - 6)

b Improving the functioning of the internal market

Fully (1 - 6)

c Safeguarding the competitiveness of European agriculture

Fully (1 - 6)

d Smooth running of international trade

Fully (1 - 6)

120 The risk assessment process to set and review MRLs involves authorities at both national and EU levels, i.e. the European Commission, the European Food Safety Authority, and Member States. Is this work

sharing necessary and beneficial?

No, both EU and national authorities should be involved, but the work should be shared differently

121 If no, please explain your reasoning below: (400 characters max.)

Support a more centralised and effecient procedure for MRL setting

Click here to view your responses

Timelines

The MRL Regulation does not set legal timeframes to the extent the PPP Regulation does. We are therefore interested in how long procedures take in your experience and if the implementation of the MRL Regulation has had an effect on the time it takes to set a maximum residue level.

122 On average, how long does it take from the date of application to applicability of a new/amended MRL to set/amend a maximum residue level? Please specify the time period in months:

a Minimum

Don't know

b Average

Don't know

c Maximum

Don't know

123 In order to obtain an authorisation for a plant protection product, MRLs must be in place for all uses. In view of the specific procedure to set MRLs to obtain an authorisation for a PPP, do you consider the time needed to set/amend MRLs appropriate? On average, would you say that it takes:

Too long

124 In order to address risks to consumers, MRLs can be set, amended, or lowered to the limit of detection. In view of the specific procedure to set MRLs to address risk, do you consider the time needed to set/amend MRLs appropriate? On average, would you say that it takes:

Too long

125 Compared to the situation before the implementation of the MRL Regulation in 2008, how has the time needed to set MRLs changed? Today, to set a MRL, it takes…

More time

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Costs and benefits

The questions in this section are intended to provide insight into the costs and benefits of the MRL Regulation. We aim to understand whether the costs of the MRL Regulation (e.g. facilitating trade and protecting consumers) are proportionate.

126 Considering the benefits of the MRL Regulation through the objectives, e.g. facilitating trade and protecting consumers, are the costs (time and resources) for the procedures to set MRLs proportionate and justified for the parties involved?

To some extent only

127 Do the benefits of the procedures regulated by the MRL Regulations (for the protection of consumers) outweigh their costs (in terms of time and resources)?

a Set/amend a maximum residue level (Art 6-10)

Benefits outweigh costs (1 - 6)

b Review a maximum residue level (Art. 12)

Costs outweigh benefits (1 - 6)

c Set an import tolerance (Art. 6(4))

Benefits outweigh costs (1 - 6)

128 Compared to the system before 2008 and after the entry into force of the MRL Regulation, are procedures today more efficient? In other words, do the benefits outweigh the costs more today or before 2008? Today, procedures are:

Don't know

129 Is it necessary to amend the current procedures on MRL setting and/or review them in order to improve efficiency?

Yes

130 If yes, please share your thoughts: (400 characters max.)

procedures could be streamlined for better effeciency and alignment with PPP reg

131 Would it improve the functioning of the system if the MRL Regulation on the setting of maximum residue levels contained more specific legal timelines to finish individual steps of the procedures?

Yes

132 Under the current system, an applicant can freely choose an Evaluating Member State for MRL setting. Do you think that the Member State acting as a Rapporteur Member State under the PPP Regulation should be legally bound to also act as the Evaluating Member State for the MRL setting?

Don't know

133 What are the typical costs (in €) that a business faces for the different authorisation and renewal processes listed below?

a Maximum residue level setting procedure (Art. 6-10)

Don't know

b Reassessment of existing maximum residue levels (Art. 12)

Don't know

c Setting of import tolerances (Art. 6(4))

Don't know

134 On average, what is the share of administrative costs stemming from the MRL Regulation as a percentage of all administrative costs for businesses? Administrative costs arise e.g. from record-keeping and reporting requirements.

Don't know

135 What has been the impact of the MRL Regulation on the sector you represent?

a Investment in research

Don't know (1 - 6)

b Profits

Don't know (1 - 6)

c Productivity

Don't know (1 - 6)

d International trade

Very negative (1 - 6)

e Marketing

Don't know (1 - 6)

f Other, please specify risk of legal non compliances

Negative (1 - 6)

Click here to view your responses