Public consultation on pharmaceuticals in the environment

Fields marked with * are mandatory.

About this consultation

This consultation is part of a study aimed at supporting the development of a European Union (EU) strategic approach to pharmaceuticals in the environment, and in turn at helping the EU achieve the United Nations Sustainable Development Goals, in particular SDG 6 ("Clean Water and Sanitation"), as well as objectives in EU legislation such as the "good status" objective in the Water Framework Directive. Adoption of the approach is to be followed by proposals for specific measures, as appropriate, which would be subject, as necessary, to full impact assessment.

Pharmaceuticals can enter the environment during their production, use and disposal. The need for a strategic approach has been prompted by concern about risks to the environment itself, and possibly to human health via the environment. Any actions to address those risks must also ensure that humans and animals can continue to benefit from the appropriate use of pharmaceuticals and that the competitiveness of EU healthcare systems is maintained.

This consultation aims to collect feedback and further information from stakeholders on their perception of the problem, the need for action, and on some of the actions that could be prioritised.

A background paper, provided with this questionnaire, describes 30 possible policy options grouped into 10 action areas. These have been identified on the basis of a review of the recent literature and preliminary consultation of stakeholders. You may wish to read the summary of the paper, or the paper itself, before answering the questions, but this is not essential.

Your responses will help the European Commission (EC) to formulate the strategic approach and prioritise areas for action. Thank you in advance.

Important note on the publication of answers

Please note that the responses received will be published on the EC’s website, together with the identity of the contributor unless the contributor objects to the publication of personal data.

*1. Please indicate your preference as regards publication of your contribution

☐ My contribution may be published, mentioning my name or the name of my organisation as well as country of residence
☐ My contribution may be published anonymously

Please note that, whatever option chosen, your answers may be subject to a request for public access to documents under Regulation (EC) N°1049/2001. Please also read the specific privacy statement referred to on the consultation webpage.

**About the respondent**

*2. Are you replying as:*
- An individual
- An EU institution
- A national/regional/local public authority
- A company
- A business or workers’ organisation
- An NGO, environmental or consumer group
- A research organisation
- Other

*3a. Please state your name or the name of your organisation (published)*

European Sustainable Phosphorus Platform (ESPP)

*3b. Please provide your email address (Please note that your email address will not be published regardless of the option chosen in question 1)*

info@phosphorusplatform.org

*5. How many members does your organisation or group represent?*

40

*6. Is your organisation registered in the Transparency Register of the European Commission?*
- Yes
- No

*7. Please enter the identification number*

260483415852-40

*8. What is your main field of activity or main area of expertise or interest?*
- Pharmaceuticals
- Human healthcare (including pharmacy)
- Veterinary care (including veterinary pharmacy)
- Water and waste water management
- Waste management
- Other
- No specific relevant expertise

*9. What is your main country of residence or activities? (published)*
- Austria
- Belgium
- Bulgaria
General questions on the issue

Awareness of the issue

*10. How would you describe your level of awareness of the issue of pharmaceuticals and the environment?
   ○ Nil (It hasn't been on my/our radar until now)
   ○ Low (I/we have heard a bit about it)
   ○ Moderate (I/we have heard a fair amount about it)
   ○ High (I/we have been looking at it in detail)

*11. What has made you aware of the issue of pharmaceuticals and the environment? (Please mark all that apply.)
   ☐ Seeing this consultation
12. Has awareness of the issue made you do any of the following? (Please mark all that apply.)

☐ Start taking unused medicines to the pharmacy (if you were not already)
☐ Stop flushing unused pharmaceuticals down the sink or toilet
☐ Talk to your pharmacist or doctor about the issue
☐ Talk to friends or family about the issue
☐ Change your consumption of over-the-counter (non-prescribed) medicines
☐ Other

* If other, please specify:

500 character(s) maximum

Collection of research and industry information

13. Do you see a connection between this issue and the development of antimicrobial resistance (AMR)? (Resistance means, for example, that existing antibiotics may no longer be effective against disease-causing bacteria.)

☐ Yes
☐ No
☐ Not sure

14. What (other) aspect of the issue (of pharmaceuticals in the environment) concerns you most?

500 character(s) maximum

Presence of pharmaceuticals (and their metabolites) in processed sewage biosolids and animal manures is a significant obstacle to the Circular Economy for nutrients, because of real or perceived concerns about possible impacts on crops, human health, soils and the environment. Food industry and public concerns are accentuated by insufficient information. This threatens current and future routes for recycling to agriculture of phosphorus, nitrogen, other nutrients and organic carbon.

Relative importance of actions

15. How do you see the need for actions (including research) to address the risk from pharmaceuticals in the environment?

A) For human pharmaceuticals

☐ Not necessary
☐ Necessary but not urgent
☐ Urgent
☐ No opinion
B) For veterinary pharmaceuticals

- Not necessary
- Necessary but not urgent
- Urgent
- No opinion

If you wish to, please explain your answer:
1,500 character(s) maximum

There are today inadequate agreed measurement methods and lack of information (data, risk assessment) concerning pharmaceuticals (and metabolites) in recycling organic wastes (treated sewage biosolids, manures, food wastes, green wastes, food industry by-products ...). This concerns fate in recycling and sanitisation processes and possible impacts on crops, human health, soils and environment. These contaminants are “emerging” (most past data addressed heavy metals and pathogens) and pharmaceuticals have been studied more in water (surface waters, sewage works discharge) than in solids (sludges, soils, recovered nutrient products) because they are generally water soluble. But residual levels of pharmaceuticals (and metabolites) in recycled organics pose a major obstacle to the nutrient and organic carbon Circular Economy, because of possible real risks and food industry and consumer perception. Levels will increase with increasing “removal” in sewage works (transfer to sludge). In order to not block current and future recycling, it is urgent to reduce levels of pharmaceuticals in recycled sewage biosolids and manures (by reductions upstream and through processing). It is important to develop monitoring, research and risk assessment, to provide objective data to support dialogue with the food industry, retailers and consumers, because zero pharmaceuticals in organics recycling is impossible.

16. Please give each of the twelve possible actions below a score between 5 and 0, where 5 = high priority action, 3 = medium priority action, 1 = low priority action, 0 = not in favour). All actions must be scored.

Please note that the actions have been numbered to indicate which action areas they relate to in the background document, but are in most cases more specific.

<table>
<thead>
<tr>
<th>Action Description</th>
<th>Score</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
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<tbody>
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<td>1. More research to better understand the risks</td>
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<td>2. &quot;Greener&quot; design of pharmaceuticals, e.g. to make them more biodegradable</td>
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<td>3. More stringent conditions for putting a pharmaceutical on the market</td>
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<td>4. Cleaner manufacturing</td>
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<td>5. Better risk mitigation, e.g. not allowing over-the-counter sale of pharmaceuticals that pose an environmental risk</td>
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<td>6. Better/more thorough post-market monitoring of pharmaceuticals in the environment and feedback to the regulatory process</td>
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<td>7. (a) Better training for medical professionals, e.g. about pharmaceuticals that are less harmful for the environment</td>
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<td>7. (b) Better information for the public, e.g. about how to dispose of unused medicines</td>
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<td>7. (c) Smaller packaging sizes, to reduce unnecessary waste/disposal</td>
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*8. Improved handling of waste pharmaceuticals

*9. (a) Improved sewage and wastewater treatment

*9. (b) Improvements in livestock farming to reduce the use/emission of pharmaceuticals

If you wish to, please explain your scoring or add brief comments on the listed actions, referring to their number.

1,500 character(s) maximum

The EU currently returns c. 50% of sewage biosolids and most manure to farmland. Preserving this recycling, whilst ensuring safety, is a priority of the nutrient Circular Economy. Soil application of anaerobically digested or composted sewage biosolids / manures returns stable organic carbon to soils, contributing to the 4/1000 soil carbon climate change commitment and to soil water retention, drought resistance, fertility, erosion prevention ... This brings economic benefits for farmers (nutrient input, manure disposal) and for taxpayers (sludge management costs are a major sewage works operating cost), reduced EU dependency on phosphorus and nitrogen fertilisers (imported phosphate rock and natural gas) and contributes to food security (nutrients, soil quality). Actions 1 and 6 should include: monitoring and risk assessment of pharmaceuticals when treated sewage biosolids and manures are used in agricultural/crop systems; development of priority pharmaceuticals lists and measurement methods for biosolids and manure use monitoring, and recovered nutrient products, and of practical programmes to reduce and control risks.

Action 2 should include degradability of pharmaceuticals in anaerobic digestion and composting.

Action 9(a) should address how different sewage/manure treatments (urine/faeces separation, sewage works configurations, anaerobic digestion processes, composting processes) can more effectively mitigate pharmaceuticals and their metabolites in output biosolids.

17. If you are aware of any actions already being taken in your own country, please mention them and provide details.

1,500 character(s) maximum

Sewage and manure management research and dialogue is often organised at a national or regional level, and there is a need to improve exchange and synergy between national actions, and to enable European level dialogue with agri-food companies and retailers which are in many cases global operators. Ongoing projects In the Netherlands and Germany to analyse pharmaceuticals in recovered struvites. Dutch programme ‘Pharmaceuticals in Water’ (Government and water chain stakeholders, 17 actions).

18. Please feel free to suggest further actions, in addition to those included in this questionnaire and the background document, or in your answer to Q.17, to address the impacts of pharmaceuticals in the environment.

1,500 character(s) maximum

It is necessary to organise dialogue at the EU level with farmers, the food and beverage industries, supermarkets and environment and consumer NGOs, with the objectives of: sharing objective information available concerning the levels of, impacts (on crops, human health, soils and the environment) and risk assessments of pharmaceuticals and their metabolites in use of processed sewage biosolids and manures in agriculture; jointly defined research, monitoring and risk assessment needs and priorities; jointly define appropriate risk reduction measures appropriate to support sustainable organic car
bon and nutrient recycling. This dialogue is needed at the EU level, because retailers and agri-food companies are global operators, as are pharmaceuticals companies, and in order to enable input to EU policies (Fertilisers Regulations, standards, chemicals policy ...).
Support for research, monitoring, risk assessment and mitigation actions addressing pharmaceuticals in organic carbon and nutrient recycling should be supported under RTD FP9, CAP and REGIO Structural Funds.

19. We invite you to suggest information sources on pharmaceuticals and the environment (titles of publications and web links are appreciated) in order to increase the evidence base on the topics addressed in this questionnaire.

1,500 character(s) maximum

Summary of workshop “Pharmaceuticals in sewage biosolids”, Malmö, November 2016, in SCOPE Newsletter n°123 www.phosphorusplatform.eu/scope123
Joint position on the need for research into organic contaminants in sewage biosolids and in manure, to support the bio- and nutrient circular economy (EEB, EBA, ECN, ECOFI, Growing Media Europe, Eureau, ESPP) 6th October 2017 http://www.phosphorusplatform.eu/organic-contaminants

If you wish to submit additional documentation (up to three pages), please upload your file here.

Contact
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