13 December 2024
EMA/CVMP/ERA/460373/2024
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Environmental Risk Assessment Working Party (ERAWP) 2025

Chairpersons:	**Status**
Chair: R. Carapeto Vice-chair: B. Kolar	Adopted by CVMP in December 2024

The activities outlined in the work plan for 2025 have been agreed considering the respective business priorities and may be subject to further review and reprioritisation in accordance with the business plan of the Agency.

1. Meetings scheduled for 2025

Plenary meetings:	3 (per meeting: Chair plus 10–12 members, 2 days) 20-21 February 2025 (virtual) 17–18 June 2025 (face-to-face) 15–16 October 2025 (virtual)
Other meetings:	
Drafting/expert groups	10–15 meetings (mostly virtual; approximately 7–10 participants per meeting)
Workshop/focus group	1 (related to the development of a guideline on the environmental risk assessment of veterinary medicinal products used in aquaculture)
Training	None

If feasible and depending on the circumstances, some of the plenary meetings could be replaced by virtual meetings. Drafting/expert group meetings are mainly regarded as complementary to plenary meetings.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

2. Product-related issues

The following table provides the expected number per year of contributions (number of involvements in dossier) for scientific advice and product assessment, including pre- and post-authorisation issues.

Expected contribution in scientific advice	Expected contribution in product assessment
0	1

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. All published guidance documents within the remit of the ERAWP

Action: Update of relevant guidance documents in order to align them with provisions outlined in Regulation (EU) 2019/6, as applicable.

Priority 3. Start date: ongoing, completion date: December 2025.

Comments: None.

3.2. Guidance documents to be released for consultation

3.2.1. Development of a guideline on the environmental risk assessment of veterinary medicinal products intended for use in aquaculture

Action: Work on the guideline to be continued.

Priority 2. Start date: ongoing, completion date: June 2026.

Comments: This item is linked to action 5.3.1.b of the "European Union Strategic Approach to Pharmaceuticals in the Environment" (COM[2019] 128 final). The organisation of a workshop bringing together relevant stakeholders in the field is envisaged for June 2025.

3.2.2. Development of a guideline on the methodology of environmental risk assessment for parasiticidal VMPs for cats and dogs

Action: Work on the guideline to be initiated.

Priority 2. Start date: Q3 2025, completion date: Q4 2027.

Comments: None.

3.2.3. Development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a VMP

Action: Work on the reflection paper to be initiated.

Priority 2. Start date: Q3 2025, completion date: Q4 2026.

Comments: Activity to be performed in consultation with the AWP.

3.2.4. Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products (EMA/CVMP/ERAWP/409328/2010)

Action: Review of the reflection paper to include reference to the newest applicable legislation (e.g. Regulation (EU) 2019/6) as well as critical review of the adequacy/appropriateness of risk mitigation measures formulated/applied since the paper's initial release in 2012.

Priority 2. Start date: ongoing, completion date: Q2 2025.

Comments: None.

3.3. New topics/concept papers to be prepared

3.3.1. Development of a concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a VMP

Action: Work on the concept paper to be continued.

Priority 2. Start date: ongoing, completion date: Q1 2025.

Comments: Activity to be performed in consultation with the AWP.

3.3.2. Development of a concept paper for the development of a guideline on the methodology of environmental risk assessment for parasiticidal VMPs for cats and dogs

Action: Work on the concept paper to be continued.

Priority 2. Start date: ongoing, completion date: Q1 2025.

Comments: None.

3.3.3. Consider the need for a revision of the 'Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6' (EMA/CVMP/ERA/622045/2020)

Action: Work on the revision of the reflection paper to be initiated.

Priority 3. Start date: Q1 2025, completion date: Q4 2025.

Comments: Activity to be performed by a dedicated expert group.

4. VICH Guidelines and activities

None.

5. EU regulatory activities

5.1. Queries raised by CMDv

Action: Provide response to queries raised by CMDv via CVMP, as required.

Comments: None.

5.2. Collaboration with EFSA

Actions: Provide contribution to EFSA opinions in accordance with Article 59 of Regulation (EC) No 726/2004, as required.

Consultations and cooperation with the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on environmental risk assessment issues, as required.

Comments: None.

5.3. Collaboration with ECHA

Action: Consultation with the ECHA PBT working group and with the biocides environment working group, as required.

Comments: None.

5.4. Assessor training

Actions: Provide advice/active participation for training of assessors, as required.

Comments: None.

5.5. Other

Actions: Provide advice to the EC and other EU Agencies on issues of mutual interest with regard to environmental risk assessment, as required.

Provide contributions to guidelines and questions raised by other working parties and *ad hoc* expert groups, as required.

Provide advice to the CVMP on questions relating to environmental risk assessment arising from referral procedures, as required.

Elaborate an EU-NTC veterinary environmental risk assessment sub-curriculum.

Work to increase capability in modelling, simulation and extrapolation within the European Regulatory Network (with applications in environmental fate and ecotoxicological assessment), for example, by seeking out and developing relevant training materials.

Comments: None.

6. Activities with external parties

6.1. Meetings with interested parties

None foreseen.

6.2. Regulatory authorities outside the EU

None foreseen.

7. Organisational matters

7.1. List of adopted organisational documents

None.

7.2. List of organisational documents to be developed/revised in the forthcoming 2 years

Mandate, objectives and rules of procedure for the CVMP Environmental Risk Assessment Working Party (EMA/CVMP/ERA/705470/2009-Rev.6).

7.3. List of proposed scientific guidelines for the next work plan[*]

None.

[*] The actual items to be included in ERAWP work plan for 2026 will be considered and agreed by the CVMP.