SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

6th Working Group meeting on certain metabolites common to several pyrazole active substances

24 November – 25 November 2025
24 Nov 2025 (14:00-18:00) and 25 Nov 2025 (09:00-13:00)
Agreed on 5 December 2025

Location: EFSA - Parma (Meeting Room 00/M06a) / Web-conference

Attendees:

- **Working Group Members**
  Coja Tamara (Chair), Thomas Kuhl, Dimitra Nikolopoulou, Danièle Court Marques
- **European Commission**
  Nikolay Tzvetkov, Mark Williams (only for the discussion item VII)
- **Hearing experts**[1]
  None
- **EFSA**
  Dimitra Kardassi, Arianna Chiusolo, Jochem Louisse, Laura Martino (MESE)

I. Welcome and Apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declarations of interest

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

[1] As defined in Article 34 of the "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Data extraction from not yet peer reviewed studies and from LoEPs

The Working Group reviewed the ongoing extraction of data from regulatory studies with the three metabolites, focusing on studies not yet peer-reviewed and the Lists of Endpoints (LoEPs) from parent compounds. Key actions included finalisation the data extraction and proving if any newly submitted Historical Control Data (HCD) were previously reviewed.

V. Template for assessment of not yet peer-reviewed studies and allocation of work

The Working Group discussed the assessment of not yet peer-reviewed studies and the work was allocated among experts. The templates to be used were agreed upon.

VI. HCD presentation and HCD for histopathology in carcinogenicity and in repeated dose toxicity studies

The new EFSA scientific opinion on Historical Control Data (HCD), published in 2025, was briefly presented, outlining a structured, stepwise methodology for collating, analysing and integrating HCD in toxicological studies. The approach emphasises protocol-driven inclusion criteria, iterative clarification, and integrated statistical and expert judgment to ensure transparency and reproducibility.

The Working Group will apply the methodology to the carcinogenicity study with desmethyl pyrazole acid. Further information might be requested from the data owners.

VII. Classification Lact H362 and relevance assessment

The Working Group, with confirmation from the European Commission, agreed to proceed with a scientific assessment of whether the groundwater metabolites of fluxapyroxad share the lactation hazard properties of the parent. This decision would provide a sound basis for future guidance and regulatory decisions. Among others, the Working Group evaluated the feasibility of using physiologically based kinetic (PBK) modelling to support understanding of transfer of fluxapyroxad and its metabolites via milk.

VIII. Draft Scientific opinion : allocation of sections Opinion

In preparation for drafting the scientific opinion, it was agreed that annexes will include protocols, templates, and inventories, while appendices will contain detailed assessments and supporting analyses. New Appendices were formulated.

IX. Distribution of the tasks

The distribution of tasks was agreed among experts.

The next WG meeting will be held on 22 January 2026 (10:00-17:00), online.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

5th Working Group meeting on certain metabolites common to several pyrazole active substances

29 September 2025 (10:00-17:00)
– Agreed on 17 October 2025

Location: EFSA - Parma / Web-conference

Attendees:

- **Working Group Members**
  Coja Tamara (Chair), Thomas Kuhl, Dimitra Nikolopoulou, Danièle Court Marques
- **European Commission**
  Nikolay Tzvetkov
- **Hearing experts**[1]
  None
- **EFSA**
  Dimitra Kardassi, Arianna Chiusolo, Dionysia Athanasiou, Jochem Louisse.

I. Welcome and Apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declarations of interest

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

[1] As defined in Article 34 of the "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Presentation of the studies which are correlated in the inventory, mainly HCD

An updated inventory worksheet was presented, demonstrating the correlation of studies in the inventory, particularly in relation to separate submission of historical control data (HCD) reports. The inventory was enhanced by adding a column to clarify links between amendments, supplements, and main study reports. Studies from the IUCLID dossier for Penthiopyrad renewal, focusing on three metabolites (PAM, PCA, DMPCA analogues), were reviewed. Twenty relevant, peer-reviewed studies were added to the inventory. A final check will be conducted to ensure it contains all necessary information and can serve as the main inventory.

V. Presentation of the full-text screening in DistillerSR

Sixty-nine articles were included in the level 2 full-text screening of SDHI literature in DistillerSR.

The working group discussed how to present the literature search results in the final report. All steps of the literature review process will be transparently described in the results chapter. The protocol for the literature search will be included as Annex to the Scientific Opinion.

VI. Carcinogenicity study with desmethyl pyrazole acid and HCD

A summary of the carcinogenicity study with desmethyl pyrazole acid was presented, highlighting neoplastic findings discussed by the study director and the use of historical control data (HCD). Identified issues with the HCD were discussed. It was agreed to request clarifications from data owners on these points. The working group agreed to apply the quantitative methodology for the collation, use, and interpretation of HCD recently developed by the PPR Panel (EFSA PPR Panel, 2025).

VII. Data extraction – overview of final change

Extraction templates were tested by the working group to identify any improvements needed before actual use. Data extraction from regulatory studies conducted with the three common metabolites, as well as from the list of endpoints for the parent compounds, will be outsourced.

VIII. Classification for lactation

A summary of the classification for effects on or via lactation of fluxapyroxad was presented, noting that it is the only parent compound among those assessed with this classification. The working group noted that this is a distinct hazard category under current regulatory frameworks. It was acknowledged that scientific and regulatory considerations related to this classification are evolving, and the topic may require further attention in future discussions.

IX. Draft Scientific opinion

The draft Scientific Opinion was circulated for review, with a request for all participants to provide feedback and suggestions to improve clarity, particularly on the restructured sections. Details regarding the literature search protocol and the list of studies to be published were discussed.

X. VIII. Distribution of the tasks

The next WG meeting will be held on **24th November** (14:00-18:00) **25th November** (9:00-13:00) 2025 at EFSA premises.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

4th Working Group meeting on certain metabolites common to several pyrazole active substances

30 June – 1 July 2025
30 June 2025 (14:00-18:00) and 1 July 2025 (09:00-13:00)
– Agreed on 11 May 2025

Location: EFSA - Parma (Meeting Room 00/M15) / Web-conference

Attendees:

- **Working Group Members**
  Coja Tamara (Chair), Thomas Kuhl, Dimitra Nikolopoulou, Danièle Court Marques
- **European Commission**
  Nikolay Tzvetkov
- **Hearing experts**[1]
  None
- **EFSA**
  Dimitra Kardassi, Arianna Chiusolo, Tommaso Giorgi, Dionysia Athanasiou

I. Welcome and Apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declarations of interest

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

[1] As defined in Article 34 of the "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Literature Review in DistillerSR and Screening Outcomes

The retrieval of full-text references was successfully completed using DistillerSR. Reviewers will begin the next phase of screening. A demonstration of the full-text screening process was provided, and the methodology for Risk of Bias (RoB) assessment was outlined. Each study will be reviewed independently by two assessors, with discrepancies resolved by the group.

The group also reviewed international and EU regulatory reports. While JMPR reports were available for all eight SDHIs and penthiopyrad, no new studies on metabolites were identified. National (EU) and international (worldwide) reports were also screened, with no additional studies on metabolites being identified.

V. Present the outcome of investigating the status of studies, not peer-reviewed and the studies on penthiopyrad

An inventory of 77 studies was compiled, distinguishing between already peer-reviewed and not-yet peer-reviewed studies. The group discussed how to correlate related studies and agreed on using data extraction templates. Relevant studies from the penthiopyrad dossier were retrieved and will be cross-checked against previous assessments.

VI. Data extraction – finalisation of the templates, both general toxicity and genotoxicity

The group discussed the feedback on data extraction templates. Final modifications adjustments to the data extraction templates for general toxicity, genotoxicity in vitro, and genotoxicity in vivo, were agreed.

The revised data extraction and endpoint templates were finalised. These will be tested by working group members before being used.

VII. Draft Scientific opinion : allocation of sections Opinion

In preparation for drafting the scientific opinion, it was agreed that annexes will include protocols, templates, and inventories, while appendices will contain detailed assessments and supporting analyses. The group also scheduled upcoming meetings and confirmed plans to invite French experts to present their assessment in early 2026.

VIII. VIII. Distribution of the tasks

The next WG meeting will be held on 29 September 2025 (10:00-17:00), online.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

3rd Working Group meeting on certain metabolites common to several pyrazole active substances

12 May 2025 (10:00-17:00)
MINUTES – Agreed on 3 June 2025

Location: EFSA - Parma / Web-conference

Attendees:

- **Working Group Members**
  Coja Tamara (Chair), Thomas Kuhl, Dimitra Nikolopoulou, Danièle Court Marques
- **European Commission**
  Nikolay Tzvetkov
- **Hearing experts**[1]
  None
- **EFSA**
  Dimitra Kardassi, Arianna Chiusolo, Tommaso Giorgi, Dionysia Athanasiou

I. Welcome and Apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declarations of interest

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

[1] As defined in Article 34 of the "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Literature Review in DistillerSR

A walkthrough of DistillerSR was presented, covering login procedures, navigation, and the review form setup. The literature review process was confirmed to follow a two-level structure: initial screening based on titles and abstracts, followed by full-text screening. In case of doubt, studies should be included for full-text review.

Regarding regulatory reports, it was agreed that those identified in the public literature search would be included if they contained relevant toxicity data. These will later be cross-checked against results from a dedicated regulatory search. A similar approach to that used in another mandate will be applied for data extraction and risk of bias assessment.

V. Status of the literature review - Discussion

The reviewers presented the screening approach in DistillerSR. Discussion took place on possible conflicts, and agreements were reached.

It was suggested that reviewer justifications be exported alongside screening decisions to support traceability and categorisation. Regulatory reports identified in the public literature search will be included if they contain relevant toxicity data and later cross-checked against those from a dedicated search.

Data extraction and risk of bias assessments will follow the approach used in other similar mandates. The schedule for the extraction of data was discussed alongside the preparatory needs.

VI. Status of the Metapath DB analysis addressing questions regarding the presence of the 3 metabolites

The results of the search for (other) common metabolites using MetaPath DB was presented. The three metabolites under review were not found in significant amounts in rat metabolism studies, limiting the direct use of existing toxicological data of parent compounds. However, structurally similar metabolites (PAM, PCA, DMPCA) were identified in penthiopyrad, differing only slightly (e.g. trifluoromethyl vs. difluoromethyl groups). Toxicological data packages, including 28- and 90-day studies, are available for these analogues. Although penthiopyrad is not part of the current mandate, its data may support future read-across or bridging assessments. The group agreed to explore further the availability of these data.

VII. Mapping of timelines and studies to identify new and already assessed studies

An inventory review confirmed the number of studies after deduplication. A mapping exercise highlighted that several older studies, particularly from 2009–2010, had not been peer-reviewed. Efforts were made to verify these, including checking original dossiers. Some studies may have been submitted under REACH process, prompting further checks of REACH dossiers and outreach to the SDHI Task Force for clarification.

VIII. Data extraction – finalisation of the templates, both general and genotox

The group discussed the feedback on data extraction templates. Final modifications adjustments to the data extraction templates for general toxicity, genotoxicity in vitro, and genotoxicity in vivo, were agreed and will be implemented.

IX. Draft Scientific opinion : allocation of sections Opinion

The draft Scientific Opinion template was presented. It was agreed to integrate the MetaPath Assessment in the Opinion.

X. Hearing experts: SDHI task Force and MSs

The working group concluded that involving RMS hearing experts at this stage was premature due to the current lack of clarity in the assessment status. The decision will be reconsidered once more definitive progress has been made in the assessment. To support this, the assessment progress will be checked with the RMS, particularly France, to ensure alignment before considering expert involvement.

XI. Distribution of the tasks

The next WG meeting will be held on 30 June (14:00-18:00) and 1 July (9:00-13:00) 2025 at EFSA premises.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

2nd Working Group meeting on certain metabolites common to several pyrazole active substances

18 March 2025 (14:00-18:00) and 19 March 2025 (09:00-13:00)
MINUTES – Agreed on 4 April 2025

Location: EFSA - Parma / Web-conference

Attendees:

- **Working Group Members**
  Coja Tamara (Chair), Thomas Kuhl, Dimitra Nikolopoulou, Danièle Court Marques
- **European Commission**
  Maristella Rubbiani (18 March 2025), Nikolay Tzvetkov (19 March 2025)
- **Hearing experts**[1]
  None
- **EFSA**
  Dimitra Kardassi, Arianna Chiusolo, Tommaso Giorgi, Isabelle Delaunois

I. Welcome and Apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declarations of interest

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

[1] As defined in Article 34 of the "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Relevant GDs (GW, RD, and water treatment), discuss any discrepancies

The WG discussed the main differences and similarities between COM Guidance on groundwater metabolites (SANCO/221/2000-rev 11, 21 October 2021) (GW GD) and PPR Panel Guidance on residue definition (2016) (RD GD).

The GW GD requires three in vitro tests for genotoxicity, while the RD GD suggests two tests based on an EFSA Scientific Committee document, 2011. The GW GD includes relevance criteria for acute toxicity and specific carcinogenicity categories, while the RD GD assumes the same hazard for metabolites as the parent compound and suggests using relative potency factors or additional uncertainty factors. For reproductive toxicity, the GW GD considers any reproductive toxicity category as relevant if the parent is classified, while the RD GD allows for additional safety factors or specific testing if the metabolite is qualitatively different. Both guidances mention alternative approaches, such as mechanistic understanding and in silico methods, but with different levels of flexibility. The draft OECD Guidance on Residue Definition will be subject to exploration once made publicly available. It was emphasized the need to develop a harmonized methodology for assessing toxicological relevance of common metabolites in groundwater, respecting the guidances and proposing a scientifically based approach.

V. New literature search and protocol for literature review including defining criteria for relevance and reliability

The literature search covering three common metabolites and eight parent compounds, was presented. The protocol for the literature review was discussed, including the inclusion and exclusion criteria for assessment of relevance. The literature search will be repeated including also regulatory reports from authorities inside and outside Europe. The inclusion criteria encompassed primary research studies, review articles, and regulatory reports, focusing on in vivo, in vitro, in silico, and genotoxicity studies involving mammals. Metabolism and kinetic studies (ADME) were included, while biomonitoring and epidemiological studies were excluded.

Reviewers for the assessment of relevance of retrieved literature in Distiller were identified.

VI. Present and discuss the status of the preparatory work conducted on the call for data and the available data collected

The studies inventory was presented, including all relevant studies submitted by the Task Force, other applicants, and member states, as well as data from EFSA's internal IUCLID collection. Some follow up actions were identified.

VII. Data extraction

A proposed template for data extraction was shared. The need for a standardized data extraction process was discussed, and it was suggested that genotoxicity studies and acute studies may need additional columns or individual templates. Hence, a new template for genotoxicity will be created. Separate entries for the three metabolites will be made initially, with the possibility of merging them later. The templates will be shared for comments and refinement.

The agreed actions include providing comments on the templates and performing the mapping of timelines and studies to understand which studies are new and which have already been assessed.

VIII. AOB : H362: May cause harm to breast-fed children

The group discussed whether a hazard classification for lactation should still trigger a classification for reproductive toxicity. It was clarified that H362 does not fall under Cat. 1A, Cat. 1B, or Cat. 2 but is another category on its own. The text states that metabolites qualifying for a classification of their reproductive toxicity (any category) are considered relevant. The group agreed to further discuss and address the classification for lactation in more detail in the Scientific Opinion.

IX. Interpretation of ToR, problem formulation and structure of the Opinion

The skeleton of the Scientific Opinion was presented. The discussion was focused on the interpretation of the ToRs and problem formulation. The WG agreed on both interpretation of the ToRs and problem formulation.

X. Distribution of the tasks

The next WG meeting will be held on 12 Many 2025 via web conference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

1st Working Group meeting on certain metabolites common to several pyrazole active substances

15 January 2025 (13:00-17:00)
MINUTES – Agreed on 31 January 2025

Location: EFSA - Parma / Web-conference **Attendees**:

- **Working Group Members**
  Coja Tamara (Chair), Thomas Kuhl, Dimitra Nikolopoulou, Daniele Court Marques
- **European Commission**
  Maristella Rubbiani
- **Hearing experts**[1]
  None
- **EFSA**
  PREV Unit : Dimitra Kardassi, Arianna Chiusolo, Tommaso Giorgi

I. Welcome and Apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declarations of interest

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

[1] As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Request for a scientific opinion on certain metabolites common to several active substances (EFSA-Q-2024-00560)

The European Commission's mandate to EFSA was introduced to the Working Group. EFSA introduced the project timeline and the chemicals of interest i.e. the pyrazole common metabolites and their precursors/parent compounds from the Succinate Dehydrogenase Inhibitor (SDHI) group. EFSA is requested to conduct an evaluation of the toxicological profile of three metabolites 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid, 3-(difluoro-methyl)-1-methyl-1H-pyrazole-4-carboxylic acid and 3-(difluoromethyl)-1-methylpyrazole-4-carboxamide and to clarify if any further data would be required to complete the assessment of their toxicological reference values. These substances are formed in soil and may also be present in groundwater as metabolites formed in soil from different active substances, namely bixafen, fluxapyroxad, isopyrazam, sedaxane, benzovindiflupyr, pydiflumetofen and are potentially formed from inpyrfluxam, and fluindapyr.

Pursuant to Article 29 (1) of Regulation (EC) No 178/2002, in conjunction with Regulation (EC) No 1107/2009, the Commission requests EFSA to provide a Scientific Opinion on certain metabolites common to several active substances to be delivered at the latest 36 months from the acceptance of the mandate (9-9-2027).

V. Discussion on the background of the mandate, interpretation of ToRs and available guidances

The background of the mandate and pertinent guidance documents to the assessment of metabolites were introduced. Differences and discrepancies among the groundwater guidance (GW GD[4]), which follows a hazard-based approach, and the Residues Definition Guidance (RD GD[5]), which follows a risk assessment-based approach, were highlighted. During the discussion, it was noted that previous work on a similar mandate involving common metabolites of pyrethroids[6] could be beneficial for the current work on SDHI metabolites.

EFSA concluded presenting the scope and terms of reference (ToRs) of the mandate, which include:
Step 1: preparatory work

- To collect, in cooperation with Member States, all available evidence relevant for the completion of step 2 and considering information for all active substances for which these metabolites occur: bixafen, fluxapyroxad, isopyrazam, sedaxane, benzovindiflupyr, pydiflumetofen and potentially inpyrflxam and fluindapyr. Information on those metabolites and the respective active substances from which there are derived is already available to EFSA in the dossiers for approval or renewal of approval of the relevant active substances. In addition, Member States may also have access to further information (for example considered during the evaluation of applications for the authorisation of plant protection products containing the active substances) and this would need to be considered too.
- To perform a literature review of published scientific literature to ensure that all relevant data are considered in the assessment;

[4] European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.

[5] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues),2016. Guidance on the establishment of the residue definition for dietary risk assessment. EFSA Journal 2016;14(12):4549, 129 pp. doi:10.2903/j.efsa.2016.4549.

[6] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), Hernandez-Jerez AF, Adriaanse P, Aldrich A, Berny P, Duquesne S, Focks A, Marinovich M, Millet M, Pelkonen O, Pieper S, Tiktak A, Topping CJ, Widenfalk A, Wilks M, Wolterink G, Binaglia M, Chiusolo A, Serafimova R, Terron A and Coja T, 2022. Scientific opinion on toxicity of pyrethroid common metabolites. EFSA Journal 2022; 20(10):7582, 31 pp. https://doi.org/10.2903/j.efsa.2022.7582.

Step 2: toxicological characterisation

- To develop a harmonised methodology for the assessment of the groundwater toxicological relevance of common metabolites in groundwater and in particular for these common metabolites, 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid, 3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxylic acid and 3-(difluoromethyl)-1-methylpyrazole-carboxamide. The current state of the art on assessment of toxicity, read-across and other alternative in silico and non-testing methods and tools should be considered, where appropriate. Criteria to confirm that the metabolites themselves would not represent a hazard for carcinogenicity or reproductive toxicity to be developed.
- To assess the available evidence in relation to the toxicity profile of the metabolites, in particular indicating whether the metabolites are of lower or comparable toxicity to the parent substances.
- If possible, health-based reference values for the metabolites to be used in risk assessment should be derived.

VI. Planning

The timeline for the Working Group's activities was presented. The first step involves a targeted call for toxicological hazard data on the three metabolites, which has been launched and it is already open until the end of February 2025. This consultation engages applicants and all Member State Competent Authorities. The EFSA Working Group on the common metabolites will evaluate the submitted data and will complete the assessment of the toxicological reference values of these metabolites. Additionally, a literature review will be conducted and the searching strategy was discussed.

VII. Distribution of the tasks

The tasks were allocated among Working Group members.

VIII. AOB

The next WG meeting will be held on 18 (14:00-18:00) and 19 (9:00-13:00) March 2025 at EFSA premises.