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Guiding principles, processes, and criteria for the work of the OECD Drone/UASS Subgroup of the Working Party on Pesticides

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Foreword

In July 2021, the OECD Working Party on Pesticides (WPP) supported a proposal to refocus the informal OECD Drones/UAV Subgroup (the Subgroup) of the WPP to provide advice on implementation of the recommendations in the 2021 *Report on the State of the Knowledge Literature - Review on Unmanned Aerial Spray Systems in Agriculture*, that outlines how the risks associated with Uncrewed Aerial Spray Systems (UASS)[1] applications could be viewed and addressed.

The Subgroup (now Drone/UASS Subgroup) serves as an advisory body to the Unmanned Aerial Pesticide Application System Task Force (UAPASTF or the Task Force) convened by industry and other Uncrewed Aerial Vehicles (UAV) groups, as appropriate, that generate, submit or share/provide access to information and data to governmental agencies to address limitations in available regulatory information and to support risk assessment in relevant governmental agencies, including in OECD Member countries.

This document describes guiding principles, processes, and criteria under which information and data considered in the Work Plan of Subgroup will be deemed acceptable by OECD Members in order that all parties are aware of expectations.

The UAPASTF is working to generate information and develop models to evaluate risks to human health and the environment from uncrewed aerial application of pesticides. The Subgroup provides input to this work. Business at OECD (BIAC), who participates in the work of the Subgroup, acts as the point of contact between the Task Force and the Subgroup.

The document aims to clearly define expectations of the members of the Subgroup and Working Party on Pesticides for data and information sharing and responsibilities of the Task Force and other UAV groups, authors of peer reviewed publications, as appropriate, so that all parties are aware of what is expected within the work of the Subgroup.

The document was endorsed by the Working Party on Pesticides 28 February 2024 and was declassified under the responsibility of the OECD Chemicals and Biotechnology Committee on 21 May 2024.

[1] UAV, unmanned aerial vehicle, refers to the “drone” aircraft. UASS, uncrewed aerial spray system, is used to indicate a drone with a spray system. UASS is used to be consistent with the International Organization for Standardization (ISO) technical committee using “UASS”. However, the ISO uses “Unmanned Aerial Spray System" and the OECD Drone/UASS Subgroup chose in 2022 to use “Uncrewed Aerial Spray System”.

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1. Introduction

1.1. The refocused OECD Drone/UASS Subgroup

In July 2021, the OECD Working Party on Pesticides (WPP) supported a proposal to refocus the OECD Drones/UAV Subgroup (hereafter, the Subgroup) to provide advice on implementation of the recommendations in the 2021 *Report on the State of the Knowledge Literature - Review on Unmanned Aerial Spray Systems in Agriculture* [ENV/CBC/MONO(2021)39] (the 2021 Report), that outlines how the risks associated with Uncrewed Aerial Spray Systems (UASS) applications could be viewed and addressed. The Subgroup (now Drone/UASS Subgroup) would serve as an international advisory body for generation of new information and data, aimed at informing the regulatory risk assessment and decision-making concerning UASS application.

The Subgroup serves as an advisory body to the Unmanned Aerial Pesticide Application System Task Force (UAPASTF) convened by industry (hereafter, the Task Force) and other Uncrewed Aerial Vehicles (UAV) groups, as appropriate, that generate, submit or share/provide access to information and data to governmental agencies to address limitations in available regulatory information and to support risk assessment in relevant governmental agencies, including in OECD Member countries.

1.2. Objectives of the work

The objectives of the Task Force are to support development of

- a database of spray drift and deposition empirical data for regression analysis to inform development of an empirical drift curve or model available to regulatory agencies. The data will be derived from studies in peer-reviewed publications and from the Task Force (or from other registrants in a wider call for submission of data; details are to be determined).
- an empirical drift curve or model to estimate off-target exposure from UASS applications which are available to regulatory agencies to inform risk assessment.
- as a long-term goal, a publicly available mechanistic model for predicting spray deposition and drift including parameters for static hovering, forward speed, and spray equipment for use by regulatory agencies for assessing risks from UASS spray drift.

The Task Force is also developing

- Requirements & Specifications for Field Drift Trials when using Uncrewed Aerial Vehicles (UAVs) (UAV field drift study protocol).
- A document describing best management practices for pesticide applications with UASS which aims to inform the UASS application regulatory risk assessment and decision-making.

The objective of the Subgroup is to draft a summary report (the Summary Report) describing

- a method of classifying UASS using their physical characteristics to aid evaluation and the tools, models and databases generated by the Task Force,
- where the resulting models and databases reside and how to access them via publicly available resources,

- how these items address the recommendations in the above-mentioned 2021 Report, and a summary of the input by the Subgroup.

1.3. Objectives of this document

In order that all parties, including the Task Force, are aware of what is expected within the work of the OECD Drone/UASS Subgroup of the Working Party on Pesticides, the OECD Secretariat in collaboration with the Subgroup drafted this document to describe the principles, processes and criteria under which information and data will be deemed acceptable by Members. The objective is to ensure:

- adequate transparency and clarity on intellectual property issues to support the use in regulatory contexts of information, data and models generated and developed.
- adequate access for all OECD Members and stakeholders to information considered by the Subgroup and the Working Party on Pesticides.
- an understanding of responsibilities regarding data sharing and confidential data within the OECD context.

2. Expectations regarding the final deliverable of the OECD Drone/UASS Subgroup in the OECD context

The following bullet points indicate the expectations regarding the final deliverable of the OECD Drone/UASS Subgroup in the OECD context.

- Publicly available resources will be understood as resources accessible to anyone in the general public, that is, freely, and readily available to all.
- The empirical database of reliable spray drift raw data will be publicly available.
- The empirical drift curve and the mechanistic model will be publicly available.
- The UAPASTF UAV field drift study protocol will be publicly available.
- A Summary Report describing the models, databases, the protocol(s) use to generate UAV field drift study data, and best management practices document generated by the Task Force, including where to find these items via publicly available resources and how they address the recommendations in the 2021 Report. If approved and declassified by OECD Members, the Summary Report will be publicly available.
- The Summary Report will also provide commentary from the Subgroup on the strength, limitations, and applicability of the model for specific regulatory contexts.
- The Summary Report will NOT include recommendations for use for a particular commercial product or for the international adoption of a harmonised approach.

3. Best Management Practices for Safe and Effective Application of Pesticides Using Unmanned Aerial Spray Systems (UASS)

The following provides expectations regarding the process leading to the development of the UAPASTF document describing current best management practices for pesticide applications with UASS.

- The UAPASTF has requested input from the OECD Drone/UASS Subgroup on drafts of the document, *Best Practice (BMP) for Safe and Effective Application of Pesticides Using Unmanned Aerial Spray Systems (UASS)*.
- The Subgroup will provide commentary on the UAPASTF BMP document in the Summary Report.
- After data become available to address the Subgroup's recommendations of the 2021 Report, the development of OECD guidance to embody the UAPASTF Best Practices could be proposed, as a separate project, for consideration by the Subgroup and WPP.

4. Process leading to establishment and use of the empirical curve and mechanistic model

The following provides expectations regarding the process leading to the establishment and use of the curve.

- The Task Force has drafted an UAPASTF UAV field drift study protocol which describes how field studies should be performed. The Subgroup provided feedback on the draft protocol for consideration by the UAPASTF.
- The Task Force and potentially other sources are accumulating data to support development of the empirical curve and mechanistic model.
- Only data of the requisite quality will be used to construct the empirical curve and mechanistic model.
    - There are existing guidelines that determine what data is deemed to be of the requisite quality. See Section 7.
    - Data should be generated under OECD Principles of Good Laboratory Practice (GLP) where possible.
    - Studies should at least have a comprehensive description of the following elements: typology of drones used, methods fully explained, controls used where applicable, environmental, and operational conditions listed, appropriate quality assurance (not GLP but rather solid QA) including calibration of application equipment, and adequate statistical analysis. Helpful methodological aspects to describe are test item, study site, trial layout, trial conduct, sample collection/handling/ transport/storage and/or analytical methods.
- The empirical curve and mechanistic models will be developed by a tripartite group (regulators, industry, and research organisations) to which the Subgroup will provide input on needs for validation and accessibility for use of models in regulatory contexts.
- Regulatory models should be peer reviewed, validated and documented, available, and relatively static in terms of model version. The Subgroup will discuss details regarding ownership, development and long-term maintenance of models and what information needs to be available on how they were derived and when the models are updated in the future.
    - *Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products*[1] (European Food Safety Authority, EFSA) provides some general principles for regulators

evaluating acceptability of a new model which might be useful / transferable, though some content may not be relevant as the document is specifically tailored towards models to assess ecological effects (ecotoxicology) rather than exposure estimates.

- Members of the Subgroup representing regulatory authorities, their networks, and the WPP members may request access to underlying data in order to make a judgement on the robustness of the resulting curve/model.
- The deliverables and supporting items will be reviewed by the Subgroup and their networks in a transparent process that allows acceptance by all OECD Members equally.
- If all underlying data supporting the curve and exposure model cannot be made available to the Subgroup and WPP members and their networks, including other elements such as underlying code and training data sets, any limitations to data access will be discussed with the Subgroup and possibly also with the WPP as this may interfere with the review by OECD Members.
- In time, the Subgroup will include in the Summary Report commentary on the strength, limitations, and applicability of the curve and model for specific regulatory contexts, for review by the WPP and WPP member networks.
- The WPP will approve the final draft Summary Report of the Subgroup. If appropriate, the report will be then approved and declassified by the OECD Chemicals and Biotechnology Committee (CBC).

5. Data sharing / accessibility

The Subgroup will review the curve/model data at a level appropriate to be able to judge the robustness of the curve/model.

The data for the curve/model will be derived from three sources: (1) The peer-reviewed data "mined" from literature reviews, (2) the Task Force, resulting from fields trials based on the UAPASTF UAV field drift study protocol, or (3) or from other registrants, researchers, etc. The following are principles and criteria for data sharing / accessibility.

- The peer-reviewed data mined from literature reviews to be used and shared require:
  - Quality check (existing guidelines and specifically, for studies related to plant protection product application by drone/UAV/RPAS equipment, must meet the criteria for triage and classification and international guidelines outlined for the OECD Drone Subgroup Open Literature Review project)
  - Author permission
  - Copyright clearance, as needed
  - All replications (e.g., 'raw data') of an off-site research study from owners/authors
- Data may be owned by the Task Force or other actors. The respective owner has the right to limit the circumstances in which their data are shared (for example, only to bodies with suitable data protection arrangements).

- Raw and summary data of studies may be essential for spray drift curves, and access may be requested by the Subgroup, WPP delegates, and/or experts within regulatory authorities, in order to offer a respective Member government view on the strengths and weaknesses of the model.
- The empirical database of reliable spray drift raw data will be available to the Subgroup representing regulatory authorities (as well as the WPP members upon request) when the exposure models which are based on the database are under review. Then the database will, subject to receiving appropriate clearances, be released for public access once the exposure models are released.
- Members of the Subgroup and others who have access to the data have a responsibility to respect and protect information which is confidential.
- Full study reports will be made available only to national authorities as part of the registration process.
- Study summaries will be publicly available and included in or referenced in the Summary Report.

6. Guiding principles behind information sharing within OECD Chemicals Programme

The work of the Subgroup is guided by existing general principles of information sharing within the OECD Chemicals Programme.

- Information discussed in the Subgroup, including inputs provided to and received by the Task Force, will be made publicly available when possible in order to maintain maximum transparency, in line with OECD rules and established practices and in light of the OECD Recommendation on Enhancing Access to and Sharing of Data [OECD/LEGAL/0463].
- Information for the consideration by the Subgroup that is classified will not be shared beyond the delegates of the Subgroup in line with OECD rules and established practices. In particular, OECD Members, including experts participating in the Subgroup, and the Secretariat must take appropriate steps to ensure the security of classified information.
- When information/data is housed on behalf of the Subgroup on a third-party server, the third party is invited to apply the OECD data retention policies.

7. Guidance on criteria under which data submitted in support of model development will be deemed acceptable by OECD Members

The principles, practices and standards described in the following are indicative of the approaches in the generation of data deemed to be of sufficient quality to support regulatory decision-making.

- Generally speaking, studies and/or data collection with regards to the environment, human or animal health and safety should be done in accordance with the OECD Principles of Good Laboratory Practice (in Annex II of the "Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals" [OECD/LEGAL/0194][2]) and the "Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice" [OECD/LEGAL/0252][3].

As this is a new and evolving area of regulation, without established standards and guidelines, data submitted in support of model development, in particular field drift trials with UAVs, need not be GLP compliant, however critical aspects of quality assurance activities required for GLP studies should still be in place, such as the archive of specimens, raw data and records and the accurate reflection in study reports, including any deviation from SOP, study plan or relevant test guidelines.

When the goal of a study is to inform occupational, applicator, or by-stander exposure, 3-dimensional measurements ("mannequins" equipped with dermal dosimeters and pumps with filter), in addition to surface deposits on the ground, should be part of the criteria for study evaluation and exposure model development.

- For most environmental regulatory studies there are guidelines that set out in detail how to design a trial or experimental set up. Irrespective of whether they apply to data required for new technology, these guidelines may still provide useful benchmarks of principles that should be followed. These include:
  - OECD Guidelines for the Testing of Chemicals
  - Fate, Transport and Transformation Test Guidelines: OPPTS 835.6100 Terrestrial Field Dissipation [EPA 712-C-08-020][4] (United States Environmental Protection Agency)
  - The list of international guidelines for measuring drift, including ISO standards, agreed by the Subgroup in the context of the 'Statement of work' for the contractor for the OECD literature review project, as well as agreed criteria for triage and classification of published papers in the literature review (see next section)
- Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products[5]; *EFSA Journal* 2022;20(1):7032). Different models are necessary for spray drift exposure to humans, animals or the environment; for humans, surface deposits on the ground and direct spray drift exposure via inhalation and the dermal route are relevant.
- Submission of scientific peer‐reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA)[6]. Though this guidance is geared towards presenting published literature in dossiers for active substances, it may provide a helpful steer in judging reliability of published papers and conducting literature reviews.
- Evaluation Guidelines for Ecological Toxicity Data in the Open Literature (United States Environmental Protection Agency, 2011)[7]
- Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment (United States Environmental Protection Agency)[8]
- Guidance by the OECD Working Party on Hazard Assessment to improve the value and the uptake of data derived from academic research in regulatory safety assessments (forthcoming). The Guidance intends to integrate non-standard, non-guideline chemical data published in scientific literature and found in various databases (ToxCast, QSAR prediction, etc.). The focus is on substance data and assessments (rather than methods and models to generate data).
- OECD Guidance Document No. 298[9] provides the Fair, Reasonable, and Non-Discriminatory (F/RAND) practices for access to models and methods and fees.

Members and the Subgroup may follow this guidance in the interest of acknowledging the investment from developers of innovative models and methods.

List of international guidelines for measuring drift and criteria for triage and classification of published papers in the literature review

The following list of international guidelines for measuring drift and agreed criteria for triage and classification of published papers in the literature review applies in the context of the "Statement of work" for the contractor for the OECD literature review project (the 2021 Report)

APPLICABLE DOCUMENTS AND GLOSSARY

Applicable Documents

Appendix I - Data Evaluation Record Template
Appendix II - OECD Drone Sub Group Open Literature Review Criteria
Appendix III - Sample List of International Study Guidelines for Measuring Spray Droplet Spectra and Spray Drift

Appendix I - Data Evaluation Record Template

Reference	Authors. Year. Title. Publication. Vol: pg. numbers. DOI (if available).
Research Category	[List all applicable categories E.g.] Spray drift Spray deposition Modelling Nozzle – number, placement on drone, VMD (droplet size categorisation) Efficacy Drone engineering Summary review of drone application method Operator / worker, bystander and residents exposure Other:_____
Confidential Information	Yes/No [if yes, identify nature of confidential data, e.g. product efficacy data, unpublished test data, product formulation information, etc.]
Executive Summary	Overview of key findings and study acceptability.
Study Methodology	Guideline followed (if applicable): GLP followed: Yes/No Raw data provided: Yes/No Study details, including (as appropriate): • Drone operating platform • Environmental conditions
Study Results	Overview of pertinent results and description of statistics, where applicable.
Review comments	
Review Conclusions	This study is considered relevant/not relevant and/but is fully reliable/reliable with restrictions/unreliable (provide details as needed).

Appendix II - OECD Drone Subgroup Open Literature Review Criteria

Screening criteria for open literature studies

In order to be considered for full review, studies related to plant protection product application by drone/UAV/RPAS equipment must meet the following criteria:

- Be relevant to one or more of the following key research areas
  - spray deposition
  - spray drift
  - modelling
  - nozzles – number, placement on drone, VMD (droplet size categorisation)
  - efficacy
  - drone engineering
  - summary review of drone application method
  - operator / worker, bystander and residents exposure
  - other research areas not mentioned but considered as relevant from a regulatory risk assessment perspective
- Full article availability (i.e., not just abstract). For articles with English-only abstracts, full translations may need to be requested if they are deemed relevant.
- Be published in a peer-reviewed journal or from a recognised research institute/government body.

Studies that meet these criteria should then be evaluated and classified according to their relevance and suitability. Studies that are found not to be relevant should be included in the summary spreadsheet with the comment 'Clearly not relevant'.

Study classification

Open literature studies can be classified according to the suitability of the information provided for informing the risk management of applying plant protection products by drone, as outlined in the table below. The classification is subjective as there is not a clear list of criteria that have to be met in order to determine scientific integrity of the study. The classification is therefore largely up to the discretion of the reviewer(s). Note that some international guidelines for spray droplet characterisation and spray drift trials do exist (e.g. ASTM, ISO, ASABE; Appendix III).

Classification	Description
Fully Reliable	• Fully compliant with the test guideline specified (if applicable), **or** • Scientifically sound study design with sufficient details provided to have confidence in reported results (e.g.): a. Methods fully explained b. Adequate replication c. Controls used when applicable d. Environmental and operational conditions listed e. Adequate data availability (raw data preferred, or if available upon request; sufficient summary data to clearly show trends/differences between trials) f. Adequate statistical analysis • Information can be used to inform regulatory decision-making.
Reliable with Restrictions	• May not be fully compliant with the test guideline specified, but nevertheless judged to provide a reliable basis for regulatory decision-making.

Classification	Description
	• Scientifically sound study design if not conducted according to test guidelines, or with identified limitations on data quality and/or availability. • Information may be used to inform regulatory decision-making, in consideration of the limitations and uncertainties identified.
Unreliable	• Not compliant with the test guideline specified, or is scientifically flawed to the point that it is not considered reliable for regulatory decision-making. • Insufficient study details or poorly presented results such that no confidence in study conclusions (e.g.): a. Lack of information of test conditions, including meteorology for outdoor spray drift trials b. Insufficient replication c. Lack of appropriate statistical methodology d. Deficiencies in reporting of study data • Will not be used to inform regulatory decision-making.

Appendix III – Sample List of International Study Guidelines for Measuring Spray Droplet Spectra and Spray Drift

ASABE (American Society of Agricultural and Biological Engineers)

- ASAE S561: Procedure for Measuring Drift Deposits from Ground, Orchard, and Aerial Sprayers[10]
- ASAE ANSI/ASABE S572.3: Spray Nozzle Classification by Droplet Spectra (February 2020 update)[11]

ASTM (American Society for Testing and Materials)

- ASTM E 641-01 Standard Methods for Testing Agricultural Hydraulic Spray Nozzles (updated in 2021)[12]
- ASTM E2798-19: Standard Test Method for Characterization of Performance of Pesticide Spray Drift Reduction Adjuvants for Ground Application[13]

US EPA (Environmental Protection Agency)

- US Environmental Protection Agency (EPA) - Drift Reduction Technology (DRT) Documents: Drift Reduction Technology (DRT) Field Studies Submission Review Guide[14]; Drift Reduction Technology (DRT) Wind Tunnel Studies Submission Review Guide[15]
- EPA 840.1000: Background for Pesticide Aerial Drift Evaluation[16]
- EPA 840.1100: Spray Droplet Size Spectrum[17]
- EPA 840.1200: Spray Drift Field Deposition[18]

ISO (International Organization for Standardization)

- ISO 22369-2: Crop protection equipment -- Drift classification of spraying equipment -- Part 2: Classification of field crop sprayers by field measurements[19]
- ISO 22866: Equipment for crop protection -- Methods for field measurement of spray drift[20]
- ISO 22856: Equipment for Crop Protection – Laboratory drift methods measurements[21]

Other

- LERAP (Local Environmental Risk Assessment for Pesticides), UK - Normative Reference Protocol for Field Measurement of Spray Drift Deposition from Agricultural and Horticultural Spraying Systems[22]
- Julius Kühn Institute (JKI), Germany (2015), Guideline for the testing of plant protection equipment 2-2.1 Procedure for the registration of plant protection equipment in the section "drift-reduction" of the register of loss reducing equipment of the descriptive list. See endnote for an updated version (2021) (in German) [23].
- JKI, Germany (2013), Guideline for the testing of plant protection equipment 7-1.5: Measuring direct drift when applying liquid plant protection products outdoors, See endnote for an updated version (2021) (in German)[24].

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