



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



Minor use authorisations

Public Hearing – Phytosanitary Measures (Bill 6.299/2002)

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Overview

- **Understanding needs, roles & responsibilities**
 - Growers
 - Registrants
 - Government and Regulatory
- **Australia's approach**
 - Data requirements & guidelines
 - Authorisation mechanisms
 - Current Government initiatives
- **Summary**



All groups have a role in delivering outcomes



What GROWERS need

Tools (chemical & biological)

- Supply a diverse range of fruits & vegetables
- Manage resistance, new pests & diseases
- Access suitable markets / trade in export

Support

- Through established programs that;
 - identify 'gaps' and potential solutions (priority setting)
 - work with registrants, regulator & other minor use programs
 - identify supporting data (locally & internationally)
 - generate data where necessary
 - compile regulatory submissions
 - keep growers informed
 - Communication with public about safety of produce

What REGISTRANTS need

Business cases

- Justification for investment (versus return)

Incentives

- Data protection
- Fee waivers
- Expedited reviews
- Liability

Predictable regulatory environment

- Consistency with other regulators (data & timeframes)
- Clear data requirements & guidelines
- Acceptance of crop grouping & extrapolation
- Acceptance of international data and packages

What GOVERNMENTS/REGULATORS need

Sufficient data

- Justification and transparency in authorisations
- Community confidence in authorisations
- Registrant engagement
- Effective & coordinated grower support

Contemporary legislation

- Comparable with other regulators (processes & timeframes)
- Options in authorisation mechanisms (ie. permits, SOLAs and others)
- Provisions that incentivise minor uses

Contemporary requirements & guidelines

- Consistency with international best practice (ie. OECD, FAO)
- Science based risk analysis – proportionate to risks being managed
- Specific provisions for minor uses (crop grouping/extrapolation)
- Acceptance of international data
- Provisions for Global Joint Assessments and Worksharing (new active ingredients = new tools for growers)

Australia's approach

Data requirements & guidelines

- Adoption of existing international guidance documents (OECD, FAO)
- Recently published guidance document on the use of international data and assessments
- Recently published crop groupings
 - currently identifying representative crops in residues, efficacy, environment and occupational safety
- Maximise use of international data for minor uses
 - data mining – access from registrant or public domain (ie. JMPR reports)
- OECD engagement – Expert Group on Minor Uses and Residue Chemistry Expert Group

Data requirements and guidance

OECD and FAO

[ate](#) > [Chemical safety and biosafety](#) > [Agricultural pesticides and biocides](#) > Publications on pesticide residues

Publications on pesticide residues

GUIDANCE DOCUMENTS

[OECD Maximum Residue Limit Calculator](#)

Series on Pesticides No. 56

Guidance Document on Residues in Livestock

Series on Pesticides No. 73

[ENV/JM/MONO\(2013\)8](#)

Second Edition Guidance Document on Crop Field Trials

Series on Pesticides No. 66 / Series on Testing and Assessment No. 164

[ENV/JM/MONO\(2011\)50/REV1](#) , [ENV/JM/MONO\(2011\)50/REV1/ANN](#)

Guidance Document on Overview of Residue Chemistry Studies

Series on Pesticides, No. 32; Series on Testing and Assessment, No. 64

[ENV/JM/MONO\(2009\)31](#)

Definition of Residue

Series on Pesticides, No. 31; Series on Testing and Assessment, No. 63; revision, published 28 July 2009

[ENV/JM/MONO\(2009\)30](#)

Guidance Document on Magnitude of Pesticide Residues in Processed Commodities

Series on Testing and Assessment, No. 96

[ENV/JM/MONO\(2008\)23](#)

Guidance Document on Pesticide Residue Analytical Methods

Series on Pesticides No. 39 / Series on Testing and Assessment No. 72

[ENV/JM/MONO\(2007\)17](#)

TEST GUIDELINES

> [TG 501](#): Metabolism in Crops

> [TG 502](#): Metabolism in Rotational Crops

> [TG 503](#): Metabolism in Livestock

> [TG 504](#): Residues in Rotational Crops (Limited Field Studies)

> [TG 505](#): Residues in Livestock

> [TG 506](#): Stability of Pesticide Residues in Stored Commodities

> [TG 507](#): Nature of Pesticide Residues in processed Commodities - High Temperature-Hydrolysis

> [TG 508](#): Magnitude of Pesticide Residues in Processed Commodities

> [TG 509](#): Crop Field Trial



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FAO
PLANT
PRODUCTION
AND PROTECTION
PAPER

225

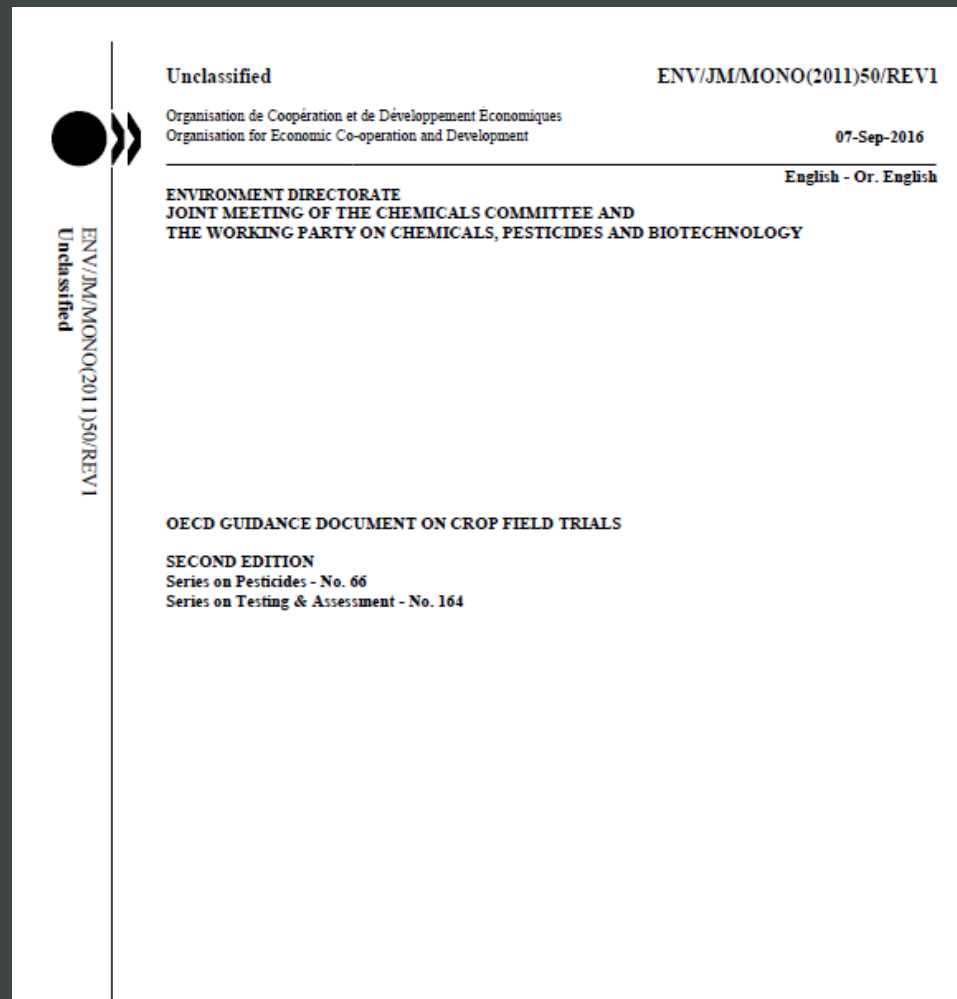
Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed

Third edition

PESTICIDE RESIDUES

Maximum Residue Limits

- **OECD guidance**
- Crop grouping
- Extrapolations
- Proportionality
- Geographical distribution
- Trial numbers



<http://www.oecd.org/chemicalsafety/pesticides-biocides/publicationsonpesticideresidues.htm>

Australia's approach

Authorisation mechanisms

- Product registration – submissions made only by the registrant
 - Global Joint Reviews – enhancing minor use authorisations and for new active ingredients
- Permit authorisations 200/annum– submissions made by grower groups (minor uses & emergencies)
 - Use international data – temporary authorisation – sometimes confirmatory data, when necessary
 - Good Laboratory Practice (GLP) - not mandatory for minor uses
 - Two-thirds MRLs established through permits for minor uses
 - Approximately 1000 permits (~650 for horticultural crops)

Australia's approach

Current Government initiatives

- Government funding for 'improved access to chemicals'
 - \$8M over 4 years
- Established cross-industry collaborative forum
 - Grower priority setting - identifying common needs across commodities
 - Involvement of registrants in identifying solutions and existing data
 - Regulator provides input into data requirements and use of international data
- Annual grant funding program
 - 2016 – 49 projects at approximately \$1.7M
 - 2017 – 53 projects at approximately \$2.1M

Summary - three core principles

Technical (science)

- Science based risk analysis
- World best practice
- Contemporary guidelines
- Tailored for minor uses
- International data

Policy

- Designated program
- Contemporary legislation
- Incentives for investment
- Options in authorisation mechanisms (permits, SOLAs, provisional)

Cooperation

- Clear roles & responsibilities
- Priority setting & planning
- International engagement
- Data mining
- Global Joint Reviews and Worksharing for new active ingredients

Questions?

- Obrigado !!

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