"How To" Demonstration on using OECD DER templates

Annabel Waggoner, Biologist
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division
US EPA, Office of Pesticide Programs
November 18, 2011

Outline of Presentation

- ✓ A brief history- EPA's Use of DER templates for Microbial Pesticides
- ✓ Various uses
- ✓ Differences in between PMRA and EPA DER templates
- ✓ "How-to" demonstration for using EPA-revised OECD DER templates
- ✓ Benefits of its use and other considerations

History of OECD DER templates for MPB

PILOT PHASE I (2005-2007)

Based draft templates (PMRA- lead country)→MPB prepared initial EPA revised DER template drafts

- ✓ Limited use due to incompatibilities with EPA FIFRA coding system and other formatting issues
- ✓ Provided feedback and recommendations to PMRA

PILOT PHASE II (2008-2011)

Adopted PMRA's revisions and continued to develop EPA-revised OECD templates

- ✓ Successful use of Draft templates for human health effects; distributed to contractors & registrants
- ✓ Eco effects were revised again
- ✓ Decision to develop ***DER template for Product Chemistry*** for EPA only

PILOT PHASES DONE!

- ✓ All EPA-revised OECD DER templates were completed for microbial pesticides for Tier I data requirements and announced in April 2011 (latest version 2.1- OCT 2011)

NEXT STEPS:

- ✓ Reviewers can now use DER templates for all scientific disciplines
- ✓ Distribution to interested registrants via email, CD-ROM, and soon to be posted on EPA/BPPD's website
- ✓ Encourage use for all data submissions (not just joint-reviews)

Various Uses of EPA-revised OECD DER templates

Data Submission

- **Reference document for Study Execution, Data Generation, and Study Report Preparation**
- **Registrants and Regulatory Consultants can submit Pre-populated DERs with Study Reports**

EPA Review

- **Contractors and MPB Reviewers can use DER templates for 1° review**
- **Reviewers can use Pre-populated DERs for 2°review**
- **FINAL DER- Acceptable as EPA Official Record**

Global Review

- **PMRA/NAFTA/OECD Reviewers can use templates for 1° review or Pre-populated DERs for 2°review; Pre-populated DERs are mutually-acceptable and can be easily divided among countries**
- **FINAL DER- Acceptable as Official Regulatory Document for Global Exchange of Reviews**

EPA and PMRA DER template Differences

MINOR→ IN GENERAL

- Addition of EPA record tracking codes
- Alternate names for Study titles and Data requirements
- Some PMRA DER templates were consolidated to a single representative DER template→ to establish ***1 template per EPA data requirement***
- Label recommendations or risk mitigation statements removed from conclusion section

EPA and PMRA DER template Differences

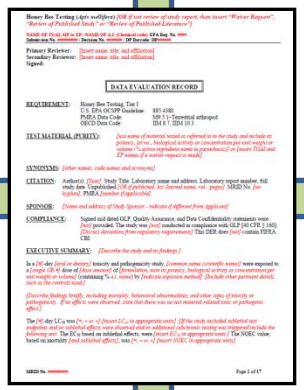
MAJOR→ Product Chemistry DER

- Separation of CBI data as Confidential Appendix
- Organization of data due to different data code numbering systems
- Some data sections were removed due to different data requirements (e.g. efficacy)
- ~80% Harmonized in data requirements

EPA DER templates (in OECD format) are fully compatible with PMRA DER templates*

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

OECD



NAFTA
North American
Free Trade Agreement

*with the exception of the PC DER template

Health Canada

Santé Canada

EXAMPLE DER template Parts

New Header

Acute Pulmonary Toxicity and Pathogenicity - *[species] [OR if not review of study report, then insert "Waiver Request", "Review of Published Study" or "Review of Published Literature"]*

NAME OF TGAI, MP or EP / NAME OF A.I. (Chemical code)/ **EPA Reg. No. ####**
Submission No. ######### / Decision No. ####### / DP Barcode: DP######

Country Study Codes

STUDY TYPE:	Acute Pulmonary Toxicity and Pathogenicity	
	U.S. EPA OPPTS Guideline:	885.3150
	PMRA Data Code:	M4.2.3–Acute Pulmonary Infectivity and Toxicity
	OECD Data Code:	IIM 5.3.3

New format for study citation

CITATION: Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen]*, PMRA *[number if applicable]*.

Revised "Compliance statement"

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were *[not]* provided. The study was *[not]* conducted in compliance with GLP [40 CFR § 160]. *[Discuss deviations from regulatory requirements]* This DER does *[not]* contain FIFRA CBI.

EPA tracking info in footer

EXECUTIVE SUMMARY

FULL STUDY SUMMARY

→ Replaces CONCLUSION section in original DER format

INCLUDES:
study design, methods, control results, conclusions and study classification

EXECUTIVE SUMMARY: In an acute pulmonary infectivity and toxicity study (MRID *[number]*), groups of *[age] [strain] [species] [#/sex/group]* were exposed by the intratracheal route to *[formulation, note its potency, biological activity or concentration per unit weight or volume]* in *[name of vehicle, if applicable]* at a dose of *[in units of potency, biological activity or concentration per kg bw or animal]*. Animals were then observed for up to *[#]* days. *[Identify other control groups, if applicable]* The pulmonary LD_{50} of the test substance is ***[=, > or <] [#] mg/ kg bw]*** **(95% C.I. if available)** *[note if limit test]* in *[male, female OR both sexes] [species]. [NOTE: include sex-specific LD_{50} values if different values].* Based on the results of this study, *[formulation, test material]* showed **[NO, LOW, SLIGHT, MODERATE, HIGH] Toxicity** on *[species]* after exposure to a single dose of *[dose level]* mg/kg by the intratracheal route *[include EPA Toxicity Category I, II, III or IV]* and *[insert formulation name] [is or is not]* pathogenic in the *[species]*.

[Include only major treatment related clinical signs, body weight or necropsy signs including onset and/or duration if any or the following statement: There were no treatment related clinical signs, necropsy findings or changes in body weight. Indicate if a pattern of clearance was achieved and when it was achieved. If applicable, note if there was a NOAEL for clinical findings (for acute reference dose consideration during subsequent risk assessment.)]

This acute pulmonary infectivity and toxicity study is classified as *[acceptable, unacceptable (why)]*. This study was *[not]* conducted in accordance with the guideline recommendations for an acute pulmonary infectivity and toxicity study (OPPTS 885.3150; PMRA: M4.2.; OECD Data Code: IIM 5.3.3) in the *[species]*. *[If it does not satisfy the requirement, concisely list only major deficiencies or refer to deficiency section.]*

CLASSIFICATION: **[ACCEPTABLE / UNACCEPTABLE / SUPPLEMENTAL, but UPGRADEABLE]**

METHODS

Provides guidance for each test parameter (based on OCSPP, PMRA DIR, and OECD guidelines)

Note any significant differences from the guidelines, protocol and its amendments

Guidance in blue text can be deleted and *[red input]* text should be replaced with requested information

2. Test Organism:

Species (common and scientific names): *[Insert name(s) of test species.]*

U.S. EPA OCSPP 885.4200 Rainbow trout is the test species for MPCAs with only terrestrial uses. For MPCAs where direct aquatic exposure is expected, two fish species (preferably rainbow trout and bluegill sunfish) shall be tested. Other species may be used if justification given based on increased susceptibility to the MPCA or ecological considerations that preclude the use of recommended species.
U.S. EPA OCSPP 850.1075 Rainbow trout is the preferred cold freshwater species and bluegill sunfish is the preferred warm freshwater species. Other species (S. salar, Salvelinus fontinalis, Ictaluris punctatus, O. kisutch, Cyprinus carpio, Pimephales promelas, Poecilia retuciatea, Oryzias latipes, Gastrosteus aculeatus or Brachydanio rerio) are also acceptable test species.
PMRA DIR 2001-02 Testing should be performed on one cold water fish species, preferably rainbow trout (Oncorhynchus mykiss), or a species of salmon such as Chinook (O. tshawytscha), coho (O. kisutch) or Atlantic (Salmo salar). If adverse effects are seen in rainbow trout, testing will also be required on salmon species.
Environment Canada EPS 1/RM/44 Rainbow trout for cool water tests with pyschrophilic microbial substances and bluegill sunfish (Lepomis macrochirus) for warm water tests with mesophilic microorganisms.
OECD 203 and 204 Zebra fish (B. rerio), Fathead minnow (P. promelas), Common carp (C. carpio), Ricefish (Or. latipes), Guppy (Po. reticulata), Bluegill, Rainbow trout are acceptable test species.

Age at test initiation: *[Insert the age of the test organisms.]*

U.S. EPA OCSPP 885.4200 Testing of young, actively feeding fish is preferable; same year class. Very young, spawning, or recently spent fish should not be used.
U.S. EPA OCSPP 850.1075 Juvenile fish, all of the same age.
PMRA DIR 2001-02 Actively feeding juvenile fish, 3–6 months old should be treated.
Environment Canada EPS 1/RM/44 Juveniles in exponential growth phase.
OECD 203 and 204 No specific recommendations.

Weight at test initiation (mean and range): *[Insert the weight of the test organisms.]*

U.S. EPA OCSPP 885.4200 Fish should weigh between 0.5 and 5.0 g.
U.S. EPA OCSPP 850.1075 Fish should weigh less than 3.0 g.
PMRA DIR 2001-02 All test fish should weigh between 0.5 and 5.0 grams and be from the same year class.
Environment Canada EPS 1/RM/44 Individual wet weights should be within ± 10% of mean wet weight, and must be within 25% of mean wet weight.
OECD 203 and 204 No specific recommendations.

Length at test initiation (mean and range): *[Insert the length of the test organisms.]*

U.S. EPA OCSPP 885.4200 The length of the longest fish no more than twice that of the shortest fish.
U.S. EPA OCSPP 850.1075 Longest fish no more than twice the length of the shortest. Fish should be of normal size for their age.
PMRA DIR 2001-02 The length of the longest fish should be no more than twice that of the shortest fish.
Environment Canada EPS 1/RM/44 Length of the longest fish no more than twice that of the shortest fish.
OECD 203 and 204 Zebra fish, Fathead minnow, Ricefish, Guppy, Bluegill fish should be 2.0 ± 1.0 cm long. Common carp should be 3.0 ± 1.0 cm long and Rainbow trout should be 5.0 ± 1.0 cm long.

Number of test species /Sex: *[Insert the number of test species tested and the sex of the test organisms.]*

U.S. EPA OCSPP 885.4200, 850.1075 No specific recommendations.
PMRA DIR 2001-02 No specific recommendations.
Environment Canada EPS 1/RM/44 No specific recommendations.
OECD 203 and 204 No specific recommendations.

Strain/Source: *[Report the strain, supplier and/or source of the test organism.]*

RESULTS

Contains guidance for accurate reporting of results

Includes NEW tables to compile cumulative mortality data

Distinguish between biologically vs. statistically significant effects either here or in the discussion section

B. **MORTALITY:** *[[Briefly summarize mortality results (if any). If values for LD_{50}, LC_{50}, LT_{50}, NOEL, NOEC are greater than the MHD level, use < symbol. Comment on dose response relationship; Slope of response, if provided. Compare the mortality with control treatment and/or the reference chemical. Data may be summarized in a table such as those presented below. Modify table to accommodate differences in experimental design.]*

From U.S. EPA OCSPP 885.0001 Overview for Microbial Pest Control Agents: The Agency realizes that it would be very difficult to establish specific LC_{50}, ED_{50}, or LD_{50} values (e.g. LD_{50} = 1,000 mg/kg) and 95 percent confidence limits for most MPCAs whose mechanism of action is pathogenicity, because test data are not likely to exhibit a log-probit dose-response relationship that is typical of chemical pesticides. Therefore, data that establishes an LC_{50}, ED_{50}, or LD_{50} that is greater than the maximum hazard dosage level (e.g. LD_{50} >1,000 mg/kg) would often be adequate for the purposes of hazard assessment and reporting in this section.

TABLE *[#].* Effect of *[test material]* on cumulative mortality of honey bees (*Apis mellifera*) in a *[contact, acute oral or dietary]* test.

Treatments *[indicate if nominal or measured (measured should be used, if provided)]*		**No. of Bees**	**Observation Period**					
			Day x1		*Day x2*		*Day n*	
			No. Dead	**% Mortality**	**No. Dead**	**% Mortality**	**No. Dead**	**% Mortality**
Negative control								
Solvent control, if used								
test concentration 1								
test concentration 2								
test concentration3								
test concentration 4								
test concentration n								
LD_{50}/LC_{50} *[insert [>] if greater than]*								
NOEL/NOEC *[insert [>] if greater than]*								
Reference chemical	*Mortality (% or No.)*							
	LD_{50}: / LC_{50}:	*[insert [>] if greater than]*						
	NOEL / NOEC	*[insert [>] if greater than]*						

RESULTS

Also includes tables for reporting Sub-lethal Effects (if applicable or triggered)

Distinguish statistical significant results- use symbol * or superscript [a] as footnote at bottom of table

B. **SUB-LETHAL TOXICITY EFFECTS:** *[Include if any sublethal effects are observed- Briefly summarize behavioral abnormalities or other signs of toxicity. . Indicate effects that were related to the test-material. Compare sub-lethal effects with control treatment and/or the reference chemical. Data may be summarized in a table such as those presented below. Modify tables to accommodate differences in experimental design. For acute oral and dietary, provide information about palatability of the treated diet, rate of consumption of diet in treated and untreated groups.]*

TABLE *[#]*. Effect of *[test material]* on *[endpoint]* of honey bees (*Apis mellifera*) in a *[contact, acute oral or dietary]* test.

Treatments *[indicate if nominal or measured (measured should be used, if provided)]*		**Observation Period**					
		Day x1		*Day x2*		*Day n*	
		endpoint 1	**% Affected**	*endpoint 2*	**% Affected**	*endpoint n*	**% Affected**
Negative control							
Solvent control, if used							
test concentration 1							
test concentration 2							
test concentration3							
test concentration 4							
test concentration n							
ED_{50}/EC_{50} or other sublethal endpoint *[insert [>] if greater than]*							
NOEL/NOEC *[insert [>] if greater than]*							
Reference chemical	*LC_{50}/ LC_{50}*	*[insert [>] if greater than]*					
	NOEL/ NOEC	*[insert [>] if greater than]*					

CONCLUSION

Focus on treatment-related effects

Explain unexpected findings that may affect the study

Separate section for reviewer comments & agreement with study author

III. CONCLUSION

A. **STUDY AUTHOR CONCLUSION:** *[Summarize the study author's conclusions]* Results of the acute pulmonary toxicity and pathogenicity study showed *[no]* mortality after a single dose of *[test substance name]* (containing % *a.i. name*) by the intratracheal route and *[is or is not]* pathogenic in *[species]*. Based on the results of this study, the pulmonary LD_{50} of *[Formulation]* is greater than # mg /kg in *[species]*.

B. **REVIEWER'S COMMENTS:** The reviewer agrees *[does not agree]* with the study author's conclusion. *[Formulation]* meets the requirements for EPA Toxicity Category *[I, II, III or IV]* for acute pulmonary toxicity. The study was *[not]* conducted in accordance with the guideline recommendations for an acute pulmonary infectivity and toxicity study (OPPTS 885.3150; PMRA: M4.2.; OECD Data Code: IIM 5.3.3) in the *[species]*.

C. **DEFICIENCIES:** *[List each deficiency with the required data to resolve the deficiency or if no data can be provided to satisfy the deficiency.]*

D. **CLASSIFICATION:** **[ACCEPTABLE / UNACCEPTABLE / SUPPLEMENTAL, but UPGRADEABLE]**

IV. REFERENCES *[Provide references that were cited in the study report: methods, protocols, studies in the open literature, references to other study reports in the submission or other studies conducted by the applicant. If no extra references were used, state "No references were cited."]*.

EPA ONLY

SINGLE DER

~80% OECD HARMONIZED

Citation Section Condensed

NEW! Separate Appendix for CBI

PRODUCT CHEMISTRY DER

DATA EVALUATION RECORD

— THIS DER TEMPLATE SHOULD ONLY BE USED FOR EPA DATA SUBMISSIONS —

STUDY TYPE: Product Identity, Manufacturing Process, Discussion of Formation of Unintentional Ingredients, Analysis of Samples, Certification of Limits, and Physical and Chemical Properties

U.S. EPA OCSPP Guideline:	885.1100, 885.1200, 885.1300, 885.1400, 885.1500, 830.6302, 830.6303, 830.6304, 830.6313, 830.6317, 830.6319, 830.6320, 830.7000, 830.7100, 830.7300
PMRA Data Code:	M2.1–M2.12
OECD Data Code:	IIM 1, IIM 2, IIM 3, IIM 4, IIM 5.3.5, IIIM 1, IIIM 2, IIIM 3, IIIM 4, IIIM 5

CITATION(S): Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen]*, PMRA *[number if applicable]*.

[NOTE: If multiple study reports were submitted, insert individual citation for each MRID No. here and under the title heading for each portion of data with a different citation. Use the same format as above]

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study was *[not]* conducted in compliance with GLP [40 CFR § 160]. *[Discuss deviations from regulatory requirements]*.

[If no CBI data is submitted]: This DER does not contain FIFRA CBI.
[If CBI data is submitted: This DER contains FIFRA CBI, however, the data claimed as CBI are excerpted from the DER and placed in ***Appendix A. Confidential Business Information***.

PRODUCT IDENTITY

Additional Citation Section to reference multiple MRIDs

Only contains a.i. data; Inerts in CBI appendix

I. PRODUCT IDENTITY (OCSPP 885.1100)

CITATION(S): Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen]*, PMRA *[number if applicable]*.

Deviations from guideline: *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

A. PRODUCT INFORMATION:

Product Name:
Trade Name:
Name and Address of Applicant:
Name and Address of Manufacturing Plant:
Name and Address of Formulating Plant:
Active Ingredient: **[include *genus, species, subspecies, isolate, strain ID No.*]** *[MCPAs should be expressed percentage of weight and as viable organisms per unit weight or volume (e.g. colony forming units/gram or cfu/g) or international units of potency per unit weight.]*
Chemical name:
Common Names:
Deposition number in a recognized culture collection:
CAS No.: *[if applicable]*
Molecular Weight: *[if applicable]*
Chemical Formula: *[if applicable]*

Regulatory Status: *[Is the a.i. currently registered with EPA (include EPA Reg. No.) or registered in other country (include country's regulatory registration number/code)? Is there an existing FFDCA exemption from the requirement of a tolerance for residues? Codex MRL ?]*

PRODUCT IDENTITY

Follows PMRA'S list of MPCA characterization data points

Report <u>ALL</u> data points and include any literature citations

ii) Alternatives / synonyms / superseded names associated with the microorganism: *[required information]*

iv) Strain origin: *[such as environmental, clinical, food isolate and culture collection; description of isolation procedure, including exact geographical origin of the MPCA isolate; and history of the strain during its development]*

vi) Natural occurrence of the microorganism: *[include information on its geographical distribution, preferred or obligate hosts, habitats, ecological niches and level of natural occurrence in the environment]*

vii) Mode of Action: *[Its toxicity, pathogenicity, type of antagonism to target hosts, infective/toxic dose, transmissibility, etc. (if known). Any known or potential hazard (such as infectivity) to mammals (including humans), the environment, and nontarget species should be discussed.]*

viii) Pest host range: *[Include spectrum of pests susceptible to MPCA]*

ix) Life cycle: *[If applicable- include the various forms of the MPCA that may occur and any significant differences in pesticidal, pathogenic or toxigenic characteristics of the various forms]*

x) Differences in morphological, physiological, biochemical, pesticidal or resistance characteristics from naturally occurring microorganism: *[If applicable- describe if such characteristics are different from the classical description of the species or microorganism]*

[NOTE: For guidance in compiling relevant information from multiple references/scientific literature- see format in "Review of Literature" section on last page on template. Include all reference citations.]

xi) History of use: *[MPCA and/or closely related strains or species]*

MANUFACTURING PROCESS

"Step-wise" approach

Prescribed guidance included

Data reported in CBI Appendix

II. MANUFACTURING PROCESS (OCSPP 885.1200)

CITATION(S): Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen]*, PMRA *[number if applicable]*.

Deviations from guideline: *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

A. DESCRIPTION OF PRODUCTION AND FORMULATION PROCESS:

[Describe process step-wise, including:

General characterization of the process (whether it is batch or continuous) and quantity produced.

The individual steps in the process should be clearly outlined, A flow chart of the chemical reactions at each step of the process is recommended.

Identities of the reactants, solvents, and catalysts used to product the product, the amounts and the order in which they are added.

Description of the equipment used that may influence the composition of the product.

Description of the conditions (temp, pressure, pH, humidity) that are controlled during each step and the limits that are maintained.]

[Description of the purification steps. Include QC/QA measures taken to limit extraneous contamination, both chemical and biological. These steps would include, preparation of culture media and inocula, scale up of culture to production volume, pilot and/or commercial scale cultivation, harvest and concentration of active ingredient, processing of final culture, formulation methods, packaging and storage steps.]

[Description of production methods should also incorporate details of the manufacturing facilities, including the approach used for good sanitary state of the production unit, equipment and instrumentation employed, procedures for cleaning and sterilizing equipment, production vessels, transfer lines, etc., and time frames for each step.]

DISCUSSION OF FORMATION OF UNINTENTIONAL INGREDIENTS

Details for theoretical discussion

Distinguish impurities associated with TGAI VS. Other impurities

Provide analytical methods for detection and validation results

[A theoretical discussion regarding the formation and/or presence of unintentional ingredients (impurities, contaminants or extraneous materials) that are likely to occur in the particular TGAI preparation should be provided. The nature and incidence of contamination will depend on the type of MPCA, the production methods and the production environment.

Examples include: microbial contaminants (with particular reference to potentially infective or antagonistic forms), microbial toxins, allergens, pathogens, dermal sensitizers and other metabolic products; impurities in materials used in the manufacturing process; by-products from chemical reactions in the manufacturing process; fermentation residues; extraneous host residues from the production of intracellular parasites in cell cultures, whole animals or other living forms; and mutants, or alternate forms of the MPCA; residues of contaminants that remain following the purification or extraction process; and impurities in chemicals used in the manufacturing process.]

The names of the unintentional ingredients (impurities, contaminants or extraneous materials), company codes *(if applicable)*, origin and description *[OR chemical structure- if applicable]* of unintentional ingredients are shown in Table 1.

Table *[x]*. Unintentional Ingredients, company codes *(if applicable)*, possible origin and description *[OR chemical structure- if applicable]* of impurities in *[Product formulation, TGAI, MP, or EP]*

Name of Unintentional Ingredient and type	Codes *(if applicable)*	Possible origin	Description *[OR chemical structure- if applicable]*

CERTIFIED LIMITS

Set to EPA's standards [40 CFR § 158.175(b)(2)]

If not- provide reason and justification

If alternative limits proposed – Conduct 5 batch analysis

TABLE *[x]*. Description of Ingredients and Certification of Limits for *[product name or TGAI, MP, or EP name]* (EPA Reg. No. ######)

Trade Name (Chemical description) EPA Reg. No. or CAS No.	Purpose in Formulation	Concentration (% by weight)		
		Nominal	Upper Limit	Lower Limit
Active Ingredient				
[Name of Product] *(containing #% active ingredient (scientific name- include subspecies and strain)* *[Include the number of units per unit volume or weight; viability data in terms of PFU, CFU, or other expression of biological activity]* *Example:* Contains a minimum of [# × $10^{\#}$] cfu/g *[Include deposition Number from nationally recognized culture collection Depository example*: ATTC #### or NRRL ####] EPA Reg. No. ######	TGAI	*[#]*%	*[#]*%	*[#]*%
Inert Ingredients				
[Trade Name] *[(chemical name/description)]* *CAS No. ###### or N/A*	*[purpose of insert]* *(example:* surfactant, emulsifier, preservative, antifoam, diluent)	*[#]*%	*[#]*%	*[#]*%
[insert additional rows for each additional inert ingredient in format presented above]				
Total		100		

PHYSICAL & CHEMICAL PROPERTIES

Check data requirements of TGAI vs. MP and EP for applicability [40 CFR §158.2120(d)]

TABLE *[x]*. Description of Chemical and Physical Properties for *[Product formulation, TGAI, MP, or EP]*			
OCSPP Guideline No.	**Property**	**Result**	**Method/Reference**
830.6302	Color		
830.6303	Physical State		
830.6304	Odor		
830.6313	Stability to normal and elevated temperatures, metals, and metal ions		
830.6317	Storage Stability		
830.6319	Miscibility		
830.6320	Corrosion characteristics		
830.7000	pH	*[#] (include range)*	
830.7100	Viscosity	*[#] (include range)*	
830.7300	Density/relative density (specific gravity)	*[#] (include range)*	

NEW WAIVER SECTION

DEVELOPED BY PMRA

I. PURPOSE *[Indicate the purpose of the study]*

II. METHOD *[Describe the experimental procedure]*

III. RESULTS *[Summarize the results using appropriate headers*

e.g., *A.* *GENERAL OBSERVATIONS:*
B. *DETECTABLE LEVELS OF MPCA IN TISSUES, ORGANS:]*

Compiles relevant points from multiple papers

I. REVIEW OF PUBLISHED LITERATURE *[Summarize the background information and published studies covered in this mini literature review. Grouping related papers for discussion under specific subheadings may be useful.*

e.g.,
A. *DISCUSSION OF FORMATION OF UNINTENTIONAL INGREDIENTS:*
1. *Article 1:* *(summarize and report findings)*
2. *Article 2:* *(summarize and report findings)*

B. *CHRARCTERIZATION OF THE ACTIVE INGREDIENT:*
1. *Article 1:* *(summarize and report findings)*
2. *Article 2:* *(summarize and report findings)*

C. *MSDS SHEETS:*
1. *Article 1:* *(summarize and report findings)*
2 *Article 2:* *(summarize and report findings)]*

e.g.,
A. *TOXICITY TESTING:*
1. *Article 1:* *(summarize and report findings)*
2. *Article 2:* *(summarize and report findings)*

B. *INFECTIVITY TESTING:*
1. *Article 1:* *(summarize and report findings)*
2. *Article 2:* *(summarize and report findings)*

C. *IRRITATION TESTING:*
1. *Article 1:* *(summarize and report findings)*
2 *Article 2:* *(summarize and report findings)]*

e.g.,
A. *ACUTE TOXICITY TESTING:*
1. *Article 1:* *(summarize and report findings)*
2. *Article 2:* *(summarize and report findings)*

B. *MESOCOSM TESTING:*
1. *Article 1:* *(summarize and report findings)*
2. *Article 2:* *(summarize and report findings)*

C. *FIELD TESTING:*
1. *Article 1:* *(summarize and report findings)*
2 *Article 2:* *(summarize and report findings)]*

FOUND in last 3 pages in all DERS

Guidance for DER Preparation

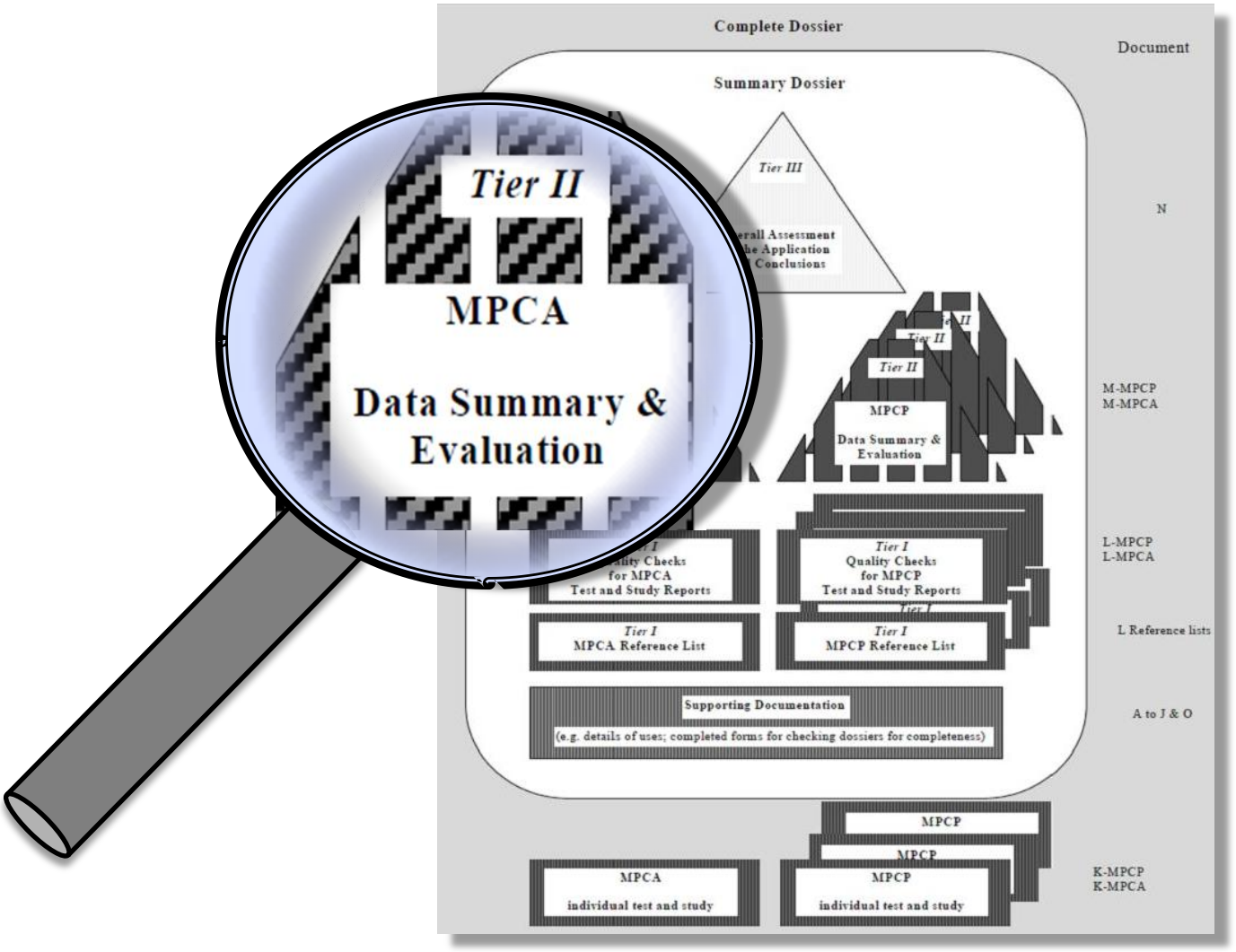
- Pre-populated DER templates alone does not constitute a complete study submission
  - Use OCSPP testing guidelines in conjunction with data preparation
- The overall structure of the templates should not be altered and data evaluation elements should not be deleted
  - Instead insert "*not applicable*" or "*not available*" with a brief explanation
  - Templates should not be combined with other guidelines or merged across guidelines
- Full characterization of MPCA is highly recommended prior to toxicological analyses to validate use of test substance
  - Note: Use same lots/batches for test material source
  - Use PC DER template as data quality check

Quality Assurance

- DER templates are considered ***"living documents"***
- MPB Internal QA tracking spreadsheet for feedback and analysis of results for continual process improvement
- Templates will evolve as we build upon our experiences
- Modifications to the DER template in the future in light of new scientific & technical advances
- MPB is dedicated to resolving any sciences issues associated with template format and as well as ensuring approaches are still harmonized with OECD

NOTE: Older template versions are acceptable

DERs ↔ Tier II Summaries in OECD dossier



Document M
very similar to DER format

Document K
individual studies

Source: *OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents – August 2006*
Website: *http://www.oecd.org/dataoecd/22/40/43435253.pdf*

Benefits for using OECD DERs

- Greater international harmonization of pesticide registration approaches
- Increased efficiency and transparency via consistent work product
- Reduce workload by sharing review burden
- Higher quality of assessment in standardization
- Reduce need for duplicative testing by saving resources and reduce animal testing
- Facilitates quicker or concurrent regulatory approval for alternative pest control substances

Other considerations

- In light of global reviews and international trade, it is important for regulatory authorities to continue to develop the most *effective means* and *established plan* to share information and expertise across national boundaries.

- This promotes a greater understanding of the *common criteria* that are used in the risk assessments and *establishing harmonization* for data sharing and joint-reviews of microbial pesticide products.

Thank you!
Merci beaucoup!
¡Muchas gracias!

ACKNOWLEDGEMENTS:

Gail Tomimatsu, MPB Lead on Joint Reviews, John Kough, MPB Senior Scientist; Sheryl Reilly, MPB Branch Chief; Michael McDavit, BPPD Associate Director; and Keith Matthews, BPPD Director

Brian Belliveau, Section Head and Denis Rochon, Senior Evaluation Officer, Microbial & Biochemical Evaluation, PMRA