

## APPENDIX 4

### FORMAT FOR COMPILATION OF *Tier I* QUALITY CHECKS

#### PART 1

#### SUMMARY REPORT - APPROPRIATE FOR STUDIES CONDUCTED IN ACCORDANCE WITH THE TEST GUIDELINES CURRENTLY SPECIFIED

#### EXAMPLE 1

1.	Data point (s)	IIM 5.3.2 Acute oral infectivity, toxicity and pathogenicity
2.	Reference point (location) in dossier	ABCD, Data point IIM 5.3.2
3.	Author	U.N. Known
	Title	Acute oral toxicity / pathogenity study of ABCD in rats
	Owner, Date	Owner, unpublished report No.xxx-000, July 14, 1992
4.	Testing Facility	Microbiological Associates, Inc. 5221 River Road, Bethesda, MD 20816
5.	Dates of work	June 2, 1992 to June 15, 1992
6.	Test Substance	ABCD (spores)
7.	Test Method	Pesticide Assessment Guideline (EPA 1989) Deviations from the protocol with respect to...
		* doses per animal: $10^8$ CFU/rat ( $1.3 \times 10^{10}$ CFU/g)
		* observation period 14 days instead of 28 days
		* clinical signs and body weight at days 4, 7, 10, 14
		* histopathological research and clearance test of spleen, liver and kidney at days 4, 7 and 14 and clearance at days 4
8.	GLP	Yes

Appendix 4 Checks	Format for Compilation of Tier I Quality	Part 1	Summary Report - appropriate for studies conducted in accordance with the test guidelines specified
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**EXAMPLE 2**

1.	<b>Data point (s)</b>	IIM 5.3.3. Acute intratracheal/inhalation infectivity, toxicity and pathogenicity	
2.	<b>Reference point (location) in dossier</b>	ABCD, Data point IIM 5.3.3	
3.	<b>Author</b>	U.N. Known	
	<b>Title</b>	Acute pulmonary toxicity / pathogenicity study of ABCD in rats	
	<b>Owner, Date</b>	Owner, unpublished report No.xxx-000, June 30, 1994	
4.	<b>Testing Facility</b>	Microbiological Associates, Inc. 5221 River road, Bethesda, MD 20816	
5.	<b>Dates of work</b>	December 14, 1993 to January 11, 1994	
6.	<b>Test Substance</b>	ABCD (spores)	
7.	<b>Test Method</b>	according to OECD guideline 403: Yes	
		Deviations from the protocol with respect to...	
		*	particle size - not submitted
		*	concentration $1 \times 10^9$ CFU/rat
		*	administration by intratracheal instillation
		*	observation period of 28 days
		*	histopathology of lungs
		*	body weights at days 1, 5, 8, 22, 29
		*	necropsy of lungs revealed lesions which were not completely reversible up to day 29
		*	infectivity/clearance of lungs after 8 days and infectivity of kidney/liver up to day 4
8.	<b>GLP</b>	Yes	

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**EXAMPLE 3**

1.	Data point (s)	IIM 5.3.4 Acute intravenous/intra peritoneal infectivity
2.	Reference point (location) in dossier	ABCD, Data point IIM 5.3.4
3.	Author	U.N. Known
	Title	Acute intraperitoneal toxicity / pathogenity study of ABCD in rats
	Owner, Date	Owner, unpublished report No.xxx-000, May 26, 1994
4.	Testing Facility	Microbiological Associates, Inc. 5221 River road, Bethesda, MD 20816
5.	Dates of work	December 15 1993 tot January 12 1994
6.	Test Substance	ABCD (spores)
7.	Test Method	guideline: unknown
		* doses per animal: 10 <sup>7</sup> CFU/rat
		* observation period 28 days
		* clinical signs and body weight (gain)
		* no histopathological research liver/kidney/spleen
		* infectivity/clearance of blood at days 1, 8, 15, 22 and 28 was tested
8.	GLP	Yes

**EXAMPLE 4**

1.	Data point (s)	IIM 5.3.6 Cell culture study, for viruses and viroids or specific bacteria and protozoa with intracellular replication
2.	Reference point (location) in dossier	NO EXAMPLE
3.	Author	
	Title	
	Owner, Date	
4.	Testing Facility	
5.	Dates of work	
6.	Test Substance	
7.	Test Method	
8.	GLP	

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**EXAMPLE 5**

1.	<b>Data point (s)</b>	IIIM 7.1.2 Acute percutaneous (dermal) toxicity	
2.	<b>Reference point (location) in dossier</b>	ABCD, Data point IIIM 7.1.2	
3.	<b>Author</b>	U.N. Known	
	<b>Title</b>	Acute dermal toxicity study of ABCD in rabbits	
	<b>Owner, Date</b>	Owner, unpublished report No.xxx-000, September 22, 1994	
4.	<b>Testing Facility</b>	Microbiological Associates, Inc. 5221 River road, Bethesda, MD 20816	
5.	<b>Dates of work</b>	July 26, 1994 to August 9, 1994	
6.	<b>Test Substance</b>	ABCD	
7.	<b>Test Method</b>	according to OECD guideline 402: Yes Deviations from the protocol with respect to...	
		*	1.08 x 10 <sup>10</sup> CFU/rabbit
		*	no infectivity/clearance test
		*	no production of beauvericine toxin (HPLC test)
		*	observation period 14 days instead of 28 days; observation after 1 and 3h and daily thereafter
8.	<b>GLP</b>	Yes	

**EXAMPLE 6**

1.	<b>Data point (s)</b>	IIIM 7.1.4 Skin irritation	
2.	<b>Reference point (location) in dossier</b>	ABCD, Data point IIIM 7.1.4	
3.	<b>Author</b>	U.N. Known	
	<b>Title</b>	Primary dermal irritation test of ABCD in rabbits.	
	<b>Owner, Date</b>	Owner, unpublished report No.xxx-000, February 7, 1995	
4.	<b>Testing Facility</b>	Microbiological Associates, Inc. 5221 River road, Bethesda, MD 20816	
5.	<b>Dates of work</b>	January 30, 1995 to February 2, 1995	
6.	<b>Test Substance</b>	ABCD	
7.	<b>Test Method</b>	according OECD 403: Yes Deviations form the protocol with respect to...	
		*	5.5 x 10 <sup>7</sup> CFU/rabbit
		*	application of 0.5 ml undiluted test substance
		*	scores of edema and erythema at 1, 24, 48 and 72 hours
		*	no dermal infections observed so no infectivity-test was needed
8.	<b>GLP</b>	Yes	

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**EXAMPLE 7**

1.	Data point (s)	IIIM 7.1.5 Eye irritation	
2.	Reference point (location) in dossier	ABCD, Data point IIIM 7.1.5	
3.	Author	U.N. Known	
	Title	Acute eye irritation study of ABCD by instillation into the conjunctival sac of rabbits	
	Owner, Date	Institut Fresius, Chemische und Biologische Laboratorien GmbH, Taunusstein, Germany, 1995	
4.	Testing Facility	Laboratory of Pharmacology and Toxicology, Hamburg, Germany	
5.	Dates of work	May 120, 1994 to May 14, 1994	
6.	Test Substance	ABCD	
7.	Test Method	according to OECD 405: Yes	
		Deviations from the protocol with respect to...	
		*	observation period of 4 days instead of 14 days
		*	observation of irritation after 1, 24, 48 and 72 hours
		*	infectivity / clearance test after 14 days was not submitted
8.	GLP	Yes	

**EXAMPLE 8**

1.	Data point (s)	IIIM 7.1.6 Skin sensitization	
2.	Reference point (location) in dossier	ABCD, Data point IIIM 7.1.6	
3.	Author	U.N. Known	
	Title	Examination of ABCD in the skin sensitisation test in guinea-pigs according to Magnusson and Kligman (Maximisation test)	
	Owner, Date	Institut Fresius, Chemische und biologische Laboratorien GmbH, Taunusstein, Germany, 1995	
4.	Testing Facility	Laboratory of Pharmacology and toxicology, Hamburg, Germany	
5.	Dates of work	January 17, 1995 to April 11, 1995	
6.	Test Substance	ABCD	
7.	Test Method	according to OECD 406: Yes	
		*	score dermal reactions after intradermal induction and topical challenge
		*	test compound not sensitising under the stringent conditions of the test
8.	GLP	Yes	

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**EXAMPLE 9**

<b>1. Data point(s)</b>	OECD point number: IIM 7 Fate and behaviour in the environment
<b>2. Reference point (location) in dossier</b>	IIM 7
<b>3. Authors (year) Title Owner, date</b>	Jones, B. Hare, E. (1996) Soil Microcosm Fate and Persistence Vatrobe, Inc. Unpublished Report No. 712, July 05, 1996
<b>4. Testing facility</b>	Cincinnati Research, Inc. Cincinnati, Ill. USA. Report CR35-A21
<b>5. Dates of work</b>	January 2, 1995 - June 2, 1996
<b>6. Test substance</b>	<i>Beauvaria wendensis strain XYZI</i>
<b>7. Test method</b>	US EPA 885.5200
<b>8. Deviations</b>	None
<b>9. GLP</b>	Yes, in accordance with US 40 CFR 160.

**EXAMPLE 10**

<b>1. Data point(s)</b>	OECD point number: IIM 8 Effects on non-target organisms
<b>2. Reference point (location) in dossier</b>	IIM 8.1
<b>3. Authors (year) Title Owner, date</b>	Faire, A. (1996) Avian Oral Study: Mallard Duck. Report, pp 5 Vatrobe, Inc. Unpublished Report No. 712, July 05, 1996
<b>4. Testing facility</b>	Norcen, Inc. Institute of Ecology Testing, Motola, Sweden, Report NC345123
<b>5. Dates of work</b>	January 10, 1995 - January 25, 1996
<b>6. Test substance</b>	<i>Beauvaria wendensis strain XYZI</i>
<b>7. Test method</b>	US EPA 885.4050
<b>8. Deviations</b>	None
<b>9. GLP</b>	Yes (laboratory certified by the National Certification Authority of Sweden)

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**EXAMPLE 11**

<b>1. Data point(s)</b>	OECD point number: IIM 8.2 Effects on fish
<b>2. Reference point (location) in dossier</b>	II M 8.2.1
<b>3. Authors (year) Title Owner, date</b>	Gentner, F.; and Couch, J. (1975) Freshwater Fish testing in Bluegill sunfish and Rainbow trout Vatrobe, Inc. Unpublished Report No. 706, July 01, 1995
<b>4. Testing facility</b>	Gulf Breeze Aquatic Testing Labs, Gulf Breeze, Fla. USA, Report GB25
<b>5. Dates of work</b>	April 3, 1974 - July 27, 1974
<b>6. Test substance</b>	<i>Beauvaria wendiensis strain XYZI</i>
<b>7. Test method</b>	US EPA 885.4200
<b>8. Deviations</b>	40 fish were used in a Maximum Hazard Dose rather than 30. The tests were carried out for 35 days rather than 30.
<b>9. GLP</b>	Yes, in accordance with US 40 CFR 160.

**EXAMPLE 12**

<b>1. Data points)</b>	OECD point number: IIM 8 .7 Effects on bees
<b>2. Reference point (location) in dossier</b>	II M 8.7
<b>3. Authors (year) Title Owner, date</b>	(1997) Honey Bee testing Vatrobe, Inc. Unpublished Report No.708, July 21, 1997
<b>4. Testing facility</b>	Eco Animals Lab, Braunschweig, Germany, Report 2357DE
<b>5. Dates of work</b>	May 9, 1997 - June 9, 1997
<b>6. Test substance</b>	<i>Beauvaria wendiensis strain XYZI</i>
<b>7. Test method</b>	US EPA 885.4380
<b>8. Deviations</b>	None
<b>9. GLP</b>	No

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EXAMPLE 13

1. Data point(s)	OECD point number: IIM 8.8 Effects on terrestrial arthropods other than bees
2. Reference point (location) in dossier	II M 8.8
3. Authors (year) Title Owner, date	(1997) Non-target terrestrial arthropods - parasitic wasps (Parasitoid) Vatrobe, Inc. Unpublished Report No.709a, September 21, 1997
4. Testing facility	Eco Animals Lab, Braunschweig, Germany, Report 2358DE
5. Dates of work	June 9, 1997 - August 9, 1997
6. Test substance	<i>Beauvaria wendiensis</i> strain XYZ1
7. Test method	US EPA 885.4340
8. Deviations	None
9. GLP	No



## PART 2

### SUMMARY REPORT - APPROPRIATE FOR STUDIES NOT CONDUCTED IN ACCORDANCE WITH THE TEST GUIDELINES CURRENTLY SPECIFIED

#### Example 1

MPCA: <i>Beauvaria wendensis</i> strain XYZI	OECD data point addressed: IIM 7	Fate and behaviour in the Environment
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- 2. Reference point:** Section IIM 7.1
- 3.1 Authors:** Report: X. XXXXXX, X. XXXXXXXXXXXXX  
Summary: X.XXXXXXXXXXX
- 3.2 Title:** Isolation of *Beauvaria wendensis* from various biotopes and plant species in Sweden and from soil and plant samples taken at various locations in Switzerland
- 3.3 Owner:** Vatrobe, Inc
- 3.4 Published:** No
- 3.5 Report No:** 801
- 3.6 Date of Report:** December 4, 1999
- 4.1 Testing Facility:** Plant Biocontrol Laboratories, University of Sweden, Uppsala, Sweden
- 4.2 Dates of experimental work:** July 1, 1999 - September 25, 1999
- 5.1 Objectives:** Prevalence of *Beauvaria wendensis* strain XYZI in the environment.
- 6.1 Test substance:** Not Applicable
- 6.2 Specification of test substance:** Not Applicable
- 6.3 Storage Stability:** Not Applicable.
- 6.4 Stability in vehicle:** Not Applicable.
- 6.5 Homogeneity in vehicle:** Not Applicable.
- 6.6 Validity:** Not Applicable.
- 6.7 Physical Form:** Not Applicable.
- 6.8 Vehicle/Solvent:** Not Applicable.
- 7.1 Test Method:** In house method. Guidelines were not available at the time the test was performed
- 7.2 Justification:** The method was developed following discussions with regulatory officials from several European authorities and the US EPA. The method used is consistent in all respects with current scientific practice.
- 7.3 Copy of method:** Description of methods included in report.
- 7.4 Choice of method:** Not Applicable.
- OECD Dossier Guidance for Microbial Pest Control Agents and Microbial Pest Control Products - August 2006

- 7.5 Deviations:** Not Applicable.
- 8.1 Certified Laboratory:** Not Applicable.
- 8.2 Certifying authority:** Not Applicable.
- 8.3 GLP:** No.
- 8.4 Justification:** University facility, not completely GLP compliant.
- 9.1 GEP:** No.
- 9.2 Type of Facility (official or officially recognized):** Not Applicable.
- 9.3 Justification:** Not Applicable.
- 10: Test system:** Sampling locations: the vicinity of Uppsala (three different locations representing five different biotopes) and from farm fields (16 localities) in southern and eastern Sweden. The Swiss material was sampled from farm fields at 22 different locations.
- Types of samples: Soil
- Analysis methods: Selective media, colonial morphology, RAPD-PCR fingerprinting in comparison with *Beauveria wendensis strain XYZI*
- 11. Statistics:** Not Applicable.
- 12.1 References:** Cravanzola F, Piatti P, Bridge P, Ozino O - 1997. Detection of genetic polymorphism by RAPD-PCR in strains of the entomopathogenic fungus *Beauveria brongniartii* isolated from the European cockchafer (*Melolontha* spp.). Letters in Applied Microbiology, 25, 289-294.
- 13. Unpublished data:** No unpublished data cited in this summary.