Draft Adverse Effect Reporting Forms

The Pest Control Products Adverse Effects Reporting Regulations were pre-published on October 23, 2004, along with a Regulatory Impact Analysis Statement (RIAS), in the Canada Gazette, Part I for public comment.

The following is a draft copy of the reporting forms which pesticide companies must use when filing adverse effects information with the PMRA. The forms indicate the type of information that is required for each adverse effect category. Once the regulations are in force, the forms will be available through a secure connexion on the Internet and must be submitted to the PMRA electronically.

The first form, "Adverse Effect Report", is a generic form for all adverse effects. The remaining forms are specific to the different categories of adverse effects. One or more category specific form may be selected for each incident depending on the type of adverse effect(s) being reported.

Please submit any comments by January 6, 2005 to:

Dana Bruce, Adverse Effects Reporting Program, Health Evaluation Division, Pest Management Regulatory Agency, Health Canada, Address Locator 6605E, 2720 Riverside Drive, Ottawa, Ontario, K1A 0K9. (Fax: (613) 736-3489; E-mail: Dana Bruce@hc-sc.gc.ca).

I) Adverse Effect Report

1.	Select appropriate form(s) for the adverse effect. II Adverse Effect in a Human III Adverse Effect in a Domestic Animal (includes pets and livestock) IV Adverse Effect in the Environment V Efficacy Failure VI Pesticide Resistance VII Residues in Food VIII Residues in Surface Water (Raw and Treated) IX Residues in Ground Water (Raw and Treated) X Packaging Failure XI Adverse Effect Identified in a Scientific Study XII Adverse Effect Reported in the Scientific Literature	
The	following relates to forms II to VII only. If VIII or XII are selected, go directly to respective form.	
3.	Date registrant/applicant was first informed of adverse effect: Location of adverse effect: City: Province: Unknown Date adverse effect occurred:	
Product description		
5.	Registration number(s) (include all tank mixes/other products involved even if they are not owned by the reporting registrant and batch number, if available): If pest control product or use is not registered, provide submission number or research permit number: Active ingredient(s) (only to be filled in if the registration number or submission number are not known): Component or derivative, other than active ingredient (provide CAS# if available or name):	
9. 10. 11. 12.	If the adverse effect occurred in US: 9. Active ingredient: 10. EPA pesticide product registration number:	
App	olication information	
15. 16.	Application rate: Unknown How many times has product been applied this season? Unknown Date of last application: Unknown Was product diluted? Yes No Unknown If yes, what was the dilution rate? Unknown	

☐ Bait station ☐ Fogger ☐ Fumigation ☐ Granular spreader ☐ Ground-boom ☐ Hand wand sprayer ☐ Hose-end sprayer ☐ Ready-to-use sprayer ☐ Other (please specify): ☐ Unknown
19. Site pesticide was applied to: Agricultural Type of crop treated: Indoor (e.g. greenhouse) Outdoor Indoor public/commercial area (includes schools) Outdoor public areas (municipal parks, school yards etc.) Industrial Specify type (e.g. wood preservative, metallurgy, antifouling paint, material manufacturing, etc.): Golf course Forest/woods Right-of-way (e.g. rail, utility, highway) Residential area Inside home Floor Carpet Hard surface Furniture Cracks and crevices Outside home Turf Garden Turf and garden Wood structure Swimming pool Animal (e.g. flea collar)
☐ Personal use (e.g. mosquito repellant) ☐ Other, describe: ☐ Unknown
20. Size of area treated: 21. Status update:

II) Adverse Effect in a Human

1.	Source of report: ☐ Data subject ☐ Medical professional ☐ Other	 Demographic information of data subject: Age (approximate if not known): Sex: □ M □ F If female, pregnant? □ Yes □ No □ Unknown
3. a)	Exposure scenario: Occupational Did exposure occur during: Mixing and loading Type of mixing and loading: Application Did the application equipment has a compared area Amount of time between application what was the re-entry activity (Manufacturing (e.g. material pressamment) Repair, maintenance or clean-up of	Open Closed Unknown have a closed cab? Yes No Unknown ation and re-entry: Unknown e.g., harvesting, pruning, thinning etc.): Unknown ervatives etc.) of application equipment es No Unknown Chemical resistant gloves Long-sleeve shirt Long
	☐ Face mask ☐ Other (plea	pants overalls (non-chemical resistant) Chemical resistant coveralls se specify):
b)	☐ Bystander Did exposure occur from: ☐ Drift of pesticide from the applica ☐ Pesticide spill ☐ Pesticide runoff ☐ Being on site during application ☐ Other (please describe):	tion site
c)	☐ Residential/Public Did exposure occur during: ☐ Mixing and loading ☐ Application ☐ Re-entry into treated area (e.g. dir pool, treated wood, etc.) Amount of time between applic What was the re-entry activity (rect contact with a treated surface such as lawn, carpet, pet, swimming ation and exposure (re-entry): □ Unknown e.g., mowing lawn, playing on lawn, weeding vegetable garden, petting
d)	If yes, check appropriate box(es): Chemical resistant gloves Description of a product Was exposure: Accidental	es
e)	☐ Other (please describe):	
4.	Route(s) of exposure: Skin Eye Oral Respiratory Unknown Other (please specify):	

Exposure data: 5. If exposure occurred during mixing, loading or applying, how much of the pest control product was handled? □ Unknown 6. Exposure duration: □ Unknown 7. Time between exposure and onset of symptoms: □ Unknown		
8. Was the person examined by a physician?		
 12. Signs and symptoms of adverse effect Describe the adverse effect in full detail. Information to include: All signs and symptoms of the adverse effect Duration of each symptom (hours, days, etc) Severity and/or frequency of each symptom Results from medical tests (if available, please input results here or provide as an electronic attachment) 		
13. Provide any explanatory or qualifying information surrounding the incident.		
14. Severity classification: ☐ Death ☐ Major ☐ Moderate ☐ Minor		
15. Status update:		

III) Adverse Effect in a Domestic Animal

1. Source of report:			
	☐ Animal's owner		
☐ Veterinarian			
Other	<u> </u>		
2. Type of animal affected:	3. Breed:		
□ Livestock	4. Number of animals exposed to the pest control product:		
☐ Dairy cattle	5. Number of animals affected:femalemale		
☐ Beef cattle	6. Number of nursing females affected:		
☐ Horse	7. Number of pregnant females affected:		
□ Sheep	8. Weight:		
□ Pig	0 P (() C		
☐ Chicken (egg laying)	9. Route(s) of exposure:		
☐ Chicken (broiler)	□ Skin		
☐ Other (please specify):	□ Eye		
☐ Companion animal			
□ Dog	☐ Respiratory		
□ Cat	☐ Unknown		
□ Fish	☐ Other (please specify):		
□ Bird	10 E 1 4 E E E		
□ Horse	10. Exposure duration: ☐ Unknown		
Rabbit	11. Time between exposure and onset of symptoms: \Box Unknown		
☐ Other (please specify):			
Circumstances of exposure			
12. How was the animal exposed?			
	ed with a pest control product (e.g., flea collar, ear tag, spray etc.).		
	posure to this product?		
If yes, was there a reaction?			
	ndirectly exposed to a pest control product (e.g. accidental ingestion of		
pesticide, contact with treated surface, spray drift, etc.).			
Describe circumstances: 12. Were other enimals in class provinity to the effected enimals, treated with a different post central product?			
13. Were other animals, in close proximity to the affected animal(s), treated with a different pest control product? □ Yes □ No □ Unknown			
If yes, with what and how much?			
14. Signs and symptoms of adverse effect Describe the adverse effect in full detail.	Information to include:		
	 All signs and symptoms of the adverse effect. (For example: convulsion, excessive salivation, vomiting, diarrhea Lethargy, loss of appetite, difficulty breathing, rash, hair loss) 		
 Duration of each symptom (hours, da 			
 Number of animals exhibiting each sy 			
Severity and/or frequency of each syr	•		
	 Results from medical tests (if available, please input results here or provide as an electronic attachment) 		
15. Was the animal examined by a veterinarian? \square Yes \square No \square Unknown			
16. Was the animal hospitalized? \square Yes \square			
If yes, for how long:			
17. Was the animal treated? \square Yes \square No	□ Unknown		
If yes, describe treatment (e.g. specia	l diet, medication, etc.):		
	ne animal, indicate number of animals for each outcome):		
`	overed from symptoms Recovered with residual effects		
☐ Fully recovered ☐ Unknown			
•	19. Provide any explanatory or qualifying information surrounding the incident.		
20. Severity classification: Death	<u> </u>		
☐ Major			
☐ Moderate			
☐ Minor			
21. Status update:			

IV) Adverse Effect in the Environment

1. Type of organism affected Bird Mammal Fish Aquatic invertebrate Amphibian Reptile Insect Plant	 2. Common name:	
Exposure information 7. Was the adverse effect a result of (can select more than one): □ Application □ Spill □ Mixing/loading □ Disposal □ Run-off □ Wash-off □ Drift □ Other (please specify): □ Unknown 8. If it was a spill, please provide details such as when, where, how much and any other applicable circumstances:		
Weather information 9. Did it rain up to 3 days before pesticide applicat 10. What were the weather conditions at the time of a Temperature: Wind speed: Amount of rain: Intensity of rainfall: light, medium, heavy 11. What were the average weather conditions for the Temperature: Wind speed: Amount of rain: Intensity of rainfall: light, medium, heavy 12. Location of the nearest weather station:	application?	
13. Were any buffer zones observed? If yes, i) what was the type of buffer zone: ii) size of buffer zone		
 14. Symptoms of adverse effect Describe the adverse effect in full detail. Include All symptoms of the adverse effect (for exan seed or fruit yield, terminal bud death, stunte Number of organisms exhibiting each sympt 	nple: death, birth defects, lethargy, leaf discolouration, reduction in ed vegetative growth etc.)	
15. Did the affected organisms recover? ☐ Yes	□ No □ Unknown	
16. What steps (if any) were taken to clean up the are	ea after the incident or to rehabilitate any organisms affected?	
17. Were appropriate environmental samples collected If yes, provide analytical report, including management of the samples collected analytical report of the samples collected analytical re		
18. Provide any explanatory or qualifying information	on surrounding the incident, such as how the adverse effect occurred.	
19. Severity classification: ☐ Severe ☐ Major ☐ Minor		
20. Status update:		

V) Efficacy Failure

Inc: 1. 2.	ident description Describe efficacy failure. Discuss any factors which may have affected the performance of the pest control product.
Bac 3. 4. 5.	Ekground information Target pest: Pest development stage at time of pesticide application: Unknown Pest density at time of pesticide application: Unknown
6.	Were additives utilized in application e.g. adjuvants, fertilizer or other modifiers? Yes No If yes, provide the product name and rate of application for each additive: If a registered adjuvant was utilized, provide registration number:
7.	Has the same active ingredient or different active ingredient with a similar mode of action been used in previous years at this site, for the same pest? Yes No If yes, for how many years?
8.	Weather information on the date of application Amount of rain: Temperature: Other relevant weather information (e.g. wind speed):
9.	Provide any explanatory or qualifying information surrounding the incident.
10.	Status update:

VI) Pesticide Resistance

Incident description 1. Describe pesticide resistance incident. 2. Discuss any factors which may have affected the performance of the pesticide.
Background information 3. Target pest: 4. Pest development stage at time of pesticide application: □ Unknown 5. Pest density at time of pesticide application: □ Unknown
6. Were additives utilized in application e.g. adjuvants, fertilizer or other modifiers? ☐ Yes ☐ No If yes, provide the product name and rate of application for each additive If a registered adjuvant was utilized, provide registration number:
7. Has the same active ingredient or different active ingredient with a similar mode of action been used in previous years at this site, for the same pest? ☐ Yes ☐ No If yes, for how many years?
8. Weather information on date of application Amount of rain: Temperature: Other relevant weather information:
9. If available, provide data, including methodology, as an electronic attachment.
10. Provide any explanatory or qualifying information surrounding the incident.
11. Status update:

VII) Residues in Food

1.	Pesticide(s) and degradate(s) analysed for:
2.	Concentration of pesticide/degradate in food:
3.	Corresponding limit of detection:
4.	Sample type:
	☐ Raw agricultural commodity
	☐ Prepared or processed food
	\square Other
	□ Unknown
5.	Method of analysis (include if a confirmatory method was used in addition to the screening method):
San	ple information:
6.	What is the reason the sample was collected (e.g. complaint, inspection, process monitoring)? \Box Unknown
7.	What organization collected the sample?
	☐ Provincial (specify agency)
	☐ Canadian Food Inspection Agency
	☐ Canadian Grain Commission
	Other
	□ Unknown
8.	What point in the distribution channel was the sample taken from?
	□ Farm
	□ Warehouse
	☐ In transit
	□ Retail
	□ Other
0	Unknown
	How large was the food commodity the sample was taken from? \Box Unknown How many samples were taken? \Box Unknown
	How large was the sample size?
	Is sample size representative of the sampled commodity?
	Was any of the violative sample retained for further analysis / confirmatory work? \Box Yes \Box No \Box Unknown
	What action was taken based on the violative residue?
1	□ No action
	☐ Shipment rejected
	☐ Shipment destroyed
	□ Other
	□ Unknown
15.	Provide analytical report, including methodology, as an electronic attachment.
16.	Provide any explanatory or qualifying information surrounding the incident.
17.	Status update:

VIII) Residues in Surface Water (Raw and Treated)

1. 2.	Date registrant/applicant was first informed of adverse effect Location of adverse effect: City: Province □ Unknown	t:
3. 4. 5.	Pesticide(s) and degradate(s) analysed for: Concentration found in water: Corresponding limit of detection:	
6. 7.	Date water was sampled: Type of surface water sampled: □ Raw water □ Treated water	
Ifra	aw water was sampled, answer questions 8 to 10.	
8.9.	Type of water body sampled: Fresh water Pond Stream River Lake Reservoir Sediment Other Salt water Estuary Bay Ocean Sediment Name of water body and location: Unknown	10. Dimensions of water body sampled.a) Surface area:b) Depth of water body:c) Volume of water body:d) If it was a reservoir, size of the watershed area:
If tr	reated water was sampled, answer questions 11 to 13.	
	Where was the treated water sampled from: Water treatment plant Tap Other If the water was sampled from a water treatment plant: a) What is the name of the water treatment plant? b) Is surface water mixed with ground water? Yes No Unknown If yes, percentage surface water to ground water:	13. What is the source of treated water? Reservoir Lake Stream Pond Dugout River Salt water Spring Standing water Pit Lagoon Unknown
15. 16.	 4. Was the water contamination a result of: ☐ Aquatic application ☐ Terrestrial application ☐ Spill ☐ Mixing and loading ☐ Disposal ☐ Run-off ☐ Wash-off ☐ Drift ☐ Other (please specify): ☐ Unknown 5. If it was a spill, please provide details such as when, where, how much and any other applicable circumstances. 6. If the water contamination occurred as a result of terrestrial application, how many years has this active ingredient been used in the watershed area? 17. Were any aquatic buffer zones observed? ☐ Yes ☐ No ☐ Unknown If yes, size of buffer zone: 	
18.	Provide analytical report, including methodology, as an elec	ctronic attachment.
19.	Provide any explanatory or qualifying information surround explains the cause of the contamination, how it occurred, the	
20.	Status update:	

IX) Residues in Ground Water (Raw and Treated)

 Date registrant/applicant was first informed of adverse Location of adverse effect: City:	e effect:	
Groundwater sampling results 3. Pesticide(s) and degradate(s) analysed for: 4. Concentration found in water: 5. Corresponding limit of detection: 6. Date water was sampled: 7. Source of sample (e.g. tap; directly from well): 8. Were physical and chemical parameters measured?] Yes □ No □ Unknown	
Description of affected site 9. Depth of groundwater: Unknown 10. Well use (e.g. drinking, irrigation): 11. Depth of screened interval: 12. Soil series: Sand Clay Silt Other Unknown 13. Aquifer description: Confined Unconfined Unknown 14. pH of water:	How was the site exposed 15. Was the water contamination a result of: □ Application □ Spill □ Mixing and loading □ Disposal □ Other (please specify): □ Unknown 16. If it was a spill, please provide details such as when, where, how much and any other applicable circumstances. 17. Were there any previous spills in the vicinity of the water contamination? □ Yes □ No □ Unknown If yes, please provide details such as when, where, how much and what: 18. How many years has this active ingredient been used in the area?	
 19. Location of the nearest weather station: 20. Are the fields irrigated? □ Yes □ No □ Unknown If yes, type of irrigation system used? 		
21. Provide analytical report, including methodology, as a	in electronic attachment.	
22. Provide any explanatory or qualifying information sur explains the cause of the contamination, how it occurr		
23. Status update:		

X) Packaging Failure

1.	Date registrant/applicant was first informed of adverse effect:
2.	Location of adverse effect:
	City:
	Province
3.	Date the incident occurred:
4.	What is the registration number of the product:
5.	What is the type of packaging (e.g. water soluble packaging, bait station, aerosol, etc.)?
6.	Did packaging failure occur during:
	\square Use of the product
	□ Storage
	☐ Transportation
	☐ Other (please describe):
7.	Describe how the packaging failed and the circumstances under which it happened:
8.	Was there human exposure due to the packaging failure? ☐ Yes ☐ No ☐ Unknown
	If yes, i) approximately how much product was the person exposed to (e.g. half of the container, 10 ml, etc.)?
	ii) what was the route of exposure:
	\Box Hands
	\Box Torso
	□ Head
	\Box Arms
	\Box Legs
	☐ Respiratory
	□ Oral
	□ Eye
9.	Provide any explanatory or qualifying information surrounding the incident.
10.	. Status update:

XI) Adverse Effect Identified in a Scientific Study

1.	Has the study already been submitted to PMRA? □Yes □No If yes, provide submission number and date submitted: If no, provide the study as an electronic attachment. If translation is required, is an extension needed? □Yes □No If yes: i) for how long? ii) attach a summary of the study in English or French.
3.	Study reference: Author(s): Date: Title:
4.	Registration number of pest control product or, if not known, active ingredient(s):
5.6.7.	Type of study (e.g. epidemiology study): Type of adverse effect identified in the study: New health or environmental hazard Increased health or environmental risk Efficacy failure Presence of a component or derivative Describe the adverse effect identified in the study (e.g. study demonstrates an increased risk to non-Hodgkin's lymphoma after exposure to pesticide X)
8. 9.	Was the study discontinued before completion? □Yes □No If yes, provide reason for discontinuation: If the study is ongoing, what is the expected completion date?
10.	Provide any explanatory or qualifying information surrounding the incident.
11.	Status update:

XII) Adverse Effect Reported in the Scientific Literature

1.	Article reference Author(s): Journal: Issue/volume/page number: Date: Title of article:
2.	Active ingredient(s):
 4. 	Type of adverse effect: Human death Human major Domestic animal death Domestic animal major Environment severe Adverse effect identified in a scientific study: New health or environmental hazard Increased health or environmental risk Efficacy failure Presence of a component or derivative Describe the adverse effect identified in the article (e.g. article indicates an increased risk to non-Hodgkin's lymphoma after exposure to pesticide X):
5.	Provide any explanatory or qualifying information surrounding the incident.