Pest Control Products Incident Reporting Regulations

SOR/2006-260

PEST CONTROL PRODUCTS ACT

Registration 2006-10-26

Pest Control Products Incident Reporting Regulations P.C. 2006-1136 2006-10-26

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 67(1) of the <u>Pest Control Products ActFootnote</u>^a, hereby makes the annexed <u>Pest Control Products Incident Reporting Regulations</u>.

• Return to footnote^aS.C. 2002, c. 28

INTERPRETATION

Marginal note: Definitions

• 1. (1) The following definitions apply in these Regulations.

```
"Act" « Loi »
```

"Act" means the Pest Control Products Act.

```
"domestic animal" « animal domestique »
```

"domestic animal" means an animal that is under the control of humans and dependent on them for its survival.

```
"incident" « incident »
```

"incident" means an incident described in section 2 whose effects relate to the health or environmental risks or the value of a pest control product. It does not include an incident that results from an act or activity that would constitute an offence under the *Criminal Code*.

```
"incident report"
« déclaration d'incident »
```

"incident report" means a report that contains the information described in section 3 and that is received by the Minister from a registrant or an applicant.

```
"individual of a species at risk" « individu d'une espèce en péril »
```

"individual of a species at risk" means an individual of a species set out in the List of Wildlife Species at Risk in Schedule 1 to the <u>Species at Risk Act</u>.

- Application of definition "incident report"
 - (2) For the purpose of applying the definition "incident report" in subsection (1), the information need not be proved or substantiated by the registrant or applicant in order to be included in the report.

CLASSIFICATION OF INCIDENTS

Marginal note: Categories

- **2.** Incidents are classified, according to the subject of the exposure to the pest control product and the degree of severity of their effects, into the following categories:
 - (a) in the case of a human being,
 - o (i) an incident whose effect is a human death,
 - (ii) an incident that has a major effect on a human, when an individual has or has had symptoms that indicate a condition that could be lifethreatening or result in adverse reproductive or developmental effects or in chronic disability,
 - o (iii) an incident that has a moderate effect on a human, when an individual has or has had symptoms that are more pronounced, more prolonged or of a more systemic nature than minimally bothersome symptoms, and for which some form of treatment is usually indicated, although the symptoms do not indicate a life-threatening condition and the individual is likely to return to their pre-exposure state of health without any chronic disability, and
 - (iv) an incident that has a minor effect on a human, when an individual has or has had minimally bothersome symptoms that normally resolve rapidly, including skin rash, itching, conjunctivitis, drowsiness, transient cough, headache, joint pain, agitation, restlessness or mild gastro-intestinal symptoms such as self-limited diarrhea, stomach cramps or nausea;
 - (b) in the case of a domestic animal,
 - o (i) an incident whose effect is a domestic animal death,
 - o (ii) an incident that has a major effect on a domestic animal, when a domestic animal has or has had symptoms that indicate a condition that could be life-threatening or result in adverse reproductive or developmental effects or in chronic disability,
 - o (iii) an incident that has a moderate effect on a domestic animal, when a domestic animal has or has had symptoms that are more pronounced, more prolonged or of a more systemic nature than minimally bothersome symptoms, and for which some form of treatment is usually indicated, although the symptoms do not indicate a lifethreatening condition and the animal is likely to return to its preexposure state of health without any chronic disability, and
 - (iv) an incident that has a minor effect on a domestic animal, when a
 domestic animal has or has had minimally bothersome symptoms,
 such as skin, eye or respiratory irritation, that normally resolve
 rapidly;
 - (c) in the case of the environment,
 - o (i) an incident that has a major effect on the environment, when

- (A) the number of individuals of a group or subgroup set out in column 1 or 2, respectively, of the schedule that die is at least the number set out in column 3, or
- (B) an individual of a species at risk has or has had at least one of the symptoms set out in column 6 of the schedule,
- o (ii) an incident that has a moderate effect on the environment, when the number of individuals of a group or subgroup set out in column 1 or 2, respectively, of the schedule that have or have had at least one of the symptoms set out in column 6 is the number, or a number within the range, set out in column 4, and
- (iii) an incident that has a minor effect on the environment, when the number of individuals of a group or subgroup set out in column 1 or 2, respectively, of the schedule that have or have had at least one of the symptoms set out in column 6 is less than the number set out in column 5;
- (*d*) an incident whose effect is residues in food, when a pest control product or one of its components or derivatives is detected in food in an amount that would result in the sale of the food being prohibited under section 4 of the *Food and Drugs Act*;
- (e) an incident of packaging failure, when packaging failure is observed that could result in the exposure of humans to a pest control product or in injury to humans; and
- (f) an incident whose effects are identified in a scientific study, when the effects are observed during a human epidemiological study or a scientific investigation, whether concluded, discontinued or ongoing, and the study or investigation is sponsored by the registrant or applicant and indicates
 - (i) any new health or environmental hazard associated with a pest control product,
 - (ii) any health or environmental risk associated with a pest control product that may be greater than the risk determined at the time of registration, or
 - o (iii) the presence of a previously undetected component or derivative of a pest control product.

PRESCRIBED INFORMATION

Marginal note: Section 13 of the Act

- 3. (1) The following information that is received by a registrant or an applicant about an incident that is associated with their pest control product or with any pest control product that has the same active ingredient, and that is required by sections 7, 8 and 16, is prescribed information for the purpose of section 13 of the Act:
 - \circ (a) contact information for the registrant or applicant;
 - (b) the date on which the incident occurred;
 - (c) the date on which the registrant or applicant received the information about the incident;

- (d) the city, province or state, and country where the incident occurred;
- (e) the identification of the pest control product;
- (f) information about the application of the pest control product, including the site, method and date
 of its application;
- \circ (g) the category of the incident, determined in accordance with section 2;
- (h) information about the circumstances of the exposure to the pest control product, including the site, date, route of exposure, weather conditions, duration and subject information, which, in the case of a human subject, is restricted to age, gender and whether the subject is pregnant;
- (i) information about the incident and its effects, including the symptoms, duration and outcome;
 and
- (j) scientific test information, including information about the sample, the method of analysis and the results.
- Marginal note:Section 13 of the Act
 - (2) The following information about an incident that is associated with the registrant's or applicant's pest control product or with any pest control product that has the same active ingredient, and that is required by section 9, is prescribed information for the purpose of section 13 of the Act:
 - (a) contact information for the registrant or applicant;
 - (b) the title and date of the study and the name of the author;
 - (c) the identification of the pest control product;
 - (d) the category of the incident, determined in accordance with section 2;
 - o (e) the scientific study and the test data generated during the study; and
 - (f) the type of scientific study, an indication of which of subparagraphs 2(f)(i) to (iii) is the reason for submitting it, and the information the study reveals about the incident and its effects.
- SOR/2009-94, s. 2.

Previous Version

GENERAL REQUIREMENTS

Marginal note: Reports deemed received

- 4. (1) Subject to subsection (2), all information about incidents and their effects that is required by these Regulations is deemed to have been received by the registrant or applicant on a certain date if it is received on that date by
 - o (a) an employee or agent of the registrant or applicant; or
 - (b) an employee or agent of a related corporation, within the meaning of the definition "related persons" in subsection 251(2) of the <u>Income Tax Act</u>, whether the related corporation is located in or outside Canada.
- Marginal note:Exception
 - (2) In the case of an incident whose effects are identified in a scientific study, if the information is received by a person described in paragraph (1)(b), the information is deemed to have been received by the registrant or applicant one year after its receipt by that person.
- **5.** [Repealed, SOR/2009-94, s. 3]

Previous Version

Marginal note:Language of reports

• **6.** (1) Incident reports must be filed in English or in French.

- Marginal note:Translation delays
 - (2) In the case of a scientific study published in a language other than English or French, if the translation of the study cannot be completed within the prescribed time for filing the incident report, the registrant or applicant must provide the Minister with a summary of the study, in English or French, when the report is filed.
- Marginal note:Translated study
 - (3) In a case described in subsection (2), the registrant or applicant must send the completed translated study as soon as possible after the report is filed.
- SOR/2009-94, s. 4.

Previous Version

INCIDENT REPORTS

Marginal note:Incidents in Canada

- **7.** Every registrant and applicant must file with the Minister, in accordance with the time limits specified in sections 10 to 14, a complete and accurate report of any information set out in subsection 3(1) that they receive about an incident that occurs in Canada, in accordance with the categories described in paragraphs 2(a) to (e).
 - SOR/2009-94, s. 5(E).

Previous Version

Marginal note:Incidents in the United States

- **8.** Every registrant and applicant must file with the Minister, in accordance with the time limits specified in sections 10 to 12, a complete and accurate report of any information set out in subsection 3(1) that they receive about an incident that occurs in the United States, if the incident fits within any of the following categories described in section 2: an incident whose effect is a human death, an incident that has a major effect on a human, or an incident whose effect is a domestic animal death.
 - SOR/2009-94, s. 5(E).

Previous Version

Marginal note: Scientific studies

- **9.** Every registrant and applicant must file with the Minister, in accordance with the time limit specified in section 11, a complete and accurate report of any information set out in subsection 3(2) about an incident whose effects are identified in a scientific study.
 - SOR/2009-94, s. 5(E).

Previous Version

REPORTING TIME LIMITS

Marginal note: Time limit — 15 days

- **10.** Every registrant and applicant must file an incident report within 15 days after the day on which they receive information about any incident in the following categories:
 - (a) an incident whose effect is a human death;
 - (b) an incident that occurs in Canada that has a major effect on a human; and
 - (c) an incident that has a major effect on the environment.

Time limit — one month

- 11. (1) Every registrant and applicant must accumulate the information that they receive in a month about incidents in the following categories and file the required incident reports before the end of the next month:
 - o (a) an incident that occurs in the United States that has a major effect on a human;
 - (b) an incident that has a moderate effect on a human;
 - (c) an incident that occurs in Canada whose effect is a domestic animal death;
 - O (d) an incident that has a moderate effect on the environment;
 - (e) an incident whose effect is residues in food;
 - (f) an incident of packaging failure; and
 - \circ (g) an incident whose effects are identified in a scientific study.
 - (2) [Repealed, SOR/2009-94, s. 6]
- SOR/2009-94, s. 6.

Previous Version

Marginal note: Time limit — table

- 12. Every registrant and applicant must accumulate the information that they receive in a reporting period set out in column 1 of the table to this section about incidents in the following categories and file the required incident reports on the date set out in column 2:
 - (a) an incident that occurs in the United States whose effect is a domestic animal death; and
 - (b) an incident that has a major effect on a domestic animal.

TABLE

	Column 1	Column 2
Item	Reporting Period	Filing Date
1.	January 1 to March 31	May 31
2.	April 1 to June 30	August 31
3.	July 1 to September 30	November 30
4.	October 1 to December 31	February 28, or February 29 in the case of a leap year

Marginal note: Filing of 12-month report

- **13.** Subject to subsection 14(4), every registrant and applicant must accumulate the information that they receive in a 12-month period established in accordance with section 14 about incidents in the following categories and file the required incident reports in accordance with that section:
 - (a) an incident that has a minor effect on a human;
 - (b) an incident that has a moderate effect on a domestic animal;
 - (c) an incident that has a minor effect on a domestic animal; and
 - (d) an incident that has a minor effect on the environment.

Time limit — table

• 14. (1) Subject to subsections (2) to (4), every registrant and applicant the first letter or number of whose name is set out in column 1 of the table to this subsection must file the incident reports described in section 13 and the annual summary described in section 15 within two months after the end of the reporting period set out in column 2.

TABLE

Column 1 Column 2	
-------------------	--

Item	First letter or number of registrant's or applicant's name	Reporting period
1.	A or a number	December 1 to November 30
2.	В	January 1 to December 31
3.	С	February 1 to January 31
4.	D	March 1 to February 28, or February 29 in the case of a leap year
5.	E, F or G	April 1 to March 31
6.	H, I or J	May 1 to April 30
7.	K or L	June 1 to May 31
8.	M	July 1 to June 30
9.	N	August 1 to July 31
10.	O, P, Q or R	September 1 to August 31
11.	S	October 1 to September 30
12.	T, U, V, W, X, Y or Z	November 1 to October 31

Marginal note:Name change

(2) If a registrant or an applicant changes their name after having filed a first incident report described in section 13 or a first annual summary described in section 15, the time limit for filing subsequent reports and summaries under those sections remains the time first established in accordance with subsection (1).

Marginal note: Amalgamation

(3) If two or more registrants or applicants amalgamate after one of them has filed a first incident report described in section 13 or a first annual summary described in section 15, the time limit for the amalgamated registrant or applicant filing subsequent reports and summaries under those sections is the earliest of their time limits first established in accordance with subsection (1).

Marginal note:No longer a registrant

- (3.1) If a registrant ceases for any reason to be the registrant of a particular pest control product, they must file the incident reports described in section 13 and the annual summary described in section 15, with respect to all information that they receive about that product before the day on which they cease to be the registrant, within one of the following time limits:
 - o (a) before the day on which they cease to be the registrant; or
 - (b) on or before the day that is 15 days after that day.

Marginal note:First report and summary

(4) The first incident report described in section 13 and the first annual summary described in section 15 that are filed in accordance with subsection (1) may be for a reporting period shorter than 12 months.

ANNUAL SUMMARY

Marginal note: When annual summary required

- **15.** (1) A registrant must file an annual summary with respect to an active ingredient in the following circumstances:
 - (a) the active ingredient is a component of a pest control product that is the subject of an incident report filed by the registrant in the year; and
 - 0 (b) the active ingredient is implicated in at least 10 such reports in the same year.

Marginal note:Content

- (2) The annual summary must contain the following information:
 - (a) with respect to each incident report referred to in paragraph (1)(b), the category of incident described in section 2; and

- (b) a concise critical analysis of all the data relating to the active ingredient, including a comparison
 with analyses of past years and commentary on any changes that arose in the year in the risk
 profile of any pest control product of which the active ingredient is a component.
- Marginal note:Timing
 - (3) The annual summary must be filed at the same time as the incident reports required by section 13.

DANGEROUS SITUATIONS

Marginal note: Health or environment

16. Every registrant must provide the Minister with all information set out in subsection 3(1) that they receive and that has not already been reported, within 24 hours after the Minister requests it for the purpose of responding to a situation that endangers human or domestic animal health or the environment.

RECORDS

Marginal note: Keep and submit on request

17. Every registrant and applicant must keep a record of every completed incident report and any information they have that relates to or is in connection with that report for six years after the day on which the report is filed with the Minister. The record must be provided to the Minister, on request, for the purpose of making comparisons or a historical analysis of the incidents or to permit the Minister to exercise powers under the Act.

PLACEMENT IN REGISTER

Marginal note:Incident reports and supplemental information

- **18.** (1) Subject to subsection (2), the Minister must place all incident reports that relate to registered pest control products in the Register, including any supplemental information in support of the reports that is volunteered by the registrant or applicant, such as any relevant opinion or commentary.
- Marginal note:Exclusion
 - (2) The Minister must remove from the incident reports, and from any supplemental information provided in connection with them, all personal information as defined in section 3 of the <u>Privacy Act</u>.

COMING INTO FORCE

Marginal note:Coming into force

19. These Regulations come into force six months after the day on which they are registered.

SCHEDULE(Paragraph 2(c))

INCIDENT EFFECTS IN THE ENVIRONMENT

	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Item	Group	Subgroup	Major Effect	Moderate Effect	Minor Effect	Symptoms
1.	Birds	(a) Predatory birds	(a) 3	(a) 1 or more but fewer than 3	(a) N/A	(a) Death, impairment of health, reproductive impairment or congenital anomalies
		(b) Birds that flock, except songbirds	(b) 150	(b) 50 or more but fewer than 150	(b) 50	(b) Death, impairment of health, reproductive impairment or congenital anomalies
		(c) Songbirds and all other birds	(c) 30	(c) 10 or more but fewer than 30	(c) 10	(c) Death, impairment of health, reproductive impairment or congenital anomalies
2.	Amphibians	Adults	30	10 or more but fewer than 30	10	Death, impairment of health, reproductive impairment or congenital anomalies
3.	Mammals	(a) Small mammals such as bats, rabbits, squirrels and mice	(a) 30	(a) 10 or more but fewer than 30	(a) 10	(a) Death, impairment of health, reproductive impairment or congenital anomalies
		(b) Large or solitary mammals such as foxes, deer and moose	(b) 15	(b) 5 or more but fewer than 15	(b) 5	(b) Death, impairment of health, reproductive impairment or congenital anomalies
4.	Reptiles		30	10 or more but fewer than 30	10	Death, impairment of health, reproductive impairment or congenital anomalies

	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Item	Group	Subgroup	Major Effect	Moderate Effect	Minor Effect	Symptoms
5.	Fish	(a) Schooling fish	(a) 1,500	(a) 500 or more but fewer than 1,500	(a) 500	(a) Death, impairment of health, reproductive impairment or congenital anomalies
		(b) Non-schooling fish	(b) 150	(b) 50 or more but fewer than 150	(b) 50	(b) Death, impairment of health, reproductive impairment or congenital anomalies
6.	Large aquatic invertebrates, such as lobsters, mussels and shrimp		600	200 or more but fewer than 600	200	Death, impairment of health, reproductive impairment or congenital anomalies
7.	Terrestrial invertebrates	(a) Honey bees	(a) 3,000 bees from each of 5 or more colonies, or 30% of the bees in any one colony	(a) 1,000 or more but fewer than 3,000 bees from each of 5 or more colonies, or 10% or more but less than 30% of the bees in any one colony	(a) 10% of the bees in any one colony	(a) Death or abnormal behavioural effects
		(b) All other non-target terrestrial invertebrates, including beneficial insects used in integrated pest management	(b) N/A	(b) N/A	(b) Any number of individuals	(b) Death
8.	Trees and shrubs		N/A	25 or more non-target plants in 5 or more incidents that occur within a calendar month	Any number of non- target plants in a single incident	More than 25% of the tree or shrub exhibits abnormal abscission or abnormal leaf discolouration, or there is a reduction in seed or fruit yield
9.	Herbaceous plants		N/A	25% or more of non-target plants within the targeted spray area or within 20 m of its edge in 5 or more incidents that occur within a calendar month	Any percentage of non-target plants in a single incident at any distance from the targeted spray area	Death; injury visible to the naked eye: chlorosis, necrosis, bleaching, vein discolouration or abnormal abscission; terminal bud death; stunted vegetative growth; reduced seed or fruit yield; reduced emergence; abnormal flower quality or number; deformities, for example, in tubers; and epinasty
10.	Aquatic plants		N/A	25% or more of the non- target plants in a body of water in 5 or more incidents that occur within a calendar month	Any percentage of the non-target plants in a body of water in a single incident	Death, abnormal plant stance or abnormal leaf discolouration