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Re-evaluation Decision

RVD2019-08

Fosetyl-aluminum and Its Associated End-use Products

Final Decision

(publié aussi en français)

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Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Fosetyl-aluminum is a systemic fungicide used to manage various diseases on a wide range of agricultural crops, ornamentals and turf. Fosetyl-aluminum is applied as a soil drench treatment and foliar spray by conventional ground application equipment. Currently registered products containing fosetyl-aluminum are listed in Appendix I.

The regulatory approach for the re-evaluation of fosetyl-aluminum was first presented in the Proposed Re-evaluation Decision PRVD2017-19, *Fosetyl-aluminum and Its Associated End-use Products* which underwent a 90-day consultation period ending on 29 January 2018¹. PRVD2017-19 proposed no products for cancellation, however a number of uses and methods of application were proposed for cancellation due to occupational postapplication risks of concern. It was proposed to: prohibit use on cut flowers; increase restricted-entry intervals (REI) for apples, blackberries, highbush blueberries, red/black raspberries, grapes, brassica leafy vegetables, onions, spinach, and ornamental plants; and, prohibit drench applications to bedding plants.

Health Canada received comments relating to the health and value assessments. These comments are summarized in Appendix II along with the responses by Health Canada. These comments and new data/information resulted in revisions to the risk assessments (see Science Evaluation Update section), and subsequently, in changes to the proposed regulatory decision as described in PRVD2017-19. A reference list of data used as the basis for the proposed re-evaluation decision is included in PRVD2017-19, and further data used in the re-evaluation decision is listed in Appendix VI of this RVD.

Outcome of Science Evaluation

Following the consultation on the proposed re-evaluation decision, Health Canada revised the occupational risk assessment based on the comments received relating to the use of fosetyl-aluminum on bedding plants, and greenhouse and outdoor cut flowers. Health risks from fosetyl-aluminum and its associated end-use products have been shown to be acceptable for all uses of fosetyl-aluminum when used according to the revised label directions. The environmental risks associated with the use of fosetyl-aluminum and its related end-use products are acceptable when used according to the revised label directions, which include advisory statements and spray buffer zones.

¹ "Consultation statement" as required by subsection 28(2) of the Pest Control Products Act.

Regulatory Decision for Fosetyl-aluminum

Health Canada has completed the re-evaluation of fosetyl-aluminum. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing fosetyl-aluminum is acceptable. An evaluation of available scientific information found that uses of fosetyl-aluminum products meet current standards for protection of human health and the environment when used according to revised label directions. Label amendments, as summarized below and listed in Appendix V, are required for all technical and end-use products. No additional data are requested.

Risk Mitigation Measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. As a result of the re-evaluation of fosetyl-aluminum, Health Canada is requiring further risk-reduction measures in addition to those already identified on fosetyl-aluminum product labels. The key risk-reduction measures are summarized below. Refer to Appendix V for details.

Human Health

- Label statements will be added to clarify that products are not to be used on residential lawns, gardens, playing fields, cemeteries, and school grounds.
- To protect mixers/loaders and applicators, additional personal protective equipment (PPE), increased minimum spray volumes, and limits on amount of product handled per day are required.
- To protect workers entering treated sites, revision or establishment of REIs, changes to the maximum number of applications per season and minimum re-treatment interval, and limiting application to soil drench only for some crops, are required.
- The use of foliar application on greenhouse ornamentals grown for cut flowers will be cancelled and prohibited on the labels.

Environment

- Standard hazard statements to inform users of the potential toxic effects to certain beneficial insects, small wild animals and aquatic organisms, as well as drift reduction measures are required.

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this decision document. Appendix I lists the products containing fosetyl-aluminum that are registered under the authority of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection² regarding this decision on fosetyl-aluminum within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of Canada.ca (Request a Reconsideration of Decision) or contact Health Canada's Pest Management Information Service.

The relevant test data on which the decision is based (as referenced in PRVD2017-19) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the Health Canada's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (hc.pmra.info-arla.sc@canada.ca).

² As per subsection 35(1) of the *Pest Control Products Act*

Science Evaluation Update

1.0 Introduction

Fosetyl-aluminum is a systemic fungicide that belongs to the Resistance Management Mode of Action Group Number PO7 (phosphonates). The mode of action of fosetyl-aluminum is not fully understood, but it is suggested that it acts by inhibiting spore germination and by blocking mycelial growth and sporulation. Fosetyl-aluminum is rapidly absorbed by leaves and roots and has unique characteristics in terms of both upward and downward movement inside the plants.

2.0 Revised Health Risk Assessment

2.1 Toxicology Summary

In response to PRVD2017-19, comments and data were received from the registrant Bayer CropScience Inc. These included a request to accept the previously proposed mode of action (MOA) for tumours in the bladder and kidneys, as well as a request to revise the point of departure used for setting toxicology reference values, based on a submitted position paper (PMRA# 2847074) regarding the adversity of foetal distended ureter in a rabbit developmental toxicity study. A 21-day dermal toxicity study with fosetyl-aluminum in rats (PMRA# 2847070) was also submitted (Appendix VI). Detailed responses to the comments received are provided in Appendix II. In consideration of all information received, Health Canada will retain the point of departure presented in PRVD2017-19 which supports the accepted daily intake (ADI), long-term occupational scenario risk assessments, and the threshold-based cancer risk assessment. As well, Health Canada will retain the no observed adverse effect level (NOAEL) for the developmental toxicity study in rabbits for occupational risk assessment.

2.2 Dietary Exposure and Risk Assessment

No comments relating to the dietary risk assessment were received during the public consultation period for PRVD2017-19. Dietary risks were shown to be acceptable in the PRVD.

2.3 Occupational and Non-Occupational Exposure and Risk Assessment

In PRVD2017-19, risks were shown to be acceptable for most uses with mitigation measures, including longer REIs. However, risks to postapplication workers were not shown to be acceptable for use of fosetyl-aluminum on cut flowers and for drench application to bedding plants. The REIs determined as a result of the re-evaluation were not considered to be agronomically feasible for these crops and cancellation of those uses was proposed to mitigate these risks.

During the PRVD consultation period, additional information and studies were received from the registrant and grower groups. This included several in vitro dermal absorption studies, as well as use pattern information. These data and information were considered and incorporated as appropriate into the revised assessment. Health Canada responses to specific comments are in Appendix II. Details and tables regarding the revised occupational risk assessment are presented in Appendix IV.

Bedding Plants

On current labels of fosetyl-aluminum, directions for drench application are specified for bedding plants. However, the type of drench application is not specified. In greenhouses, drench application can be either overhead drench, resulting in foliar residues, or it can be directed soil drench. In PRVD2017-19, an assessment was conducted for both foliar drench and soil drench, based on the current label directions. For soil drench applications, it was unknown whether this could result in foliar residues, since bedding plants can have foliage very close to the soil. Risks to workers were not shown to be acceptable when residues are present on the foliage, whether from foliar drench or soil drench, and therefore, drench applications to bedding plants were proposed for cancellation. Comments were received from stakeholders stating that directed soil drench application, which would not result in foliar residues, would be a feasible mitigation measure. Worker exposure from contact with treated soil was assessed in PRVD2017-19, and risks were shown to be acceptable when there are no residues on the foliage. Label directions for drench applications on bedding plants will be revised specifying soil drench application only and that the pesticide solution must not contact foliage. See Appendix V for specific label directions.

Cut Flowers – Revised Rate

On current labels of fosetyl-aluminum, directions for foliar application are specified for ornamentals, which would include cut flowers. In PRVD2017-19, although postapplication worker risks were shown to be acceptable for non-cut flower ornamentals, risks were not shown to be acceptable for both outdoor and greenhouse cut flower ornamentals. Clarifications on the use pattern for cut flowers were received and the risk assessment was revised accordingly to include a rate of 2.24 kg a.i./ha, and a maximum of 3 applications per season with a 14-day application interval. At the revised rate, risks for foliar application on outdoor cut flowers were shown to be acceptable with a 4-day REI, which is considered to be feasible based on comments received from stakeholders. Directions clarifying the use pattern, as well as the REI for outdoor cut flowers, will be added to product labels. See Appendix V for specific label directions for outdoor cut flowers. For greenhouse cut flowers, risks were still shown to be not acceptable for foliar application.

Cut Flowers – Soil Drench

Comments were received from stakeholders stating that, for cut flowers, soil drench application would be feasible and that it is a typical practice. Postapplication worker risks for soil drench of greenhouse and outdoor cut flowers were shown to be acceptable. Due to the risks associated with foliar application to greenhouse cut flowers, label directions will be revised prohibiting this application; label directions will specify soil drench application only for greenhouse cut flowers. For all soil drench applications (greenhouse and outdoors), label directions will specify that the pesticide solution must not contact foliage. See Appendix V for specific label directions for soil drench to cut flowers.

3.0 Environmental Risk Assessment

No comments relating to the environmental risk assessment were received during the public consultation period for PRVD2017-19. Environmental risks were shown to be acceptable in the PRVD.

4.0 Value Assessment

Fosetyl-aluminum provides control of various fungal diseases, mainly damping-off, root rot and downy mildew on a wide range of agricultural crops as well as on ornamentals and turf. Fosetyl-aluminum has a low risk for developing resistance in fungal diseases. It can be used in rotation with other mode of action fungicides, including fungicides that are at high risk for developing resistance, to help delay resistance development.

Being systemic, fosetyl-aluminum can be taken up by the roots or absorbed through the leaves, providing growers with flexibility in application methods. Fosetyl-aluminum is one of the few fungicides registered in Canada to suppress a quarantine pest, sudden oak death, in greenhouse and field grown ornamental plants including certain trees.

Comments received on value did not result in changes to the regulatory decision (see Appendix II). In addition to risk mitigation noted above, revisions to improve clarity of labels are required (see Appendix V).

5.0 Conclusion of Science Evaluation

With respect to human health, additional mitigation measures are required which include: prohibiting foliar application on greenhouse cut flowers; longer REIs for outdoor cut flowers, apples, blackberries, highbush blueberries, red/black raspberries, grapes, brassica leafy vegetables, onions, spinach, and ornamental plants; and prohibiting use on residential ornamentals and turf sites. Exposure from all remaining uses is also unlikely to affect human health when used according to the updated mitigation measures and revised label directions.

Fosetyl-aluminum enters the environment when used outdoors. Health Canada has concluded that the environmental risks associated with the use of fosetyl-aluminum and its associated end-use products are acceptable when these products are used according to the revised label directions.

List of Abbreviations

↑	Increased
↓	Decreased
♀	Females
♂	Males
abs	Absolute
a.i.	Active ingredient
ADI	Acceptable daily intake
Al	Aluminum
ARTF	Agricultural Re-entry Task Force
ATPD	Area treated per day
bw	Body weight
BWG	Body weight gain
Ca	Calcium
cm ²	Square centimeter
d	Day(s)
DA	Dermal absorption
DACO	data code (PMRA)
DFR	Dislodgeable foliar residue
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FGC	Flowers Canada Growers
g	Gram
HD	High-dose
h(hr)	Hour
ha	Hectare
HDT	Highest dose tested
IPCS	International Programme on Chemical Safety
JMPR	Joint Meeting on Pesticide Residues
kg	kilogram
L	Litre
LOAEL	Lowest observed adverse effect level
m	Metre
m ³	Metres cubed
m ²	Square meter
mg	Milligram(s)
mL	Millilitre
M/L/A	Mixer/loader/applicator
MOA	mode of action
MOE	Margin of Exposure
MPHG	Mechanically-pressurized hand gun
MPHW	Manually-pressurized hand wand
NA	Not applicable
NOAEL	No observed adverse effect level
PCPA	<i>Pest Control Products Act</i>
PHED	Pesticides Handlers Exposure Database

PHI	Pre-Harvest Interval
PCP	Pest control product
PMRA	Pest Management Regulatory Agency
PPE	Personal Protective Equipment
PRVD	Proposed Re-evaluation Decision
REI	Restricted-entry interval
RVD	Re-evaluation Decision
TC	Transfer coefficient
µg	Microgram
µL	Microliter
USEPA	United States Environmental Protection Agency
VUI	Verified use information
WHO	World Health Organization
WOE	Weight of evidence
Wt	Weight

Appendix I Registered Fosetyl-aluminum Products in Canada

Table 1 Registered Fosetyl-aluminum Products in Canada¹

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
24563	Technical	Bayer CropScience	Fosetyl-aluminum Technical	Dust or Powder	97%
24458	Commercial	Bayer CropScience	Aliette WDG Systemic Fungicide	Wettable Granules	80%
24564	Commercial	Bayer CropScience	Aliette Wettable Powder Systemic Fungicide	Wettable Powder	80%
27557	Commercial	Bayer CropScience	Chipco Aliette Ornamental Fungicide	Wettable Granules	80%
27688	Commercial	Bayer CropScience	Aliette Systemic Fungicide Water Dispersible Granule	Wettable Granules	80%
28299	Commercial	Bayer CropScience	Chipco Aliette Signature Fungicide	Wettable Granules	80%
32800	Commercial	Bayer CropScience	Signature XTRA Stressgard	Wettable Granules	60%

¹ as of 25 March 2019, excluding discontinued products or products with a submission for discontinuation

Appendix II Comments and Responses

In response to the consultation for the fosetyl-aluminum proposed re-evaluation decision, the following comments were received.

1.0 Comments Related to the Health Risk Assessments

Health Canada received written comments from the technical registrant, Bayer CropScience Inc., and Flowers Canada Growers (FCG). The comments and Health Canada responses were summarized and grouped together based on common scientific themes, and are presented below.

1.1 Toxicology

1.1.1 Comment relating to point of departure selection for the ADI, long-term occupational scenarios, and the cancer risk assessment approach

The registrant requested that the point of departure chosen for the ADI be revised. The registrant stated that the increased incidence of urinary bladder inflammation and tumours in male rats are not a risk relevant to humans. The registrant noted that the critical urinary tract effect in male rats was determined to be not relevant for humans according to the 2017 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) review of fosetyl-aluminum. Furthermore, the registrant questioned Health Canada's reasoning for not accepting the tumorigenic mode of action (MOA) of fosetyl-aluminum.

Health Canada Response

In PRVD2017-19, Health Canada selected a point of departure derived from the combined chronic dietary toxicity/carcinogenicity study in rats as a basis for the ADI, long-term occupational scenarios, and for the threshold-based cancer risk assessment approach. The point of departure was based on increased urinary bladder inflammation in male rats.

Although a biologically plausible MOA for the observed tumours exists and was proposed by the registrant, Health Canada's evaluation of the proposed MOA concluded that it is not fully supported under the IPCS framework.³ It should be noted that no new data related to the MOA was submitted with the comments to PRVD2017-19.

In a chronic dietary toxicity/carcinogenicity study in rats with fosetyl-aluminum, increased incidences of urinary bladder inflammation and tumours in the bladder and kidneys were observed. The proposed MOA and evaluation was discussed previously in PRVD2017-19 (p.8). Additional details on the evaluation of the proposed fosetyl-aluminum tumourigenic MOA data, in accordance to the IPCS framework, are provided below.

³ IPCS Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis. Regulatory Toxicology and Pharmacology 34, 146-152 (2001) Available online from: doi:10.1006/rtph.2001.1493 [Last accessed Dec, 2018]

The proposed MOA suggests that prolonged mechanical irritation by calculi present as a result of the calcium-phosphorus imbalance at high dose levels ultimately leads to transitional cell papilloma and carcinoma in the bladder and kidney.

The key and associative events for this MOA include:

- increased urinary excretion of calcium and phosphorous caused by the metabolism of fosetyl-aluminum;
- precipitation of calcium phosphonate or calcium phosphate leading to formation of calculi/stone (urolithiasis) in the urinary system;
- physical abrasion/irritation of the kidney and bladder by the calculi leading to inflammation and cytotoxicity, followed by;
- proliferation of the epithelium and regenerative hyperplasia, and
- ultimately, transitional cell papilloma and carcinoma.

Dose-Response Relationship: In PRVD2017-19, it was noted that “Even though clear evidence of calculi formation and progressive histopathological changes of the urinary system were noted in the 13-week oral rat study, which is consistent with the proposed MOA, the lack of a clear dose-response for calculi formation, inflammation and tumors in the chronic rat study was considered a limitation.” To clarify further, while a dose-response was evident for bladder inflammation, hyperplasia, and bladder/kidney tumours (although evidence of oncogenicity was apparent only in rats, and only above the limit dose of testing), a clear dose-response was not apparent for calculi formation following chronic dietary exposure to fosetyl-aluminum. A dose-response relationship is required for all key events defined in the proposed MOA.

Temporal Association: The key and associative events occurred in the appropriate temporal sequence. Several initial effects were observed at about 2-3 weeks of treatment, or slightly earlier at high doses. Increased calciuria and faecal P occurred in rats after 2-3 weeks of treatment in a 30 day mechanistic rat study (PMRA# 1208600); findings were more pronounced in male rats and showed a dose-response relationship. Concurrently, epithelial cells in renal tubules showed signs of degeneration in a dose-response manner. Papillary hyperplasia of bladder mucosa, predominantly in mid- and high-dose male rats, was present after two weeks of treatment in a 13-week dietary rat study; however there was no increase in the incidence of this effect with a longer duration of exposure of up to eight weeks. Kidney histopathological findings were noted as early as week two of treatment, and included kidney hydronephrosis, papillary necrosis, and dilatation of collecting tubules and transitional cell hyperplasia of the pelvis. Urinary calculi formation, showing high calcium and phosphorus content, was seen mainly at higher doses, starting after two weeks of exposure, with male rats being more sensitive than females. Data for the time period between 13 weeks and two years was limited to the unscheduled deaths occurring up to two years. At termination in the rat chronic dietary toxicity/carcinogenicity study, bladder inflammation was noted at the mid-dose in males, and effects in the high-dose (above the limit dose) included urinary bladder calculi and kidney calculi, hydroureter, hydronephrosis in kidney, urinary bladder inflammation and transitional cell hyperplasia, urinary bladder transitional cell papilloma and combined bladder papilloma and carcinoma, and kidney-pelvis papilocarcinoma. These more severe histopathological effects (hydroureter, papillomas and carcinomas) were recorded following chronic treatment only.

Strength, consistency, and specificity of association of tumour response with key events: In a 90-day toxicity study with a 21-week recovery period, there was reversal of the adverse changes in the urinary tissues, with the exception of increased kidney weights at the high dose level. Some key events were observed consistently in both the 90 day and two-year dietary rat studies, including the presence of urinary calculi/uroliths, hydronephrosis in kidney, altered kidney weights, and kidney and bladder hyperplasia.

Biological Plausibility and Coherence of the Database: The proposed MOA is biologically plausible. The induction of urinary bladder tumours by the irritating effect of foreign bodies, such as calculi or implanted foreign material (for example, glass beads and paraffin wax pellets), is well established in the published literature. An available mechanistic study showed increased Ca and P excretion and associated renal tubular changes in rats. To further support their request for reconsideration of the point of departure, the registrant noted that the 2017 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) review of fosetyl-aluminum accepted the proposed tumourigenic MOA. In addition, JMPR noted that human exposure levels do not approach the urinary solubility limit of calcium phosphate or calcium phosphonate (>1000 mg/kg bw/day). These compounds form in urine from phosphite (fosetyl-aluminum urine metabolite) and increased urinary calcium ion concentration caused by uptake interference by the Al component of fosetyl-aluminum. Thus, humans are unlikely to experience the formation of uroliths due to exposure to fosetyl-aluminum, and therefore, are unlikely to experience irritation of the urinary bladder, one of the key events for tumour formation.

Other potential MOAs: The registrant did not identify or discuss alternate MOAs for the observed lesions. Several potential MOAs for the kidney and lower urinary tract were identified in the literature. Potential MOAs include DNA reactivity, cytotoxicity and regeneration, increased apoptosis and regeneration, $\alpha_2\mu$ -globulin binding, enhanced age-related nephropathy, metal overload with consequent oxidative damage, the direct or indirect formation of urinary solids, alterations in urinary composition, cytotoxicity and regeneration, or direct mitogenesis. The most plausible MOA, considering the available data, is the MOA proposed by the registrant.

Uncertainties, inconsistencies and data gaps: A clear dose-response relationship for the incidence of calculi formation in the chronic toxicity/carcinogenicity study in rats, one of the initial key events of the proposed MOA, was not demonstrated. The incidences of kidney-cortex urolithiasis in control, low-, mid-, high dose-animals were 8, 10, 17, 7 in males and 27, 27, 19, 5 in females, respectively, (80-81 animals/dose, PMRA# 1208660, Table 1 p.18). Similarly, incidences of kidney-medulla/pelvis urolithiasis in control, low-, mid-, and high- (above limit) dose animals were 6, 11, 5, 3 in males, and 48, 45, 20, 7 in females, respectively, (80-81 animals/dose). Clearly, a dose-response was not present in the examined tissues; the incidence of uroliths decreased with increasing dosage of fosetyl-aluminum. The lack of dose concordance for this key event weakens overall support for the MOA.

Final Assessment: The overall level of confidence in the data provided to support the MOA is moderate. The proposed MOA is biologically plausible, however, support for one of the key events in the MOA, namely, a dose-response relationship for calculi formation, is lacking. As stated in the PRVD2017-19, fosetyl-aluminum is not likely to pose a tumourigenic hazard in

humans, based on an assessment of the weight of evidence (WOE). A threshold approach to tumor development is still deemed appropriate for risk assessment purposes.

In consideration of the information summarized above, the point of departure, which is based on urinary bladder inflammation, is protective of any other potential adverse effects. Inflammation is an adverse effect observed in treated animals and exhibits a clear dose-response relationship. It's relevance to humans cannot be dismissed given that the proposed MOA is not fully supported by the submitted data. Thus, for all long-term risk assessment scenarios, this point of departure, namely urinary bladder inflammation, was utilized. For fosetyl-aluminum, Health Canada will use a threshold-based approach for cancer risk assessment recognizing that:

- fosetyl-aluminum is not genotoxic, and
- evidence of oncogenicity was apparent in rats only, and only above the limit dose of testing, and
- while not fully supported, the proposed MOA is likely, and
- human exposure levels are unlikely to produce uroliths, and therefore the development of related tumours is also unlikely.

Therefore, Health Canada will retain the point of departure presented in PRVD2017-19 which supports the ADI, long-term occupational scenario risk assessments, and the threshold-based cancer risk assessment.

1.1.2 Comment relating to the point of departure chosen for short- and intermediate-term occupational dermal risk assessment

The registrant requested reconsideration of the no observed adverse effect level (NOAEL) for the rabbit gavage developmental toxicity study used in PRVD2017-19 as the basis for the point of departure chosen for short- and intermediate-term occupational dermal risk assessment. In their opinion, the lowest observed adverse effect level (LOAEL), which was based on a variation – distended ureter, is not considered adverse, either by the registrant, or a subject expert (Position paper, Fosetyl-aluminum: Selection of the Rabbit Developmental Toxicity Study NOAEL, 2017, PMRA# 2847074). The registrant recommended a NOAEL of 300 mg/kg bw/day instead of the current 100 mg/kg bw/day.

To further support their request to revise this point of departure for occupational risk assessment, a 21-day dermal toxicity study was submitted (PMRA# 847070), which showed no clinical signs or adverse findings up to the limit dose of testing, unlike the dermal toxicity studies on file (PMRA# 1208603 and PMRA# 2337299) that included effects of dermal irritation and inflammatory changes. These studies supported the value of 50% dermal absorption (DA), as further discussed in the occupational risk section 1.2.2 of the comments and responses.

Health Canada Response

In a rabbit developmental toxicity study, distended ureter was observed at a dose causing no maternal toxicity (NOAEL of 100 mg/kg bw/day; LOAEL of 300 mg/kg bw/day), indicating sensitivity of the young.

Distended ureter is a variation and, while not considered serious, was considered adverse by Health Canada since it was statistically significant, the incidence was outside the range of available historical controls, and there is a durational effect for changes in kidney and bladder.

In the most recent reassessment of fosetyl-aluminum in the European Union, (approved: 24 May 2018, doi: 10.2903/j.EFSA.2018.5307), the NOAEL for maternal and developmental toxicity for this study was identified as 100 mg/kg bw/day based on decreased body weight gain observed during the first days of dosing (maternal) and on increased incidence of dilated ureter (developmental), respectively. The EFSA decision supports Health Canada's interpretation regarding the adversity of the distended ureter finding in young rabbits.

Health Canada reviewed the 21-day dermal toxicity study in rats submitted during the comment period, and agrees that there were no compound-related effects indicative of systemic toxicity in any of the dose groups. No dermal irritation was noted in any dosed animal, and no treatment-related effects were noted on food consumption, body weight or body weight gain up to the limit dose of 1000 mg/kg bw/day. In the previously reviewed single dose 21-day dermal rat toxicity study (PMRA# 2337299), the NOAEL for systemic toxicity was ≥ 1050 mg/kg bw/day, although acute inflammation at the site of treatment, increased neutrophil counts, decreased eosinophil counts in females, hyperkeratosis, and crusted areas and erosions were noted at this dose level. In a 28-day dermal toxicity study in rabbits, the NOAEL for systemic toxicity was 1500 mg/kg bw/day, with slight to well-defined or moderate dermal irritation, acanthosis and inflammatory changes, and hyperkeratosis noted at and above 750 mg/kg bw/day.

Based on the 50% DA factor currently used by Health Canada, as noted in PRVD2017-19, the dermal systemic NOAEL of 1000 mg/kg bw/day from the new rat dermal toxicity study corresponds to an oral NOAEL of 500 mg/kg bw/day. This is greater than the NOAEL of 100 mg/kg bw/day and corresponding LOAEL of 300 mg/kg bw/day, from the gavage developmental toxicity study in rabbits, and therefore, would not be protective of the developmental endpoint of concern. More specifically, since the dermal toxicity studies with technical grade fosetyl-aluminum do not assess developmental endpoints, it is necessary to ensure that when dermal endpoints are used, they are protective of any effects in developmental studies.

Consequently, Health Canada will retain the NOAEL for the developmental toxicity study in rabbits for occupational risk assessment.

1.2 Comments Related to Occupational Exposure

1.2.1 Comments relating to use information

Comment: The registrant and FCG requested that the drench use be maintained for bedding plants. They further stated that soil drench application with no foliar contact, thus resulting in no foliar residues, is a feasible mitigation measure.

Health Canada Response

In PRVD2017-19, a postapplication risk assessment for bedding plants (80 kg a.i./ha) showed that risks from dermal exposure were acceptable from soil contact only. Therefore, drench applications to bedding plants will be maintained; label directions will be revised specifying soil

drench applications only and clarify that the pesticide solution must not contact foliage during application.

Comment: The registrant and FCG requested that the application rate on cut flowers be modified, indicating that some farmers could accept extended REIs, fewer applications, longer intervals between applications, and/or lower application rates (where efficacious).

Health Canada Response

Health Canada has considered this information and revised the risk assessment for cut flowers. The use directions were revised to include a foliar application rate of 2.24 kg a.i./ha, with a maximum of 3 applications and minimum treatment interval of 14 days. The outcome of the revised risk assessment maintains foliar application on outdoor cut flowers with an extended REI of 4 days. For greenhouse cut flowers, risks were still not shown to be acceptable for foliar applications.

Comment: The registrant and FCG requested restricting drench application on cut flowers to soil drench. They further stated that soil drench application with no foliar contact, thus resulting in no foliar residues, is a feasible mitigation measure.

Health Canada Response

The application rate for soil drench application on cut flowers is the same as for bedding plants; therefore, as noted above, postapplication risks from soil contact were shown to be acceptable. Therefore, soil drench applications to cut flowers (indoors and greenhouses) will be maintained with clarifications to the use directions on the label. These include:

- Specifying soil drench application only to cut flowers in greenhouses;
- Specifying that the pesticide solution must not contact the foliage; and
- Clarifying the rate, number and frequency of applications.

Comment: FCG provided details on the differences in production practices between cut roses and commonly produced cut flower crops grown in Canada.

Health Canada Response

There was no information available on how to relate these differences in production practices (for example, potential impact on transfer coefficients as described in Regulatory Proposal PRO2014-02, *Updated Agricultural Transfer Coefficients for Assessing Occupational Post-Application Exposure to Pesticides*) to the cut flower postapplication worker assessment.

Comment: The registrant commented that typically, for field bedding plants, an irrigation pipe is set at the start of the season and remains in place with little, if any further movement. It was proposed that label statements be added to mitigate risks resulting from specific activities, for example, irrigation (hand set), such that workers must not move the irrigation pipe within a specified period of time from application.

Health Canada Response

Health Canada acknowledges that clearer label language is required. For hand set/hand line irrigation, the description of the activity has been modified to “hand set/hand line irrigation *related activities involving workers contacting foliage*”, where the italicized text is new. Note: all REIs refer to a specified period of time following application.

For bedding plants specifically, the foliar application rate is to be clarified on the label and the resulting REI for hand set/hand line irrigation is 12 hours. See Appendix V for specific label directions.

1.2.2 Comments relating to dermal absorption

The registrant submitted four recently completed in vitro human dermal absorption studies (Odin, 2016; Muhamedi, 2016; Hassler, 2017a; Hassler, 2017b).

Health Canada Response

As detailed in PRVD2017-19, a dermal absorption value of 50% was determined based on a weight-of-evidence approach using the available human and rat in vitro study (Ward, 2000), the physical-chemical properties of fosetyl-aluminum and its metabolites, and observations from toxicology studies. The results of the 4 human in vitro studies submitted during the consultation period support the conclusions from PRVD2017-19 to refine the dermal absorption value from 100% to 50%. Without additional dermal absorption data, such as an acceptable rat in vivo study or studies to support a triple pack approach, the dermal absorption value cannot be refined to less than 50% at this time. This is consistent with Health Canada’s position on the use of in vitro dermal absorption data in risk assessment, as outlined in Science Policy Note SPN2016-02, *Dermal Absorption: Position Papers from the North American Free Trade Agreement (NAFTA) Technical Working Group (TWG)* (PMRA, 2016).

1.2.3 Comments relating to Agricultural Re-entry Task Force (ARTF), including Transfer Coefficients (TC) and Dislodgeable Foliar Residues (DFR)

Comment: FCG commented that regulatory decisions are made using ARTF proprietary data that provides no transparency to stakeholders who may wish to evaluate the scientific reliability of these decisions.

Health Canada Response

In order to support the registration of a currently registered pesticide, companies that wish to have the right to sell a pest control product in Canada must submit detailed information and data to be evaluated by Health Canada. Companies must provide all the scientific studies necessary for determining that the product is acceptable in terms of human health. This includes the health and safety of workers who enter sites previously treated with a pesticide in order to conduct activities such as harvesting and pruning. In order to address this data requirement, the ARTF was formed. Rather than providing chemical-specific studies for all pesticides for all crops for all activities, ARTF conducted and purchased studies to generate a database of generic agricultural re-entry transfer coefficients that would be applicable to all crop/activity scenarios. The technical

registrant for fosetyl-aluminum is a member of the ARTF, and as such, has provided this data to Health Canada in order to conduct postapplication worker exposure and risk assessments for all agricultural fosetyl-aluminum uses. Health Canada's review of the studies and determination of the transfer coefficients are presented in Regulatory Proposal PRO2014-02 *Updated Agricultural Transfer Coefficients for Assessing Occupational Post-application Exposure to Pesticides*. Confidential test data are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). Alternatively, stakeholders can consider contacting ARTF or the technical registrant to request this information. Health Canada encourages stakeholders to contact the technical registrants regarding the data, including the adequacy of the data, used to support a registration.

Comment: FCG commented that all ARTF-generated data relating to ornamental crops was derived with the surrogate chemical, malathion, which is very rarely used in production. It is difficult for growers to accept that ARTF results would be replicated with alternate active ingredients.

Health Canada Response

As noted in Regulatory Proposal PRO2014-14 *Updated Agricultural Transfer Coefficients for Assessing Occupational Post-application Exposure to Pesticides*, as part of the data development process, ARTF conducted an analysis of the "genericness" of transfer coefficients, that is the applicability of studies conducted with one chemical for use in assessing exposures for a different chemical. The early work performed in establishing TCs demonstrated that postapplication exposure was primarily a function of the degree of body immersion in treated foliage and that it could be used as a generic tool for estimating exposures to workers based on a chemical-specific DFR dissipation curve. Regulatory experience in the use of TCs has demonstrated this to be valid for conventional pesticides whose physical and chemical properties fall within a similar range, and where dislodgeable foliar residues are neither very low nor very high. For most conventional pesticides, TCs can be used generically between different active ingredients; however, DFR and TTR data are chemical-specific. This process is considered a reasonable method for assessing exposure while saving time and resources associated with conducting passive dosimetry or biological monitoring exposure studies for all proposed pesticide registrations and registration reviews, including the multitude of scenarios and uses therein.

As noted above, Health Canada encourages stakeholders to contact the technical registrants regarding the data, including the adequacy of the data, used to support a registration.

Comment: FCG noted that the Health Canada default transfer coefficient used for hand harvesting cut flowers (Gcf, 4000cm²/hr) and default dislodgeable foliar residue data assumptions (2.3% dissipation/day for greenhouse ornamentals) contribute overwhelmingly to determinations of unacceptable risk and subsequent cancellation/removal or exclusion from pesticide labels.

Health Canada Response

As there were no chemical-specific exposure studies available for fosetyl-aluminum, TCs as presented in Regulatory Proposal PRO2014-14, *Updated Agricultural Transfer Coefficients for Assessing Occupational Post-application Exposure to Pesticides*, and default dissipation values as presented in Science Policy Note SPN2014-02 *Estimating Dislodgeable Foliar Residues and Turf Transferable Residues in Occupational and Residential Postapplication Assessments*, were used. Health Canada uses the best available data to conduct the re-evaluations of pesticides and makes regulatory decisions accordingly. Pesticide companies are encouraged to contact Health Canada regarding data generation that may allow for further refinement in order to maintain specific uses. Other stakeholders are encouraged to contact pesticide companies regarding this data, including the adequacy of the data, used to support a registration.

For cut flowers, as a result of the comments received and clarifications on the use pattern, Health Canada will not be cancelling the use, but rather will require mitigation measures on all labels. For outdoor cut flowers, this includes label directions on the use rate and an REI of 4 days; for greenhouse cut flowers, this includes prohibiting foliar applications, allowing soil drench applications only, and stating that the pesticide solution must not be in contact with foliage.

Comment: FCG commented that Health Canada's regulatory decisions for Canadian greenhouse crops differ vastly to those of many regulatory agencies in OECD nations including USEPA. Greenhouse ornamental growers are discouraged by this and find it troubling that Health Canada relies heavily on published research reports, from what appear to be non-good lab practices accredited facilities (Brouwer et al, 1992) that go into the determination of many regulatory conclusions. In addition, these studies focus on crops not produced by ornamental farms in Canada (in other words, cut carnations). They further indicate that many farmers question the credibility and scientific integrity of this research given that it was generated: outside of Canada; in what appear to be non-good lab practices accredited facilities; on a crop not grown in Canada (in other words, cut carnations); over 25 years ago when production practices and integrated pest management (IPM) integration may have been less robust than at present; and with pest and disease complexes that may diverge from present realities.

Health Canada Response

Regarding the studies used for the evaluation, as noted above, pesticide companies must provide all the scientific studies necessary for determining that the product is acceptable in terms of human health. Health Canada uses the best available data to conduct the re-evaluations of pesticides and makes regulatory decisions accordingly. This includes studies that are available in the peer-reviewed scientific literature. Health Canada is not aware of any recent Canadian-specific exposure studies that have been conducted for the purpose of deriving transfer coefficients for crops grown in Canada, or that directly measure exposures that reflect Canadian production practices. These exposure studies include passive dosimetry studies or chemical-specific biological monitoring studies. Stakeholders are encouraged to conduct such studies, or alternatively, contact pesticide companies to conduct studies in order to support registrations for cut flowers.

For cut flowers, Health Canada used three studies (Brouwer et al., 1992; Schneider, et al., 2002; and ARF055), which represent a number of cut flower crops and active ingredients, thus capturing a range of variables. This is the best data currently available to determine postapplication exposure for cut flowers.

Health Canada has assessed the degree of alignment between Health Canada and the USEPA for many postapplication exposure scenarios. It was determined that the exposure assessment methodologies are generally aligned between the two agencies. However, registration decisions and the extent of risk mitigation measures may differ for several reasons including: differences in selected hazard endpoints or uncertainty factors, differences in the timing of the assessments, differences in availability of data when assessments are conducted, and differences in regulatory policy.

Comment: FCG commented that Health Canada should consider financially assisting a study to determine the accuracy of default TC's and DFR defaults presently used in risk assessments.

Health Canada Response

In order to support the registration of a currently registered pesticide, companies that wish to have the right to sell a pest control product in Canada must submit detailed information and data for evaluation by Health Canada. As noted above, other stakeholders may also conduct the necessary studies, or alternatively contact pesticide companies to discuss data requirements.

1.2.4 Comments relating to personal protective equipment (PPE) for postapplication workers

Comment: FCG commented that Health Canada should consider that workers do utilize PPE after pesticide application while working in greenhouses – including when hand harvesting cut flowers. It is felt that this protective measure could address many exposure concerns.

Health Canada Response

Studies that are used currently to estimate postapplication worker exposure are based on workers wearing long-sleeved shirts, long pants, socks and footwear. It is also understood that many postapplication workers may wear gloves for their own personal comfort. However, there is no reliable data to indicate the degree of protection that various types of gloves may provide to postapplication workers, or conversely, the extent that gloves may enhance exposure under certain conditions (see below).

Before Health Canada can estimate risk to workers wearing gloves or other PPE, worker exposure studies comparable to those currently used by Health Canada are required. Studies that are currently used are discussed further in the Regulatory Proposal PRO2014-02, *Updated Agricultural Transfer Coefficients for Assessing Occupational Postapplication Exposure to Pesticides*. Most, if not all, studies conducted by the ARTF, submitted by registrants, or available in the scientific literature and used to determine the Health Canada transfer coefficients did not include gloves as a basis to estimate exposure with gloves.

Gloves may have been worn in some of the studies, but they functioned as dosimeters to measure hand exposure without gloves, rather than exposure as a result of protection from the glove. In addition, some available studies suggest that exposure actually increases when wearing gloves (Brouwer, 2000; Boman et al., 2005; Garrigou et al., 2011; Graves et al., 1995; Keifer, 2000; Rawson et al., 2005).

2.0 Comments Related to the Value Assessment

2.1 Value Assessment

2.1.1 Comments related to the value of fosetyl-aluminum to Canadian flower and ornamental growers

Comment: The lack of harmonization of registered greenhouse ornamental pesticides between Canada and other OECD nations is an economic barrier for Canadian farmers. FCG indicated that flower growers need tools at their disposal quickly in order to remain competitive, and have expressed dissatisfaction that crops grown outside of Canada but imported into Canada can be treated with pesticides not available to them – as will be the case with fosetyl-aluminum if the Canadian registration is cancelled. This creates an enormous competitive advantage for foreign flower farmers and harms the Canadian economy.

Health Canada Response

Health Canada acknowledges the importance of fosetyl-aluminum for the management of fungal diseases on greenhouse ornamentals. During consultation with stakeholders, Health Canada received additional information related to greenhouse ornamental production practices and the use of fosetyl-aluminum. This information was used to refine the assessment of risks associated with use of fosetyl-aluminum and as a result, most of the greenhouse uses of fosetyl-aluminum will be retained except for foliar use on cut flowers. The final decision maintains the registration of the soil drench application to greenhouse cut flowers, which will control the listed root rot diseases.

Comment: Fosetyl-aluminum specifically, is registered for use against *Phytophthora ramorum*, a quarantine disease in Canada. Losing access to this registration would be limiting for ornamental growers who may in the future need to treat *Phytophthora ramorum* or risk losing their entire crop.

Health Canada Response

Health Canada agrees that fosetyl-aluminum is important for *Phytophthora ramorum* (sudden oak death) management. The use of fosetyl-aluminum for the suppression of sudden oak death on a wide variety of ornamental and tree species will be retained.

Appendix III Additional Toxicity Study

Table 1 Summary of additional toxicity study submitted in response to PRVD2017-19

NOTE: Effects noted below are known or assumed to occur in both sexes unless otherwise specified.

Short term Toxicity Studies	
21-day dermal toxicity study Wistar Rat 97.1% a.i 5/sex/group 6 hrs/day for 5 days/wk 2 recovery groups: 5/sex/control and HDT for 14-days PMRA# 2847070	NOAEL (systemic) = 1000 mg/kg bw/day There were no compound-related effects on mortality, clinical signs of toxicity that were indicative of systemic toxicity up to the limit dose. No dermal irritation was noted in any treated animals, and no treatment-related effects were noted on food consumption, body weight or body weight gain. ≥ 1000 mg/kg bw/day: ↑ abs and rel adrenal wt (♂) but no correlated histopathology

Appendix IV Occupational Mixer/Loader/Applicator (MLA) and Postapplication Exposure and Risk Estimates for Fosetyl-aluminum

Details and tables for the revised risk assessment are included in this Appendix. Only changes from the assessments in PRVD2017-19 are included. Please refer to PRVD2017-19 for additional information.

Revised Rate for Cut Flowers

Clarifications were provided on the use pattern for cut flowers. The foliar application rate for greenhouse and outdoor cut flowers has been revised to 2.24 kg a.i./ha, with a maximum of 3 applications and treatment interval of 14 days. Previously, the assessed rate was 4 kg a.i./ha, with maximum of 4 applications and treatment interval of 14 days. The risk assessments were updated accordingly resulting in the following risk conclusions:

- For mixer/loaders and applicators, risk are shown to be acceptable; no change from risk conclusion in PRVD2017-19.
- For postapplication workers in greenhouses, the calculated MOE (60) is below the target MOE of 100 (Table 2); therefore, risks are not shown to be acceptable; no change from risk conclusion in PRVD2017-19.
- For postapplication workers outdoors, the target MOE is reached at an REI of 4 days, which is considered to be feasible based on comments received from stakeholders.

Soil Drench Application on Bedding Plants

Postapplication worker exposure from contact with treated soil was assessed in PRVD2017-19, and risks were shown to be acceptable. Label directions for drench applications on bedding plants will be revised specifying soil drench application only and that the pesticide solution must not contact foliage. See Appendix V for specific label directions.

Soil Drench Application on Cut Flowers

On current labels of fosetyl-aluminum, directions for foliar application are specified for ornamentals, which would include cut flowers. In PRVD2017-19, risks were not shown to be acceptable for both outdoor and greenhouse cut flowers. As noted above, clarifications on the use pattern for cut flowers were received and the risk assessment was revised accordingly to include a rate of 2.24 kg a.i./ha, and a maximum of 3 applications per season with a 14-day application interval. At the revised rate, risks for foliar application on outdoor cut flowers were shown to be acceptable with a 4-day REI, which is considered to be feasible based on comments received from stakeholders. For greenhouse cut flowers, risks were still not shown to be acceptable for foliar application.

Comments were received from stakeholders stating that for cut flowers, soil drench application would be feasible and that it is a typical practice. Similar to the assessment for bedding plants, postapplication worker risks for soil drench of cut flowers (in greenhouses and outdoors) were shown to be acceptable. Label directions will be revised prohibiting foliar application to greenhouse cut flowers; label directions will specify only soil drench application in greenhouses and that the pesticide solution must not contact foliage. For outdoor cut flowers, risks were shown to be acceptable for both foliar (see above) and soil drench applications. See Appendix V for specific label directions for soil drench to cut flowers.

Table 2 Revised Intermediate-Term Postapplication Occupational Exposure and Risk Assessment

Crop	Maximum Application Rate (kg ai/ha)	Number of Applications per Season	Application Interval (days)	Activity	Transfer Coefficient (cm ² /hr)	Dislodgeable Foliar Residue Inputs			Day 0 Estimates		Required REI ^b	REI specified on current labels (days)
						Peak	Disp.	DFR ₀	Exp	MOE ^a		
Outdoor ornamental plants and trees (foliar application, for suppression of Sudden Oak Death)	4	4	14	Hand set/hand line irrigation related activities involving workers contacting foliage	1750	25%	10%	12.9	1131	88	2 days	Do not re-enter treated area until residues have dried.
Greenhouse ornamental plants and trees (foliar application, for suppression of Sudden Oak Death)	4	4	14	All activities	230	25%	2.3%	26.2	301	332	12 hours	
Outdoor ornamentals, including bedding plants, except cut flowers (foliar application)	2.24	3	14	Hand set/hand line irrigation related activities involving workers contacting foliage	1750	25%	10%	7.2	628	159	12 hours	
Outdoor cut flowers (foliar application)	2.24	3	14	Disbudding, Harvesting, Pruning	4000	25%	10%	7.2	1435	70	4 days	
Greenhouse ornamentals, including bedding plants, except cut flowers (foliar application)	2.24	3	14	All activities	230	25%	2.3%	12.6	144	692	12 hours	
Greenhouse cut flowers (foliar application – for reference)	2.24	2	30	Disbudding, Harvesting, Pruning	4000	25%	2.3%	8.4	1677	60	23 days ^c	

DFR = Dislodgeable Foliar Residue, Peak = Peak DFR as Percent of Rate, Disp = Percent Dissipation per Day, DFR₀ = Day 0 DFR (µg/cm²), Exp = Exposure (µg/kg bw/day), MOE = Margin of Exposure, REI = Restricted-Entry Interval.

a. Dermal exposure (µg/kg bw/day) = DFR (µg/cm²) × TC (cm²/hr) × work duration (8 hr) × DA (Refined default 50%)/BW (80 kg). Based on an intermediate-term dermal NOAEL of 100 mg/kg bw/day and target MOE of 100; shaded cells indicate estimates of concern or the proposed REIs are not considered agronomically feasible. If target MOE is met, REI is set at 12 hours.

b. Day at which the calculated MOE reaches the target MOE. Where the calculated REI is less than the current label REI, it will be increased to match the current label REI. Shaded cells indicate REIs that are not considered to be agronomically feasible.

c. Following PRVD comment period, number of applications was reduced to 2 applications and interval is increased to 30 days, but the resulting REI of 23 days is not agronomically feasible.

Appendix V Label Amendments for End-use Products Containing Fosetyl-aluminum

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

The following use is being cancelled and must be prohibited on applicable labels:

- Foliar application on greenhouse ornamentals grown for cut flowers.

General label changes:

1. On the front panel, booklet and supplemental label, replace “Group U Fungicide” and “Group 33 Fungicide” with “Group PO7 Fungicide”.
2. On the front panel and booklet and supplemental label replace “Guarantee” with “Active Ingredient”.
3. Update the “Resistance Management Recommendations” section according to Regulatory Directive DIR2013-04, *Pesticide Resistance Management Labelling Based on Target Site/Mode of Action*, including updating the mode of action group to reflect “Group P07 Fungicide”.
4. Remove any general tank mix recommendations or statements, as per Section 3.10 of Regulatory Directive DIR2016-02, *Notification/Non-notification*.
5. Under the DIRECTIONS FOR USE section, just before the use direction tables, insert the following statement:
“When applied as directed, (product name) will control the listed diseases, unless otherwise indicated as suppression”.
6. Delete all extra spacing by correcting existing formatting issues.

The following statements are to be added under **PRECAUTIONS** to the end-use product labels:

For airblast application, replace “hat” with “chemical-resistant headgear,” and add “Chemical-resistant headgear includes Sou’Wester hat, chemical-resistant rain hat or large brimmed waterproof hat and hood with sufficient neck protection”.

For mechanically-pressurized hand gun application: “Wear chemical-resistant coveralls when using mechanically-pressurized hand gun equipment.”

To minimize public exposure to spray drift, the following statement is to be added under **PRECAUTIONS** to all labels:

“Apply only when the potential for drift to areas of human habitation and human activity (other than golf courses) such as parks, school grounds, and playing fields is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer setting.”

The following statements are to be added under **DIRECTIONS FOR USE** to the end-use product labels:

“Do not apply this product using handheld or automated fogging or mist blower equipment.”

“Do not apply this product using ultra-low volume (ULV) equipment.”

“Not for use on other residential turf sites including residential lawns, gardens, playing fields, cemeteries, and schools.”

For use on blackberries, red/black raspberries and strawberries:

Wettable granule products:

“For mechanically-pressurized hand gun applications, use a spray volume of 250 – 1000 L water per hectare.”

Wettable powder products:

“For mechanically-pressurized hand gun applications, use a spray volume of 300 – 1000 L water per hectare.”

For use of wettable powder product(s) on turf at a rate of 16 kg a.i./ha, the following statement under APPLICATION RATE must be added:

“Do not handle more than 320 kg fosetyl-aluminum per person per day.”

Buffer Zone Related Label Statements Required:

Field sprayer application:

DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:

Use of the following spray methods or equipment **DOES NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment and soil incorporation.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Buffer Zones

Method of application	Crop	Buffer Zones (meters) Required for the Protection of:				
		Aquatic Habitat of Depths:		Marine Habitat of Depths:		Terrestrial habitat
		Less than 1 m	Greater than 1m	Less than 1 m	Greater than 1m	
Field sprayer*	All Crops	1	1	1	0	0
	Turf	2	1	1	1	0

*For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The following statements are to be added under **ENVIRONMENTAL HAZARDS** to end-use product labels:

“TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

Toxic to small wild mammals.

Toxic to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application site such as hedgerows and woodland.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.”

Product specific changes

1.0 CHIPCO ALIETTE® ORNAMENTAL FUNGICIDE (Registration No. 27557)

1.1 On the front panel and Booklet, page 1

Replace:

“SYSTEMIC FUNGICIDE FOR USE ON GREENHOUSE CONTAINER AND FIELD GROWN ORNAMENTALS (INCLUDING CONIFERS) AND BEDDING PLANTS”

With: “SYSTEMIC FUNGICIDE FOR USE ON GREENHOUSE AND FIELD GROWN ORNAMENTALS (INCLUDING TREES)”.

1.2 Page 2, under General Information Section

Replace:

“CHIPCO ALIETTE® Ornamental Fungicide can be used to control *Phytophthora* and *Pythium*”

With: “CHIPCO ALIETTE® Ornamental Fungicide can be used to control root rot caused by *Phytophthora* spp. and *Pythium* spp. and suppression of Sudden Oak Death disease.”

1.3 Page 3, under Directions for use

Replace:

“GREENHOUSE ORNAMENTALS - CONTROL OF PYTHIUM AND PHYTOPHTHORA(Chinese evergreen (*Aglaonema*), *pothos*, *shefflera*, *spathiphyllum*, *azalea*)

Foliar Applications:

Apply a maximum of 3 applications. Apply at 14-30 day intervals.

Application Rate: Apply at a rate of 2.8 kg product/ha.
DO NOT APPLY BY AIR.

BEDDING PLANTS - CONTROL OF PYTHIUM AND PHYTOPHTHORA

(Begonia, Geranium, Vinca, Celosia, Petunia, Salvia and Impatiens)

Foliar Applications:

Apply a maximum of 3 applications at 14 day intervals

Application Rate: Apply at a rate of 2.8 kg product/ha.
DO NOT APPLY BY AIR.

Drench Applications:

Apply a maximum of 3 applications, one application every 30 days. Apply before disease onset.

Application Rate: Use 360 g product/380 L water to cover 36m²
DO NOT APPLY BY AIR.”

With:

**“GREENHOUSE ORNAMENTALS INCLUDING BEDDING PLANTS and
ORNAMENTALS GROWN FOR CUT FLOWERS - Control of root rot caused by
Pythium spp. and *Phytophthora* spp.**

**Greenhouse ornamentals including bedding plants (no ornamentals grown for cut
flowers)**

Foliar Applications:

Apply at a rate of 2.8 kg product/ha, with a maximum of 3 applications per crop cycle. If disease persists, re-apply at 14-30 day intervals. **DO NOT** make foliar applications to ornamentals grown for cut flowers – apply as a soil drench application only.

**Greenhouse ornamentals including bedding plants and ornamentals grown for
ornamentals grown for cut flowers**

Soil Drench Applications:

Apply 360 g product/380 L water to cover 36m². Apply a maximum of 3 applications per crop cycle, with a 30 day re-application interval. **DO NOT** allow pesticide solution to contact foliage. Apply preventatively, before disease onset.

**OUTDOOR ORNAMENTALS INCLUDING BEDDING PLANTS and
ORNAMENTALS GROWN FOR CUT FLOWERS - Control of root rot caused by
Pythium spp. and *Phytophthora* spp.**

Foliar Applications: Apply at a rate of 2.8 kg product/ha, with a maximum of 3 applications per year. Re-apply at 14 day intervals if disease persists.

Soil Drench Applications: Apply 360 g product/380 L water to cover 36m². Apply a maximum of 3 applications per year, with a 30 day re-application interval. **DO NOT** allow pesticide solution to contact foliage. Apply preventatively, before disease onset.

DO NOT APPLY BY AIR.”

1.4 On Page 4,

Replace:

**“DIRECTIONS FOR USE
GREENHOUSE CONTAINER AND FIELD-GROWN ORNAMENTAL PLANTS
IN NURSERIES AND LANDSCAPE PLANTINGS AND CONIFERS GROWN IN
NURSERIES AND LANDSCAPE PLANTATION**

**NOTE TO USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR
THE INDICATED SPECIAL USE APPLICATIONS:**

The DIRECTIONS FOR USE for this product for the use(s) described below were developed by persons other than Bayer CropScience and accepted for registration by Health Canada under the User Requested Minor Use Label Expansion program. Bayer CropScience itself makes no representation or warranty with respect to performance (efficacy) or crop tolerance (phytotoxicity) claims for this product when used on the crop(s) listed below. Accordingly, the Buyer and User assume all risks related to performance and crop tolerance arising, and agree to hold Bayer CropScience harmless from any claims based on efficacy or phytotoxicity in connection with the use(s) described below.

GREENHOUSE CONTAINER AND FIELD-GROWN ORNAMENTAL PLANTS IN NURSERIES AND LANDSCAPE PLANTINGS AND CONIFERS GROWN IN NURSERIES AND LANDSCAPE PLANTATION

For Suppression of Sudden Oak Death caused by *Phytophthora Ramorum* on those ornamentals deemed susceptible to this disease by the Canadian Food Inspection Agency (CFIA). For a complete list of the ornamental species, refer to the publication “List of Plants Regulated for *Phytophthora Ramorum* (Sudden Oak Death),” which is updated regularly. www.inspection.gc.ca/english/plaveg/protect/dir/sodspe.shtml. CHIPCO ALIETTE® Ornamental is registered for ground application only as a foliar spray.

Foliar Application:

Apply at 5 kg of product per hectare. Apply in a water volume not greater than 1000 L/ha. Spray to wet. Do not apply to run-off. Maximum of 4 applications per year.

TIMING: Apply when conditions favour disease development (high soil moisture and cool temperatures), before disease onset, and repeat if necessary 2-3 weeks later. Treat when there is sufficient leaf area present to take up the spray; when leaves are actively growing, and at least 30 days prior to leaf drop in deciduous species.

Note: Not all species have been tested for phytotoxicity. It is recommended that the user test a small sample before applying to the entire crop.”

**With: “DIRECTIONS FOR USE
GREENHOUSE AND FIELD-GROWN ORNAMENTAL PLANTS AND TREES
(INCLUDING CONIFERS)**

NOTE TO USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR THE INDICATED SPECIAL USE APPLICATIONS:

The DIRECTIONS FOR USE for this product for the use(s) described below were developed by persons other than Bayer CropScience and accepted for registration by Health Canada under the User Requested Minor Use Label Expansion program. Bayer CropScience itself makes no representation or warranty with respect to performance (efficacy) or crop tolerance (phytotoxicity) claims for this product when used on the crop(s) listed below. Accordingly, the Buyer and User assume all risks related to

performance and crop tolerance arising, and agree to hold Bayer CropScience harmless from any claims based on efficacy or phytotoxicity in connection with the use(s) described below.

GREENHOUSE AND FIELD-GROWN ORNAMENTAL PLANTS AND TREES (INCLUDING CONIFERS)

For suppression of Sudden Oak Death caused by *Phytophthora ramorum* on those ornamentals deemed susceptible to this disease by the Canadian Food Inspection Agency (CFIA).

For a complete list of the ornamental species CHIPCO ALIETTE® can be applied to, refer to the CFIA website publication “List of Plants Regulated for *Phytophthora Ramorum* (Sudden Oak Death),” which is updated regularly. <http://www.inspection.gc.ca>

Foliar Application:

Apply 5 kg of product* per hectare in a maximum water volume of 1000 L/ha. Make a maximum of 4 applications per year. Spray to wet. Do not apply to run-off.

Timing: Apply when conditions favour disease development (high soil moisture and cool temperatures), but before disease onset. If disease persists re-apply 14-21 days later. Treat when there is sufficient leaf area present to take up the spray, when leaves are actively growing, and at least 30 days prior to leaf drop in deciduous species.

DO NOT apply CHIPCO ALIETTE® as a soil drench application to ornamentals or trees to manage Sudden Oak Death disease.

DO NOT apply CHIPCO ALIETTE® as a foliar application to ornamentals grown for cut flowers, apply as a soil drench application only, to manage Sudden Oak Death disease.

***Note:** Not all species have been tested for phytotoxicity. It is recommended that the user test a small sample before applying to the entire crop.”

1.5 Page 3, under Directions for use

Replace:

“GREENHOUSE ORNAMENTALS - CONTROL OF PYTHIUM AND PHYTOPHTHORA(Chinese evergreen (*Aglaonema*), *pothos*, *shefflera*, *spathiphyllum*, *azalea*)

Foliar Applications:

Apply a maximum of 3 applications. Apply at 14-30 day intervals.

Application Rate: Apply at a rate of 2.8 kg product/ha.
DO NOT APPLY BY AIR.

BEDDING PLANTS - CONTROL OF PYTHIUM AND PHYTOPHTHORA
(Begonia, Geranium, Vinca, Celosia, Petunia, Salvia and Impatiens)

Foliar Applications:

Apply a maximum of 3 applications at 14 day intervals

Application Rate: Apply at a rate of 2.8 kg product/ha.
DO NOT APPLY BY AIR.

Drench Applications:

Apply a maximum of 3 applications, one application every 30 days. Apply before disease onset.

Application Rate: Use 360 g product/380 L water to cover 36m²
DO NOT APPLY BY AIR.”

**With: “GREENHOUSE ORNAMENTALS INCLUDING BEDDING PLANTS and
ORNAMENTALS GROWN FOR CUT FLOWERS - Control of root rot caused by
Pythium spp. and *Phytophthora* spp.**

Foliar Applications:

Apply at a rate of 2.8 kg product/ha, with a maximum of 3 applications per crop cycle. If disease persists, re-apply at 14-30 day intervals. **DO NOT** make foliar applications to ornamentals grown for cut flowers – apply as a soil drench application only.

Soil Drench Applications:

Apply 360 g product/380 L water to cover 36m². Apply a maximum of 3 applications per crop cycle, with a 30 day re-application interval. **DO NOT** allow pesticide solution to contact foliage. Apply preventatively, before disease onset.

**OUTDOOR ORNAMENTALS INCLUDING BEDDING PLANTS and
ORNAMENTALS GROWN FOR CUT FLOWERS - Control of root rot caused by
Pythium spp. and *Phytophthora* spp.**

Foliar Applications: Apply at a rate of 2.8 kg product/ha, with a maximum of 3 applications per year. Re-apply at 14 day intervals if disease persists.

Soil Drench Applications: Apply 360 g product/380 L water to cover 36m². Apply a maximum of 3 applications per year, with a 30 day re-application interval. **DO NOT** allow pesticide solution to contact foliage. Apply preventatively, before disease onset.

DO NOT APPLY BY AIR.”

1.5 On Page 4

Replace:

**“DIRECTIONS FOR USE
GREENHOUSE CONTAINER AND FIELD-GROWN ORNAMENTAL PLANTS
IN NURSERIES AND LANDSCAPE PLANTINGS AND CONIFERS GROWN IN
NURSERIES AND LANDSCAPE PLANTATION**

NOTE TO USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR THE INDICATED SPECIAL USE APPLICATIONS:

The DIRECTIONS FOR USE for this product for the use(s) described below were developed by persons other than Bayer CropScience and accepted for registration by Health Canada under the User Requested Minor Use Label Expansion program. Bayer CropScience itself makes no representation or warranty with respect to performance (efficacy) or crop tolerance (phytotoxicity) claims for this product when used on the crop(s) listed below. Accordingly, the Buyer and User assume all risks related to performance and crop tolerance arising, and agree to hold Bayer CropScience harmless from any claims based on efficacy or phytotoxicity in connection with the use(s) described below.

GREENHOUSE CONTAINER AND FIELD-GROWN ORNAMENTAL PLANTS IN NURSERIES AND LANDSCAPE PLANTINGS AND CONIFERS GROWN IN NURSERIES AND LANDSCAPE PLANTATION

For Suppression of Sudden Oak Death caused by *Phytophthora Ramorum* on those ornamentals deemed susceptible to this disease by the Canadian Food Inspection Agency (CFIA). For a complete list of the ornamental species, refer to the publication “List of Plants Regulated for *Phytophthora Ramorum* (Sudden Oak Death),” which is updated regularly. www.inspection.gc.ca/english/plaveg/protect/dir/sodspe.shtml.

CHIPCO ALIETTE® Ornamental is registered for ground application only as a foliar spray.

Foliar Application:

Apply at 5 kg of product per hectare. Apply in a water volume not greater than 1000 L/ha. Spray to wet. Do not apply to run-off. Maximum of 4 applications per year.

TIMING: Apply when conditions favour disease development (high soil moisture and cool temperatures), before disease onset, and repeat if necessary 2-3 weeks later. Treat when there is sufficient leaf area present to take up the spray; when leaves are actively growing, and at least 30 days prior to leaf drop in deciduous species.

Note: Not all species have been tested for phytotoxicity. It is recommended that the user test a small sample before applying to the entire crop.”

With: “DIRECTIONS FOR USE

GREENHOUSE AND FIELD-GROWN ORNAMENTAL PLANTS AND TREES

NOTE TO USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR THE INDICATED SPECIAL USE APPLICATIONS:

The DIRECTIONS FOR USE for this product for the use(s) described below were developed by persons other than Bayer CropScience and accepted for registration by

Health Canada under the User Requested Minor Use Label Expansion program. Bayer CropScience itself makes no representation or warranty with respect to performance (efficacy) or crop tolerance (phytotoxicity) claims for this product when used on the crop(s) listed below. Accordingly, the Buyer and User assume all risks related to performance and crop tolerance arising, and agree to hold Bayer CropScience harmless from any claims based on efficacy or phytotoxicity in connection with the use(s) described below.

**GREENHOUSE AND FIELD-GROWN ORNAMENTAL PLANTS AND TREES
For suppression of Sudden Oak Death caused by *Phytophthora ramorum* on those
ornamentals deemed susceptible to this disease by the Canadian Food Inspection
Agency (CFIA).**

For a complete list of the ornamental species CHIPCO ALIETTE® can be applied to, to suppress this disease, refer to the CFIA website publication “List of Plants Regulated for *Phytophthora Ramorum* (Sudden Oak Death),” which is updated regularly.
<http://www.inspection.gc.ca>

Foliar Application:

Apply 5 kg of product* per hectare in a maximum water volume of 1000 L/ha. Make a maximum of 4 applications per year. Spray to wet. Do not apply to run-off.

Timing: Apply when conditions favour disease development (high soil moisture and cool temperatures), but before disease onset. If disease persists re-apply 14-21 days later. Treat when there is sufficient leaf area present to take up the spray, when leaves are actively growing, and at least 30 days prior to leaf drop in deciduous species.

DO NOT apply CHIPCO ALIETTE® as a soil drench application to ornamentals or trees to manage Sudden Oak Death disease (apply as a foliar application only).

DO NOT apply CHIPCO ALIETTE® to ornamentals grown for cut flowers, either as a foliar application or as a soil drench application, to manage Sudden Oak Death disease.

***Note:** Not all species have been tested for phytotoxicity. It is recommended that the user test a small sample before applying to the entire crop.”

**2.0 Supplemental Label - CHIPCO ALIETTE® T&O FUNGICIDE (Registration
Number : 27557)**

2.1 On page 1,

Replace:

“SUPPLEMENTAL USE LABEL FOR THE PREVENTATIVE CONTROL OF
FOLIAR AND BASAL ROT ANTHRACNOSE ON TURFGRASS IN GOLF
COURSES, SOD FARMS, AND TURF AREAS”

With: “SUPPLEMENTAL USE LABEL FOR THE PREVENTATIVE CONTROL OF FOLIAR AND BASAL ROT ANTHRACNOSE ON TURFGRASS IN GOLF COURSES AND SOD FARMS”

2.2 On page 4, Under Directions For use

Replace:

“GOLF COURSES, SOD FARMS, TURF AREAS – PREVENTATIVE CONTROL OF FOLIAR AND BASAL ROT ANTHRACNOSE”

With: “GOLF COURSES AND SOD FARMS – PREVENTATIVE CONTROL OF FOLIAR AND BASAL ROT ANTHRACNOSE (*Colletotrichum cereale*)”

2.3 Add the following statement in use direction section: “DO NOT apply to residential areas”

3.0 SIGNATURE XTRA STRESSGARD Fungicide (Registration Number: 32800)

3.1 On page 7 in the directions for use table, add:

“(Pythium spp.)” after “For control of Pythium blight”.

“(Pythium spp.)” after “For suppression of Pythium root rot”.

“(Pythium spp.)” after “For control of Pythium root rot”.

3.2 On page 8, add:

“*Colletotrichum cereale*” after “For control of anthracnose (basal rot and foliar blight)”.

4.0 CHIPCO ALIETTE® SIGNATURE FUNGICIDE (Registration Number: 28299)

4.1 On page 4, under the DIRECTIONS FOR USE, add:

“(Pythium spp.)” after “Control of Pythium Diseases”

“*Colletotrichum cereale*” after “Preventative Control of Foliar and Basal Rot Anthracnose”

5.0 ALIETTE® SYSTEMIC FUNGICIDE (Registration Number: 27688)

5.1 On page 3, under DIRECTIONS FOR USE, add: “When applied as directed, Aliette Systemic Fungicide will control the listed diseases, unless otherwise indicated as suppression.”

5.2

Replace: “APPLES – CONTROL OF PHYTOPHTHORA CROWN AND ROOT ROT”

With: “APPLES – CONTROL OF PHYTOPHTHORA CROWN AND ROOT ROT (*Phytophthora* spp.)”

5.3 On page 4, add the causative pathogen name: “*Pseudomonas syringae* pv. *papulans*” after “BLISTER SPOT.”

5.4 In the “FOLIAR APPLICATION” use directions, add: “Apply the higher rate under conditions of high disease pressure.”

5.5 Add the causative pathogen name: “*Bremia lactucae*” after “DOWNY MILDEW”

5.6 On page 5

Replace: “ONIONS - CONTROL OF DOWNY MILDEW AND PURPLE BLOTCH”

With: “ONIONS - CONTROL OF DOWNY MILDEW (*Peronospora destructor*) AND PURPLE BLOTCH (*Alternaria porri*)”

5.7 On page 6

Replace:

“STRAWBERRY - CONTROL OF RED STELE

Apply a maximum of four (4) applications per crop season. Use a foliar spray by ground application only. Begin application when plants start active growth. Repeat at 30-60 day intervals. Observe a PHI of 30 days.

APPLICATION RATE: Apply at 5.6 kg product/ha.”

With: “STRAWBERRY - CONTROL OF RED STELE (*Phytophthora fragariae*)

Apply a maximum of four (4) applications per crop season. Use a foliar spray by ground application only. Begin application when plants start active growth. Repeat at 30-60 day intervals. Observe a PHI of 30 days.

APPLICATION RATE: Apply at 5.6 kg product/ha. For mechanically pressurized hand gun applications, use a spray volume of 250 – 1000 L water per hectare.”

5.8

Replace: “GINSENG – CONTROL OF PHYTOPHTHORA, FOLIAR AND ROOT ROT”

With: “GINSENG – CONTROL OF PHYTOPHTHORA, FOLIAR AND ROOT ROT (*Phytophthora* spp.)

5.9 On page 7

Replace: “TOBACCO (Flue-Cured, Burley, Black)- CONTROL OF BLUE MOULD”

With: “TOBACCO (Flue-Cured, Burley, Black)- CONTROL OF BLUE MOULD (*Peronospora hyoscyami* f.sp. *tabacina*)”

5.10

Replace:

RED/BLACK RASPBERRY, BLACKBERRY – CONTROL OF PHYTOPHTHORA ROOT ROT

APPLICATION RATE: Apply at 5.5 kg product per hectare in a minimum of 200 – 1000 L water per hectare.

With: RED/BLACK RASPBERRY, BLACKBERRY – CONTROL OF PHYTOPHTHORA ROOT ROT

APPLICATION RATE: Apply at 5.5 kg product per hectare in a minimum of 200 – 1000 L water per hectare. For mechanically pressurized hand gun applications, use a spray volume of 250 – 1000 L water per hectare.

6.0 ALIETTE® WDG SYSTEMIC FUNGICIDE (Registration Number: 24458)

6.1 On the front panel (Page 0) and on the booklet (page 3)

Replace:

“APPLES, GINSENG, RED/BLACK RASPBERRIES, BLACKBERRIES, CRANBERRY, GRAPES, STRAWBERRIES, LETTUCE, GREENHOUSE LETTUCE IN BC, SPINACH, ONIONS, BRASSICA HEAD AND STEM VEGETABLES (CROP GROUP 5-13) AND BRASSICA LEAFY VEGETABLES (CROP GROUP 4-13B), GREENHOUSE-GROWN BRASSICA HEAD AND STEM VEGETABLE TRANSPLANTS (CROP GROUP 5-13), GREENHOUSE-GROWN BRASSICA LEAFY GREEN TRANSPLANTS (CROP SUBGROUP 4-13B), KOHLRABI, RUTABAGA, BELGIAN ENDIVE, Highbush blueberries, TOBACCO, GREENHOUSE CONTAINER AND FIELD GROWN ORNAMENTALS (INCLUDING CONIFERS) AND BEDDING PLANTS”

With:

“APPLES, GINSENG, RED/BLACK RASPBERRIES, BLACKBERRIES, CRANBERRY, GRAPES, STRAWBERRIES, LETTUCE, GREENHOUSE LETTUCE IN BC, SPINACH, ONIONS, BRASSICA HEAD AND STEM VEGETABLES (CROP GROUP 5-13) AND BRASSICA LEAFY VEGETABLES (CROP GROUP 4-13B), GREENHOUSE-GROWN BRASSICA HEAD AND STEM VEGETABLE TRANSPLANTS (CROP GROUP 5-13), GREENHOUSE-GROWN BRASSICA LEAFY GREEN TRANSPLANTS (CROP SUBGROUP 4-13B), KOHLRABI, RUTABAGA, BELGIAN ENDIVE, Highbush blueberries, TOBACCO, GREENHOUSE AND FIELD GROWN ORNAMENTALS (INCLUDING TREES)”

6.2 On page 1 and page 4, under General Information in line 3 after Phomopsis Canker, add: “and Sudden Oak Death”

6.3 On page 6, under DIRECTIONS FOR USE, add: “When applied as directed, Aliette Systemic Fungicide will control the listed diseases, unless otherwise indicated as suppression.”

6.4**Replace:**

“APPLES – CONTROL OF PHYTOPHTHORA CROWN AND ROOT ROT”

With: “APPLES – CONTROL OF PHYTOPHTHORA CROWN AND ROOT ROT

(*Phytophthora* spp.)”

6.5 In the “FOLIAR APPLICATION” use directions, add: “Apply higher rate under conditions of high disease pressure.”

6.6 On page 7**Replace:**

“APPLES (MUTSU, JONAGOLD, GOLDEN DELICIOUS) - CONTROL OF BLISTER SPOT”

With: “APPLES (MUTSU, JONAGOLD, GOLDEN DELICIOUS) - CONTROL OF BLISTER

SPOT (*Pseudomonas syringae* pv. *papulans*)”

6.7**Replace:**

“GREENHOUSE LETTUCE IN BRITISH COLUMBIA - CONTROL OF DOWNY MILDEW”

With:

“GREENHOUSE LETTUCE IN BRITISH COLUMBIA - CONTROL OF DOWNY MILDEW (*Bremia lactucae*)”

6.8**Replace:**

“LETTUCE - CONTROL OF DOWNY MILDEW”

With: “LETTUCE - CONTROL OF DOWNY MILDEW (*Bremia lactucae*)”

6.9**Replace:**

“ONIONS - CONTROL OF DOWNY MILDEW AND PURPLE BLOTCH”

With: “ONIONS - CONTROL OF DOWNY MILDEW (*Peronospora destructor*) AND PURPLE BLOTCH (*Alternaria porri*)”

6.10 On page 8**Replace:**

“RED/BLACK RASPBERRY, BLACKBERRY – CONTROL OF PHYTOPHTHORA ROOT ROT”

APPLICATION RATE: Apply at 5.5 kg product per hectare in a minimum of 200 – 1000 L water per hectare

With: “RED/BLACK RASPBERRY, BLACKBERRY – CONTROL OF PHYTOPHTHORA ROOT ROT (*Phytophthora* spp.)”

APPLICATION RATE: Apply at 5.5 kg product per hectare in a minimum of 200 – 1000 L water per hectare. For mechanically pressurized hand gun applications, use a spray volume of 250 – 1000 L water per hectare.

6.11 On page 9**Replace:**

“STRAWBERRY - CONTROL OF RED STELE”

Apply a maximum of four (4) applications per crop season. Use a foliar spray by ground application only. Begin application when plants start active growth. Repeat at 30-60 day intervals. Observe a PHI of 30 days.

APPLICATION RATE: Apply at 5.6 kg product/ha.

With:

“STRAWBERRY - CONTROL OF RED STELE (*Phytophthora fragariae*)”

Apply a maximum of four (4) applications per crop season. Use a foliar spray by ground application only. Begin application when plants start active growth. Repeat at 30-60 day intervals. Observe a PHI of 30 days.

APPLICATION RATE: Apply at 5.6 kg product/ha. For mechanically pressurized hand gun applications, use a spray volume of 250 – 1000 L water per hectare.

6.12 Replace the existing wording for use on ornamentals for control of Pythium and Phytophthora root rot, and Sudden Oak Death with the wording outlined under sections 1.4 and 1.5.

6.13 On page 11**Replace:**

“GINSENG – CONTROL OF PHYTOPHTHORA, FOLIAR AND ROOT ROT”

With:

“GINSENG – CONTROL OF PHYTOPHTHORA, FOLIAR AND ROOT ROT
(*Phytophthora cactorum*)”

6.14**Replace:**

“TOBACCO (Flue-Cured, Burley, Black)- CONTROL OF BLUE MOULD”

With:

“TOBACCO (Flue-Cured, Burley, Black)- CONTROL OF BLUE MOULD
(*Peronospora hyoscyami* f.sp. *tabacina*)”

6.15 On page 12

Replace: “(*Phomopsis vaccini-i*)”

With: “(*Phomopsis vaccinii*)”

7.0 ALIETTE® WETTABLE POWDER SYSTEMIC FUNGICIDE (Registration Number: 24564)

7.1**Replace:**

“FOR CONTROL OF PHYTOPHTHORA CROWN AND ROOT ROT IN APPLE TREES, BLISTER SPOT IN APPLES (Mutsu, Jonagold, Golden Delicious), RED STELE ON STRAWBERRIES, DOWNEY MILDEW IN LETTUCE AND GREENHOUSE LETTUCE IN B.C., PURPLE BLOTCH AND DOWNEY MILDEW IN ONIONS AND PHYTOPHTHORA, FOLIAR AND ROOT ROT IN GINSENG, PHYTOPHTHORA ROOT ROT IN RED/BLACK RASPBERRIES, BLACKBERRIES, BLUE MOULD IN FLUE-CURED TOBACCO, PYTHIUM AND PHYTOPHTHORA IN GREENHOUSE ORNAMENTALS AND BEDDING PLANTS, PYTHIUM DISEASES IN TURF AND DOWNY MILDEW (*Peronospora parasitica*) IN BROCCOLI and BOK CHOY”

With:

“FOR CONTROL OF PHYTOPHTHORA CROWN AND ROOT ROT IN APPLE TREES, BLISTER SPOT IN APPLES (Mutsu, Jonagold, Golden Delicious), RED STELE ON STRAWBERRIES, DOWNEY MILDEW IN LETTUCE AND GREENHOUSE LETTUCE IN B.C., PURPLE BLOTCH AND DOWNEY MILDEW IN ONIONS AND PHYTOPHTHORA, FOLIAR AND ROOT ROT IN GINSENG, PHYTOPHTHORA ROOT ROT IN RED/BLACK RASPBERRIES, BLACKBERRIES, BLUE MOULD IN FLUE-CURED TOBACCO, PYTHIUM AND PHYTOPHTHORA ROOT ROT IN GREENHOUSE AND OUTDOOR ORNAMENTALS AND BEDDING PLANTS, PYTHIUM DISEASES IN TURF, AND DOWNY MILDEW (*Hyaloperonospora parasitica*) IN BROCCOLI AND BOK CHOY”

7.2

Under GENERAL INFORMATION, replace:

“Aliette Systemic Fungicide can be used to control Phytophthora crown and root rot of apple trees. Aliette is completely systemic. Product applied to leaves will move downwards to the roots. Aliette is most effective when used as a preventative treatment. Trees displaying early disease symptoms of crown and root rot are most likely to benefit from this treatment.”

With:

“Aliette Systemic Fungicide can be used to control diseases on listed crops. Aliette is completely systemic. Product applied to leaves will move downwards to the roots. Aliette is most effective when used as a preventative treatment. Plants displaying early disease symptoms are most likely to benefit from this treatment”.

7.3

Replace: “APPLES – CONTROL OF PHYTOPHTHORA CROWN AND ROOT ROT (Phytophthora)”

With: “APPLES – CONTROL OF PHYTOPHTHORA CROWN AND ROOT ROT (*Phytophthora* spp.)”

7.4

In the “FOLIAR APPLICATION” use directions, add: “Apply higher rate under conditions of high disease pressure.”

7.5

Replace: “APPLES (MUTSU, JONAGOLD, GOLDEN DELICIOUS) - CONTROL OF BLISTER SPOT”

With: “APPLES (MUTSU, JONAGOLD, GOLDEN DELICIOUS) - CONTROL OF BLISTER SPOT (*Pseudomonas syringae* pv. *Papulans*)”

7.6

Replace: “GREENHOUSE LETTUCE IN BRITISH COLUMBIA - CONTROL OF DOWNY MILDEW”

With: “GREENHOUSE LETTUCE IN BRITISH COLUMBIA - CONTROL OF DOWNY MILDEW (*Bremia lactucae*)”

7.7

Replace: “LETTUCE - CONTROL OF DOWNY MILDEW”

With: “LETTUCE - CONTROL OF DOWNY MILDEW (*Bremia lactucae*)”

7.8

Replace: “ONIONS - CONTROL OF DOWNY MILDEW AND PURPLE BLOTCH”

With: “ONIONS - CONTROL OF DOWNY MILDEW (*Peronospora destructor*) AND PURPLE BLOTCH (*Alternaria porri*)”

7.9

Replace: “RED/BLACK RASPBERRY, BLACKBERRY – CONTROL OF PHYTOPHTHORA ROOT ROT”

APPLICATION RATE: Apply at 4.48 kg ai / ha (5.5 kg product / ha) in a minimum of 200 – 1000L water per hectare.

With: “RED/BLACK RASPBERRY, BLACKBERRY – CONTROL OF PHYTOPHTHORA ROOT ROT (*Phytophthora* spp.)”

APPLICATION RATE: Apply at 4.48 kg ai / ha (5.5 kg product / ha) in a minimum of 200 – 1000L water per hectare. For mechanically pressurized hand gun applications, use a spray volume of 300 – 1000 L water per hectare.

7.10

Replace: “STRAWBERRY - CONTROL OF RED STELE”

Apply a maximum of four (4) applications per crop season. Use a foliar spray by ground application only. Begin application when plants start active growth.

Repeat at 30-60 day intervals. Observe a PHI of 30 days.

APPLICATION RATE: Apply at 5.5 kg product/ha.

With: “STRAWBERRY - CONTROL OF RED STELE (*Phytophthora fragariae*)”

Apply a maximum of four (4) applications per crop season. Use a foliar spray by ground application only. Begin application when plants start active growth. Repeat at 30-60 day intervals. Observe a PHI of 30 days.

APPLICATION RATE: Apply at 5.5 kg product/ha. For mechanically pressurized hand gun applications, use a spray volume of 300 – 1000 L water per hectare.

7.11

Replace: “GINSENG – CONTROL OF PHYTOPHTHORA, FOLIAR AND ROOT ROT”

With: “GINSENG – CONTROL OF PHYTOPHTHORA, FOLIAR AND ROOT ROT (*Phytophthora cactorum*)”

7.12

Replace: “TOBACCO (Flue-Cured, Burley, Black)- CONTROL OF BLUE MOULD”

With: “TOBACCO (Flue-Cured, Burley, Black)- CONTROL OF BLUE MOULD (*Peronospora hyoscyami* f.sp. *tabacina*)”

7.13

Replace: “BROCCOLI and BOK CHOY – CONTROL OF DOWNY MILDEW (*Peronospora parasitica*)”

With: “BROCCOLI and BOK CHOY – CONTROL OF DOWNY MILDEW (*Hyaloperonospora parasitica*)”

7.14

Replace: “GOLF COURSES, SOD FARMS, TURF AREAS - CONTROL OF PYTHIUM DISEASES”

With: “GOLF COURSES, SOD FARMS, TURF AREAS - CONTROL OF PYTHIUM BLIGHT (*Pythium* spp.)”

7.15

Replace: “DIRECTIONS FOR USE GREENHOUSE ORNAMENTALS - CONTROL OF PYTHIUM AND PHYTOPHTHORA”

With: the wording outlined in section 1.4.

Restricted Entry Intervals (REIs) (to be added to all end-use products):

For golf courses:

Replace: “Do not re-enter treated area until residues have dried.”

With: “Do not enter or allow entry into treated areas until sprays have dried.”

For all other uses:

Table 3 lists the REI to be added to applicable fosetyl-aluminum labels. Where deemed necessary, REIs are subdivided according to postapplication activities.

For agricultural products, add the following to the label under PRECAUTIONS:

“DO NOT enter or allow workers entry into treated areas during the restricted entry intervals (REIs) specified in the following table.”

Include a table on each label in this section that includes the crops, activities, and REIs from Table 3 for the crops registered on that label. **Do not add crops that are not on the specific product label.**

Example of Restricted-Entry Interval Table

Crop	Re-entry Activity	Restricted-Entry Interval ^a	Pre-Harvest Interval ^b
Example crop #1	Corresponding activity from Table 3	Corresponding REI from Table 3	Corresponding PHI from Table 3
Example crop #2	Corresponding activity from Table 3	Corresponding REI from Table 3	Corresponding PHI from Table 3
	Corresponding activity from Table 3	Corresponding REI from Table 3	Corresponding PHI from Table 3

^a If the REI for hand harvesting and the pre-harvest interval (PHI) are different, follow the longer of the two intervals for both the REI and PHI. If the crop is harvested mechanically, with no contact with treated foliage or crop, follow the PHI.

^b Include PHI only if applicable to crop/use. If the PHI is not applicable, follow the REI.

Table 3 Restricted-Entry Intervals

Crop/Site	Activity	REIs^a	PHI
Apple	Thinning by hand	4 days	30
	All other activities	12 hours	
Belgian endive For use on roots for Belgian endive (chicon) production only	All activities	12 hours	21
Blackberry, red/black raspberry	Hand set/hand line irrigation related activities involving workers contacting foliage	2 days	60
	All other activities	12 hours	
Blueberries, highbush	Hand set/hand line irrigation related activities involving workers contacting foliage	3 days	1
	All other activities	12 hours	
Broccoli, Brussels sprouts, cauliflower, cavolo broccolo	Harvesting, hand	11 days	7
	Weeding, hand	9 days	
	Scouting (full foliage), topping, tying/training	9 days	
	All other activities	12 hours	
Bok choy (chinese cabbage), broccoli raab (rapini), Chinese broccoli (gai lon), Chinese mustard cabbage (gai choy), collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach, rape greens	All activities	12 hours	7
Cabbage, Chinese cabbage (napa)	Weeding, hand	9 days	7
	All other activities	12 hours	
Cranberry	All activities	12 hours	3
Ginseng	All activities	12 hours	31
Grapes (except table grapes)	Harvesting, hand; Tying/training, leaf pulling by hand	18 days	15
	Hand set/hand line irrigation related activities involving workers contacting foliage	3 days	
	All other activities	12 hours	
Table grapes	Girdling/turning	22 days	15
	Harvesting, hand; Tying/training, leaf pulling by hand	15 days	
	All other activities	12 hours	

Crop/Site	Activity	REIs^a	PHI
Greenhouse lettuce - BC only	All activities	12 hours	14
Lettuce	All activities	12 hours	7
Onions	Weeding, hand	8 days	7
	All other activities	12 hours	
Rutabaga	All activities	12 hours	7
Sod farms	All activities	12 hours	Not applicable _b
Spinach	Hand set/hand line irrigation related activities involving workers contacting foliage	4 days	3
Strawberry	All activities	12 hours	30
Tobacco (flue-cured, burley, black)	All activities	12 hours	5
Outdoor ornamental trees (foliar application, for suppression of Sudden Oak Death)	Hand set/hand line irrigation related activities involving workers contacting foliage	2 days	Not Applicable ^b
	All other activities	12 hours	
Outdoor ornamentals, including bedding plants, except ornamentals grown for cut flowers (foliar application)	All activities	12 hours	
Outdoor ornamentals grown for cut flowers (foliar application)	Cut flower, hand harvesting, disbudding, hand pruning (full foliage)	4 days	
	All other activities	12 hours	
Outdoor ornamentals, including bedding plants and ornamentals grown for cut flowers (soil drench application)	All activities	12 hours	
Greenhouse ornamentals, including bedding plants, except ornamentals grown for cut flowers (foliar application)	All activities	12 hours	
Greenhouse ornamentals, including bedding plants and ornamentals grown	All activities	12 hours	

Crop/Site	Activity	REIs ^a	PHI
for cut flowers (soil drench application only)			

^a If the REI for hand harvesting and the PHI are different, follow the longer of the two intervals for both the REI and PHI. If the crop is harvested mechanically, with no contact with treated foliage or crop, follow the PHI.

^b If the pre-harvest interval (PHI) is not applicable, follow the REI.

Appendix VI References Considered Following Publication of PRVD2017-19

A. Information Considered for the Toxicological Risk Assessment

List of Additional Studies/Information Submitted by Registrant – Toxicology

PMRA Document Number	Reference
2847070	2013. 21- Day sub acute dermal toxicity study of fosetyl-aluminum in Wistar rats with 14-day recovery. DACO 4.2.2
2847074	2017. POSITION PAPER: Fosetyl-aluminum (AE F053616). CONTENTS: Selection of the Rabbit Developmental Toxicity Study NOAEL.

Additional Information Considered Published Information

PMRA Document Number	Reference
	Peer review of the pesticide risk assessment of the active substance fosetyl. EFSA Journal 2018;16(7):5307 Available online from doi: 10.2903/j.efsa.2018.5307
	IPCS Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis. Regulatory Toxicology and Pharmacology 34, 146-152 (2001) Available online from: doi:10.1006/rtp.2001.1493

B. Information Considered in the Dietary Assessment

No additional studies or information relating to dietary assessment were submitted during the PRVD comment period.

C. Information Considered in the Occupational and Residential Assessment

List of Additional Studies/Information Submitted by Registrant

PMRA Document Number	Reference
2846582	Bayer CropScience Inc. 2018. Comments on Proposed Re-evaluation Decision PRVD2017-19, Fosetyl-aluminum and Its Associated End-use Products. January 30, 2018.
2847071	Odin, 2016. Fosetyl-aluminum WG 71.11 (FEA+FLC WG 66.67+4.44): [14C]-

PMRA Document Number	Reference
	Fosetyl-aluminum In vitro dermal absorption study using human skin. Bayer CropScience, Valbonne, France. Study ID: SA 14048. Unpublished.
2847072	Muhamedi, 2016. FMD+FEA+IPV WG 60.8: [14C]-Fosetyl-aluminum in vitro dermal absorption study using human skin. Bayer CropScience, Valbonne, France. Study ID: SA 15027. Unpublished.
2847075	Hassler, 2017a. In vitro Percutaneous Penetration of [14C]-Fosetyl-aluminum Formulated as CMX+FEA+FLP WG 79 (4+50+25) Through Human Skin Membranes. Innovative Environmental Services, Witterswil, Switzerland. Study Number: 20170063. Unpublished.
2847076	Hassler, 2017b. In vitro Percutaneous Penetration of [14C]-Fosetyl-aluminum Formulated as FEA+FLP WG 75 (50+25) Through Human Skin Membranes. Innovative Environmental Services, Witterswil, Switzerland. Study Number: 20170062. Unpublished.
2204552	Ward R.J., 2000, Fosetyl-aluminum: In vitro Absorption from a 800g/kg WG Formulation Through Human and Rat Epidermis. Central Toxicology Laboratory, Cheshire, UK. Study Number JV1598. Unpublished.

Additional Information Considered Published Information

PMRA Document Number	Reference
	Boman, A., Estlander, T., Wahlburg J.E., Maibach, H.I. 2005. Protective Gloves for Occupational Use Second edition. CRC Press LLC.
	Brouwer, R., Brouwer, D.H., Tigssen, S., van Hemmen, J.J. 1992. Pesticides in the Cultivation of Carnations in Greenhouses: Part II- Relationship Between Foliar Residues and Exposures. Am. Ind. Assoc. J. 53(9): 582-587.
	Brouwer, D.H., de Vreede, S.A.F., Meuling, W.J.A., van Hemmen, J.J. 2000. Determination of the efficiency for pesticide exposure reduction with protective clothing: a field study using biological monitoring. Chapter 5 In: Assessment of Occupational Exposure to Pesticides in Dutch Bulb Culture and Glasshouse Horticulture. Doctoral Thesis of D.H. Brouwer. pp.158-179.
	Garrigou, A., Baldi I., Le Frious P., Anselm R., Vallier M. 2011. Ergonomic contribution to chemical risks prevention: an ergotoxicological investigation of the effectiveness of coveralls against plant pest risk in viticulture. 42: 321-330.
	Graves, C.J., Edwards, C., Marks R. 1995. The effects of protective occlusive gloves on stratum corneum barrier properties. Contact Derm 33: 183-187.
	Keifer, M.C., 2000. Effectiveness of Interventions in Reducing Pesticide Overexposure and Poisonings. American Journal of Preventive Medicine. 18 (4S); 80-89.
	Rawson, B.V., Cocker, J., Evans, P.G. Wheeler, J.P. and Akrill, P.M. 2005. Internal contamination of Gloves: routes and Consequences. Am. Occup. Hyg.

PMRA Document Number	Reference
	49 (6): 535-541.
	Schneider, F; Hernandez, B.; Benson, C. 2002. Pesticide Exposure of Workers in Greenhouses. Health and Safety Report HS-1835. California Environmental Protection Agency. Nov.19, 2002.
	PMRA, 2016. Science Policy Note SPN2016-02, Dermal Absorption: Position Papers from the North American Free Trade Agreement (NAFTA) Technical Working Group (TWG)

Unpublished Information

PMRA Document Number	Reference
2115788	Agricultural Reentry Task Force (ARTF). 2008. Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients. Submission# 2006-0257
2846336	Flowers Canada Growers Inc. 2018. Comments on Proposed Re-evaluation Decision PRVD2017-19, Fosetyl-aluminum. January 9, 2018.