Registration Decision RD2026-05

3-Chloro-4-methylaniline hydrochloride and DRC-1339

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Under the authority of the *Pest Control Products Act*, pesticides must be assessed before they are sold or used in Canada in order to determine that they do not pose unacceptable risks to humans or the environment and have value when used according to the label instructions. The pre-market assessment considers available data and information[1] from pesticide registrants, published scientific reports, other governments, and international regulatory agencies, as well as written comments directly related to the proposed decision, such as comments directed to the Science evaluation, if received during public consultations. Health Canada applies internationally accepted current risk assessment methods as well as risk management approaches and policies. More details, on the legislative requirements, risk assessment and risk management approach, are provided under the Evaluation approach of this document.

Registration Decision Statement[2] for 3-chloro-4-methylaniline hydrochloride

Health Canada's Pest Management Regulatory Agency (PMRA), pursuant to subsection 8(1) of the Pest Control Products Act, is granting registration for the sale and use of DRC-1339 Technical and DRC-1339, containing the active ingredient 3-chloro-4-methylaniline hydrochloride, for control of corvids in relation to greater sage-grouse recovery.

The Proposed Registration Decision PRD2025-12, *3-Chloro-4-methylaniline hydrochloride and DRC-1339*, containing the detailed evaluation of the information submitted in support of this registration, underwent a 30-day consultation period ending on 16 November 2025. The evaluation found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable. Health Canada received written comments relating to the health, environmental and value assessments during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. Health Canada also received comments that were not directly related to the proposed decision in PRD2025-12, *3-Chloro-4-methylaniline hydrochloride and DRC-1339.*

Comments and responses

Health Canada received comments from the public, academia, and a non-governmental organization (NGO) on the health, environmental and value assessments of 3-chloro-4-methylaniline hydrochloride and DRC-1339. The responses are provided below.

Comments relating to the human health assessment

1. Comment related to the hazardous properties associated with the chlorinated aniline class of chemicals

The NGO commenter stated that Health Canada failed to provide sufficient evidence to support the assertion that, despite belonging to the chlorinated aniline class of chemicals, 3-chloro-4-methylaniline hydrochloride lacks the hazardous properties associated with this chemical class, such as bladder cancer, cyanosis at lethal doses, and skin sensitization.

[1] Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*.
[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

Health Canada response:

Similar hazardous properties to those known to be associated with other compounds in the chlorinated aniline class were identified in PRD2025-12 for 3-chloro-4-methylaniline hydrochloride. The active ingredient was identified as being of high acute toxicity via the oral route and a potential skin sensitizer, and information in the literature suggested a potential to cause methemoglobinemia, which is characterized by cyanosis, at acute lethal doses. The available chronic toxicity studies with 3-chloro-4-methylaniline hydrochloride did not identify bladder tumours as a treatment-related effect.

Considering the extensive risk mitigation measures put in place for DRC-1339, exposure is expected to be limited when used according to the legally binding label. Consequently, a qualitative approach to the human health risk assessment was considered appropriate and was undertaken in accordance with the PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products.[3]

2. Comment related to toxicity data gaps, data waivers, and potential future uses

The NGO commenter stated that Health Canada inappropriately waived many of the critical studies normally required for pesticide registration based on restricted use patterns, especially since future proposed uses cannot be predicted. They commented that "a restricted use does not eliminate the hazard". The commenter further stated that Health Canada cannot consider the toxicology database to be limited and also adequate for the current assessment.

Health Canada response:

As noted above, a qualitative approach to the human health risk assessment was undertaken given the extensive risk mitigation measures put in place for DRC-1339. Health Canada conducts a risk-based assessment of pest control products proposed for registration in Canada, which includes consideration of the potential hazards of a chemical substance in combination with the expected exposures based on the proposed uses of the pest control product.

With respect to the human health exposure assessment for 3-chloro-4-methylaniline hydrochloride, since it was determined that a qualitative approach was appropriate for the single specific use request (that is, for use as a management tool to reduce nest predation by corvids on critically endangered greater sage-grouse in Alberta), toxicology reference values were not required. Furthermore, the weight of evidence, under this qualitative approach, included consideration of the limited use pattern, restricted class designation of DRC-1339, low volume of product handled per year, and significant exposure mitigation measures.

[3] Health Canada (2024) *A Framework for Risk Assessment and Risk Management of Pest Control Products* – PMRA Guidance Document. April 12, 2024

PRD2025-12 also states the following: “In the future, if new uses, use patterns or exposure scenarios are proposed or identified, the acceptability of the existing toxicology database and the requirement for additional studies will be reconsidered.” In other words, should the applicant wish to amend the conditions of registration, such as increasing the amount of product handled or use of the product for purposes other than for the greater sage-grouse recovery program, the requirement for supporting toxicology data will be reconsidered.

3. Comment related to the reasons for not conducting a cancer risk assessment

The NGO commenter stated that Health Canada’s decision to not conduct a cancer risk assessment for 3-chloro-4-methylaniline hydrochloride on the basis of limited exposure to the pest control product and equivocal evidence of tumourigenicity is faulty as there is no reasonable certainty that there is no carcinogenic risk.

Health Canada response:

The designation of “equivocal” is used by Health Canada if the findings are ambiguous, not clearly attributable to treatment or where the overall weight of evidence supports a non-treatment-related etiology, despite some remaining uncertainty. In its evaluation of the available studies with 3-chloro-4-methylaniline hydrochloride, Health Canada concluded that the endometrial stromal polyps observed in female rats were equivocally related to treatment.

Health Canada performed an extensive review of the available data on endometrial stromal polyps, a benign lesion that is not uncommon in aging rats. Several factors were taken into consideration when reviewing the tumours. Body weights of the high-dose animals were decreased when compared to control animals and, based on the magnitude of the decrease, it is believed that the administered high-dose was approaching the maximum tolerated dose, suggesting that the polyps were observed at the dose level causing excessive stress on the animals, thus lowering concern for a primary carcinogenic effect. It was noted that there was an unusually low incidence of endometrial stromal polyps in the control group (0%) when compared to the historical control incidence (9.8%) that could have been related to the low number of control animals (20 controls versus 50 in each treatment group). The disparity between the number of animals per dose level could have contributed to the differences in the incidences of polyps observed at the different dose levels. The incidence of endometrial stromal polyps in the high-dose females (9/50, 18%) exceeded historical control values (28/284, 9.8%); however, while the Cochran-Armitage test indicated a statistically significant ($p = 0.018$) positive association between dosage and the incidence of endometrial stromal polyps, the Fisher exact test using Bonferroni criterion did not demonstrate statistical significance.

Overall, the weight of evidence suggested that the tumours were equivocally related to treatment, and in consideration of the quite limited exposure for the proposed use, it was concluded that there is a low level of concern for this lesion. Further, with respect to the cancer assessment for 3-chloro-4-methylaniline hydrochloride, since it was determined that a qualitative approach was appropriate for the single specific use request (that is, for use as a management tool to reduce nest predation by corvids on critically endangered greater sage-grouse in Alberta), and in consideration of the limited use pattern, restricted class designation of DRC-1339, low volume of product handled per year, and significant exposure mitigation measures, it was concluded that a cancer assessment was not necessary.

4. Comment related to the limitations in the long-term mouse and rat studies

The NGO commenter stated that the long-term mouse and rat studies had significant limitations and therefore could not be considered adequate for the determination of carcinogenic potential.

Health Canada response:

Health Canada acknowledges that the long-term studies in mice and rats are dated and have limitations according to current standards and relevant test guidelines. However, the studies were conducted by a reputable laboratory through a recognized testing program (that is, the National Cancer Institute of the National Institutes of Health (NIH) through the Carcinogenesis Testing Program) and followed an acceptable test protocol in place at the time of study conduct.

With respect to the human health exposure assessment for 3-chloro-4-methylaniline hydrochloride, since it was determined that a qualitative approach was appropriate for the single specific use request (that is, for use as a management tool to reduce nest predation by corvids on critically endangered greater sage-grouse in Alberta), toxicology reference values were not required, thereby eliminating the concern for the limitations in the available long-term studies for the purpose of this specific use. Furthermore, PRD2025-12 states the following: “In the future, if new uses, use patterns or exposure scenarios are proposed or identified, the acceptability of the existing toxicology database and the requirement for additional studies will be reconsidered.” In other words, should the applicant wish to amend the conditions of registration, such as increasing the amount of product handled or use of the product for purposes other than for the greater sage-grouse recovery program, the impact of the limitations in the available long-term studies will be reconsidered.

5. Comment related to the genotoxic potential of 3-chloro-4-methylaniline hydrochloride

The NGO commenter stated that the positive finding in the chromosome aberration study in the presence of metabolic activation is a serious concern.

Health Canada response:

Health Canada acknowledges the positive results in the in vitro chromosome aberration study in the presence of metabolic activation. Normally, an in vivo mutagenicity study would be required to further elucidate the mutagenic potential of a test substance; however, since it was determined that a qualitative approach was appropriate for the human health exposure assessment as the extensive risk mitigation measures in place would result in limited human exposure, an in-depth toxicology hazard identification/characterization was not necessary for this registration, and an in vivo mutagenicity study was not required.

6. Comment related to the potential for methemoglobin formation

The NGO commenter stated that Health Canada did not adequately address the potential for methemoglobin formation at levels relevant to occupational exposure scenarios.

Health Canada response:

With respect to the human health exposure assessment for 3-chloro-4-methylaniline hydrochloride, since it was determined that a qualitative approach was appropriate for the single specific use request (that is, for use as a management tool to reduce nest predation by corvids on critically endangered greater sage-grouse in Alberta), toxicology reference values were not required as the extensive risk mitigation measures in place would result in limited human exposure. Therefore, further clarification of the potential for methemoglobinemia was not required for this specific use.

7. Comment related to the use of surrogate data for the long-term studies

The NGO commenter stated that the reliance on data from long-term studies that use a surrogate substance (that is, 3-chloro-4-methylaniline) introduces an additional uncertainty.

Health Canada response:

In their reporting on the toxicology of 3-chloro-4-methylaniline, the National Institutes of Health (NIH) through the National Library of Medicine and PubChem indicate that 3-chloro-4-methylaniline hydrochloride is an associated chemical, indicating there are significant similarities between these compounds. Also of note is that 3-chloro-4-methylaniline had historically been used as an intermediate in the production of a dye used for treating materials such as wool and paper, and in light of an increased incidence of bladder cancer observed in workers of the dye manufacturing industry, the National Cancer Institute elected to conduct studies to assess the chronic toxicity and potential carcinogenicity of 3-chloro-4-methylaniline. Therefore, Health Canada concluded that 3-chloro-4-methylaniline was an acceptable surrogate for 3-chloro-4-methylaniline hydrochloride.

8. Comment relating to personal protective equipment (PPE) and compliance

The NGO commenter stated that the expectation of 100% compliance with such burdensome PPE requirements, particularly in remote field settings, is unrealistic and unquantified.

Health Canada response:

The Government of Alberta workers using DRC-1339 are trained in reading and following label instructions and in properly using personal protective equipment. The proper use of the product is monitored by Health Canada's Regulatory Operations and Enforcement Branch, which provides regulatory oversight for users handling a product regulated under the *Pest Control Products Act*. DRC-1339 is mixed/loaded and injected into eggs in a controlled laboratory environment where the required PPE includes coveralls over long-sleeved shirt, long pants, chemical-resistant (CR) gloves, socks, chemical-resistant footwear, protective eyewear (goggles or face shield) and a respirator. Government of Alberta workers handling the baited eggs in the field must wear a long-sleeved shirt, long pants, CR-gloves, socks and shoes. This single layer of PPE is typical when working in field environments and handling pest control products; therefore, it is not expected to be burdensome.

9. Comment relating to PPE and heat stress

The NGO commenter stated that wearing this level of PPE during spring/summer field work in sage-grouse habitat creates risk of heat-related illness.

Health Canada response:

The high level of PPE is required only for those mixing/loading and injecting the end-use product in a controlled laboratory environment. When handling the baited eggs in the field, the required PPE is only a single layer (long-sleeved shirt, long pants, CR-gloves, socks and shoes). This level of PPE is not considered to be a source of heat stress for workers in the field.

10. Comment relating to the lack of a quantitative human health exposure assessment

The NGO commenter expressed concern that a quantitative risk assessment was not required, stating that "no actual exposure assessment was conducted. This is not a scientifically based approach. The conclusion of acceptable risk is based solely on the assumption of perfect PPE compliance."

Health Canada response:

Health Canada has well-established, standardized, and scientifically-based, qualitative and quantitative approaches for conducting human health exposure assessments. These approaches are also aligned with international practices for evaluating exposure prior to characterizing risks. A qualitative approach is considered to be acceptable when mitigation measures are so restrictive that exposure is expected to be limited when used according to the legally binding label. Available risk mitigation and management options are further explained in the PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products. These options include, but are not limited to, label restrictions, personal protective equipment, marketing classification and engineering controls.

11. Comment relating to the corrosive properties of the product

The NGO commenter stated that the product is corrosive to eyes and skin, and accidental exposure could cause severe injury.

Health Canada response:

The product is corrosive to the eyes and skin, which is why trained workers must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and protective eyewear (goggles or face shield) when handling DRC-1339. Health Canada establishes PPE requirements for pest control products based on the approved use pattern and not accidental exposure.

Comments relating to the environmental assessment

12. Comment related to a requirement for proof of no harm

The NGO commenter stated that the scientific approach under the *Pest Control Products Act* requires the registrant to establish reasonable certainty that no harm to human health, future generations or the environment will result from the use of a pest control product and that the PMRA cannot rely on mitigation measures to establish a reasonable certainty of no harm.

Health Canada response:

Health Canada completed the environmental risk assessment according to the approach described in PMRA Guidance Document, Health Canada's Approach to Environmental Risk Assessment for Pest Control Products.[4] Health Canada considers the proposed conditions of use of a pest control product, including mitigation measures, when determining the acceptability of risk. DRC-1339 is a restricted product, with a very limited use pattern, to be used only by designated employees of Alberta Environment and Protected Areas to control corvids in relation to greater sage-grouse recovery. Risks to the environment were determined to be acceptable when considering the proposed use pattern, the conditions of use, the fate of 3-chloro-4-methylaniline hydrochloride in the environment and the protection goals for non-target species.

13. Comment related to environmental persistence

The NGO commenter stated that chlorinated aromatic compounds tend to be persistent and undergo complex environmental transformations, which contrasts with the PMRA's assessment that DRC-1339 is unstable in the environment and degrades rapidly.

Health Canada response:

Health Canada's environmental data requirements are based on the use pattern. The use of 3-chloro-4-methylaniline hydrochloride to control corvids in relation to greater sage-grouse recovery does not result in its application over a large area. Rather, 3-chloro-4-methylaniline hydrochloride is injected into hard-boiled eggs and placed in dummy nests. A maximum of 10 eggs are permitted per bait set, with a maximum of 18 eggs per baited site.

The following studies were reviewed to evaluate the fate of 3-chloro-4-methylaniline hydrochloride in the environment:

- A hydrolysis study;
- Two biotransformation in aerobic soil studies;
- An adsorption/desorption study; and,
- A soil column leaching study.

These studies show that 3-chloro-4-methylaniline hydrochloride rapidly dissipates in aerobic soil to form four major transformation products, carbon dioxide and unextracted residues. 3-Chloro-4-methylaniline hydrochloride and three of its transformation products were determined to be

[4] *Health Canada's Approach to Environmental Risk Assessment for Pest Control Products* – PMRA Guidance Document. September 20, 2023

non-persistent in the environment, with DT_{50} values of less than 6.1 days. The fourth transformation product, produced at a mean maximum of 10.6% applied radioactivity (AR), was classified as slightly persistent with a DT_{50} value of 24 days. High levels of unextracted residues were rapidly formed in the studies. The unextracted residues were determined to be irreversibly bound to the soil following multiple extractions with solvents of varying polarities as well as the use of a hot extraction.

Two documents were cited in the NGO's comment:

- PestSmart Australia (2006) DRC-1339 Information Sheet - "Is the use of DRC-1339 humane?"
- Frontiers in Microbiology (2015) - "Bacterial degradation of monocyclic aromatic amines."

The first document does not discuss the persistence of DRC-1339 and is not relevant to the points raised in this comment; however, the information related to ecotoxicity and risk to non-target species presented in the document is consistent with the information presented in PRD2025-12. The second study presents a review of the bacterial degradation pathways for monocyclic aromatic amines. It does not provide information on the persistence of 3-chloro-4-methylaniline hydrochloride in the environment and does not present new information that is relevant to the environmental assessment. The fate assessment in PRD2025-12 was based on environmental fate studies conducted with 3-chloro-4-methylaniline hydrochloride or DRC-1339 as the test item.

14. Comment related to persistence, bioaccumulation and cumulative environmental concerns

The NGO commenter considered annual use of less than 100 g per year to be continuing environmental loading of a persistent, toxic substance. The commenter expressed concern that the unextracted (bound) residues in soil could persist for years, could accumulate over time with annual application, may be slowly released over time and could have unknown ecological effects. They stated that the toxicity of the three unidentified transformation products is unknown, and that these should have been identified and assessed.

Health Canada response:

As noted in the response to Comment 13 above, the environmental fate data show that 3-chloro-4-methylaniline hydrochloride and its major transformation products will rapidly dissipate in the environment, and form residues in soil that are considered to be irreversibly bound. These residues were determined to be irreversibly bound to the soil following multiple extractions with solvents of varying polarities as well as the use of a hot extraction. As noted in the response to Comment 13, minimal amounts of the transformation products would be formed in the environment based on the proposed use pattern (<50 g/year).

DRC-1339 is not broadcast onto soil. It is injected into hard-boiled eggs and then placed in dummy nests, with a maximum of 10 eggs per bait set (equivalent to 200 mg a.i.), and a maximum of 18 eggs per site (equivalent to 3600 mg a.i.). The treated eggs are expected to be consumed, but in the event that they are not consumed, the eggs would decompose, and the 3-

chloro-4-methylaniline hydrochloride would be broken down by microorganisms. Very small amounts of DRC-1339 and/or its transformation products are expected to reach soil, and this would be very localized to the location of the bait set.

While there would be enough eggs treated with DRC-1339 at a bait site to poison non-target birds and mammals under 12 kg, as noted in PRD2025-12, the potential for toxicity at the bait sites will decrease as the eggs are consumed by animals or as they decompose. The small amounts of residues bound to soil that could be present at the sites are not expected to pose a concern to the environment, even if they are slowly released over time. Significant accumulation of bound residues at the bait sites from annual use is not expected.

15. Comment related to risks to the endangered swift fox

The NGO commenter stated that risk to the endangered swift fox should be sufficient grounds to deny the registration of DRC-1339. They also commented that Alberta Environment and Protected Areas has a conflict of interest because they are responsible for the protection of both species at risk (swift fox and greater sage-grouse).

Health Canada response:

DRC-1339 is not permitted to be used in a manner that endangers protected species. Alberta Environment and Protected Areas is responsible for the protection of both the swift fox and the greater sage-grouse in Alberta. This is not a conflict of interest. As an authority, they are best placed to understand how to use this product in accordance with the label, and in a manner that protects both of these species and which complies with the recovery strategies for both.

16. Comment related to primary and secondary poisoning of non-target animals

Commenters expressed concerns that DRC-1339 is an indiscriminate poison that will kill non-target animals, including species at risk, and will also kill the endangered greater sage-grouse. There were also concerns regarding ecosystem-level effects and that scavengers would be harmed by the carcasses of poisoned animals (secondary poisoning). A commenter also noted that tissue residues from poisoned corvids were not considered in the assessment.

Health Canada response:

3-Chloro-4-methylaniline hydrochloride is toxic to birds and mammals. When used to control corvids in relation to greater sage-grouse recovery, DRC-1339 is injected into hard-boiled chicken, turkey or duck eggs and deployed in greater sage-grouse habitat in Alberta during the spring breeding season to control corvids preying on greater sage-grouse nests. Animals that do not consume the egg baits will not be poisoned by 3-chloro-4-methylaniline hydrochloride. It should be noted that the greater sage-grouse diet consists of plants and insects. They are not expected to consume eggs and, therefore, will not be poisoned by the use of 3-chloro-4-methylaniline hydrochloride to control corvids.

Health Canada's protection goal for birds and mammals is population-level, with the exception of species at risk, which may be considered on an individual basis. For more information on Health Canada's environmental protection goals, please consult the PMRA Guidance Document, Health Canada's Approach to Environmental Risk Assessment for Pest Control Products. It is

acknowledged that individual non-target birds and mammals that consume the egg baits may be poisoned; however, population-level effects in common birds and mammals or destabilization of the ecosystem are not expected when 3-chloro-4-methylaniline hydrochloride is used in relation to greater sage-grouse recovery because the duration of use, size of the affected area and amount of DRC-1339 applied are very limited. Secondary poisoning of scavengers that consume poisoned carcasses is not expected to be a concern because 3-chloro-4-methylaniline hydrochloride is mostly metabolized and excreted by animals after ingestion, prior to death. It is possible that a predatory or scavenging animal could be poisoned by eating an animal that has consumed 3-chloro-4-methylaniline hydrochloride before the chemical has been metabolized; however, this secondary poisoning would not result in population-level effects for the reasons mentioned above. Given the limited duration of use, size of the affected area and amount of DRC-1339 applied, tissue residues from poisoned corvid carcasses would not change the outcome of the assessment.

As noted in PRD2025-12, when used according to label directions, there would be enough 3-chloro-4-methylaniline hydrochloride treated eggs at bait sites to cause toxic effects to the threatened swift fox, if the eggs are consumed. However, Alberta Environment and Protected Areas, which is responsible for the protection of both the greater sage-grouse and the swift fox in Alberta, has previously reported that wildlife cameras deployed at bait sites did not record any non-target animals, including swift fox, feeding on the egg baits. DRC-1339 is not permitted to be used in a manner that will endanger protected bird or mammal species.

The use of 3-chloro-4-methylaniline hydrochloride and DRC-1339 is restricted to designated employees of Alberta Environment and Protected Areas to control corvids in relation to greater sage-grouse recovery. Given this limited use, the environmental risks are considered to be acceptable when 3-chloro-4-methylaniline hydrochloride is used according to label directions in the context of a species at risk recovery program.

17. Comment related to the bird and mammal risk assessment

The NGO commenter disagreed with the bird and mammal risk assessment and stated that the PMRA is not protecting the environment from harm because it acknowledges that DRC-1339 is toxic to non-target birds and mammals. The commenter disagreed with the PMRA assumption that corvids are expected to be the main species exposed to DRC-1339 and that exposure of other species will be low. The commenter noted that the rodent studies reviewed for the health assessment found “equivocal evidence of tumourigenicity” as well as methemoglobinemia in rats, mice and rabbits following intraperitoneal or intravenous dosing, which were not considered in the environmental assessment. According to the commenter, the environmental risk assessment acknowledges significant risks to non-target species but concludes that the risks are acceptable in the context of endangered species recovery. They state that this is not scientifically or legally justified.

Health Canada response:

Health Canada uses a risk-based approach to regulating pesticides, as described in PMRA Guidance Document, Health Canada’s Approach to Environmental Risk Assessment for Pest Control Products, rather than a hazard-based approach.

Health Canada acknowledges that animals other than corvids may consume the DRC-1339-treated eggs; however, as noted in the response to Comment 16 above, population-level effects in common birds and mammals are not expected.

Alberta Environment and Protected Areas has identified corvids as the most significant nest predator of the greater sage-grouse in Alberta. Health Canada's assumption that corvids are expected to be the main species exposed to DRC-1339 is based on information from Alberta Environment and Protected Areas, an authority on this subject. If corvids are the main species preying on greater sage-grouse nests, they are also the most likely to consume the DRC-1339-treated eggs.

The bird and mammal risk assessment uses apical endpoints for survival, growth, reproduction and abundance. The endpoints for small, wild mammals considered in the environmental risk assessment are included in Table 3 of PRD2025-12. Seven endpoints were considered in the assessment for mammals, including the most sensitive endpoint affecting survival, growth, reproduction or abundance from the rodent studies reviewed for the health assessment.

18. Comment related to aquatic toxicity

The NGO commenter disagreed with the PMRA's conclusion that exposure of the aquatic environment to DRC-1339 is not expected. They noted that sage-grouse habitat in Alberta includes areas near wetlands and seasonal water bodies, and that the PMRA did not consider that rain or wash-off could occur even though spring is a period of snowmelt and rain, or that animals could transport the eggs into water.

Health Canada response:

As noted in the response to Comment 13 above, Health Canada considers the use pattern when determining the data requirements for the environmental risk assessment. DRC-1339 is not permitted to be used in water. When used to control corvids in greater sage-grouse habitat in Alberta, DRC-1339 is injected into hard-boiled eggs in a fumehood or secure outdoor space and then deployed into the terrestrial bait sites. Given that DRC-1339 will be injected into the yolk of each egg, rain and wash-off are not expected to be large factors in the movement of DRC-1339 in the environment. If the DRC-1339-treated eggs are not consumed, decomposition of the eggs and the active ingredient by microorganisms is expected to be the main pathway of dissipation.

Risk is based on both the dose (exposure) as well as the toxicity of a chemical. The most sensitive endpoint available for aquatic organisms is a 48-h EC_{50} of 0.079 mg a.i./L for *Daphnia magna*. The endpoints for other aquatic species are orders of magnitude higher, as shown in Table 3 of PRD2025-12. Health Canada applies uncertainty factors to endpoints to calculate effects metrics for use in environmental risk assessment, as described in section 3.3 of PMRA Guidance Document, Health Canada's Approach to Environmental Risk Assessment for Pest Control Products. An uncertainty factor of 2 is typically applied to acute endpoints for freshwater invertebrates. As such, the effects metric from *Daphnia magna* would be 0.0395 mg a.i./L (0.079 mg/L divided by 2). When considering Health Canada's standard assumptions for the aquatic risk assessment of a 1-ha, 80-cm deep waterbody to assess risks to freshwater invertebrates, it would take 878 eggs, each containing 2.5 mg a.i., to reach an estimated environmental concentration of 0.0396 mg a.i./L in the water, and exceed the level of concern of one for

Daphnia magna. A maximum of 18 eggs are permitted per bait site. Given the nature of the use, it is highly unlikely that DRC-1339 would enter aquatic systems at concentrations that would result in adverse effects, when used according to the label directions.

19. Comment related to prevention of environmental risk

The NGO commenter stated that corvids play an important ecological role, and that their removal from the ecosystem in an attempt to benefit another species does not promote biological diversity or protect the ecosystem. The removal of corvids from the ecosystem may have cascading effects that cannot be predicted.

Health Canada response:

The proposed use pattern is targeted and very limited in terms of duration, area and amount. 100 g annually is equivalent to 5000 treated eggs. The corvid species that overlap with greater sage-grouse territory (for example, crows, ravens and magpies) are common and abundant species, with secure populations. The amount of 3-chloro-4-methylaniline hydrochloride used per year is not sufficient to cause population-level effects in corvid species. Corvids that are removed by the use of 3-chloro-4-methylaniline hydrochloride in relation to greater sage-grouse recovery are expected to be replaced by breeding and migration from surrounding areas.

20. Comment related to the Toxic Substances Management Policy (TSMP) and the Canadian Environmental Protection Act (CEPA)

The NGO commenter stated that the TSMP assessment is incomplete and inadequate, and that DRC-1339 is clearly CEPA-toxic. They commented that the TSMP assessment ignored the formation of multiple transformation products of unknown toxicity and bioaccumulation potential, did not adequately characterize the unextracted residues and failed to address long-term environmental fate when DRC-1339 is used repeatedly at the same sites year after year. Additionally, the commenter noted that more relevant information could be obtained from tissue residue data from exposed corvids, which was not done. They also noted that any registered pesticide by definition is “predominantly anthropogenic”.

Health Canada response:

The TSMP is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. More information on the TSMP can be found on the Toxic Substances Management Policy on Canada.ca. An objective of the TSMP is the virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative (in other words, Track 1 substances). There are four criteria that must be met for a substance to be classified as Track 1.

1) Is the substance CEPA toxic or CEPA toxic equivalent?
2) Is the substance predominantly anthropogenic?
3) Is the substance persistent in environmental media?
4) Is the substance bioaccumulative?

Health Canada initially assumes that all pesticides are CEPA-toxic for the purpose of the TSMP assessment. Additionally, Health Canada considers that a substance is predominantly anthropogenic if its concentration in the environment is largely due to human activity rather than natural sources or releases. The TSMP assessment of 3-chloro-4-methylaniline hydrochloride and its transformation products is shown in Table 5 of PRD2025-12. 3-Chloro-4-methylaniline hydrochloride and its major transformation products (3-chloro-4-methyl-acetanilide and three unidentified compounds) were considered to be both CEPA toxic and predominantly anthropogenic for the TSMP assessment.

For persistence, the TSMP assessment considered persistence data from environmental fate studies for soil, and AOPWIN modelling for air. Persistence data for all four transformation products in soil were considered. AOPWIN modelling was conducted for 3-chloro-4-methylaniline hydrochloride and two of the major transformation products with known molecular structures; however, modelling for two of the major transformation products could not be conducted because their molecular structures are unknown. These unidentified transformation products were produced from the biotransformation of 3-chloro-4-methylaniline hydrochloride in aerobic soil at maximum mean concentrations of 10.5 and 21.1% AR, respectively. These transformation products were observed to dissipate rapidly in aerobic soil, and minimal amounts are expected to be formed in the environment based on the proposed use pattern (<50 g/year). As such, additional data were not required. Based on the available data, the persistence criterion was not met for 3-chloro-4-methylaniline hydrochloride or its transformation products.

The bioaccumulation criterion was assessed based on KOWWIN estimates of the log K_{ow} values for 3-chloro-4-methylaniline hydrochloride and two of its major transformation products. The estimated log K_{ow} of 2.27 for 3-chloro-4-methylaniline hydrochloride was conservatively used; however, empirical data show that its log K_{ow} ranges from 0.67 to 1.39, as reported in Section 1.2 of PRD2025-12. As with the AOPWIN modelling discussed above, KOWWIN modelling for two of the unidentified major transformation products could not be conducted as their molecular structures are unknown. Based on the molecular structures and physical properties of 3-chloro-4-methylaniline hydrochloride and the other two transformation products, there is no indication that bioaccumulation would be a concern for the unknown transformation products. As noted above, minimal amounts of these substances would be formed in the environment based on the proposed use pattern. The bioaccumulation criterion was not met for 3-chloro-4-methylaniline hydrochloride or its transformation products.

3-Chloro-4-methylaniline hydrochloride and its four major transformation products do not meet all four of the TSMP Track 1 criteria. Tissue residue data from exposed corvids would not be useful to inform the TSMP assessment, as it would not provide information on persistence or bioaccumulation.

The TSMP assessment is conducted based on the active ingredient and the individual transformation products. The bound residues were not considered in the TSMP assessment because their composition is unknown and may represent a mixture of the parent and transformation products, which were assessed individually.

Comments relating to the value assessment

21. Comments on the efficacy of predator control programs and the efficiency of predator control for protecting endangered species

Commenters expressed concerns over the effectiveness of the program, that controlling corvids does not address the root cause of the sage-grouse decline, and that it risks destabilizing ecosystems.

Health Canada response:

Management programs, including the Alberta corvid control program to assist in greater sage-grouse recovery, do not fall under the *Pest Control Products Act* and Regulations. Therefore, while the value assessment of pest control products takes into consideration the value and efficacy of pest control products, which includes how the proposed use can contribute as a tool amongst others in an integrated pest management program, it does not assess the overall performance of management programs.

22. Comments on the type of information reviewed as part of the value assessment

Commenters expressed concern about the type of information that was reviewed in the value assessment.

Health Canada response:

Details on Health Canada's approach to assessing the value of pest control products and the types of information which may be submitted to support the value of pest control products can be found in the PMRA Guidance Document, Value Assessment of Pest Control Products,[5] which can be accessed on the Canada.ca website. Health Canada's value approach for pest control products considers efficacy, effects on host crops or use sites, social and economic impact and health, safety and environmental benefits. This approach is characterized by flexibility in the type of information that can be provided by applicants and uses a weight of evidence approach to consider all information provided to support the value assessment. Applicants may provide use history, results of research trials, scientific rationales or published information, as appropriate. The intent is to assess the overall value of the product or new use by considering product performance as well as the benefits it provides to users. A combination of some or all of these types of information may be used to support the value of a pest control product.

23. Comment on the lack of discussion on the health, safety and environmental benefits and social and economic impact of the product

The NGO commenter expressed concern that there was no discussion on the health, safety and environmental benefits and social and economic impact under the value assessment for DRC-1339.

[5] Health Canada (2022) *Value Assessment of Pest Control Products* – PMRA Guidance Document. March 18, 2022

Health Canada response:

As part of the weight of evidence to support the value of DRC-1339, Health Canada's value review considered the following:

Social and economic impacts: The use of DRC-1339 as a management tool to reduce corvid predation on critically endangered greater sage-grouse (*Centrocercus urophasianus*) has demonstrated value with an established history of use in Canada as tool for protecting this endangered species from extirpation in Canada. Greater sage-grouse was listed as endangered in Alberta in June 2000 and an Emergency Protection Order for greater sage-grouse has been in effect since 2014. Corvid nest predation was identified as a key risk factor in greater sage-grouse survival, with over 63% of monitored greater sage-grouse nests depredated by corvids in 2010–2013. Without avian predator control, it is expected that greater sage-grouse would be extirpated from Alberta within 3–5 years.

Health, safety and environmental benefits: Protection of critically endangered greater sage-grouse populations has the environmental benefit of ensuring the continuation of this species in its native habitat. DRC-1339 has value as a tool to aid in the management of greater sage-grouse egg predation.

24. Comment on the lack of quantitative efficacy data

The NGO commenter expressed concern that the value assessment did not include a review of quantitative efficacy data on the impact of a DRC-1339 corvid control program in ensuring greater sage-grouse nesting success.

Health Canada response:

A large number of scientific studies with quantitative data on the efficacy of DRC-1339 under various use scenarios, including the use pattern proposed for registration, were provided by the applicant and reviewed by Health Canada. These data were sufficient to establish that egg baits treated according to the DRC-1339 label would control corvids that consume the baits. While quantitative efficacy data from the emergency registration for the use of DRC-1339 in Alberta were not available, the use of this product from over 10 years of annual emergency registrations provided a qualitative history of use in support of the value of the registration of DRC-1339 as a tool for management of corvids in a program for protecting critically endangered greater sage-grouse populations.

25. Comment on the lack of discussion on non-chemical alternatives

The NGO commenter expressed concern that non-chemical alternatives to corvid control were not discussed as part of the value review.

Health Canada response:

As part of the weight of evidence for the value of DRC-1339, several non-chemical alternatives were considered under the assessment of compatibility of DRC-1339 with current management practices for corvids. Non-chemical alternatives included physical control, such as shooting, and cultural control measures, such as reducing corvid roosting sites. Egg-baiting with DRC-1339 is

compatible with such control measures. No alternative pest control products are registered for this use. A lack of alternative chemical or non-chemical control products adds additional weight of evidence to support the overall value of a pest control product. However, the existence of alternatives does not detract from the value of the product, which must still establish value through weight of evidence of submitted value information.

26. Comment relating to DRC-1339 being banned in other countries

Commenters from the public stated that the use of DRC-1339 in Canada should not be expanded because it has been banned in other countries.

Health Canada response:

The use of 3-chloro-4-methylaniline hydrochloride to control the rook (*Corvus frugilegus*) population is banned in Hungary; however, this use was much more widespread than, and is not comparable to, the proposed restricted use of 3-chloro-4-methylaniline hydrochloride in Canada. Health Canada is unaware of this active ingredient being banned by any other countries.

PRD2025-12 proposed registration of DRC-1339 Technical and DRC-1339, containing the active ingredient 3-chloro-4-methylaniline hydrochloride, for control of corvids in relation to greater sage-grouse recovery. The product would be registered as a restricted class product and its storage, use and handling can only be done by designated employees of Alberta Environment and Protected Areas. It would only be used during the spring breeding season. This pesticide has had an emergency registration for the same use since 2014. As such, this registration is not an expansion of the use of 3-chloro-4-methylaniline hydrochloride in Canada. 3-Chloro-4-methylaniline hydrochloride is also a restricted pest control product that is used in the United States and New Zealand.

27. Comment related to corvids as a pest and the PMRA's jurisdiction over DRC-1339

The NGO commenter stated that corvids in sage-grouse habitat do not meet the definition of a pest under the *Pest Control Products Act*. The commenter claims that there is a distinction between pest control and wildlife management and the proposed use of DRC-1339 falls outside of the PMRA's jurisdiction.

Health Canada response:

Health Canada is not responsible for determining whether corvid control should be used to support greater sage-grouse recovery. Decisions about whether predator management is required are made by wildlife authorities under the *Species At Risk Act* and provincial wildlife legislation. Health Canada's role is different. Under the *Pest Control Products Act*, Health Canada must assess the health and environmental risks and value of any product proposed for pest control use in Canada, including certain products used in wildlife or conservation settings.

Under the *Pest Control Products Act*, a pest includes any organism that is injurious, noxious or troublesome, whether directly or indirectly. Health Canada may register products for wildlife management or conservation when a species meets this definition in a particular context. In relation to the sage-grouse recovery effort, wildlife authorities have identified corvid predation as a major threat to the survival of the greater sage-grouse, which could disappear from Alberta

within 3 to 5 years without predator control. DRC-1339 is a restricted-use product registered as an option for controlling corvids in greater sage-grouse habitat, and it is currently the only corvid control product available in Canada.

Health Canada uses a rigorous risk assessment process to evaluate health risks, environmental risks, and product value. For 3-chloro-4-methylaniline hydrochloride and DRC-1339, Health Canada assessed the available scientific information and found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

Comment in support of this registration

An individual associated with farmers/growers expressed support for the registration of DRC-1339, suggesting future expansion of the use pattern to include control of other bird species that are nuisance pests on farms.

Other information

The relevant confidential test data on which the decision is based (as referenced in PRD2025-12, *3-Chloro-4-methylaniline hydrochloride and DRC-1339*) are available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

Any person may file a notice of objection,[6] which must be based on scientific grounds, regarding this registration decision on 3-chloro-4-methylaniline hydrochloride and DRC-1339 within 60 days from the date of publication of this Registration Decision through the Public Engagement Portal (Public Engagement Portal forms – Notice of Objection). The request for reconsideration must include the Notice of Objection form, the scientific explanation of the objection and the supporting scientific evidence in possession of the requestor that would not already be in the PMRA's possession or cite specific PMRA documentation they wish to rely on as supporting evidence (for example, scientific reports) in the form of electronic copies of cited references. Each of the references provided or cited must be clearly associated with the objection it supports. Failure to provide a complete package may result in the Notice of Objection being considered ineligible for further consideration by the PMRA. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Canada.ca website or contact the PMRA's Pest Management Information Service.

[6] As per subsection 35(1) of the *Pest Control Products Act.*

Evaluation approach

Legislative framework

The Minister of Health's primary objective under the *Pest Control Products Act* subsection 4(1) is to prevent unacceptable risks to individuals and the environment from the use of pest control products.

As noted in the preamble of the Act, it is in the national interest that the attainment of the objectives of the federal regulatory system continue to be pursued through a scientifically-based national registration system that addresses risks to human health, the environment and value both before and after registration and applies to the regulation of pest control products throughout Canada; and that pest control products with acceptable risk and value be registered for use only if it is shown that their use would be efficacious and if there is acceptable risk to human health and the environment, taking into account the conditions of registration.

For the purposes of the Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions of registration as per subsection 2(2) of the *Pest Control Products Act*.

Risk for the human health and environment, and value are defined under the Act subsection 2(1) as follows:

> **Health risk**, in respect of a pest control product, means the possibility of harm to human health resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.
>
> **Environmental risk**, in respect of a pest control product, means the possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.
>
> **Value**, in respect of a pest control product, means the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.

When evaluating the health and environmental risks of a pesticide and determining whether those risks are acceptable, subsection 19(2) of the *Pest Control Products Act* requires Health Canada to apply a scientifically-based approach. The science-based approach to assessing pesticides considers both the toxicity and the level of exposure of a pesticide in order to fully characterize risk.

Pre-market assessments are based on a required set of scientific data that must be provided by the applicants for pesticide registrations. Additional information from published scientific reports, other government departments and international regulatory agencies are also considered.[7]

Risk and value assessment framework

Health Canada uses a comprehensive body of modern scientific methods and evidence to determine the nature as well as the magnitude of potential risks posed by pesticides. This approach allows for the protection of human health and the environment through the application of appropriate and effective risk management strategies, consistent with the purpose described in the preambular text set out above.

Health Canada's approach to risk and value assessment is outlined in A Framework for Risk Assessment and Risk Management of Pest Control Products.[8] A high-level overview is provided below.

i) Assessing potential health risks

With respect to the evaluation and management of potential health risks, Health Canada's risk assessments follow a structured, predictable process that is consistent with international approaches and the Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks.[9]

The evaluation of potential health risks begins with a consideration of the toxicological profile of a pesticide to establish reference doses at which no adverse effect is expected and against which the expected exposure is assessed. This includes, where appropriate, the use of uncertainty (protection) factors to provide additional protection that accounts for the variation in sensitivity among members of human population and the uncertainty in extrapolating animal test data to humans. Under certain conditions, the *Pest Control Products Act* requires the use of another factor to provide additional protection to pregnant women, infants, and children. Other uncertainty factors, such as a database deficiency factor, are considered in specific cases. More details related to the application of the uncertainty factors are provided in SPN2008-01.[10]

Assessments estimate potential health risks to defined populations[11] under specific exposure conditions. They are conducted in the context of the proposed or registered conditions of use, such as the use of a pesticide on a particular field crop using specified application rates, methods and equipment. Potential exposure scenarios consider exposures during and after application of the pesticide in occupational or residential settings, food and drinking water exposure, or exposure when interacting with treated pets.

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7 Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*.

8 PMRA Guidance Document*, A Framework for Risk Assessment and Risk Management of Pest Control Products*.

9 Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks - August 1, 2000.

10 Science Policy Note: *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*.

11 Consideration of Sex and Gender in Pesticide Risk Assessment.

Also considered are the anticipated durations (short-, intermediate- or long-term) and routes of exposure (oral, inhalation, or skin contact). In addition, an assessment of health risks must consider available information on aggregate exposure and cumulative effects.

ii) Assessing risks to the environment

With respect to the evaluation of environmental risks, Health Canada's environmental risk assessments follow a structured, tiered approach to determine the likelihood that exposure to a pesticide can cause adverse effects on individual organisms, populations, or ecological systems. This involves screening assessments starting with simple methods, conservative exposure scenarios and sensitive toxicity effects metrics, then moving on, where required, to more refined assessments that can include exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods.

The environmental assessment considers both the exposure (environmental fate, chemistry, and behaviour, along with the application rates and methods) and hazard (toxic effects on organisms) of a pesticide. The exposure assessment examines the movement of the pesticide in soil, water, sediments and air, as well as the potential for uptake by plants or animals and transfer through the food web. The possibility for the pesticide to move into sensitive environmental compartments such as groundwater or lakes and rivers, as well as the potential for atmospheric transport, is also examined. The hazard assessment examines effects on a large number of internationally recognized indicator species of plants and animals (terrestrial organisms include invertebrates such as bees, beneficial arthropods, and earthworms, birds, mammals, plants; aquatic organisms include invertebrates, amphibians, fish, plants and algae), and includes considering effects on biodiversity and the food chain. Acute and chronic effects endpoints are derived from laboratory and field studies that characterize the toxic response and the dose–effect relationship of the pesticide.

The characterization of environmental risk requires the integration of information on environmental exposure and effects to identify which, if any, organisms or environmental compartments may be at risk, as well as any uncertainties in characterizing the risk.

iii) Value assessment

Value assessments consist of two components: an assessment of the performance of a pest control product and its benefits.

Assessing pesticide performance involves an evaluation of the pesticide's efficacy in controlling the target pest and the potential for the pesticide to damage host crops or use sites. Where the efficacy of a pesticide is acceptable, the assessment serves to establish appropriate label claims and directions and an application rate (or rate range) that is effective without being excessive, and with no unacceptable damage to the use site or host organism/crop (and subsequent hosts or crops) under normal use conditions.

In many cases, proof of performance alone is sufficient to establish the value of the pesticide, so that an in-depth or extensive evaluation of benefits may not be required. However, a more thorough assessment of benefits may be undertaken in particular cases where performance alone does not sufficiently demonstrate value, or while developing risk management options.

Risk management

The outcomes of the assessments of risks to human health and the environment, and the assessment of value, form the basis for identifying risk management strategies. These include appropriate risk mitigation measures and are a key part of decision-making on whether health and environmental risks are acceptable. The development of risk management strategies take place within the context of the pesticide's conditions of registration. Conditions can relate to, among other things, the specific use (for example, application rates, timing and frequency of application, and method of application), personal protective equipment, pre-harvest intervals, restricted-entry intervals, buffer zones, spray drift and runoff mitigation measures, handling, manufacture, storage or distribution of a pesticide. If feasible conditions of use that have acceptable risk and value cannot be identified, the pesticide use will not be eligible for registration.

The selected risk management strategy is then implemented as part of the registration decision. The pesticide registration conditions include legally-binding use directions on the label. Any use in contravention of the label or other specified conditions is illegal under the *Pest Control Products Act*.

Following a decision, continuous oversight activities such as post-market assessments, monitoring and surveillance, including incident reporting, all play an essential role to help ensure the continued acceptability of risks and value of registered pesticides.

List of abbreviations

%	percent
a.i.	active ingredient
AOPWIN	Atmospheric Oxidation Estimation Program for Windows
AR	applied radioactivity
CEPA	*Canadian Environmental Protection Act*
CR	chemical-resistant
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
EC_{50}	effective concentration on 50% of the population
g	gram(s)
ha	hectare(s)
K_{ow}	octanol-water partition coefficient
KOWWIN	Octanol-water Partition Coefficient Estimation Program for Windows
L	litre(s)
mg	milligram(s)
NGO	non-governmental organization
NIH	National Institutes of Health
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
TSMP	Toxic Substances Management Policy