

**Subject:** Chemistry Science Advisory Council (ChemSAC) Meeting Minutes

**Meeting Date:** July-13-2022

## **Chlorophacinone and Diphacinone: Further Food/Non-Food Considerations.**

### **Background**

Chlorophacinone and diphacinone can be formulated into, among others, loose meal bait and applied above-ground as a spot or broadcast (including scatter and aerial) treatment, as well as a below-ground (in-burrow) treatment via a drilled or tapped pipe. Application sites include some cropped areas such as orchards, groves, vineyards, alfalfa, rangeland/pastureland, and fallow land. These loose meal bait formulations are typically comprised of a rodent bait such as rolled oats or rolled wheat treated with the compound and a colorant agent (for visibility of treated areas and of bait acceptance).

The recent ChemSAC (ChemSAC Minutes 04/06/2022) concluded that loose meal bait applications of the active ingredients chlorophacinone and diphacinone as above-ground scatter/bait or below-ground to an agricultural cropped area applied during dormant periods are unlikely to result in residues occurring within food commodities and can therefore be considered non-food uses. These conclusions were based on a weight-of-evidence determination including the fate/physiochemical properties of the active ingredients, and that the following label restrictions are applied for applicable product labels with agricultural areas (cropped areas). Specific labeling recommendations from the 04/06/2022 ChemSAC decision were:

- Above-ground application of loose meal bait formulation of chlorophacinone/diphacinone applied as a scatter/spot treatment around an agricultural cropped area may be considered non-food with the following label restrictions, (i) applications cannot be made directly to food or feed crops; (ii) the application can only be made during the non-growth period of the target crop; and (iii) application is made along fence lines, border areas, and buffer strips adjacent to target crops.
- Below-ground or in-burrow use of chlorophacinone and diphacinone applied in an agricultural cropped area may be considered non-food with the following label restrictions: (i) applications must be made below-ground into the main run of the burrow; (ii) the application is only made during the non-growth period of the target crop.

### **Current ChemSAC Issues**

The Pesticide Re-evaluation Division (PRD) is seeking further guidance and clarification on several aspects of chlorophacinone/diphacinone (C/D) labeling and use as C/D labels are inconsistent. To provide context for the questions being posed to ChemSAC, a survey of C/D labels was made so that examples of specific label language, relevant to the respective charge question, can be presented. The presentation of existing label language is for context only. This consultation to ChemSAC is to determine the committee's recommendation for appropriate labeling while considering:

- (i) There is no residue data generated with chlorophacinone/diphacinone, and

- (ii) Field uses (e.g., uses in cropped areas, rangeland/pastureland, fallow land) are important uses for these compounds and so there is a desire to maintain them to the extent possible.

## **Questions**

### **1) Chlorphacinone/Diphacinone (C/D) Use on Rangeland and Pastureland**

As noted above, the 04/06/2022 ChemSAC decision was made with respect to C/D application to cropped land. While pastureland/rangeland is represented by crop group 17, it was not specifically considered in the 04/06/2022 ChemSAC discussion. PRD is seeking clarification on the appropriate restrictions for C/D applications to pastureland/rangeland to maintain nonfood use status. This question has been split into the following considerations:

- 1a) Bait Placement - What restriction to bait placement is appropriate for this use to be considered a nonfood use?
- 1b) Pre-grazing/feeding restriction - What pre-grazing/feeding restriction is appropriate to be considered a nonfood use?
- 1c) Timing - What restriction to application timing is appropriate to be considered nonfood use?

#### **1a) Bait Placement - Regarding bait placement for C/D labels for use on rangeland/pastureland to be considered nonfood use.**

Several existing C/D labels permit application to rangeland/pastureland but do not specify that applications must be made below-ground (e.g., EPA Reg. Nos. 7173-305; 36029-17; -20, and -24). Example language from these labels includes:

- *This product may not be broadcast.*
- *On rangeland, make application only by spot baiting or bait station.*

However, several existing C/D labels do require application to rangeland/pastureland be made underground only (e.g., 7173-244; 7173-286, 72500-9 and others). Example language from these labels includes:

- *Do not apply bait above-ground.*
- *Remove or bury any bait spilled on the ground during application.*

#### **To be considered a nonfood use, does ChemSAC recommend that C/D applications to rangeland/pastureland be restricted to below-ground applications only?**

The ChemSAC concludes that C/D applications to rangeland/pastureland are to be restricted to below-ground use because: (i) given the lack of available residue data, below-ground applications are less likely to result in potential residues in animal feed items due to the lack of potential contact with the feed crop; and (ii) most existing C/D labels for use on rangeland/pastureland are already restricted to below-ground applications.

The ChemSAC concludes that all C/D labels for rangeland/pastureland uses be revised for consistency. The use of a tamper resistant bait station is not directly addressed for rangeland/pastureland. The use of tamper resistant bait stations on rangeland/pastureland would still allow classification as a non-food use.

1b) Pre-grazing/feeding restrictions - Regarding grazing restrictions specified on C/D labels for use on rangeland/pastureland to be considered nonfood use.

Several C/D labels for use on rangeland/pastureland provide specific pre-grazing restrictions (e.g., EPA Reg. Nos. 7173-242; - 286; -303, 72500-22; -27). Example of language from these labels includes:

- *Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above-ground.*

One C/D label (EPA Reg. No. 7173-242) which is not labeled for use on rangeland/pastureland but on orchard sites, included the following grazing restrictions:

- *Do not allow animals to graze in treated areas.*
- *Do not use hay cut after application for feed or bedding.*

**To be considered a nonfood use, does ChemSAC recommend a grazing/feeding restriction for C/D labels that specify uses on range/pastureland? If so, does ChemSAC believe a one-year grazing/feeding interval or restriction is recommended? Based on the 04/06/2022 ChemSAC minutes, could the restriction be reduced?**

The ChemSAC concludes that if C/D applications to rangeland/pastureland are restricted to below-ground and/or tamper resistant bait station applications, then the applications are not likely to result in residues in animal feed items due to the lack of crop contact. As such, there would be no anticipated residues for livestock feeding on rangeland/pastureland that was previously treated following the proposed application restrictions. Based on these considerations, a grazing/feeding interval and/or restriction would not be necessary. Moreover, feeding restrictions to rangeland/pastureland are not considered practical. Therefore, the ChemSAC does not recommend a grazing/feeding interval for rangeland/pasturelands.

1c) Timing - Regarding application timing restrictions for C/D labels applied to rangeland/pastureland to be considered nonfood use.

Several C/D labels (e.g., EPA Reg. Nos. 7173-286, 72500-22, 72500-27) with uses on rangeland/pastureland specify an application timing. Example of language from these labels includes:

- *Apply between October 1 and March 15 of the following year when animals will most readily take the grain bait.*

**If recommendations are made for bait placement, and a grazing/feeding interval, does ChemSAC agree that C/D applications to rangeland/pastureland do NOT need to have**

**specific restrictions with respect to application timing to be considered a nonfood use?**

The ChemSAC does not recommend restricting the C/D application timing for rangeland/pastureland use because residues are not likely to result in animal feed items due to lack of contact (below ground application).

**2) Broadcast applications of C/D to cropped areas**

Some C/D labels (e.g., EPA Reg. Nos. 61282-63, 12455-136) permit broadcast applications to cropped areas (although most labels prohibit broadcast applications to cropped areas).

**To be considered nonfood use to cropped areas, does ChemSAC agree that broadcast applications should have the same restrictions enumerated in the 04/06/2022 ChemSAC recommendations for spot and scatter bait applications?**

The ChemSAC concludes that C/D labels are not clear as to the type of broadcast applications (hand-broadcast or mechanical broadcast). The ChemSAC recommends that broadcast applications to cropped areas be permitted only when performed according to the previous ChemSAC recommendations, (i) applications are not made directly to food or feed crops; (ii) the applications are made only during the non-growth period of the target crop; and (iii) application is made along fence lines, border areas, and buffer strips adjacent to target crops.

**3) Aerial broadcast applications of C/D to cropped areas**

Certain C/D labels (e.g., EPA Reg. No. 12455-136, 61282-45, 61282-63) permit aerial applications to orchard crops (e.g., bearing and non-bearing fruit tree orchards, nut orchards, Christmas tree farms, commercial nurseries, and tree plantations). However, per the labels, aerial applications to orchard crops are only permitted in specific states and have an application timing restriction (e.g., after fall harvest and before new spring growth). C/D labels (e.g., 12455-147, 56228-35) also specify aerial applications associated with USDA managed rodent eradication program uses.

**To be considered a nonfood use to cropped areas, does ChemSAC recommend that aerial applications of C/D directly to a cropped area (e.g., dormant orchards) be prohibited?**

The ChemSAC concludes that the currently permitted aerial applications directly to a cropped area (e.g., dormant orchards) not to the perimeter/adjacent to target crops would be contrary to the ChemSAC decision of 04/06/2022. Unless there is residue data to demonstrate that there would be no residues resulting from application during the dormant period, the use for direct applications to crops is prohibited.

**If aerial applications are made according to the 04/06/2022 ChemSAC recommendations for above-ground applications, does ChemSAC agree this would still be considered a nonfood use?**

The ChemSAC would not consider this a non-food use since it is unlikely that direct aerial applications would be made following the restrictions for above-ground applications. It does not

seem practical based on the equipment type.

### **Does ChemSAC agree that aerial applications for rodent eradication programs should continue to be permitted?**

The ChemSAC concludes that no information about the rodent eradication program is provided in the ChemSAC proposal. The ChemSAC notes that if rodent eradication programs target areas not associated with food/feed crops, then these applications would not be considered for dietary exposure and risk assessment. However, further consideration for whether these uses should continue to be permitted, is a bit broad for the ChemSAC since other risk factors such as occupational handler and post-app are taken in to consideration when making this decision.

#### **4) Defining “dormant” on C/D labels**

For C/D labels that do specify an application timing, there is inconsistency in how/whether the dormant period is defined. Given the ChemSAC decision of 04/06/2022, PRD is requesting additional ChemSAC guidance on the term “dormant” and/or “non-growth period”. Example C/D label language characterizing “dormant period” includes:

- *Apply only after fall harvest (including drops), before new spring growth and when no rain or snow is expected for three consecutive days.*
- *Apply between October 1 and March 15 of the following year when animals will most readily take the grain bait.*
- *Orchards, groves, and vineyards: only after harvest and during the dormant period, not after tree and vine growth resumes in spring.*

### **Does ChemSAC agree that the terms “dormant period” and “non-growth period” (when referring to application to a target cropped area) are interchangeable?**

### **Does ChemSAC agree that no specific recommendation should be made to define or characterize either term?**

The ChemSAC concludes that the terms “dormant period” and “non-growth period” could be used interchangeably and does not recommend any specific language to define or characterize the “dormant period” of a target cropped area. This would provide adequate flexibility in the label language to account for variations in these periods across crop types. In addition, at a minimum, the term “dormant period” or “non-growth period” should be clearly indicated in the directions for use for C/D products being applied to cropped areas; and further characterization is at the discretion of the risk manager/registrant.

#### **5) Applications to Non-Bearing Crops**

C/D labels permit application to non-bearing crops. PRD seeks clarification from ChemSAC on any specific application restrictions that should be required for these uses to retain a nonfood use status.

**Does ChemSAC agree application of C/D to non-bearing crops is considered a nonfood use provided the label contains a restriction for harvesting food/feed from that crop within 1 year of application?**

The ChemSAC concludes that non-bearing crops are considered nonfood uses provided the label contains a restriction for harvesting food/feed from that crop within 1 year of application (as stated in guideline 860.1000).

**ChemSAC Conclusions**

The ChemSAC concluded that the chlorphacinone/diphacinone non-food determination of agricultural cropped area specified in the ChemSAC Minutes 04/06/2022 does not apply to rangeland and pastureland. The ChemSAC concludes rangeland and pastureland are non-food uses when applied below-ground only. The ChemSAC provided further information for use patterns and parameters to clarify food/non-food determinations.

**Summary of ChemSAC Labeling Recommendations for Chlorophacinone/Diphacinone**

- Above-ground application of loose meal bait formulation of chlorophacinone/diphacinone applied as a scatter/spot or broadcast treatment around an agricultural cropped area may be considered non-food with the following label restrictions, (i) applications cannot be made directly to food or feed crops; (ii) the application can only be made during the non-growth period of the target crop; and (iii) application is made along fence lines, border areas, and buffer strips adjacent to target crops.
- Below-ground or in-burrow use of chlorophacinone and diphacinone applied in an agricultural cropped area may be considered non-food with the following label restrictions: (i) applications must be made below-ground into the main run of the burrow; (ii) the application is only made during the non-growth period of the target crop.
- Application of chlorophacinone/diphacinone to rangeland/pastureland must be below-ground.

The conclusions of these minutes clarify and further characterize chlorophacinone/diphacinone food/non-food determinations presented in the 04/06/2022 ChemSAC meeting minutes.

<b>Item</b>	<b>Response for Database</b>
Meeting Date	07/13/2022
Presenter	Meheret Negussie
Chemical	Chlorophacinone and Diphacinone
Title	Chlorophacinone and Diphacinone: Further Food/Non-Food Considerations/Additional PRD Questions.
Generic or Chemical Specific	Chemical Specific
Topic/Subject	Food/Non-food use determination
Guideline No.	NA

Crop Group/Livestock	NA
Crop/Livestock	NA
Commodity	NA
Publicly Releasable	Yes
Precedent Setting	No
IR-4 Item	No
PMRA Item	No