Standard Operating Procedure (SOP)

Science Advisory Council for Exposure (ExpoSAC)
Health Effects Division (HED)
Office of Pesticide Programs (OPP)

Policy Number:	14.1
Regarding:	Standard Operating Procedures (SOPs) for Seed Treatment
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I. INTRODUCTION

Treated seed is defined as seed that is given an application of pesticide to reduce, control or repel disease organisms, insects, or other pests that attack seed. This definition includes control of pests while the seed is in storage and after planting. Seeds commonly treated are corn, small grains or cereals (barley, oats, rye, wheat, and rice), sorghum, millets, soybeans, sugar beets, sunflowers, cotton, and flax; however, seeds for other crops (e.g., vegetable seeds) are also treated and are covered by this policy. Seed treatment pesticides are applied as either dusts, slurries, or liquids.

The potential for exposure from seed treatment can be divided into two main categories: treating seed and loading/planting treated seed. Within the treating seed category, potential exposure scenarios can include mixing, loading, applying formulations; packaging of treated seed (for commercial seed treatment only); and other activities, such as cleaning and calibrating treatment equipment. Within the loading/planting treated seed category, potential exposure includes loading of the treated seed into the planter and planting of the treated seed.

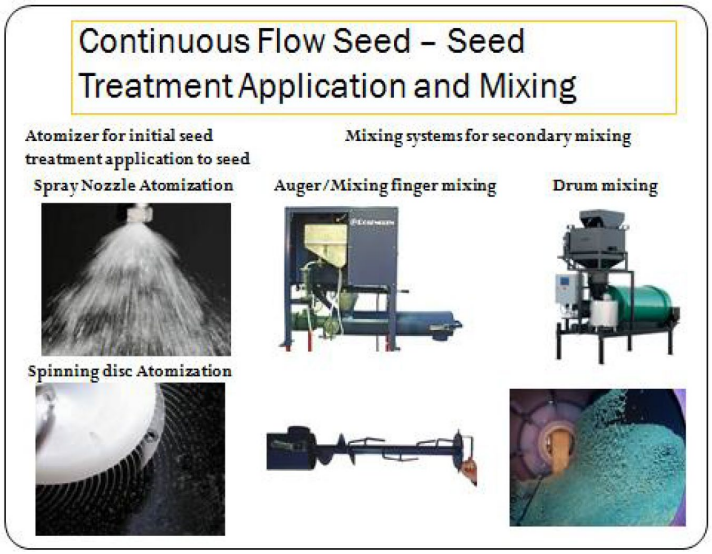
This seed treatment standard operation procedure (SOP) contains all known scenarios associated with commercial and on-farm seed treatment, as well as planting of treated seed. It is important to note what scenarios and activities are not covered by this policy. Specifically, certain crops are not produced from seed, for example nursery and floriculture production. Similarly, certain perennial crops are not grown from seed, like trees and shrubs. The assessment of loading/planting seed only pertains to treated seed and does not cover treating or planting transplants.

There are multiple venues for treating seeds, including large commercial companies, smaller downstream companies, and local on-farm businesses. Commercial seed treatment companies are seed producers that own or license their own seed lines and provide seed enhancement services in addition to seed treatment. Downstream seed treatment companies obtain cleaned and ready-for-planting processed seed from other sources such as seed producers and growers. These companies include retailers, distributors, and agricultural cooperatives. On-farm businesses treat batches locally on a per order basis. For additional clarification and definitions of the various terminologies used in seed treatment practices, see the glossary in ExpoSAC Policy 15.

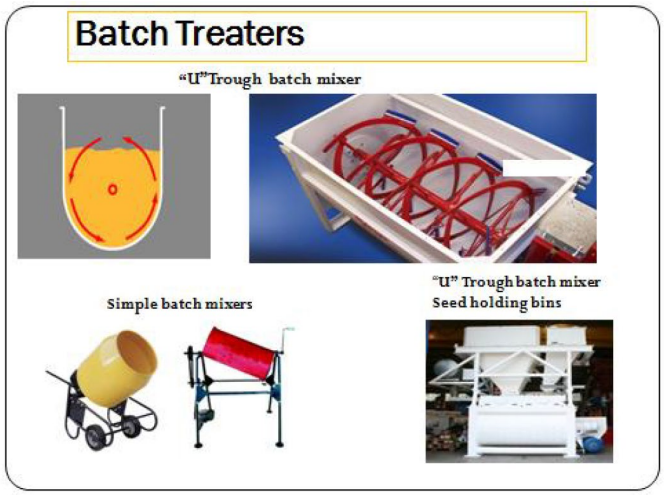
Commercial seed treatment can involve three different seed treater types:

1. Continuous flow treaters which treat a steady flow of untreated seed with the seed treatment product (photos copied from AHETF 2014[1])

[1] Agricultural Handler Exposure Scenario Monograph for Commercial Seed Treatment Scenarios. Report Number AHE1008. March 2014.



2. Batch treaters which treat a single batch (or given amount of seed) at a time (photos copied from AHETF 2014[1])



3. Continuous batch treaters which are a combination of a continuous flow and a batch treater, utilizing seed from a steady flow of untreated seed, and treating the seed in batches until the seed source is depleted or a predetermined number of batches are treated (photos copied from AHETF 2014[1])

In commercial seed treatment facilities, seed is professionally treated and packaged in small bags, mini-bulk containers (e.g., bins or large bags), or loose bulk containers (e.g., seed wagons or trucks), and then delivered later to growers (photos copied from AHETF 2014[2]).

[2] Agricultural Handler Exposure Scenario Monograph for Commercial Seed Treatment Scenarios. Report Number AHE1008. March 2014.

Downstream facilities process much of their seed as loose bulk, where treated seed is conveyed into a grower's truck or wagon directly from the treater. This is distinctly different from on-farm seed treating where seed is treated on-site and planted without bagging. All on-farm seed treatment systems have a method to transfer and treat clean untreated seed from bulk storage to a seed wagon or truck, or from a truck or wagon to the planter.

On-farm seed treatment generally involves workers that operate any on-farm seed treating equipment, including mixing, loading and application of a pesticide to untreated seed, and any associated tasks such as maintaining the treating equipment and planting the treated seed. This scenario applies to any seed type labeled for on-farm seed treatment. On-farm seed treating equipment typically involves some type of mechanical conveying or augering system that accommodates treatment as the seed is moved into equipment such as a seed truck (such as for transport to the field), onto a conveyor (such as for transport into temporary storage), or directly into a planter. All on-farm seed treaters are continuous flow treaters, meaning the seed treatment process continues until the seed supply is depleted. On-farm systems are manual in design and require an operator to stop and start the seed treating process (photos copied from AHETF 2014[3]).

[3] Agricultural Handler Exposure Scenario Monograph for Commercial Seed Treatment Scenarios. Report Number AHE1008. March 2014.

For commercial seed treatment, depending on seed type, exposure duration may vary between short- and intermediate-term (i.e., up to 6 months of exposure). For on-farm seed treatment, the exposure duration is anticipated to be short-term only (i.e., up to 30 days of exposure).

II. SEED TREATMENT "UNIT EXPOSURES"

The data contained in this document are for worker exposure estimation, were generated by the pesticide industry, and were primarily submitted by the Agricultural Handler Exposure Task Force (AHETF). Exposure estimates are from studies monitoring workers during actual seed treatment and are based on physical factors of a handler scenario (e.g., commercial seed treatment, on-farm seed treatment, planters, etc.). "Unit exposures" have been developed from these data sources for seed treatment scenarios and are typically expressed as mass of pesticide active ingredient exposure per unit mass of active ingredient handled (e.g., µg/lb ai). The Agency then uses these unit exposures "generically," irrespective of chemical identity, to estimate

exposure for other seed treatment pesticides.

This revised SOP is primarily based on four submissions from the AHETF:

- The AHETF Monograph for Commercial Seed Treatment (CST) (Bruce and Holden, 2014) provides a summary of eleven studies (conducted between 2000 and 2010) supporting the commercial seed treatment scenario and reflects potential for worker exposure from activities such as treating seed, packaging treated seed, and cleanout of treatment equipment.
- The AHETF Monograph for Loading and Planting Treated Seed (LPTS) (Standart and Holden, 2014) provides a summary of two studies (conducted in 2007 and 2008) supporting the loader/planter scenario and reflects potential for worker exposure from tasks commonly performed during loading of commercially treated seed and subsequent planting of the seed using planting equipment with enclosed cabs.
- The AHETF Monograph for On-Farm Seed Treatment and Planting with Liquids (OFST/P-L) (Standart and Holden, 2014) provides a summary of three studies (conducted in 1999 and 2006) supporting the on-farm seed treatment with liquid formulations scenario and reflects potential for worker exposure from mixing, loading and applying a liquid pesticide to seeds using on-farm equipment, including any associated tasks such as maintaining the treating equipment, and planting the treated seed.
- The AHETF Monograph for On-Farm Seed Treatment and Planting with Solids (OFST/P-S) (Klonne and Holden, 2008) provides a summary of one study (conducted in 2005) supporting the on-farm seed treatment with solid formulations scenarios and reflects potential for worker exposure from loading/applying a solid/dust pesticide to seeds using on-farm equipment, including any associated tasks such as maintaining the treating equipment and planting of the treated seed.

All of the studies and monographs included in the AHETF submissions were reviewed by EPA and considered acceptable. In addition to the AHETF submitted studies, EPA also chose to include one additional study in the CST dataset[4]. This study was completed in 2014 (after the studies included in the AHETF submission), was reviewed separately by EPA and considered acceptable. A list of the included studies is provided in Appendix A. EPA's monograph reviews also identify other studies that were considered by either the AHETF and/or EPA for inclusion in the datasets but were ultimately excluded for various reasons.

As opposed to the OFST and LPTS datasets, where the monitored workers all performed the same activities, workers in the CST dataset conducted various activities and were grouped according to the activities they performed. Each monitored worker was assigned one of seven activity patterns, based on common CST tasks performed. The activity pattern classifications were treat (T), package (P), cleanout (C), treat/package (TP), treat/cleanout (TC), package/cleanout (PC), and treat/package/cleanout (TPC). In the AHETF CST monograph, these worker activities were grouped into three proposed scenarios: (1) CST-TM - treating/multiple

[4] EPA MRID 49421402 (Lange, 2014). Abamectin/Thiamethoxam Observational Study to Determine Dermal and Inhalation Exposure of Workers in Commercial Seed Treatment Facilities to Abamectin During Cotton Seed Treating and Equipment Cleaning Activities Final Report

activities (which includes the following work activity assignments: T, TC, TP, and PC)[5], (2) CST-P - packaging (includes P only), and (3) CST-C - cleaning (includes C only). EPA agreed with the proposed worker scenarios with one small change. While the treater/multiple activity scenario covers activities other than treating (including some packaging and cleaning), EPA is proposing that this scenario be referred to as simply the "treating" scenario and that risk concerns be addressed only relative to treating activities, since packaging and cleaning would be addressed by the other two scenarios.

The summary tables below provide the dermal and inhalation unit exposures with different types of personal protective equipment (PPE) for activities related to seed treatment and planting treated seed.

- Table 1 provides unit exposures for commercial seed treatment,
- Table 2 provides unit exposures for loader/planters of commercially treated seed,
- Table 3 provides unit exposures for on-farm seed treatment and planting of seeds using liquid formulations, and
- Table 4 provides unit exposures for on-farm seed treatment and planting of seed using solid/dust formulations.

A few items of note related to the unit exposures for these scenarios and implications for risk assessment:

<u>Commercial Seed Treatment scenarios</u>

- In the AHETF submission, workers involved in loading of a chemical into a treater all used closed systems. There are no data available for use of open loading commercial seed treatment systems. The AHETF's proposal is that the CST dataset be used to represent closed loading systems only. They suggest that open pour loading for seed treatment could be conservatively estimated using data for workers conducting routine open pour loading of liquids in agricultural settings. However, those unit exposures are numerically very close or lower than the EPA-proposed closed loading seed treatment unit exposures based on the new dataset. While exposure may be expected to be higher with use of an open loading system, the impact of a closed versus open loading system on total exposure for treaters is not straightforward because workers did other activities beyond just loading of the chemical (e.g., calibrating treater, treating/coating seed, sampling "wet" treated seed). Therefore, EPA agrees with the AHETF that the CST dataset will only represent closed loading systems; however, EPA will not quantify exposure from the use of an open loading system using the available agricultural open loading unit exposures but may include characterization in the risk assessment around the potential impact on exposure from the use of open loading systems.
- For purposes of risk management, the recommendation is that any risk concerns based on the treating dataset should be addressed relative to treating seed (i.e., mixing and loading chemical, calibrating the treater, treating/coating the seed and sampling "wet" treated

[5] TPC would also have been included in this scenario, however, there were no monitoring units identified as having conducted this activity category.

seed), and risk management of any risk concerns for packaging treated seed or cleaning seed treatment equipment be based on the assessment for those exclusive activities.

- Since the CST scenario represents commercial seed treatment only, for risk assessment purposes, it would be paired with the LPTS scenario. The OFST/P scenarios (both liquid and solid) represent both on-farm seed treatment and planting of treated seed and would be stand-alone scenarios.
- For the cleaning scenario, the unit exposure is expressed in terms of the application rate and activity duration rather than an absolute amount of chemical handled. After review of the monitoring times reported for this activity in the studies, a default activity duration of 2.5 hours is proposed for use in the calculation of exposure for clean-out activities.

<u>Loading/Planting Treated Seed scenario</u>

- Exposure to workers' hands was monitored separately during loading of the treated seed and while planting the treated seed; therefore, unit exposures were able to be calculated for both "no gloves" and "gloves" for each of those activities. While the data were available to calculate these different options, for the purposes of risk mitigation, the policy only provides unit exposures assuming a worker is wearing gloves while both loading and planting treated seed or assuming a worker is not wearing gloves while both loading and planting treated seed. The additional combinations (e.g., wearing gloves while loading but not while planting) are available in the LPTS monograph (D460313).
- For the planters, it is assumed that there is no difference in exposure between open versus closed cabs based on the likelihood that most worker exposure while planting treated seeds is coming from activities occurring outside the planter/tractor cab (i.e., maintenance activities).

<u>On-Farm Seed Treatment and Planting (solids and liquids) scenarios:</u>

- The AHETF intended for this scenario to cover both open and closed loading systems. Out of the 48 monitoring units (MUs) monitored during chemical loading procedures, two of them (both from the same study) involved a closed loading system. EPA has decided that due to the limited data representing closed loading systems, the OFST/P-L dataset will be used to represent open loading systems only. While exposure may be expected to be lower with use of a closed loading system, the impact of a closed versus open loading system on total exposure is not straightforward because workers did other activities beyond just loading chemical (e.g., loading treated seed into planters and planting treated seed). EPA did consider the use of unit exposures for closed loading of liquids in agricultural settings; however, those values are much lower than would be expected if on-farm seed treatment was conducted using closed loading. Therefore, EPA proposes that the OFST/P-L dataset will only represent open loading systems. EPA will not quantify exposure from the use of a closed loading system but may include characterization in the risk assessment around the potential impact on exposure from the use of closed loading systems.
- For OFST/P-L, the unit exposures are intended to cover any kind of on-farm seed treatment and planting equipment appropriate for the job using liquid formulations or formulations applied as liquids (e.g., wettable powders and dry flowables).

- For OFST/P-S, the unit exposures are representative of solid/dust formulation applications via hopper box but will be used as surrogate data for the use of other similar equipment used on-farm with solid/dust formulations.

Table 1. Summary of Commercial Seed Treatment (CST) Unit Exposure Values.

Type	Exposure Scenario	Exposure Route	PPE	Statistic	Unit Exposure (ug/lb ai, except for cleaners: (µg ai/hr)/(lb ai/lb seed))
Commercial Seed Treatment (CST)	Treating All Formulations	Dermal	Single layer/no gloves	Mean	349
			Single layer/gloves		51.2
			Double layer/gloves		42.2
		Inhalation	No Respirator		1.2
			PF10		0.12
	Packaging All Formulations	Dermal	Single layer/no gloves	Mean	68
			Single layer/gloves		16.9
			Double layer/gloves		13.1
		Inhalation	No Respirator		3.6
			PF10		0.36
	Cleaning All Formulations	Dermal	Single layer/no gloves	Mean	138,210,600
			Single layer/gloves		23,262,800
			Double layer/gloves		21,238,200
		Inhalation	No Respirator		106,100
			PF10		10,610

Table 2. Summary of Loading/Planting of Commercially Treated Seed (LPTS) Unit Exposure Values.

Type	Exposure Scenario	Exposure Route	PPE			Statistic	Unit Exposure (ug/lb ai)
Loader/Planters	Loading/Planting Treated Seed (LPTS) All Formulations	Dermal	Single layer	Loader: No Gloves	Planter: No Gloves	Mean	3,994
				Loader: Gloves	Planter: Gloves		797
			Double layer	Loader: Gloves	Planter: Gloves		530
		Inhalation	No Respirator				66

Table 2. Summary of Loading/Planting of Commercially Treated Seed (LPTS) Unit Exposure Values.					
Type	Exposure Scenario	Exposure Route	PPE	Statistic	Unit Exposure (ug/lb ai)
			PF10		6.6

Table 3. Summary of On-Farm Seed Treatment and Planting using Liquid Formulation (OFST/P-L) Unit Exposure Values.					
Type	Exposure Scenario	Exposure Route	PPE	Statistic	Unit Exposure (ug/lb ai)
On-Farm Seed Treatment	On-Farm Seed Treatment/ Planting with Liquids* (OFST/P-L)	Dermal	Single layer/no gloves	Mean	1094
			Single layer/gloves		226
			Double layer/gloves		186
		Inhalation	No Respirator		37.1
			PF10		3.71

* Liquid formulations and formulations applied as liquids (e.g., wettable powders and dry flowables)

Table 4. Summary of On-Farm Seed Treatment and Planting using Solid (Dust) Formulation (OFST/P-S) Unit Exposure Values.					
Type	Exposure Scenario	Exposure Route	PPE	Statistic	Unit Exposure (ug/lb ai)
On-Farm Seed Treatment	On-Farm Seed Treatment/ Planting with Solids* (OFST/P-S)	Dermal	Single layer/no gloves	Mean	27,887
			Single layer/gloves		7,574
			Double layer/gloves		5,532
		Inhalation	No Respirator		633
			PF10		63.3

*Solid and dust formulations

III. SEED TREATMENT SCENARIOS

The following sections provide an overview of the various seed treatment scenarios. A more detailed description of the scenarios and the underlying data can be found in the accompanying monograph and study reviews noted below.

Table 5. Summary of Supporting Documents for Policy 14		
Scenario	Monograph (EPA Review Code)	Study (EPA Review Code)
Commercial Seed Treatment (CST)	D460312	D419699
Loading/Planting of Commercially Treated Seed (LPTS)	D419699	D460311
On-Farm Seed Treatment and Planting of Seeds treated with Liquid Formulations (OFST/P-L)	D419862	D460310

Table 5. Summary of Supporting Documents for Policy 14		
Scenario	Monograph (EPA Review Code)	Study (EPA Review Code)
On-Farm Seed Treatment and Planting of Seeds treated with Solid Formulations (OFST/P-S)	D460314	D392522

A. Commercial Seed Treatment (CST)

Eleven studies support the CST scenario and provide a summary of the potential dermal and inhalation exposure for workers conducting activities related to commercial seed treatment including treating seed, packaging treated seed, and cleanout of the equipment. The studies monitored dermal and inhalation exposure to workers at 57 facilities located in Great Britain, Germany, Canada, France, and the United States between 2000 and 2014. In total, there were 423 monitoring units included in this dataset. In all studies, a liquid seed treatment formulation was used. Overall, 11 different active ingredients were monitored. Seed treatment equipment varied across sites and included both continuous flow, continuous batch, and single batch treaters. Examples of specific types of commercial seed treatment equipment used in the studies underlying the seed treatment exposure data are provided in Appendix B. Treated seed was packaged into small bags, mini-bulk containers, and/or loose bulk storage containers using bagging/closing and stacking systems ranging from manual to automated levels of operation. The types of seed treated included oilseed, corn, small grain, and cotton.

The tasks monitored included those associated with treating the seed (i.e., operating the treating equipment, loading the chemical, or calibrating the treating equipment), packaging the treated seed (i.e., bagging, closing, tagging, stacking, or forklifting), and cleanout of the treatment chamber. Tasks not involving direct contact with the test substance were also routinely performed during the monitoring time, such as daily maintenance (i.e., sweeping, cleaning, vacuuming) and loading of untreated seed. Each monitoring unit was assigned one of seven activity patterns, based on the tasks performed. The activity pattern classifications are treat (T), package (P), cleanout (C), treat/package (TP), treat/cleanout (TC), package/cleanout (PC), and treat/package/cleanout (TPC). For the CST unit exposure dataset, the worker activities described above were grouped into three scenarios: (1) Treating (which includes the following work activity assignments: T, TC, TP, and PC)[6], (2) Packaging (includes P only), and (3) Cleaning (includes C only).

For the most part, it is anticipated that worker exposure for an entire CST workday could be described using either the treating or packaging scenarios. The packaging scenario was included because workdays devoted exclusively to packaging tasks are expected to be common in many CST facilities. Workdays devoted entirely to cleanout are thought to be infrequent. It is more likely that cleanout tasks would be of shorter duration and mixed with other chemical handling tasks during the same workday which would be covered by the treating scenario. However, cleanout of seed treating equipment is a task that can involve intensive contact with

[6] TPC would also have been included in this scenario, however, there were no monitoring units identified as having conducted this activity category.

contaminated surfaces and often involves workers wearing extra PPE, such as Tyvek clothing. Therefore, this scenario was kept separate in order to provide the ability to determine exposure and risk mitigation for those particular workers.

CST-Treating:
The CST-Treating scenario represents any possible CST workday during which CST worker exposure is the result of performing any combination of packaging, treating, or cleanout tasks, but not exclusively packaging or exclusively cleanout. This scenario includes several tasks that are very critical to the CST process and generally involve just a few specially trained workers at each facility, including mixing and loading chemical, calibrating the treater, treating/coating the seed and sampling "wet" treated seed. Worker-day exposure associated with these scenario-specific tasks is expressed relative to the amount of active ingredient handled (AaiH).

All of the MUs included in the overall dataset conducted loading using closed systems (examples in Figure 1). Five workers from one study and four workers from another study were rejected for using open pour methods in the mixing/loading procedures. The AHETF rejected these monitoring units because of an insufficient number and diversity of replicates to characterize the impact of open-pour on the exposure to multiple-activity scenarios. The AHETF suggested that open pour could be conservatively estimated using open pour liquid M/L scenario data; however, those unit exposures are numerically very close or lower than the EPA proposed closed loading seed treatment unit exposures based on the new dataset. While exposure may be expected to be higher with use of an open loading system, the impact of a closed versus open loading system on total exposure for treaters is not straightforward because workers did other activities beyond just loading of the chemical (e.g., calibrating treater, treating/coating seed, sampling "wet" treated seed). Therefore, EPA agrees with the AHETF that the CST dataset will only represent closed loading systems; however, EPA will not quantify exposure from the use of an open loading system using the available agricultural open loading unit exposures but may include characterization in the risk assessment around the potential impact on exposure from the use of open loading systems.

Figure 1. Example of Closed Loading Systems

While there were "treater-only" monitoring data, the possibility of having only those monitoring units in the treating scenario was rejected because the available treater-only MUs were considered inadequate to characterize a treating-only scenario. The exposure data represented only six different workers in four corn seed treating facilities. No oil seed or small grains facilities are represented at all. Unlike packaging and cleanout where a number of monitored workers exclusively conducted those activities over their entire workday, it is unclear whether treating seed should be treated as an exclusive activity. Of the 396 available data points, only 18 can be categorized as "treating only", representing only six workers. Therefore, the CST-Treating scenario conceptually represents a general CST scenario pertaining to any worker-day not devoted exclusively to either packaging or cleanout.

While the CST-Treating scenario represents workers performing activities beyond just treating of the seed, ultimately, for purposes of risk management, EPA recommends any risk concerns based on the CST-Treating dataset should be addressed relative to treating seed. As noted above, "treating" involves not only loading of the chemical, but also calibration of the treater, treating/coasting the seed, and sampling "wet" treated seed. EPA feels this is appropriate considering that activities other than those involved in treating will be addressed by the other two scenarios (CST-Packaging and CST-Cleaning). Risk management of any risk concerns for packaging treated seed or cleaning seed treatment equipment will be based on the assessment for those exclusive activities.

CST-Packaging:

The CST-Packaging scenario represents any possible CST workday during which CST worker exposure is the result of performing one or more packaging tasks, but none of the treating or cleanout tasks. The packaging-related tasks identified include bagging, closing/sewing, tagging, stacking, and moving packaged seed via forklift (examples shown in Figure 2). Worker-day exposure associated with these scenario-specific tasks is expressed relative to the amount of active ingredient handled (AaiH).

Figure 2. Examples of Packaging-related Tasks

CST-Cleaning:

The CST-Cleaning scenario represents any possible CST workday during which CST worker exposure is the result of performing cleanout-related tasks. Cleanout of seed-treating equipment is a task that can involve intensive contact with contaminated surfaces and often involves workers wearing extra PPE (such as Tyvek clothing). In the available studies, workers that

cleaned the seed treatment equipment utilized a number of different approaches/methods including scraping, wiping, brushing, compressed air, pressurized water, vacuum cleaners, etc.

Cleanout tasks might occupy a worker anywhere from a few minutes up to a large portion of the workday. The cleanout activity frequently involves intermittent cleanout tasks that occur for short durations periodically during a workday. If such workdays involve packaging and/or treating tasks as well, then total workday exposure would be described by the CST-Treating scenario. The CST-Cleaning scenario would only describe that part of the workday exposure resulting from the cleanout activity. Unlike the CST-Packaging and CST-Treating scenarios, worker exposure characterized by the CST-Cleaning scenario is not normalized by the amount of active ingredient handled (AaiH). Rather, exposure is expressed relative to the product of the active ingredient application rate associated with the seed treatment and the amount of time devoted to the cleanout activity (ARxT). As noted earlier, the measured monitoring time is used as a surrogate for worker-day cleanout time.

B. Loading and Planting of Commercially Treated Seed (LPTS)

Three studies support the LPTS scenario and provide a summary of the potential dermal and inhalation exposure for workers loading commercially treated seed in bulk or by bag and then planting the commercially treated seed using planting equipment with an enclosed cab tractor. The studies were conducted in France, Italy, and Germany in 2005 using either wheat seed treated with the active ingredients tefluthrin and fludioxonil (but only worker exposure to tefluthrin was measured) or maize kernels treated with the active ingredient imidacloprid. In total, there were 21 monitoring units included in this dataset. A variety of loading and planting techniques were monitored. The workers loaded commercially treated seed into the hopper by manually pouring the seed from small bags or by a forklift from mini-bulk containers or large loose-bulk containers. The seed was planted using conventional or pneumatic machines, which were pulled by tractors driven by the worker. The tractors were equipped with closed cabs, although the window or the door of the cab was open during all or part of the monitoring period for approximately 30% of workers.

Even though this scenario is identified as involving enclosed cab tractors only, the assumption is that there would be no significant difference in planter exposure between open versus closed cabs, and therefore, the same dataset is used for both. This assumption is based on the likelihood that most worker exposure while planting treated seeds is coming from activities occurring outside the planter/tractor cab (i.e., maintenance activities).

Manual loading of commercially treated seed involves seed that is packaged in small bags (see Figure 3). Small bags allow the worker to carry the bags from trailers or pallets, for example, to the hopper by hand, and then manually open the bag and pour the seed into the hopper. Small bags generally contain 50 kg (110 lb) of seed or less since it is difficult for workers to lift and pour heavier bags; one of the LPTS studies utilized 50-kg bags and the bag size in the other study was not specified in the sponsor report. Mechanical assisted loading of commercially treated seed involves seed that is loaded from mini-bulk containers or as loose bulk. One

example is loading seed from a truck via auger (see Figure 4). Another example is using a forklift when seed is packaged in large containers. In this situation, the container, such as a big bag or bin, is mechanically positioned over the seed hopper and the seed dispensed when the worker opens the bottom of the container. Bags containing 600 kg (1322 lb) of seed and metal bulk containers requiring mechanical (i.e., semi-automatic) loading were used by some workers in one of the LPTS studies.

Figure 3. Manual loading of seed packaged in small bags

Figure 4. Mechanical assisted loading via auger

During planting, the planter typically performs other tasks in addition to operating the equipment by driving the tractor through the field, such as making sure that the seed is properly planted (e.g., by checking seed depth and making adjustments or repairs as needed) or leveling the seed in the hopper as needed. It would also include any 'background' exposure such as contact with contaminated surfaces or equipment in the workday environment.

C. On-Farm Seed Treatment and Planting of Treated Seeds with Liquid Formulations (OFST/P-L)

Three studies support the OFST/P-L scenario and provide a summary of the potential dermal and inhalation exposure for workers mixing, loading and applying a liquid pesticide (or a dry pesticide applied as a liquid such as wettable powders or dry flowables) to seeds and planting the treated seed. The OFST/P-L scenario is broadly defined by formulation, equipment and activity. In general, it involves workers that operate any on-farm seed treating equipment, including mixing, loading and application of the pesticide to untreated seed, and any associated tasks such as maintaining the treating equipment and planting the treated seed. Examples of on-farm seed treatment equipment used in the studies underlying the seed treatment exposure data are provided in Appendix B. The studies were conducted in Canada (in 2006) and the United States (in 1999 and 2006) using either wheat seeds or potato seed pieces, which were treated with either the active ingredients difenoconazole or imidacloprid. In total, there were 48 monitoring units included in this dataset. In two of the studies, workers both treated seed and planted the treated seed, while in one study, workers only treated seed. For those workers that planted treated seed, the studies note that the majority of planter tractors had enclosed cabs.

A variety of treating and planting techniques were monitored. Figures 5, 6 and 7 illustrate examples of open and closed mixing/loading systems.

Figure 5. Open Pour

Figure 6. Open with Mechanical Transfer

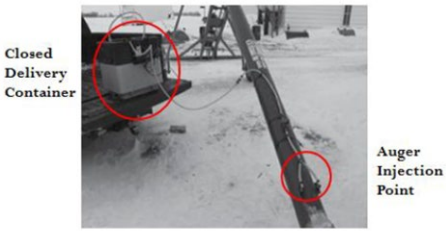


Figure 7. Totally Closed Loading

On-farm seed treating equipment typically involves some type of mechanical conveyer or auger system that accommodates treatment as the seed is moved into equipment such as a seed truck (for transport to the field), onto a conveyor (for transport into temporary storage), or directly into a planter as illustrated in Figures 8 and 9.

Figure 8. Auger transfer of seed to wagon/truck

Figure 9. Filling Planters in Field

Conveyer systems allow for the mixing of product with the seed to obtain some degree of uniform seed coating. Examples of application techniques include dribbling the product directly from the jug onto the seed, applying product to the seed by gravity feed, and using pressurized spray systems (depicted in Figure 10). Gravity feed techniques may differ in the way product is dispensed from the jug. Pressurized systems consist of spray tanks of varying sizes and a pump that delivers product over the seed as it is moved along, including sometimes in enclosed chambers.

Figure 10. Example of Application Techniques

In one of the three studies, wheat seed was treated by manually pouring, dripping or spraying onto the auger directly from the product jug or using a small hose which was screwed onto the product jug and directed at the grain inlet (using gravity or pressurized pump). In one case, the test product was poured directly onto the wheat seed from within a storage bin, and the seed was then shoveled into the auger. In another study, the workers manually poured the seed treatment product into a measuring cup and then into a mixing container, and/or directly into the reservoir of the seed treater. The product was applied to the seed as it moved along the auger using a spray nozzle in an enclosed chamber, or seed treatment occurred in the mixing chamber. In this study, seed treatment primarily took place outdoors, except in one case where treatment took place inside a metal Quonset-type farm building with open doors at both ends of the building. In the third study, the worker performed the mixing, loading and applying operations and also other treatment-related tasks, which often included assisting on the cutting/sorting table. Monitoring of twelve of the treaters was conducted indoors and four were conducted outdoors. Indoor ventilation conditions varied at each site.

The MUs in this dataset used a wide range of treaters. Sixteen MUs used a variety of Gustafson treaters, 15 used barrel- or cannon-style (i.e., auger-style) treaters, and the remaining 16 MUs used seed-conveying augers with a variety of manual and spray set-ups. This is consistent with North American treating procedures covering a variety of seed types. Four MUs used seed treating equipment at commercial locations; however, one used on-farm equipment typical for

smaller farming operations that treat their own seed, and the other three used equipment that can be found in large farming operations where farmers store their own seed.

As mentioned above, in one of the three studies, potential exposure during planting was not monitored; however, in the other two studies, workers were monitored while also planting seed after treatment. In both of those studies, wheat seed was planted using a conventional planter (i.e., drill, air, disc, hoe, press) which was pulled by a tractor with either a closed, open, or partly open cab. The majority of tractors had closed cabs, however, in one study, ten had closed cabs, four had open cabs and two had modified cabs (closed cabs with window open). The use of air conditioning in the cab was not reported.

As with the LPTS scenario, even though the OFST/P-L scenario is identified as involving enclosed cab tractors only, the assumption is that there would be no significant difference in planter exposure between open versus closed cabs, and therefore, the same dataset is used for both. This assumption is based on the likelihood that most worker exposure while planting treated seeds is coming from activities occurring outside the planter/tractor cab (i.e., maintenance activities).

The workers often performed tasks other than treating and planting during the monitoring period. These tasks may have included quickly cleaning the auger (mixing) system or planter after treatment was finished or shoveling treated seed into the auger or directly into a planter. Other tasks may have included checking auger or spray nozzle operation, fixing auger problems, spreading untreated seed in seed hopper with foot or gloved hand, climbing into treated seed truck to spread seed into transfer auger, checking seed depth during planting, adjusting seed equipment (without gloves), and removing dirt build-up on the planter.

The AHETF intended for this scenario to cover both open and closed mixing/loading systems. Out of the 48 monitoring units (MUs) monitored during chemical loading procedures, two of them (both from the same study) involved a closed loading system. EPA has decided that due to the limited data representing closed loading systems, the OFST/P-L dataset will be used to represent open loading systems only. While exposure may be expected to be lower with use of a closed loading system, the impact of a closed versus open loading system on total exposure is not straightforward because workers did other activities beyond just loading chemical (e.g., loading treated seed into planters and planting treated seed). EPA did consider the use of unit exposures for closed loading of liquids in agricultural settings; however, those values are much lower than would be expected if on-farm seed treatment was conducted using closed loading. Therefore, EPA proposes that the OFST/P-L dataset will only represent open loading systems. EPA will not quantify exposure from the use of a closed loading system but may include characterization in the risk assessment around the potential impact on exposure from the use of closed loading systems.

D. On-Farm Seed Treatment and Planting of Treated Seeds with Solid Formulations (OFST/P-S)

One study supports the OFST/P-S scenario and provides a summary of the potential dermal and inhalation exposure for workers mixing, loading and applying a solid (dust) pesticide to seeds, and any associated tasks such as maintaining the treating equipment and planting the treated seed. The study data is composed of 16 separate workers monitored at nine different locations in two states. On-farm seed treatment was monitored as a powdered product was transferred from a bag onto the cotton seed placed in the hopper box of a seed planter. Each planter consisted of 8 or 12 hopper boxes and the boxes were filled 1, 2, or 3 times per work period. The treated seed was then planted using closed cab tractors to pull the planters.

While there is only one study used as the basis for this scenario, it is believed to be representative for several reasons: (1) currently available types of equipment used for this task are of similar construction and configuration, (2) other powder formulations in the seed treatment market have similar concentrations of active ingredient to the product used in the study, (3) the tasks of treating the seed in the hopper box is quite similar across the commercially available hopper box configurations, and (4) there is only a small range of use rates for the products in this particular scenario.

This scenario is intended to cover hopper box (or similar) on-farm seed treatment and planting equipment appropriate for the job and specifically enclosed cab tractors. As with the LPTS and OFST/P-L scenarios, even though the OFST/P-S scenario is identified as involving enclosed cab tractors only, the assumption is that there would be no significant difference in planter exposure between open versus closed cabs, and therefore, the same dataset is used for both. This assumption is based on the likelihood that most worker exposure while planting treated seeds is coming from activities occurring outside the planter/tractor cab (i.e., maintenance activities).

Products commonly used for on-farm applications to seed in hopper boxes are relatively limited. Dusts or powders are representative solid formulations used for seed treatment, as they provide the best coverage of the seed and would likely provide a worst-case surrogate for exposure potential. Crops treated on-farm by adding solid products to seed in hopper boxes include cotton, soybeans, corn and small cereal grains. Although only a small portion of crop seed is treated in this manner, these crops are among the largest commercial crops in the U.S., thus the amount of seed treated in this manner is still a significant use pattern.

The workers in the study partially loaded untreated seed into the hopper boxes (examples provided in Figure 11), added treatment chemical and mixed it with the seed, completed loading of the seed, added more chemical to the top and mixed again, and then closed the lid of the hopper box.

Figure 11. Seed Hoppers for Conventional and Air Planters

The OFST/P-S monograph indicates that hopper box planters are typically used for planting cotton and other seed types where seed is treated in the box. The AHETF cites a cotton grower survey they conducted which indicates that planters come in a variety of sizes based on the number of hopper boxes on the planter. Common number of hoppers include 6, 8, 10, 12, and 16 where each hopper provides seed for one row of plants. In this study, 8 or 12 row planters were used.

In terms of planting equipment, the available options include air-assisted, vacuum-assisted and gravity feed techniques. For air-assisted planters, the AHETF notes that there may be too much air pressure for a dust or powder coating to continue to adhere to the seed; therefore, in all but one case, planters other than air-assisted were used for planting in the study. The tractor type for pulling the planter could be either open or closed; however, all the workers monitored in this study used only closed cab tractors. The AHETF notes that the cotton grower survey indicated that at least 2/3 of the respondents used closed cab tractors, while the other 1/3 did not indicate which type they used.

Similar to the OFST/P-L dataset, EPA has decided that the OFST/P-S dataset will be used to represent open loading systems only. While exposure may be expected to be lower with use of a closed loading system, the impact of a closed versus open loading system on total exposure is not straightforward because workers did other activities beyond just loading chemical (e.g., loading treated seed into planters and planting treated seed). EPA will not quantify exposure from the use of a closed loading system but may include characterization in the risk assessment around the potential impact on exposure from the use of closed loading systems.

Appendix A. Summary of Studies in Included in Policy 14

Table A1. Studies included in Policy 14.

AHETF #	Dataset	MRID	Study Year	Study Title	EPA Review	Active Ingredient	PC Code	Formulation	Crop/Seeds
AH806	CST	49084501 (48024010)	2010	Observational Study to Determine Dermal and Inhalation Exposure to Workers in Commercial Seed Treatment Facilities: Mixing/Treating with a Liquid Pesticide Product and Equipment Clean-out	D419699 (commercial studies review); D381970 (original review)	clothianidin, metalaxyl	044309, 113501	liquid	corn, canola
AH809		49084502	2003	Determination of Operator Exposure to Tebuconazole during Treatment of Barley Seed with Raxil® S (040 FS) in the UK	D419699 (commercial studies review)	tebuconazole	128997	liquid	cereals
AH810		49084503	2003	Determination of Operator Exposure to Tebuconazole during Treatment of Barley Seed with Raxil® S (040 FS) in Germany	D419699 (commercial studies review)	tebuconazole	128997	liquid	cereals
AH812		49084504	2005	Determination of Operator Exposure to Methiocarb during Seed Treatment of Maize with Mesurol® S (FS 500) in Germany	D419699 (commercial studies review)	methiocarb	100501	liquid	maize
AH813		49084505	2004	Determination of Operator Exposure to Imidacloprid during Seed Treatment of Oilseed Rape with Chinook® FS 200 in UK	D419699 (commercial studies review)	imidacloprid	129099	liquid	oilseed rape
AH814		49084506	2006	Determination of Operator Exposure to Imidacloprid during Seed Treatment of Oilseed Rape with Chinook® FS 200 in Germany	D419699 (commercial studies review)	imidacloprid	129099	liquid	oilseed rape
AH815		49044501	2005	Fludioxonil: Determination of Operator Exposure during Bagging of Treated Small-grain Cereal Seed and Cleaning Seed Treatment Equipment at UK static sites following Treatment with 'Beret Gold' Fungicide 25 g/L fluioxonil as a flowable concentrate formulation) using Batch or Constant Flow Seed Treatment Equipment	D419699 (commercial studies review)	fludioxonil	071503	liquid	cereals
AH816		49044502	2005	Fludioxonil: Determination of Operator Exposure during Bagging of Treated Small-grain Cereal Seed and Cleaning Seed Treatment Equipment (Chamber) at Static Sites in France following Treatment with a Fungicide containing 10 g/L and/or 25 g/L Fluioxonil as a Flowable	D419699 (commercial studies review)	fludioxonil	071503	liquid	cereals

Table A1. Studies included in Policy 14.									
AHETF #	Dataset	MRID	Study Year	Study Title	EPA Review	Active Ingredient	PC Code	Formulation	Crop/Seeds
				Concentrate Formulation) using Batch or Constant Flow Seed Treatment Equipment					
AH817		49001401	2009	Fluquinconazole and Prochloraz: Determination of Operator Exposure during Cereal Seed Treatment with 'Jockey' Fungicide in Germany, United Kingdom and France	D419699 (commercial studies review)	fluquinconazole/ prochloraz	128851	liquid	cereals
AH820		49044503 (45200002)	2000	Commercial Seed Treatment Plant Worker Exposure Study with Helix 289FS Seed Treatment on Canola	D419699 (commercial studies review); D273566 (original review)	thiamethoxam	060109	liquid	canola
NA		49421402	2014	Observational Study to Determine Dermal and Inhalation Exposure of Workers in Commercial Seed Treatment Facilities to Abamectin During Cotton Seed Treating and Equipment Cleaning Activities.	D419699 (commercial studies review)	abamectin	122804	liquid	cotton
AH823	LPTS	49117004	2008	Determination of Dermal and Inhalation Exposure to Operators During Loading and Sewing Seed Treated with Austral Plus Net Using Conventional or Pneumatic Sowing Machines	D460311 (loader/planter studies review)	tefluthrin	128912	liquid	wheat
AH825		49117005 / 48249101	2007	Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds under Realistic Field Conditions in Germany and Italy	D460311 (loader/planter studies review)	imidacloprid	129099	liquid	maize
AHE10	OFST/P-S	46634103	2005	Determination of Dermal and Inhalation Exposure to Workers During On-Farm Application of a Dry Hopper Box Pesticide Treatment ot Seed, and Planting of Treated Seed	D392522	acephate	103301	dust	cotton
AH610	OFST/P-L	49117001	1999	On-Farm Operator Exposure Study with DIVIDEND 36 FS Seed Treatment on Wheat	D460310 (on-farm studies review)	difenoconazole	128847	liquid	wheat
AH803		49117002 (47054701)	2006	GAUCHO 480 SC – Worker Exposure During On-farm and Commercial Seed Treatment of Cereals	D460310 (on-farm studies review); D386913 (original review)	imidacloprid	129099	liquid	cereals

Table A1. Studies included in Policy 14.									
AHETF #	Dataset	MRID	Study Year	Study Title	EPA Review	Active Ingredient	PC Code	Formulation	Crop/Seeds
AH804		49117003 (47054702)	2006	ADMIRE 240F – Determination of Dermal and Inhalation Exposure of Workers during On-Farm Seed Piece Treatment of Potatoes	D460310 (on-farm studies review)	imidacloprid	129099	liquid	potato pieces

Appendix B. Summary of Seed Treating Equipment Used in Studies

The following is a list of seed treatment equipment used in the Policy 14 studies. This list is not comprehensive of all types of seed treatment equipment but is meant to give examples of the types that can be used and of which the exposure data may be representative.

Commercial Seed Treaters

- SATEC batch treater
- Gustafson treaters
- Forsberg fluidized zone batch mixer
- PC5000 (Precision coater)
- Braceworks Automation batch treater
- Murray Vanguard batch treater
- Rosengren batch treater
- Maxtron M continuous flow treater
- Twin Vanguard batch treater
- Rosengren continuous flow treater
- Dow/Elanco Vite continuous flow treater
- NIKLAS W.N. 5/50 batch treater
- Niklas WN 10 continuous flow treater
- PETKUS CT%-25 continuous flow treater

On-farm Seed Treatment (liquid)

- Gustafson treater models
- Potato seed piece treaters (cannon- or barrel-style)
- On-farm seed treatment equipment that utilizes an auger system for moving seed from a seed truck or grain bin into a seed wagon on an air seeder, into a truck, or into a pile on the floor

On-farm Seed Treatment (dust)

- Hopper boxes