Contamination Prevention in the Manufacture of Crop Protection Products

Self-Assessment Checklist

CropLife INTERNATIONAL

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Contamination Prevention in the Manufacture of Crop Protection Products

Self-Assessment Checklist

Scope

This form is intended for use by manufacturers of crop protection products, and/or their current and potential future External Manufacturers and service providers involved in contractual manufacturing of intermediates, active ingredients, formulations, and (re) packaging as well as warehousing and transport of finished products, raw materials, and packaging materials.
Also applicable are contracts covering storing and handling of finished products in bulk facilities at distributors / dealers.

Purpose

This checklist is based on Appendix B from CropLife International publication: "*Contamination Prevention in the Manufacture of Crop Protection Products - Guidelines and Best Practices",* Fourth Edition (2019)[1], Self-Assessment Checklist.

It serves as a tool to self-assess the alignment to the manufacturing and management processes in place.

[1] Electronic copies available on the CropLife International Website:
https://croplife.org/wp-content/uploads/2019/01/CPMCPP_4th-Edition_Mar_2019_HR.pdf

Site Summary

Company name	
Company Address	
Address evaluated site / facility	
GPS position of the manufacturing facility	
Country	

Date	
Name of Assessor	
Phone (list extension)	
e-mail etc.	
Function// position	
Signature	

The Self-Assessment procedures will help Manufacturers and their current and potentially future External Manufacturers (EMs)* to assess compliance of their manufacturing processes and technical equipment with the key Contamination Prevention criteria and the competency of their staff. A negative reply to questions in the checklist, which do not have informative character, should have a corresponding action plan to improve, or an explanation of why an improvement is not needed.

This checklist can also be used as the Contamination Prevention section of a client's (EM) audit checklist.

The frequency of the Self-Assessment / External Manufacturer audits is determined by each manufacturer, and the EMs individually based on their own Contamination Prevention risk assessments and must be adjusted to cover events that impact the Contamination Preventions risk.

Frequent audits will be required whenever:

- The product mix in a multi-purpose facility has been changed and a new active ingredient has been added to the (EM's) portfolio.
- After completion of the action plan to correct any non-conformity with the Contamination Prevention criteria.

When a proven, reliable Contamination Prevention performance has been demonstrated, and no equipment or portfolio changes have taken place, the (EM's) facilities may be audited less frequently.
Both in the case of Contamination Prevention Self-Assessment and EM audits, the lead auditor should preferably be an outside expert (e.g. the QC manager from a different site of the same company, or an independent Contamination Prevention consultant).

Contents

* In this checklist "EM" includes: External Manufacturers and service providers involved in contractual manufacturing of intermediates, active ingredients, formulations, and (re) packaging as well as warehousing and transport of finished products, raw materials, and packaging materials. Also applicable are contracts covering storing and handling of finished products in bulk facilities at distributors / dealers.

1.	Management Responsibility	Yes	No	Comments/ Proposed Action Plans
1.1 Standards	Does your site have a company standard / guideline / policy covering Contamination Prevention? Are the Standards / Guidelines published in the CropLife International booklet: "Contamination Prevention in the Manufacture of Crop Protection Products - Fourth edition (2019)" being implemented? If other, please describe.			
1.2 Responsible Person	Do you have an appointed person in your organization for the implementation & maintenance of the Contamination Prevention program? Name: In the role since (date):			
1.3 Training	Do you provide regular Contamination Prevention awareness training to: Existing personnel? New personnel, including temporary personnel? Functions? How often?			

1.	Management Responsibility	Yes	No	Comments/ Proposed Action Plans
1.3 cont'd	Do you have a formal Contamination Prevention training module? Are training records maintained? ▪ For permanent staff only? ▪ Both permanent and temporary staff? Record retention period?			
1.4 Awareness raising	Describe any other awareness raising activities.			

2.	Information Exchange	Yes	No	Comments/ Proposed Action Plans
2.1 Contact person	Who is the focal point in your company for your clients for any discussions on information exchange? Name:			
2.2 Confiden-tiality of clients' information	Do the contracts with your clients allow you to disclose the name of the preceding products and their active ingredients to the following client? If not, due to existing secrecy agreements: Does your previous clients allow disclosure of their company's name and the name of their contamination prevention contact person to your succeeding client?			
2.3 Active ingredients	Do you provide your clients with a list of all active ingredients handled on your site, listed by production units? Do you provide your clients with updates of this list when new AIs ingredients are added to your portfolio? Do you report changes immediately? If yes, with which frequency?			

2.	Information Exchange	Yes	No	Comments/ Proposed Action Plans
2.4 Plant configu- ration	Do you discuss the configuration of the equipment with the client when you make a product for the first time? If the unit can be combined from different parts, do you inform the client of all active ingredients which were last in all these parts? **Example:** The formulation vessel was used for the previous product, but the charging hopper that will be used contained a product with a different active ingredient in the previous production run.			

3.	Type of Operation and Product Mix	Yes	No	Comments/ Proposed Action Plans
3.1 Type of Operation	Does the manufacturing site: ▪ **Synthesize?** ▪ **Formulate:** -solids? -liquids? ▪ **Package:** -solids? -liquids?			
3.2 Product mix agricultural chemicals	▪ Does the manufacturing site manufacture, formulate or package: ▪ Low application rate herbicides (= LARH) (≤ 560 g to ≥ 50 g AI/ha)? ▪ Highly active herbicides (= HAHs) < 50 g AI/ha; see table 1)? ▪ Normal rate herbicides (= NRH) (> 560 g AI/ha)? ▪ Plant growth regulators? ▪ Insecticides / fungicides for foliar or soil application? ▪ Insecticides / fungicides for seed treatment? ▪ Insecticides for foliar applications?			

3.	Type of Operation and Product Mix	Yes	No	Comments/ Proposed Action Plans
3.2 cont'd	▪ Insecticides belonging to the Neonicotinoids family or other insecticide families with high toxicity to non-target arthropods (e.g. honey bees)? ▪ Rodenticides? ▪ Non-crop pest control?			
3.3 Product mix non-agricultural chemicals	Does the manufacturing site manufacture, formulate and/or package: ▪ Food and feed stuffs (inclusive vitamins)? ▪ Human pharmaceutical products which are applied orally, topically or as an injection? ▪ Veterinary products which are applied orally, topically or as an injection? ▪ Human cosmetics and other health care products?			
3.4	Please provide a list of all active ingredients handled in each of the production units on this site.			
3.5 Risk assessment	Describe your Risk based approach			

4.	Separation / Segregation of Product Groups			Comments/ Proposed Action Plans
If the manufacturing site handles more than one of the product groups mentioned in 3.2, please answer all questions in chapter 4.				
4.1 Herbicides and insecticides / fungicides	Are the production units completely separated (except steam, nitrogen, and compressed air lines) by: ▪ Being in separate buildings? ▪ Being in same building, but fully compartmentalized, with • no common ventilation system or other potential cross flows, • ancillary equipment (e. g. vacuum cleaners, air filters, tools, used spare parts) dedicated either to herbicides or to non-herbicides and marked accordingly? ▪ Are operating staff when moving from herbicides to insecticides / fungicides required to change footwear and work clothing?	Yes	No	
4.2 Highly active herbicides (HAHs)	Are the production units completely segregated (except steam, nitrogen, and compressed air lines) from other product groups (including other herbicides) by: • Being in separate buildings?			

4.	Separation / Segregation of Product Groups	Yes	No	Comments/ Proposed Action Plans
4.2 cont'd	▪ Being in same building, but fully compartmentalized, with: ▪ no common ventilation system or other potential cross flows, • ancillary equipment (e. g. vacuum cleaners, air filters, tools, used spare parts) dedicated either to highly active herbicides or to other product groups and marked accordingly? ▪ Are the operating staff, maintenance workers and visitors required to change (over)shoes, protective equipment and overalls/ overcoats when moving from highly active herbicide areas to other areas? ▪ Are measures taken that no unfiltered air blows outside, e.g. non-opening windows, locked doors, etc.? ▪ Is the room under negative pressure and regularly monitored?			
4.3 Plant growth regulators (PGR)	Do you manufacture PGRs on shared lines together with: ▪ Herbicides? ▪ Insecticides / fungicides?			

4.	Separation / Segregation of Product Groups	Yes	No	Comments/ Proposed Action Plans
4.4 Rodenticides and non-crop pest control products:	Are the production units completely separated (except steam, nitrogen, and compressed air lines) from other product groups by: ▪ Being in separate buildings? ▪ Being in same building, but fully compartmentalized?			
4.5 Agricultural chemicals and non- agricultural chemicals (see 3.3)	Are the production units completely separated (except steam, nitrogen, and compressed air lines) by: • Being in separate buildings?			
4.6 Incomplete separation	Do herbicides and insecticides / fungicides, **if not segregated**, share equipment like: **Fixed equipment:** ▪ Bulk storage tanks in a tank farm: • For raw materials / intermediates? • Final product? • Container loading / • unloading stations? • Transfer lines (“pipelines”) with manifolds? • Common ventilation system? • Mobile equipment: • Containers for intermediates / products?			

4.	Separation / Segregation of Product Groups	Yes	No	Comments/ Proposed Action Plans
4.6 cont'd	▪ Pumps? ▪ Flexible hoses? ▪ Filters? ▪ Charging devices, e.g. ▪ funnels, ▪ suction pipes? ▪ Vacuum cleaners? ▪ Tools, e.g. shovels, spoons, sampling devices? ▪ Others? Please list.			
4.7	**Fixed Equipment**			
4.7.1 Common bulk storage tanks ("tank farm") for ingredients	Are there one-way valves or other backflow protections installed? Can these common bulk storage tanks feed ingredient to the herbicide and insecticide / fungicide process at the same time?			
4.7.2 Manifold connecting transfer lines, if applicable	How do you identify the correct connectors when you set up the transfer? Do you change the connections at the manifold during a running manufacturing campaign? How do you clean the transfer lines and the connectors at the manifold? Please describe.			

4.	Separation / Segregation of Product Groups	Yes	No	Comments/ Proposed Action Plans
4.8	**Mobile equipment**			
4.8.1	Is all the mobile equipment mentioned (e.g. pumps, flexible hoses, vacuum cleaners, tool kits, refillable containers etc.): ▪ Dedicated to herbicide or insecticide / fungicide production units? **or:** ▪ Assigned to a specific product, never being removed from the line at least during the whole manufacturing campaign and cleaned as part of the changeover process?			
4.8.2	Are there written procedures for the cleaning of mobile equipment?			
4.8.3	Is this mobile equipment properly labeled or color coded, showing its dedicated use? Is there a log book or tagging system for each interchangeable piece of equipment? Do these records include: ▪ The last product this equipment was used for?			

4.	Separation / Segregation of Product Groups	Yes	No	Comments/ Proposed Action Plans
4.8.3 (Cont'd)	▪ Date of last use? ▪ Date when the equipment was last cleaned? ▪ Cleaning method applied? ▪ Cleaning status?			
4.8.4 Mobile bulk containers	Are mobile bulk containers (e.g. IBCs, isotainers, big-bags, road / rail tanks, waste containers) assigned to the manufacture of a single product for the entire manufacturing campaign? Are they used for dedicated, temporary storage of: ▪ Inert ingredients? ▪ Active Ingredient (AI) containing materials (premix, final product e.g. prior to packaging)? ▪ Waste (e.g. used cleaning medium to be recycled) Do such containers remain dedicated to the same product after the end of its manufacturing campaign?			
4.8.5	Are the bulk containers properly labeled with clear identification of the product? ▪ Is the adhesion of the labels adequate? ▪ Is the history of these containers traceable, i.e. the last product? ▪ Is the cleaning status shown?			

4.	Separation / Segregation of Product Groups	Yes	No	Comments/ Proposed Action Plans
4.8.6	Are all types of bulk containers decontaminated **in-house?** ▪ If not, please list exceptions ▪ If yes, is there a Standard Operating Procedure (SOP)? Please describe. Is the decontamination of bulk containers **sub-contracted?** If yes: ▪ Which cleaning standard must the sub-contractor adhere to? ▪ How do you verify the cleanliness of the bulk containers?			

4.	Separation / Segregation of Product Groups	Yes	No	Comments/ Proposed Action Plans
4.9 Melting products in drums	If drums need to be placed in a hot water bath or hot air oven, e.g. for melting an active ingredient or lowering the viscosity of certain surf ▪ Are measures taken to prevent labels being lost / destroyed and traceability being lost, e.g. by marking the top of the drum with the name of the product with permanent, waterproof paint? ▪ Are the hot water baths or hot air ovens dedicated to the campaign of one single product, i.e. no raw materials or active ingredients for other products will share the hot water bath or hot air oven at the same time? See history 10.12 in the Contamination Prevention booklet.			

4.	Separation / Segregation of Product Groups	Yes	No	Comments/ Proposed Action Plans
4.10	**Handling / warehousing of common raw materials to herbicides and non-herbicides manufacture**			
4.10.1 Handling	Are there raw materials that are common to both herbicides and non-herbicides e.g. solvents, surfactants etc.? Is it ensured that a partially consumed container of a common material - after it has been opened in the herbicide area - will never be taken into the non-herbicides area? Are such containers labeled "For Use in Herbicides only" and stored with the herbicide ingredients?			
4.10.2 Ware-housing	How are herbicide and non-herbicide active ingredients or materials for further processing segregated? Please specify: ▪ In segregated buildings? ▪ In different compartments or in dedicated, clearly marked areas in the same building, e.g. clear markings on the floor, walls and /or signs and/or color coding? ▪ In a different store room with clear visual markings?			

5.	Product Changeover	Yes	No	Comments/ Proposed Action Plans
5.1	**Changeover management and cleaning levels**			
5.1.1 Change-over management	Has a person been assigned responsibility for the approval of the release of the cleaned equipment for the next manufacturing campaign, including sign-off?			
5.1.2 ACLs - Cleaning levels	Is there a system in place to make sure the equipment is cleaned immediately after the production run? Are there up-to-date ACLs available for each production sequence in each unit (see booklet, chapter 5.2.7)? Do the ACLs include all active ingredients handled in the production units? Is there a procedure to ensure that the cleaning levels are updated whenever the product mix or production sequences are changed in a shared production unit? Is the client informed immediately? Do the clients provide the required ACLs? If not, how are the ACLs obtained / determined?			

5.	Product Changeover	Yes	No	Comments/ Proposed Action Plans
5.2	**Analysis of cleaning levels (residual impurity)**			
5.2.1	Are there analytical capabilities available to determine residual impurities below the ACLs requested by the client? ▪ For “contaminant in the “rinsate” analysis? ▪ For “contaminant in the succeeding product” analysis?			
5.2.2	Where are trace analyses of the residual impurities performed? ▪ In the analytical laboratory on site? ▪ In an external contract laboratory? ▪ Which company? *Please name:* ▪ In the client’s analytical laboratory?			
5.2.3	Is the residual impurity analytical method validated in the target cleaning level range: ▪ For linearity? ▪ For recovery?			

5.	Product Changeover	Yes	No	Comments/ Proposed Action Plans
5.2.4	Are the residual impurities determined: **in the succeeding product?** If yes: ▪ How many batches are typically analyzed? ▪ Is a sample taken from the vessel? ▪ Is a sample taken from the 1st pack? or: ▪ ***in the last rinsate*** ▪ Is the cleaning medium analyzed? ▪ **At every product changeover?** ▪ If not, please explain:			
5.2.5	Are analytical samples, laboratory samples and / or retained samples (at the end of their storage period): ▪ Prevented to be recycled back to the process? ▪ Disposed of?			

5.	Product Changeover	Yes	No	Comments/ Proposed Action Plans
5.3	**Cleaning procedures**			
5.3.1	Are there written and validated cleaning procedures in place? How was the cleaning validation done? Please describe:			
5.3.2	Does the cleaning procedure specify: ▪ The cleaning medium to be used? ▪ The cleaning equipment to be used? ▪ The cleaning conditions to be used (e.g. temperature, time)? ▪ The sequence in which the individual parts of the manufacturing line are to be cleaned? ▪ How to charge the cleaning medium into the equipment? ▪ The number of cleaning cycles, the duration of each cleaning cycle and the minimum quantity of cleaning medium per rinse? ▪ Dismantling and manual cleaning where required? ▪ Sampling locations?			

5.	Product Changeover	Yes	No	Comments/ Proposed Action Plans
5.4 Recycling of used Cleaning medium	Is the used cleaning medium recycled back into the process? If yes, please provide more details. Is the client in agreement that the used cleaning medium is recycled into his product? If the used cleaning medium is recycled, are the containers collected immediately labeled after the cleaning has been completed? Are containers for used cleaning medium cleaned before use, i.e. before filling with the used cleaning medium?			
5.5	**Release procedure for the cleaned equipment of the production unit**			
5.5.1 Release procedure	Is there a release procedure for the cleaned equipment prior to starting the next campaign? Does this procedure include the following: ▪ Visual confirmation for adequate cleanliness? ▪ Verification of the cleaning record for completeness to ensure traceability?			

5.	Product Changeover	Yes	No	Comments/ Proposed Action Plans
5.5.1 (cont'd)	▪ Verification whether the installations and the shared equipment (pumps, flexi hoses etc.) are properly labeled including the name of the previous active ingredient and the cleaning levels achieved? ▪ Verification that results of the RI analysis meet the specified cleaning limit (as the confirmation for effective cleaning)?			
5.5.2 Complete- ness check for cleaned equipment	Do the operators, involved in readying the equipment for the next production run, put their signature on the cleaning record and enter the time at which the individual cleaning steps have been completed? If a step in the cleaning of the equipment is not carried out, will this be marked on the cleaning record with a brief explanation? Is it ensured that the next campaign cannot be started before the person responsible for the equipment release has inspected the cleaned installation and has signed the appropriate documentation?			

5.	Product Changeover	Yes	No	Comments/ Proposed Action Plans
5.6	**Release procedure for the product manufactured after changeover**			
5.6.1	Does the product release procedure include the following: ▪ Who is authorized to release the product? ▪ Steps to be agreed with the client for the release of non-conforming product? ▪ Quarantine of product manufactured after changeover until the first batch(es) is (are) formally released? ▪ Release decision based on the residual impurity analysis to confirm that the agreed ACL has been achieved?			

6.	Documentation	Yes	No	Comments/ Proposed Action Plans
6.1 Records retention	Are records retained? How long do you retain the following documents? Cleaning records: ….. Years? Batch cards: ….. Years? Analytical results of residual impurity levels, including chromatograms: …. Years?			
6.2 Final product sample retention	Do you keep retained samples? ▪ If yes, how long are they retained? ▪ Are the storage conditions for retained samples defined? Please describe storage conditions: ▪ Are these samples kept under lock and key?			

7.	Material Identification and Traceability	Yes	No	Comments/ Proposed Action Plans
7.1 Raw material identifica-tion	Are incoming goods identified by: ▪ Name, material code (“identity number”) and the batch number(s) mentioned on the bill of lading? ▪ Chemical / physical analysis to confirm identity? ▪ Chemical / physical analysis to confirm quality?			
7.2 Production preparation / staging point	Are controls in place to ensure that the correct and released material is delivered from the warehouse to the production unit and added to the process? Please specify how:			
7.3 Material trace-ability	Are production records / batch cards completed and retained for each individual batch manufactured? Do the records itemize the following details: ▪ Batch numbers and the exact quantities of raw materials added into the process? ▪ Batch number and quantity of each batch produced?			

7.	Material Identification and Traceability	Yes	No	Comments/ Proposed Action Plans
7.3 cont'd	▪ The names of the operators and their initials for each step completed? ▪ RI analysis result? ▪ QC result?			
7.4 Labels	Is there a procedure to ensure that only the correct labels will be applied to the products (This includes temporary labels.)? Please explain methodology: In case temporary labeling is required before the final labels can be attached, do these labels include (as a minimum) the following information: ▪ Product name and product code? ▪ Batch number and production date? Quantity? (for bulk containers only)			

8.	Equipment Design for Improved Cleaning Effectivity	Yes	No	Comments/ Proposed Action Plans
8.1 Pipe work	Is the equipment aligned from top floor down to bottom floor, with no U-shaped pipe work in the manufacturing line where material could get trapped? Is the pipe work sloped to allow easy drainage? Does the pipe work provide valves at the lowest point to allow easy drainage? Does the pipe work avoid bends with small radius (especially in solids and flowables production units) to minimize the risk of trapping material? Does the pipe work offer enough cleaning access panels for easy access with cleaning equipment and easy visual inspection? Please provide a brief description:			
8.2 Technical equipment	Are formulation and packaging lines equipped with “Clean in Place” (CIP) installations? Do you apply an automated cleaning process controlled by a Process Control System?			

8.	Equipment Design for Improved Cleaning Efficiency	Yes	No	Comments/ Proposed Action Plans
8.2 cont'd	Are unloading and packaging stations closed in (i.e. in their own compartment), and in the case of powders equipped with dedicated pre-filters? Does the technical equipment (reactors, mills, driers etc.) have: ▪ Enough cleaning access panels to allow easy access with cleaning equipment and thorough visual inspection for cleanliness? ▪ Internal surfaces that are corrosion proof and smooth to avoid trapping of product? ▪ Adequate surrounding space and logical disassembly points equipped with quick fittings to allow rapid dismantling and inspection? ▪ An air handling system (air intake and exhaust) suited to prevent contamination? (please describe)			
8.3 Change of equipment-configure-ation	In case the configuration of the production unit is changed (e.g. new apparatus, different [e.g. larger or smaller] vessels, filling line, changed geometry of pipe work) are the following steps undertaken: ▪ Are the clients informed in writing about the change of the configuration? When, e.g. before start-up of the campaign? ▪ Are the cleaning procedures revalidated and adjusted if required?			

9.	Further Contamination Prevention Aspects	Yes	No	Comments/ Proposed Action Plans
9.1	Are product spills ever returned into the process?			
9.2	At which stage the client is informed when material does not meet final product specification?			
9.3	Is reconditioning of off-spec material done following a procedure approved by the client following the relevant government regulations and with written authorization of the client for each occurrence?			
9.4	Which rules are implemented for movement of personnel (e.g. from a herbicide unit to a fungicide unit)?			
9.5	Which outside influences (e.g. ventilation exhaust of a herbicide unit in the neighborhood) could potentially cause a product integrity incident? Please list:			
9.6	Are transportation aspects part of the contamination prevention considerations? Please provide examples and the corresponding risk assessments:			
9.7	Which recycling processes are used, e.g. recycled solvents? How do you check whether these materials are not contaminated?			
9.8	Are there any pest or weed control measures used on site? If any, please specify:			