## ANNEX 5 Veterinary Pesticides (Ectoparasiticides)

Adequate validated cleaning procedures should be employed to prevent cross contamination, and steps should be taken to ensure the secure storage of the veterinary pesticide product in accordance with the guide.

#### 5.1 Introduction

Ectoparasiticides are those products applied externally to animals to control only external parasites.

Ectoparasiticides differ from most other veterinary chemical products in that they contain pesticides that may be toxic and generally incompatible with other forms of medicinal products. Consequently, ectoparasiticides should not be manufactured in the same area as other veterinary chemical products unless special precautions are taken to prevent cross-contamination. These precautions might include the use of dedicated equipment that is adequately separated from other processing areas or, where the same equipment is to be used for incompatible products, the use of scheduling and validated cleaning procedures.

Because some of the active materials are also used for agricultural chemicals, ectoparasiticides are occasionally manufactured in plants that also make agricultural chemicals. In those circumstances, rigorous precautions need to be taken to eliminate the risk of cross-contamination with pesticides, herbicides and incompatible materials.

Some of the products such as acaricides for dipping, are made in large volumes using solvents and other materials that are highly inflammable that are stored in drums or specially constructed storage vessels. Outdoor storage of such materials may be acceptable, provided storage conditions such as temperature are appropriate for the materials involved.

Safety issues, such as the explosion hazard of excessive dust generation and the possibility of inhalation of chemical laden dust by personnel (e.g. organophosphate pesticides), should be considered in the design and location of ectoparasiticide manufacture.

Attention is drawn to the need to comply with dangerous goods and hazardous substances legislation that may require special storage condition for goods that are of a dangerous or hazardous nature.

#### 5.2 Buildings and grounds

As a general rule, ectoparasiticides should not be manufactured in the same area as other veterinary chemical products. They should be made in segregated areas or separate buildings, using equipment that is dedicated to this type of product. However, use of common equipment may be accepted, if cross-contamination is controlled by scheduling and use of a validated cleaning procedure.

Similarly, where ectoparasiticides are manufactured in a facility that also manufactures agricultural chemicals, they should be made in a separate area of the plant, using equipment dedicated to veterinary chemical manufacture. Special measures are needed to prevent cross-contamination with agricultural chemicals, particularly where shared facilities, such as packing rooms, are used.

Bunding may be required in some situations to meet the requirements of dangerous goods and environment protection legislation.

Outside storage of high-volume materials (e.g. solvents in 200 litre drums) may be acceptable, provided they are in adequately sealed containers and outside storage conditions are unlikely to adversely affect their quality.

#### 5.3 Manufacture

Manufacturing processes that involve the application of a liquid premix onto an inert carrier powder should ensure adequate dispersion of the liquid and, therefore, the active ingredient(s). Mixing times and methods should ensure batch homogeneity.

Measures should be in place to prevent cross-contamination from hoses, fixed pipework and connections.

**5.4 Personnel** ‌‌

By adopting these strategies, employers can reduce the risk of pesticide exposure and poisoning in the workplace. It is important to also provide workers with clear instructions and guidelines for handling and disposing of pesticides, and to regularly review and update safety procedures to ensure they are effective and up to date

* Following safe handling and disposal procedures for pesticides: Handle pesticides carefully, and follow all safety guidelines when mixing, and blending of pesticides. Store pesticides in a secure area, away from food, water, and other sensitive areas. ‌‌
* Providing appropriate personal protective equipment (PPE) to workers: Provide workers with the necessary PPE, such as gloves, goggles, respirators, and protective clothing, to reduce exposure to pesticides. ‌‌
* Conducting regular training on safe pesticide handling practices: Provide workers with regular training on safe handling practices, including how to use PPE, how to read and follow pesticide labels, and how to properly mix and apply pesticides.‌‌
* Monitoring workers for signs of pesticide exposure: Regularly monitor workers for signs of pesticide exposure, such as respiratory symptoms, skin irritation, or other symptoms. Encourage workers to report any symptoms or concerns.‌‌
* Implementing an integrated pest management (IPM) program: Implement an IPM program that uses a combination of strategies to control pests, including non-chemical methods such as sanitation, exclusion, and mechanical control.

Appropriate measures should be established and implemented to prevent cross-contamination from personnel, materials, etc. moving from one dedicated area to another.

Any production activities (including weighing, milling, or packaging) of highly toxic non-pharmaceutical materials such as herbicides and pesticides should not be conducted using the buildings and/or equipment being used to produce APIs. Handling and storage of these highly toxic nonpharmaceutical materials should be separate from other non-related products.

**5.5 In-process control**

Pesticides can pose various health and environmental hazards. Some of the hazards associated with these chemicals include toxicity, flammability, corrosiveness, irritancy, and explosiveness. It is essential to understand the hazards associated with each chemical and take appropriate safety measures to protect oneself, other people, livestock, and the environment.

Provide most appropriate sources of possible waste/explosive gases according to the operations in the manufacturing plant:

5.5.1“**Normal” temperature processes**, such as production, handling or

work-up processes, with the main contaminants:

1. Volatile organic compounds such as solvents
2. Inorganic gases, such as hydrogen halides, hydrogen sulphide, ammonia, carbon monoxide
3. Particulates in the form of dust

**5.5.2 Incineration processes, with** main contaminants:

1. Particulates in the form of ashes and dust, containing soot,metal oxides
2. Fuel gases such as carbon monoxide, hydrogen halides, sulphur-oxygen compounds (SOx), nitrogen-oxygen compounds (NOx)

Records must make it possible to trace all steps in the manufacture considering the Principle of Air Pollution Control Technology as listed below.

Principle of air pollution control technology can be broadly classified into

following groups.

1. Separation techniques
2. Gas solid separation
3. Liquid-liquid separation
4. Gas liquid separation
5. Conversation to harmless end product
6. Thermal destruction

These are illustrated below.

Detailed SOP should be provided including records of all pollution control processes where necessary.

**5.5.3 Separation techniques**

In case of gas solid separation, the following techniques are employed:

1. Separator
2. Cyclone
3. Multiclone
4. Electrostatic precipitator
5. Wet dust scrubber
6. Fabric filter including ceramic filter

With respect to liquid-gas or liquid-liquid separation, the following techniques

are considered:

1. Mist filter
2. Condensation
3. Adsorption
4. Wet scrubbing

**5.5.4 Thermal destruction**

Thermal destruction is generally used, when toxic and carcinogenic chemicals are emitted from the process. The thermal destruction technology generally used is stated below:

1. Thermal oxidation
2. Catalytic oxidation
3. Flaring

**5.5.5. Conversion to harmless product**

These techniques are used for organic pollutants; The techniques are:

1. Bio filtration
2. Bio scrubbing
3. Bio trickling

**5.5.6. Combination approach**

The technique for cleaning of pipe gases can combine both recovery and

reduction. The techniques are as follows:

1. Dry sorbent injection
2. Semi dry sorbent injection
3. Selective non-catalytic reduction (SNCR) of NOx
4. Selective catalytic reduction (SCR) of NOX.