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Foreword

This guidance document sets out the minimum manufacturing requirements for agricultural pesticides (products) that should be met by manufacturers of pesticide end use formulations. The scope of the document is for synthetic chemistry and excludes products such as biologicals, biocides, public health pest control, vertebrate toxic agents. It aims to advise and assist manufacturers of pesticide products to comply with international manufacturing standards and best practices to manage the risks associated with the manufacture of products to ensure they are of the appropriate quality for their use. A risk-based approach under pins the recommendations outlined in this guidance document.

This project was led by New Zealand.

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Table of contents

1. Introduction

1.1 Purpose

This guidance document sets out the minimum manufacturing requirements for agricultural pesticides (products) that should be met by manufacturers of pesticide end use formulations (to be referred to as pesticides throughout the document).

This has been adopted to advise and assist manufacturers of products to comply with international manufacturing standards and best practices to manage the risks associated with the manufacture of products to ensure they are of the appropriate quality for their use.

If a manufacturer operates in accordance with any other standard, the manufacturer should provide a justification for equivalence of the other standard and have appropriate documentation and systems to manage the risks.

1.2 Scope

This document provides guidance for the following areas of manufacture:

- quality management
- personnel and training
- premises, plant, equipment and utilities
- documentation management and records
- materials production
- quality control and testing
- contract manufacture, testing and analysis, and supplier management
- product complaints and product recalls
- monitoring, maintenance and internal audit
- product release to market at destination
- registrant's responsibilities

It is acknowledged that manufacturers vary in size, scope and the complexity of their products and manufacturing processes. Therefore a risk-based approach should be taken when addressing the recommendations outlined in this guidance document to ensure that risks associated with each manufacturer's specific site and product range are managed appropriately, the end products are of the required quality, and in compliance with authorised specifications such as composition (contents of active ingredients, inert ingredients and impurities) and labelling. This should include an appropriate form of record-keeping which allows for traceability and investigation in the event of a problem being identified.

Excluded from the scope of this guidance document are products such as biologicals, biocides, public health pest control, vertebrate toxic agents and the manufacturing of products which may require stricter standards such as Good Manufacturing Practices (GMP).

1.3 Definitions and abbreviations

Product quality: Compliance of a product with the specifications and tolerances documented in the market authorisation/registration.

Manufacture: In relation to any product, 'manufacture' includes all the following aspects: acquiring materials, making up, preparing, producing or processing, and examining, assessing or quality control testing the materials and the product for release; it also includes the filling, refilling, packing, repacking, labelling, and relabelling of a product in a container for the purposes of sale.

Manufacturer: Any person (or business entity) who manufactures a product. Where the process of manufacturing a product is carried out on different sites or by independent contractors, all such participants are manufacturers.

2. Background and Risk Reasoning

It is essential that the entity responsible for the manufacture of a product takes steps to ensure that it is manufactured in a way that has considered the risks associated with the manufacturing process. This ranges from consideration of standards of ingredients used, and confirming that all critical standards are met, to ensuring that the correct label is affixed to the containers, to addressing and minimising the potential for contamination during the manufacturing process itself.

While there will be many aspects in common, the risk assessment will differ for each product. For example, ingredients used in manufacture of a fungicide to be applied over flowering should be considered for the effect on pollinators. Herbicide active ingredients have differing activities towards different species and are of particular concern from the perspective of cross contamination due to their inherent phytotoxicity. Manufacturing lines and equipment used may require different cleaning protocols before use depending on the ingredients in the product previously manufactured. For some products, the risks may be such that manufacture of the product is restricted to specific equipment or facilities. For example, the risks associated with highly potent herbicide products such as those with sulfonyl urea active ingredients may be managed by manufacturing them on separate production lines or even in different buildings from lower potency herbicides or non-herbicide products. In each case, a documented system should be in place to show what has been considered, identify the risks and include appropriate steps to manage them. The risk assessment therefore shall also consider the cleaning levels required based on the acceptable residual impurity level (ARIL) for the formulated products. ARILs are likely to be set at the national level to meet their individual requirements. The risk management documentation should be made available to the regulator as required by local legislation and policies.

In many cases, the entity that bears the legal responsibility for the supply of registered product to the market (the registrant), is not the entity directly manufacturing the product. Instead, the product may be manufactured by a third party manufacturer under contract to the registrant. In these cases, the registrant is expected to be able to provide assurances to the regulator and to their customers that appropriate quality management is implemented by the manufacturer. How this is managed should be clearly documented in a contract and agreed by the parties involved and be sufficient to assure regulators that the parties are aware of the risks associated with manufacture of that product. Where multiple entities carry out different steps of manufacture for a product, the entity bearing the responsibility for the management of the entire manufacturing process should be identified. Under these arrangements some of the requirements under Section 3, including those specified under Section 3.7, for individual manufacturers can be exempted where they are properly covered by other manufacturer(s) for the product.

3. Recommendations

3.1 Quality management and assurance

3.1.1 A manufacturer of a product should have a quality management system that is able to ensure that the product is fit for its intended use and conforms its specifications.

3.1.2 The quality management system should include a comprehensively designed and correctly implemented system of quality assurance incorporating best practices and quality control. The quality management system should be fully documented, and its effectiveness monitored.

3.1.3 The quality management system should ensure that all parts of the quality assurance system are adequately resourced with appropriately qualified and competent personnel.

3.1.4 In order to be considered acceptable, the quality management system should demonstrate the responsibility and commitment of senior management, the participation and commitment by staff in different departments and at all levels within the company, and by the company's suppliers and its distributors.

3.1.5 A Quality Risk Management process should be used to assess and control the cross-contamination risks, including but not limited to ensuring appropriate cleaning protocols are followed, appropriate equipment is used, work areas are clear of previous products, etc. Factors including facility/equipment design and use, personnel and material flow, microbiological contamination controls, physico-chemical characteristics of the active ingredient, process characteristics, cleaning processes and analytical capabilities relative to the relevant limits established from the evaluation of the products should also be considered.

3.1.6 The outcome of the Quality Risk Management process should be the basis for determining the extent to which premises and equipment should be dedicated to a particular product or product family. This may include dedicating contact parts or of the entire manufacturing facility to a specific product. It may be acceptable to confine manufacturing activities to a segregated, self-contained production area within a multiproduct facility, where justified.

3.2 Personnel and Training

3.2.1 There must be sufficient and appropriately qualified personnel, as specified in the site master file, to carry out all the tasks that are the responsibility of the manufacturer.

3.2.2 Job descriptions must be documented for staff with specific responsibilities and be clearly understood by the staff concerned.

3.2.3 All personnel must be aware of the specifications in this standard that affect them and receive initial and continuing training relevant to their needs.

3.3 Documentation Management and Records

3.3.1 All documentation should be complete, clearly written, accurate and information should be indelible.

3.3.2 Entries on all documents should be signed and dated, and traceable. Electronic signatures are acceptable provided they are traceable and secure.

3.3.3 Documentation relating to materials, ingredients, manufacture and product tests should be retained, at least until one year after completion of the expiry of the product manufactured, or five years from the date of manufacture when no expiry period has been established.

3.2.4 An up-to-date site master file containing the following information should be maintained for each manufacturing site:

- site contact details
- details of the nature of manufacture performed and types of products manufactured
- site and building plans with key plant and equipment locations, air systems and production flow paths indicated
- details of staff engaged in production and quality control

3.2.5 Documentation covering the following aspects should be present as a minimum requirement:

- staff organisation diagram
- staff position descriptions
- staff training records
- materials specifications (raw material, active ingredient etc.)
- materials certificates of analysis (raw material, active ingredient etc.)
- materials test/inspection and release records (raw material, active ingredient etc.)
- Product Master Formula / recipe
- manufacturing procedures and batch records
- final product specifications
- quality control procedures and test records (e.g. batch analyses, certificates of analysis)
- packaging specifications
- packing procedures
- label reconciliation procedure and records
- line clearance procedure and records
- cleaning procedures and records
- product distribution records
- complaints procedure and records
- product recall procedure and records
- internal audit procedure and records
- plant maintenance procedures and records
- plant and systems validation for key product equipment, utilities and systems that directly impact product quality or Key product contact or quality impacting equipment, utilities and system validation or qualification records (where applicable and appropriate)
- cleaning validation records
- process validation records
- equipment calibration records.

3.2.6 There should be appropriately authorised and dated specifications for starting and packaging materials and finished products.

3.2.7 Specifications for starting materials should include or provide reference to, if applicable:

a) A description of the materials, including:
   - The designated name and the internal code reference;
   - Specifications (purity, impurity limits, grade, as applicable);
   - The approved suppliers and, if reasonable, the original producer of the material;
b) Directions for sampling and testing;
c) Qualitative and quantitative requirements with acceptance limits;
d) Storage conditions and precautions;
e) The maximum period of storage before re-examination.

3.2.8 Specifications for primary or printed packaging materials should include or provide reference to, if applicable:

a) A description of the materials, including:
   - The designated name and the internal code reference;
   - Specifications/material type/composition
   - The approved suppliers;
b) A specimen of printed materials;
c) Directions for acceptance into stock (if applicable);
d) Storage conditions and the maximum period of storage (if applicable).

3.2.9 Specifications for intermediate and bulk products should be available for critical steps or if these are purchased or dispatched. The specifications should be similar to specifications for starting materials or for finished products, as appropriate.

3.2.10 Specifications for finished products should include or provide reference to:

a) The designated name of the product and the code reference where applicable;
b) The formula;
c) A description of the form of the product and package details;
d) Directions for sampling and testing;
e) The qualitative and quantitative requirements (test parameters), with the acceptance limits and details of the test methods and test conditions as required;
f) The storage conditions and any special handling precautions, where applicable;
g) The shelf-life (if applicable).

3.2.11 There should be documented information for the receipt of each delivery of each starting material (including bulk, intermediate or finished goods), primary, secondary and printed packaging materials. There should be documented information for internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate. The records of the receipt should include:

a) The name of the material on the delivery note, and the containers;
b) The "in-house" name and/or code of material (if different from a);
c) Date of receipt;
d) Supplier’s name and manufacturer’s name;
e) In addition, for starting materials, the following should also be supplied.

f) Manufacturer's batch or reference number;
g) Total quantity and number of containers received;
h) The batch number assigned after receipt;

3.2.12 Approved, written Manufacturing Formula and Processing Instructions should exist for each formulation and batch size to be manufactured. The Manufacturing Formula should include:

a) The name of the product, with a product reference code relating to its specification;
b) A description of the formulation type, strength of the product and batch size;
c) A list of all starting materials to be used, with the amount of each, described; mention should be made of any substance that may disappear in the course of processing;
d) A statement of the expected final composition with the acceptable limits, and of relevant intermediate composition, where applicable.

3.2.13 The Processing Instructions should include:

a) A statement of the processing location and the principal equipment to be used;
b) The methods, or reference to the methods, to be used for preparing the critical equipment (e.g. cleaning, assembling, calibrating, sterilising);
c) Checks that the equipment and work area are clear of previous products, documents or materials not required for the planned process, and that equipment is clean and suitable for use;
d) Detailed stepwise processing instructions [e.g. checks on materials, pre-treatments, sequence for adding materials, critical process parameters (time, temp etc)];
e) The instructions for any in-process controls with their limits;
f) Where necessary, the requirements for bulk storage of the products; including the container, labelling and special storage conditions where applicable;
g) Any special precautions to be observed

3.2.14 Approved Packaging Instructions should exist. Not all information must be available in one single document per product. Referring to general SOPs and central data systems is acceptable. These should include, or have a reference to, the following:

a) Name of the product; including the batch number of bulk and finished product;
b) Description of its formulation type, and strength where applicable;
c) The pack size expressed in terms of the number, weight or volume of the product in the final container;
d) A complete list of all the packaging materials required, including quantities, sizes and types, with the code or reference number relating to the specifications of each packaging material;
e) Where appropriate, an example or reproduction of the relevant printed packaging materials, and specimens indicating where to apply batch number references, and shelf-life or expiry date of the product;
f) Special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before operations begin;
g) A description of the packaging operation, including any significant subsidiary operations, and equipment to be used;
h) Details of in-process controls with instructions for sampling and acceptance limits.

3.2.15 A Batch Processing Record should be kept for each batch processed. It should be based on the relevant parts of the currently approved Manufacturing Formula and Processing Instructions, and should contain the following information:

a) The name and batch number of the product;
b) Dates and times of commencement, of significant intermediate stages and of completion of production;
c) Identification (initials) of the operator(s) who performed each significant step of the process and, where appropriate, the name of any person who checked these operations;
d) The batch number and/or analytical control number as well as the quantities of each starting material (including the batch number and amount of any recovered or reprocessed material added);
e) Any relevant processing operation or event and major equipment used;
f) A record of the in-process controls and the initials of the person(s) carrying them out, and the results obtained;
g) The product yield obtained at different and pertinent stages of manufacture;
h) Notes on special problems including details, with signed authorisation for any deviation from the Manufacturing Formula and Processing Instructions;
i) Approval by the person responsible for the processing operations.

3.2.16 A Batch Packaging Record should be kept for each batch or part batch packaged. It should be based on the relevant parts of the Packaging Instructions and should contain the following information:

a) The name and batch number of the product;
b) The date(s) and times of the packaging operations;
c) Identification (initials) of the operator(s) who performed each significant step of the process and, where appropriate, the name of any person who checked these operations;
d) Records of checks for identity and conformity with the packaging instructions, including the results of in-process controls;
e) Where practical, the following should be undertaken and recorded for possible investigations when there is a non conformance
f) Details of the packaging operations carried out, including references to equipment and the packaging lines used;
g) Whenever possible, samples of printed packaging materials used, including specimens of the batch coding, expiry dating and any additional overprinting;
h) Notes on any special problems or unusual events including details, with signed authorisation for any deviation from the Packaging Instructions;
i) The quantities and reference number or identification (e.g. batch number) of all containers, closures (lids and seals), printed packaging materials (including labels applied to containers) and bulk product issued, used, destroyed or returned to stock and the quantities of obtained product, in order to provide for an adequate reconciliation. Where there are robust electronic controls in place during packaging there may be justification for not including this information;
j) Approval by the person responsible for the packaging operations.

3.3 Premises, plant, equipment and utilities

3.3.1 Premises, plant and equipment should be located, designed, constructed, adapted and maintained to suit the operations to be carried out, and be recorded appropriately.

3.3.2 Their layout and design should aim to minimise the risk of errors and permit effective cleaning and maintenance to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the specified quality of products.

3.3.3 Production premises, plant and equipment should be of sufficient capacity for their intended use and be maintained in a clean and orderly manner.

3.3.4 Products for use on or in humans or veterinary medicines, should not be manufactured in the same facilities or equipment as products unless appropriate separation and validated

cleaning procedures are implemented and documented.

3.3.5 Environmental conditions within manufacturing premises should be appropriate for the operations and not adversely affect operations carried out.

3.3.6 Separation of critical processes should be provided during manufacturing operations to prevent cross-contamination of products.

3.3.7 Separation of quality control laboratories and testing procedures from production activities that might adversely impact manufactured product quality should be provided.

3.3.8 Consider where staff eating areas and toilets are located,

3.4 Materials and Production

3.4.1 Production operations should be appropriate for the product(s) being manufactured to ensure appropriate quality.

3.4.2 Production operations should establish, control and follow clearly defined and documented procedures.

3.4.3 All materials, in-process and final products should be labelled to define their identity and status.

3.4.4 Incoming materials and finished products should be physically or administratively quarantined immediately after receipt or processing, until they have been released for use or distribution.

3.4.5 When working with dry materials and products, special precautions should be taken to prevent the generation and dissemination of dust.

3.4.6 Processes and equipment critical to manufacturing operations should be validated.

3.4.7 Operations on different products should not be carried out simultaneously or consecutively in the same room unless the risk of mix-up or cross contamination has been addressed.

3.4.8 Contamination of a starting material or of a product by another material or product should be prevented. The risk of accidental cross-contamination resulting from the uncontrolled release of dust, gases, vapours, aerosols, genetic material or organisms from active substances, other materials (starting or in-process), and products in process, from residues on equipment, and from operators' clothing should be assessed. The significance of this risk varies with the nature of the contaminant and that of the product being contaminated.

3.4.9 The identity and quality of all starting materials should be known and approved prior to use in production.

3.4.10 Storage and use of pre-printed labels should be controlled to prevent mislabelling occurring during packaging operations.

3.4.11 Separation of packaging operations and line clearance should be documented to prevent product mixing.

3.4.12 All returned, damaged or rejected materials or products should be quarantined and clearly identified.

3.4.13 Based on product shelf-life, a sample retention schedule for manufactured batches should be defined. Retention samples shall be representative of the batch and stored for at least one year after its expiry or five years from the date of manufacture when no expiration period has been established.

3.5 Quality control and Testing

3.5.1 The quality control functions should be independent and separate from production.

3.5.2 Procedures should be in place for the assessment and formal release of raw materials for use in production, and of final product to the market.

3.5.3 Sampling and testing of raw materials as appropriate, of in-process materials (intermediate products), and final products should be carried out according to predetermined and documented test methods and standard operating procedures. Samples should be representative of each batch the sample is taken from (whether a raw material/active ingredient, intermediate or finished products).

3.5.4 Test methods should be validated as appropriate, testing equipment should be calibrated, and controls employed when appropriate.

3.5.5 Laboratory documentation should include:

a) Specifications;
b) Procedures describing sampling, testing, records (including test worksheets and/or laboratory notebooks), and recording and verifying results;
c) Procedures for and records of the calibration/qualification of instruments and maintenance of equipment;
d) A procedure for the investigation of Out of Specification results, and Out of Trend results when necessary;
e) Testing reports and/or certificates of analysis;
f) Data from environmental (air, water and other utilities) monitoring, where required;
g) Validation records of test methods, where applicable.

3.5.6 Test records should include:

a) Name of the material or product and, where applicable, product type;
b) Batch number and, where appropriate, the manufacturer and/or supplier;
c) References to the relevant specifications and testing methods;
d) Test results, including observations and calculations, and reference to any certificates of analysis;
e) Dates of testing;
f) Traceability regarding the persons who performed the testing;
g) Traceability regarding the persons who verified testing and the calculations, where appropriate;
h) A clear statement of approval or rejection (or other status decision) and appropriate release details;
i) Reference to the equipment used.

3.6 Contract manufacture, testing and analysis, and supplier management

3.6.1 Contract manufacture and analysis should be correctly defined, agreed and controlled in order to avoid misunderstandings that could result in a product or work of unsatisfactory quality.

3.6.2 There should be a written contract between the contract giver and the contract acceptor that clearly establishes the duties of each party.

3.6.3 Changes affecting the contract agreed between the parties should be documented.

3.6.4 The contract should clearly state the way in which the authorised person releasing each batch of product for sale exercises their full responsibility.

3.6.5 The contract acceptor should not deviate from conditions on the materials, or processes used, as specified in the contract.

3.6.6 Communication exchanges with details regarding non-conformances, changes to approved manufacturing processes etc., shall be documented.

3.6.7 The contract between a registrant and a contract manufacturer should contain sufficient details regarding the product and approved particulars to ensure that the manufacturer can produce every batch of the product(s) in compliance with the registration, and to ensure that the registrant can be confident that all of their requirements will be met. Lines of communication should be in place to facilitate both parties becoming aware of any changes which impact the registration or manufacture in a timely manner.

3.6.8 Contractors providing manufacturing or testing services should be able to meet the necessary requirements appropriate to the functions they perform and retain appropriate evidence for regulatory authority approval as a part of the manufacturing process.

3.7 Product Complaints and Product Recalls

3.7.1 All complaints and other information concerning potentially defective products should be carefully reviewed and documented according to written procedures, including such information as necessary (e.g. identification details for the complainant, details of the problem – time, date and nature, identification details for the defective product, such as product name, batch number, date of manufacture, details of any corrective action taken, and correspondence with the complainant, registrant, regulatory authorities, or other parties).

3.7.2 A system should be provided to enable, if necessary, the prompt and effective recall from the market of any batch of product.

3.8 Monitoring, Maintenance and Internal Audit

3.8.1 Internal audits should be conducted in order to monitor compliance with the guidance and to implement any necessary corrective measures.

3.8.2 Internal audits should be carried out to a predetermined programme, be documented and reviewed as part of the quality management process.

3.9 Product Release to market at destination

3.9.1 The entity responsible for release of the product to the market should be clear and known. It will usually be the product registrant, but where it is contracted to the manufacturer or another entity, these

parties should be aware of the relevant parts of the registration particulars and approved product details relevant to enable appropriate product checks and release. These should be clearly outlined in a quality agreement, along with the responsibilities (as per Section 3.6).

3.9.2 The entity responsible for release should ensure that, before release of the product to the relevant market:

a) the product conforms to the approved product and manufacturing specifications, including formulation and manufacturing particulars in the registration.
b) the product is labelled with the correct approved product label, and all parts of the product label are present.
c) transport of the product has been conducted as required to manage product-specific risk such as cold chain transport.
d) all final checks related to distribution and supply of the trade name product have been completed; and
e) all distribution and sales restrictions (eg sales restricted to certain persons or organisations) are adhered to.

3.9.3 For products manufactured outside of country for sale, the entity responsible for release to market should ensure that the product has arrived in the country without any negative impacts on product conformance and quality in addition to all of the requirements above

3.9.4 Registrants may nominate themselves as the release to market entity for their own products or nominate a third party to perform this function.

3.10 Registrant Responsibilities

3.10.1 The registrant should ensure that the manufacturer meets all the specifications of the products. Any registrant country specific manufacturing requirements or limitations should be communicated to the manufacturer with confirmation that these requirements can be met, and agreement that these will be met and maintained; any changes will be agreed upon before implementation. Documentation in a contract between the parties is considered sufficient.

3.10.2 The registrant should ensure that raw materials and packaging of the appropriate quality including registered active ingredients (and the specified source of manufacture) are used to manufacture their product, and that ingredients are not changed without agreement from the registrant, so that appropriate registration variation applications can be made to the relevant regulatory authorities (where applicable).

3.10.3 The registrant should have documented processes for managing, investigating and actioning product complaints and adverse events, and initiating and conducting product recalls. These should include the reporting process for reporting to the regulator in the event non-compliant product is identified in the market, or in the event an adverse event is reported to them. Processes for the handling / disposal of unsold, returned or recalled product should also be in place.

3.10.4 The registrant should establish a shelf-life for the product based on the stability of the product under conditions representative for the region where it is distributed and sold. The manufacturer (or relabeller, if labelled at a site that isn't the manufacturer) should be appropriately notified.

3.10.5 The registrant should agree with the manufacturer (or repacker or relabeller as appropriate) on a process for checking that the product meets release specifications, and that the correct batch specific information, label and packaging have been used, before release to the relevant market.

3.10.6 Local country legislation requirements shall be met. It is the registrant's responsibility to ensure applicable requirements are met.