agriculture,
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REPUBLIC OF SOUTH AFRICA

GUIDELINE FOR SHELF LIFE EXTENSION OF PESTICIDES IN SOUTH AFRICA

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ABREVIATIONS

FAO: Food and Agriculture Organization of the United Nations

WHO: World Health Organization

CIPAC: Collaborative International Pesticides Analytical Council

DEFINITIONS OF TERMS

Formulation: A pesticide preparation containing active ingredient(s) and formulant(s), in a form suitable for practical use.

Finished pack: Primary sales package that is in contact with the formulation.

Shelf life specification: Physical and chemical parameters within which the properties of a formulation will remain after a minimum of 2 years storage, if no other statement as to storage period is made.

Shelf life: Period of time during which the product remains suitable for use, and within the shelf life specification, when stored in the unopened original container under conditions of the area where it is marketed and following the recommendations of the manufacturer.

FAO/WHO Specifications: International Standards of quality for pesticides evaluated and published by FAO/WHO.

Manufacturing date: The date from which the supplier guarantees a shelf-life of at least 2 years, unless stated otherwise.

Packaging date: The date the product was packed, from bulk container, into the final retail sales packaging.

FAO tolerances: Tolerances (established by FAO) on the active ingredient content taking into account analytical and sampling errors and the manufacturing variance [2].

Ambient temperature: Average temperature in the region where the product is marketed.

CIPAC methods: Analytical and physical test methods published by CIPAC.

1. INTRODUCTION

The biological efficacy of pesticides gradually decreases with time. The pesticide shelf-life is the period of time that a pesticide can be stored before it deteriorates. Nearly all pesticides have a limited shelf-life. It is normal convention that information on storage stability is given only if the product cannot be stored for at least 2 years in unopened original containers. In order for a shelf-life claim of more than 2 years to be made, the manufacturer must ensure that studies demonstrating the stability of the product for these extended periods are available and clearly demonstrate to that the shelf-life specification continues to be met at the end of the extended storage period. Accelerated storage and/or real time stability data must generated to support the shelf-life extension of the pesticide product.

This guideline provides a comprehensive guide to be conducted for of stability testing for pesticide products to support the shelf-life extension of the pesticide product as well as the procedures for applying for shelf-life extension. This guideline has been constructed to closely follow the Manual on the development and use of FAO and WHO specifications for pesticides (JMPS 2010) (FAO/WHO pesticide specifications) and Crop-life international, "Guidelines for Specifying the Shelf Life of Plant Protection Products";Technical Monograph no 17, 2nd Edition, June 2009.

2. TESTS TO BE CONDUCTED

2.1 General consideration

These products can be divided into two categories:

Category 1
Products supplied with a certificate of analysis for each batch of manufactured product.

Data on real time stability tests conducted for longer than two years, showing that the active ingredient content of the product still complies with the FAO tolerances and the degradation is not more than 10 % from the initial measured value.

Category 2
Products supplied without a certificate of analysis for each batch manufactured and no real time stability data to prove that the product is stable for longer than two years.

Analysis of the product should only commence once the product passes the stability of the packaging material and the visual inspection.

The active ingredient concentration should initially be established as a quick determinant for the A.I. being within its specified limits or not, regardless of which category (i.e. category 1 or category 2) the product falls. Once active ingredient stability has been confirmed only then proceeds to perform the other key physical tests of the formulation. As a general rule, sealed containers are to be submitted for testing.

2.2 Parameters to be tested for Category 1

The following parameters should be tested:

a) Packaging stability.
b) Visual inspection of the sample.
c) Active ingredient content of the product.
d) In addition to appearance and content of active constituent, the relevant physical chemical properties of each formulation type should be monitored before and after storage where applicable as stipulated, the physical properties mentioned in the FAO/WHO pesticide specifications

If all of the above tests are still compliant with the specifications – extend the shelf life of the product for another two years or the maximum real-time stability period minus the age of the current batch. It is advisable that each batch must be tested to ensure that it still fit for use.

2.3 Parameters to be tested for Category 2,

The following parameters should be tested:

2.3.1 Initial testing

a) Packaging stability.
b) Visual inspection of the sample.
c) Active ingredient content of the product.
d) In addition to appearance and content of active constituent, the relevant physical chemical properties of each formulation type should be monitored before and after storage where applicable as stipulated, the physical properties mentioned in the FAO/WHO pesticide specifications.

If all of the above tests are still compliant with the specifications - continue with accelerated storage stability in the current packaging material.

2.3.2 Accelerated storage stability

Perform accelerated storage stability in the current packaging material. Ideally the sealed container should be placed under the storage condition. If the container size is too big, a smaller size of the same packaging material may be used.

Note: *Not all the accelerated storage stability can be conducted at 54 °C for 2 weeks. If possible, consult with the manufacturer on the conditions (2 weeks at 54°C, 4 weeks at 50°C, 6 weeks at 45°C, 8 weeks at 40°C, 12 weeks at 35°C, 18 weeks at 30°C).*

After accelerated storage stability test of the product for (a – d) and compare with the results obtained in 2.3.1.

If all of the above tests are still compliant with the specifications the registration holder may appeal to the Registrar of Act 36 to provisionally extend the shelf life of the product for another two years, provided that real time stability testing will be conducted to support accelerated storage stability (refers to paragraph 2.3.3)

Accelerated storage and/or real time stability data can be generated to support shelf-life of the product.

Accelerated storage are usually conducted for 2 weeks at 54°C but certain flexibility in choosing test conditions is necessary due to the different nature of products, e.g. a lower temperature if the active ingredient in a solid formulation melts below 54°C. If no significant chemical or physical changes occur in the accelerated tests the conclusion is that the product will most likely comply with the shelf life specification of 2 years. If changes are observed it may be difficult to draw meaningful conclusions based on accelerated tests alone and additional storage data will be needed.

In all cases the measured active ingredient content of the product should comply with the FAO tolerances and the degradation should not be more than 10 %.

Degradation = (A – B)/B x 100

A - Measured value of the active ingredient content after storage.
B - Measured value of the active ingredient content after manufacturing.

2.3.3 Real time stability testing

At least one sealed container should be stored at 20 °C ± 5 °C for the next 2 years and analysed after the storage period. After the 2 year period the product should be tested and the results compared with the results obtained in 2.3.1.

If no significant deviations were observed, then the registration holder may appeal to the Registrar of Act 36 to in future extend the shelf life of the product to 4 years given that the product will be re-tested after 2 years as set out in 4.1.2. If significant deviations does occur the registration holder may not appeal for a shorter shelf life e.g. 3 years,

unless the real time stability of the product was tested at that time interval and no significant deviations were observed. The registration holder may test at more intervals e.g. every 3 or 6 months.

3. PRODUCTS BEING RE-PACKED FROM BULK CONTAINERS.

If a product is re-packed from bulk containers, normally several months after manufacturing, and stability data (either for more than 2 years, then the product can be tested just before packaging as set out in 2.2. If all of the above tests are still compliant with the specifications an analysis date can be stated on the product. The shelf life of the product will then be accepted as 2 years from the packaging date and not 2 years from the manufacturing date.

4. REFERENCES:

1. Crop-life International, “Guidelines for Specifying the Shelf Life of Plant Protection Products”;Technical Monograph n°17, 2nd Edition, June 2009

2. Manual on Development and Use of FAO and WHO Specifications for Pesticides, March 2006 revision of the First Edition (available only on internet): http://www.fao.org/agriculture/crops/corethemes/theme/pests/pm/jmps/manual/en/