TECHNICAL MONOGRAPH N°17

3RD EDITION

GUIDELINES FOR SPECIFYING AND MANAGING SHELF LIFE AND EXPIRY DATE OF CROP PROTECTION PRODUCTS

By CropLife International

the Specifications Experts Group (CLI-SEG)

with the support of the Product Integrity Team (CLI-PIT)

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Contents

1. INTRODUCTION

Crop Protection Products (CPPs) are designed to be stable and fit for use when stored according to label instructions for a defined period (Shelf Life). During development, manufacturers routinely conduct both accelerated storage tests at elevated temperatures and real time storage tests at ambient temperatures to determine the stability of their products.

To register a CPP, relevant stability data must be submitted to the competent authorities. Depending on country specific regulations, registration can be granted based on stability data from accelerated storage tests meeting the data requirements. In some countries, stability data from real time storage tests are additionally required to achieve registration. Based on the submitted stability data a Regulatory Shelf Life is granted for the CPP.

When setting and managing the Expiry Date of a batch, the Regulatory Shelf Life of the product must be respected.

2. PURPOSE AND SCOPE

The purpose of this Technical Monograph is to provide guidance to all manufacturers of CPPs for establishing a Regulatory Shelf Life based on stability data and managing the Batch Expiry Date of products in their final sales pack.

All CPPs are in scope. The principles of this monograph may be also applied to biological, biocidal or products for animal or public health such as vector control products, though some requirements may differ.

3. BACKGROUND

Conditions during storage and transport may affect the stability and quality of a CPP through changes of physical properties (e.g. separation of multi-phase systems, thickening, claying, particle size increase, etc.), degradation of the active ingredient(s) or interaction with the packaging material.

Therefore, the climatic conditions under which products are likely to be transported and stored must be considered, especially where CPPs are distributed globally. Stability tests can be carried out under conditions simulating different climate zones. For liquid products additional low temperature studies may be required.

Any Shelf Life claim made by a manufacturer shall be supported by studies demonstrating the stability of the product for the claimed Shelf Life period.

It is already common practice that a CPP which was not applied during the current growing season can be used in the following season, i.e. before the product is 2 years old. Nevertheless, from a quality point of view, many products remain fit for use much longer and can thus be still applied in subsequent seasons.

When CPPs are intended to be used after the assigned Expiry Date, they should be retested before expiry to decide on their continued fitness for use and to set a new Expiry Date, provided country specific regulations allow this practice.

4. SHELF LIFE OF A PRODUCT AND ITS ASSOCIATED BATCH EXPIRY DATE

It is important to carefully distinguish two technical terms which often are used in the same context:

- Shelf Life (period of time)
- Expiry Date (point in time)

The Shelf Life of a CPP is a property indicating the period in which a CPP is fit for use. Any shelf life statement shall be supported by appropriate stability data.

The Expiry Date of a batch is a property defined for a particular batch. Setting an Expiry Date is an operational task and is done at manufacturing level at time of the batch release. The period between batch release and Expiry Date cannot be longer than the Shelf Life.

Note: The Shelf Life is established for a formulated product in general (including its packaging) and applies to all its manufactured batches, whereas the Expiry Date is always related to a particular batch of a formulated product.

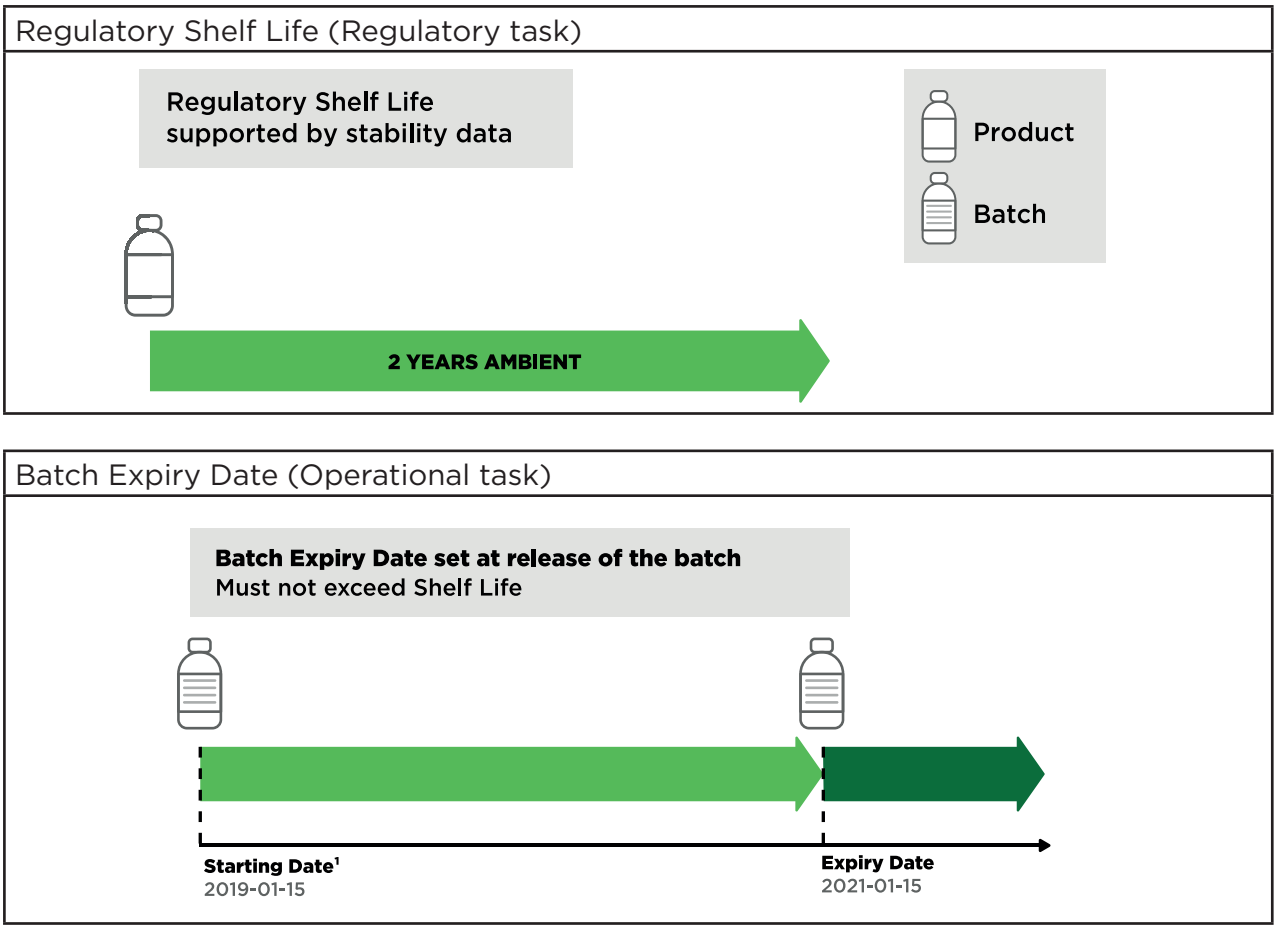

Figure 1: Distinguishing Regulatory Shelf Life and Batch Expiry Date (example)

[1]: For definition of Starting Date see Glossary

5. SHELF LIFE AND FITNESS FOR USE

During storage, CPPs may undergo chemical and physical changes at a rate which depends on the nature of its active ingredient(s), co-formulants, formulation type, packaging material and storage conditions. The product remains fit for use if changes have no negative impact on its applicability, biological performance and operator-, consumer- or environmental safety. An essential condition for fitness for use of a CPP is its compliance with the registration during the whole Shelf Life. In general, products are expected to meet requirements as outlined in the FAO/WHO manual(1). For some countries, regulatory requirements provide limits for the content of active ingredient(s) or toxicologically relevant impurities as well as for key physical properties of the product.

5.1. Active ingredient(s) content

The manufacturer must ensure that at the time of release all batches fulfil the specification and that the average active ingredient(s) content during a production campaign complies with the declared content. Unless country specific requirements apply, all batches must be within the tolerance range for the active ingredient(s) as defined in the FAO/WHO manual (1) and CropLife Technical Monograph no. 1 (2). Typically, a relative deviation of +/-10% from the declared active ingredient content will not significantly influence the biological efficacy of a CPP.

For analysis of the content of active ingredients, validated company internal methods or published methods, e.g. by CIPAC (3) when available, can be used.

5.2. Relevant impurities

Where applicable, the manufacturer must ensure that the content of relevant impurities does not exceed the allowed registered limit(s).

For analysis of the content of relevant impurities, validated company internal methods or published methods, e.g. by CIPAC when available, can be used.

5.3. Physical properties

For most key formulation types, the FAO/WHO manual provides guidance on the physical parameters required to be tested before and after storage. The formulation shall comply with relevant limits to ensure that the formulation can be handled and applied without difficulties during the entire Shelf Life.

The determination of physical properties should be based on CIPAC methods or other international methods. Where company internal methods are used, this should be justified.

5.4. Packaging

The effect of the formulation on the packaging material and vice versa is important and information on the compatibility of the packaging material is required. Commercial sales packs (finished product containers) made of plastic materials also have an Expiry Date.

6. DIFFERENT TYPES OF STORAGE STUDIES

In order to define and support the Shelf Life of a CPP, different types of stability studies can be performed. Guidance on the required tests that need to be performed before and after storage is given by the relevant clauses of the FAO/WHO manual.

Note: It is recommended that a storage test is conducted on a single batch of formulation in the commercial sales pack material or an equivalent one.

The different types of stability studies are outlined in the following.

6.1. Accelerated storage tests according to CIPAC MT 46.4

Accelerated storage tests at elevated temperatures are performed to generate information on the expected Shelf Life relatively quickly. Accelerated storage tests involve extrapolation from higher to lower temperatures and from shorter to longer storage periods. Since formulations are complex mixtures and higher temperatures can induce a degradation pathway that may not exist at lower temperatures, there is uncertainty involved in such extrapolations, unless the formulation proves to be stable after real time storage at ambient conditions.

At the initial stage of a registration process a complete set of real time data is usually not available. In this case data from accelerated storage tests can be used to support registration. This approach is accepted in many countries, however, for some countries data from real time storage tests at ambient temperature are additionally required.

Different storage regimes as defined in CIPAC MT 46.4 and referred to in the FAO/WHO manual can be used to perform accelerated storage tests. The listed alternative conditions (2 weeks / 54°C, 4 weeks / 50°C, 6 weeks / 45°C, 8 weeks / 40°C, 12 weeks / 35°C, 18 weeks / 30°C) are accepted as equivalent.

If no significant chemical, physical or packaging changes occur in the accelerated storage test the CPP is expected to meet the specification after 2 years storage at ambient conditions. However, if significant changes are observed, real time data at ambient conditions may be needed to support a Shelf Life claim.

Note: The purpose of accelerated storage tests is to extrapolate from higher temperature data after short term storage to lower temperature data after long term storage, according to the Arrhenius equation.

6.2. Real time storage tests

In contrast to accelerated storage tests, real time testing does not rely on extrapolation and therefore is always acceptable for the declaration of a Shelf Life. Storage is usually performed at ambient temperature for at least 2 years or longer and the formulation must meet the specified limits at the end of the stated storage period.

Storage tests can be carried out at constant temperature under controlled laboratory conditions or e.g. in a warehouse where the temperature is recorded during the test period and reported. Depending on country specific regulations, stability tests may need to be conducted at defined temperatures reflecting the respective climate zone. In the absence of such regulatory guidance it is suggested to perform stability studies at ambient temperatures or under controlled condictions at e.g. 20°C ± 2°C or 25°C ± 2°C.

The following ranges of annual average temperatures are considered typical for different climate zones:

- moderate climate: 18 - 22°C
- hot climate: 23 - 27°C
- very hot climate: 28 - 31°C

6.3. Low temperature storage tests

Cold temperatures may impact physical properties of certain formulation types e.g. due to crystallization of the active ingredient(s) or separation of multi-phase systems. For liquid products, the FAO/WHO manual requires low temperature storage tests according to CIPAC MT 39.3. After storage the product shall continue to comply with the relevant clauses listed in the FAO/WHO manual in section 4.6.1 “Stability at 0 °C”.

7. GENERATING DATA FOR ASSIGNING A SHELF LIFE

7.1. Establishing the Shelf Life of a new product

Data must be generated on physical, chemical and technical properties before and after storage as well as on packaging compatibility.

According to some guidelines, interim data (e.g. 6, 9, 12 or 18 months) of formulated products may be required, e.g. where a formulation is expected to have a Shelf Life of less than 2 years.

Where a Shelf Life longer than 2 years can be demonstrated, e.g. 3 years, and is supported by appropriate stability data, these data again ensure fitness for use during the entire storage period, e.g. up to 3 years and no interim data for 2 years or shorter are required.

Where a formulation is stable under storage conditions representative of a hotter climatic zone, it is automatically suitable for use in colder zones (as specified in section 6.2).

The Shelf Life of a new product can be established as illustrated below:

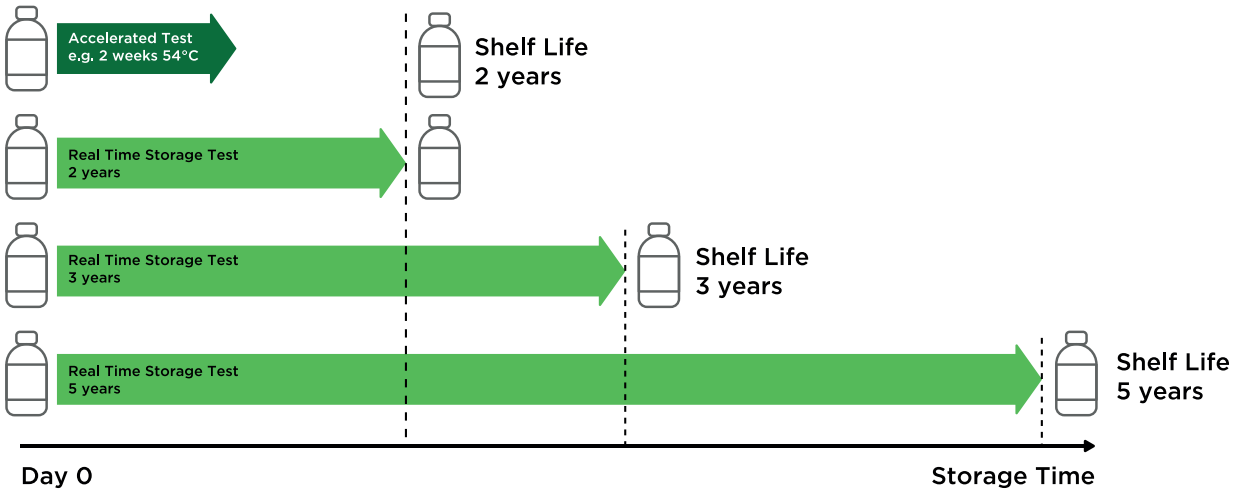

Figure 2: Testing scheme to establish the Shelf Life of CPPs (example)

Note: When real time data (e.g. after 2, 3 or 5 years of storage) are available demonstrating the stability of a CPP, interim data after shorter storage periods are not required.

7.2. Extending Shelf Life and Setting a new Batch Expiry Date

This chapter provides guidance on how to extend the Shelf Life of CPPs beyond the established 2 years period for both new product developments (7.2.1) as well as for established products (7.2.2). For examples, see Appendix 1.

Additionally, guidance is given on how to set a new Expiry Date for a batch in the market channel which is about to expire (7.2.3).

7.2.1. Prolonged accelerated storage test to provide data for extended Shelf Life

Most active ingredients and their formulations are known to be stable over many years. To provide the basis for an extended Shelf Life claim of such formulations a prolonged accelerated storage test is proposed. It can be performed during the development of new products to generate data supporting an extended Shelf Life claim within a short period of time. This is particularly of interest where a submission of data to support Shelf Life can be made only once during the registration process.

The concept of prolonging the accelerated storage test is based on the established approach of accelerated storage tests according to CIPAC MT 46.4 and referred to in the FAO/WHO manual. It consists of performing studies by prolonging, e.g. doubling, the standard storage times for accelerated storage at the relevant temperatures as defined in CIPAC MT 46.4, e.g. from 2 weeks / 54°C to 4 weeks / 54°C. Alternative temperatures and accordingly prolonged storage times (e.g. 8 weeks / 50°C, 12 weeks / 45°C, 16 weeks / 40°C, 24 weeks / 35°C, 36 weeks / 30°C) adapting the respective test regimes of CIPAC MT 46.4 are also acceptable.

The mathematical prediction of Shelf Life based on accelerated storage data at higher temperature is based on the effect of temperature on the kinetic of a chemical reaction (as described by the Arrhenius equation) and the Reaction Rate Law. Combining the two equations, the Shelf Life at ambient temperature is directly proportional to the time of the accelerated storage test. Based on this, doubling the accelerated storage time from e.g. 2 weeks / 54°C to 4 weeks / 54°C allows extrapolation of the Shelf Life at ambient conditions up to 4 years. Depending on country specific regulations, an additional real time storage test at ambient temperature may be required to support this extended Shelf Life.

If a formulation continues to comply with the relevant limits after the prolonged accelerated storage test, these data are considered qualified to support a Shelf Life of e.g. up to 4 years after accelerated storage for 4 weeks / 54 °C. For further examples of this concept see Appendix 1.

7.2.2. Extend the Shelf Life of already registered CPPs

In the context of climatic changes, shifting seasons and more demanding transport requirements manufacturers wish to extend the Shelf Life of CPPs which are already on the market. This is particularly important for products which have been registered with a Shelf Life of two years only to enable end users making longer use of the products. Another aspect is to avoid unnecessary disposal of expired batches which are stable and remain fit for use beyond the Regulatory Shelf Life but lack supporting data.

Even though a manufacturer can initiate a new real time storage test at ambient temperature with a freshly manufactured batch of the product to generate stability data beyond 2 years, a useful alternative is to perform an additional storage test on a product batch having already a certain age (e.g. 2 years). This process is described in the following:

- A representative sample of a batch stored in its commercial sales pack or a representation thereof at ambient conditions (e.g. in a warehouse) is tested according to the relevant clauses of the FAO/WHO manual or regulatory requirements, as applicable. If the quality continues to comply with the registration, a new accelerated storage test can be performed with another sample of the same batch. Preferably, the sample should not be repacked, and storage should be performed in the original, unopened container. However, sub-sampling or repacking may become necessary if the product was stored in bulk or in big volume containers.

- Suitable accelerated storage conditions are given in section 6.1 of this monograph. For alternative time/temperature conditions see Appendix 1. After storage the physical, chemical and technical properties of the sample and the interaction with the container are retested. If the product continues to comply with the registration, the original Shelf Life can be extended as supported by the accelerated storage test, e.g. by further 2 years after storage for 2 weeks / 54°C.

- Depending on country specific regulations, an additional real time storage test may be required to support the extended Shelf Life. This real time storage test (for storage conditions see 6.3) will be performed with another sample of the same batch in its original, unopened container. Storage can be initiated in parallel to the accelerated storage test. After storage the physical, chemical and technical properties of the sample and the interaction with the container are retested. If the product continues to comply with the registration, the original Shelf Life can be extended by the duration of the real time storage test.
- Batches of any age can be used if no sample of an age of 2 years is available. To meet the desired extended Shelf Life, the length of the real time storage test can be adapted accordingly.

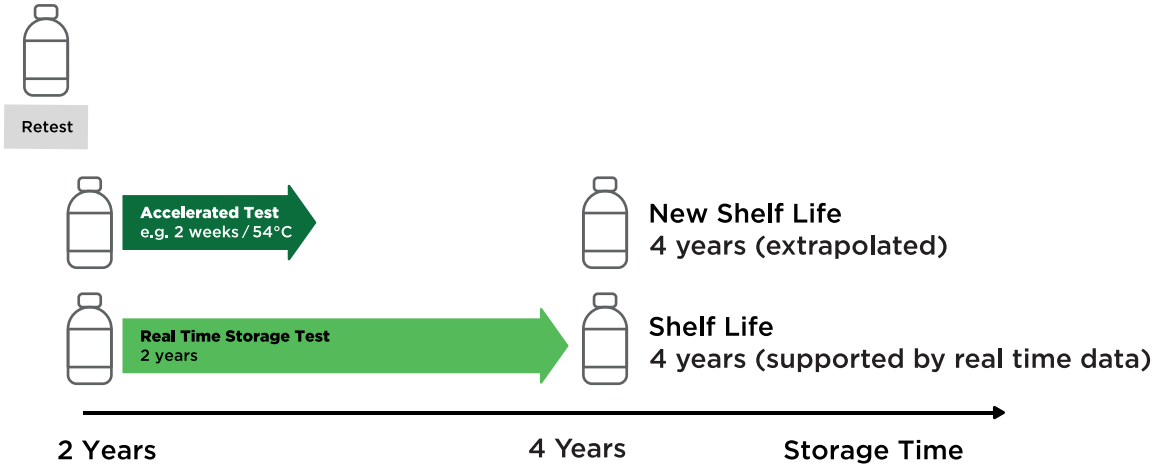

Figure 3: How to extend the Regulatory Shelf Life of an already registered product

7.3. Setting a new Expiry Date for a product batch in the market channel

Favorable conditions like lower disease pressure or changes in weather may delay the use of a batch before its Expiry Date is reached. In line with country specific regulations, the manufacturer may extend the Expiry Date of a batch.
This must happen before the Expiry Date of the batch has been reached.
Setting an Expiry Date is a supply chain task and it is under the full responsibility of the manufacturer of the CPP. In order to set a new Expiry Date the manufacturer initiates a requalification process:

- A representative sample of the batch, e.g. from the market in its commercial sales pack, is tested for relevant parameters such as active ingredient content, physical properties and packaging integrity, e.g. according to the clauses of the FAO/WHO manual or the specifications, as applicable. The analysis must be done by the manufacturer or by a contract laboratory authorized by the manufacturer applying approved methods.

- The decision on setting a new Expiry Date is the responsibility of the manufacturer, which must generate the supporting data. Provided country specific regulations allow this practice the following options are considered acceptable:
    - Stability data from development or registration are available supporting the new Expiry Date. This is typically the case when further long-term stability data have been generated while the CPP was already on the market.
    - Stability data from CPPs of similar composition (e.g. minor change) are available supporting the new Expiry Date.
    - Stability data from an additional accelerated storage test have been obtained. Such an accelerated storage test shall be performed with the batch in its sales pack (see 6.1). If the batch still meets the specification after the accelerated storage test (e.g. performed 2 weeks / 54°C), the Expiry Date can be prolonged e.g. by another 2 years.

If the data from the requalification process ensures that the batch will continue to comply with the registration, a new Expiry Date can be assigned.

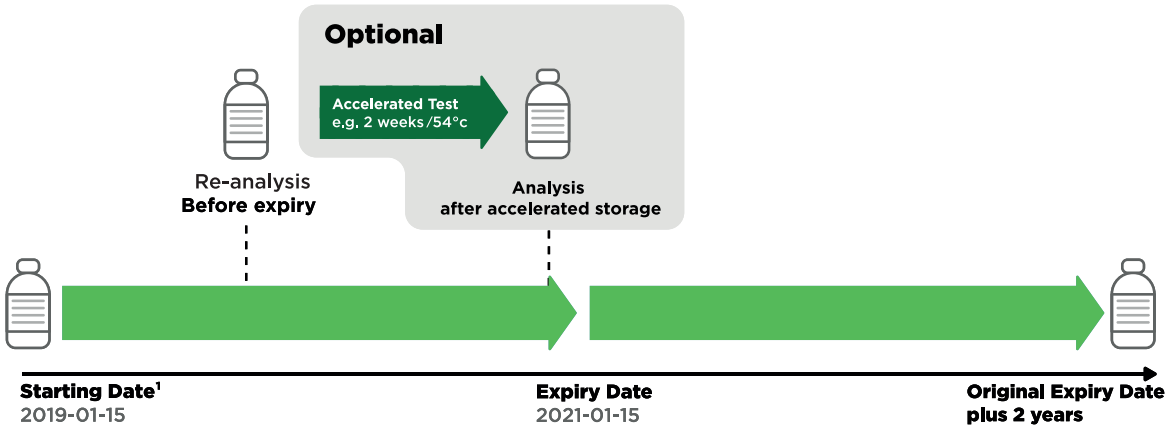

Figure 4: Option for generating supportive data for setting a new Batch Expiry Date

Note: It is important that the re-analysis is performed before the batch has expired.

The new Batch Expiry Date shall not exceed the Expiry Date of the packaging in which it is contained.

8. SUITABILITY OF PACKAGING MATERIALS

8.1. Different types of packaging materials

Tests must be performed to ensure compatibility of the formulation with the packaging material. The packaging material is examined for its integrity and tightness throughout storage.

[1]: For definition of Starting Date see Glossary

A range of packaging materials is available with different levels of barrier properties. HDPE (High Density Polyethylene) is the most widely used material for water-based formulations. Products containing organic solvents may need an additional barrier to prevent loss of solvent or damage to the HDPE polymer. Typical materials are HDPE co-extruded with a second polymer like Polyamide (HDPE-PA), Ethylene vinyl alcohol (HDPE-EVOH) or inline-fluorinated HDPE (fluorinated HDPE, F-HDPE). Commonly used PET bottles (Polyethylene terephthalate) offer a good solvent barrier.

For solid formulations which are not sensitive to humidity, HDPE bottles or LDPE lined cardboard boxes can be used. For protection against humidity, multi-layer bags with aluminium layers are available. Other materials may also be available.

8.2. Testing compatibility and stability of packaging materials

Storage stability tests should be performed in the commercial sales pack or a representative thereof. Tightness of the container and the closure, absence of any seepage, absence of strong panelling or ballooning, and no significant weight change are recommended evaluation criteria.

8.3. Extrapolation of packaging materials

As a general principle data are required to support the packaging material in which a CPP is authorized. In certain instances, extrapolating data from one packaging material to another is possible according to international guidelines (4).

8.3.1. Extrapolation for liquid formulations

According to international guidelines, the following extrapolations are acceptable:

- For water-based formulations (e.g. SC, FS, SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of the others.

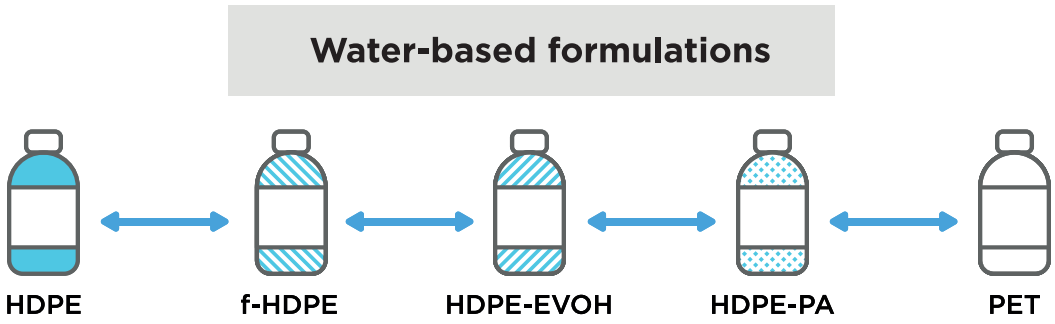

Figure 5: Example for extrapolation between packaging materials for water-based formulations

- For organic solvent containing formulations (e.g. EC, SE, EW): extrapolating stability data of the product in HDPE to higher barrier HDPE-type materials (HDPE-PA, HDPE-EVOH, f-HDPE) is acceptable without generating further stability data when stability in HDPE was demonstrated. For different plastics like PET, it is recommended as a minimum to provide data on seepage.

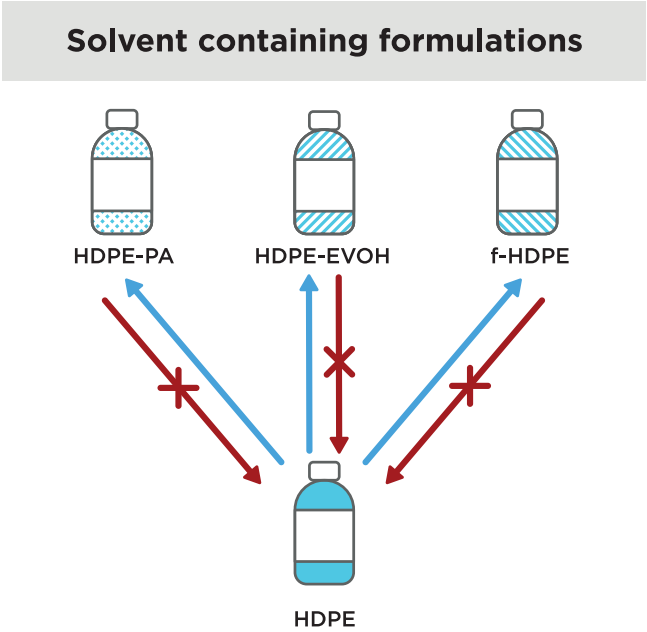

Figure 6: Examples for extrapolation from HDPE to higher barrier packaging materials used for solvent containing formulations

- Extrapolation between higher barrier HDPE-type materials (HDPE-PA, HDPE-EVOH, f-HDPE) for solvent containing formulations is acceptable when stability of the product in any of these materials was demonstrated and data show that no seepage and no significant weight change occur.

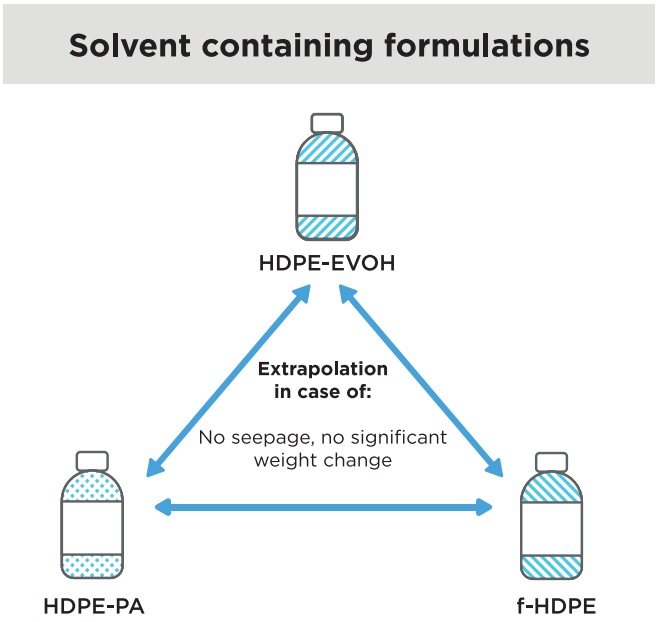

Figure 7: Examples for extrapolation between higher barrier HDPE-type materials for solvent containing formulations

8.3.2. Extrapolation for solid formulations

Extrapolation of stability data is possible between all types of packing materials when they are waterproof or have a waterproof lining or where the formulation is not moisture sensitive. This can be demonstrated by showing that the weight and moisture content of the packed product has not changed during storage.

8.3.3. Packaging and label information

Whereas article 10.2.6 of the FAO/WHO International Code of Conduct on Pesticide Management (5) requires labels that clearly show the release date (month and year) of the batch, Expiry Date (if necessary – see below) and relevant information on the storage stability of the product, it is normal convention that information on storage stability is given only if the CPP cannot be stored for at least 2 years in unopened original sales packs. This situation can apply e.g. to CPPs with instable active ingredients or to some biological products.

In cases where the Shelf Life is shorter than 2 years, a justification must be given, and the label must show both release date and Expiry Date.

Label statements should be made according to country requirements. In case there are no specific rules the release date (month and year) and relevant storage stability information of the product will be based on paragraph 10.2.6 of the FAO Code of Conduct.

Note: It is important to note that commercial sales packs made of plastic materials also have Expiry Dates.

9. CHANGE OF FORMULATIONS DURING PRODUCT LIFE CYCLE

During the product life cycle changes of the composition of a formulation may occur e.g. due to using alternative raw materials, using an alternative process or replacing co-formulant sources which are no longer available.

If such a change falls into the category of a “minor change” (definition and guidance is given in CropLife Technical Monograph 19 (6) the previously established Shelf Life can be assigned to the new formulation variant without further testing.

10 REFERENCES

Links to the intranet given in this Technical Monograph were valid at the date of its publication and may change. Please refer to the intranet for updated references.

(1) Manual on development and use of FAO and WHO specifications for pesticides (FAO PLANT PRODUCTION AND PROTECTION PAPER 228, Third Revision of the First Edition, Rome, 2016)

http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/manual/en/ (March 2021)

Amendments to the third revision of the first edition of the Manual on development and use of FAO and WHO specifications for pesticides (2016)

- Amendment to the third revision of the first edition of the Manual - Section 9 (2018)
- Amendment to the third revision of the first edition of the manual - Section 3 - Tier 2 (2018)
- New version of the Manual in preparation. Please refer to the appropriate FAO / WHO webpage.

(2) CropLife International, Technical Monograph, no. 1, Use of tolerances in the determination of active ingredient content in specifications for plant protection products (CropLife International, March 2005)

(3) Collaborative International Pesticides Analytical Council (CIPAC) Handbooks **https://www.cipac.org/** (March 2021)

(4) Guidelines published by authorities describing extrapolation of packaging materials (extract):

- Belgium: Guidance document for the extrapolation of packaging materials of plant protection products in Belgium (Version 1.2, 2018) **https://fytoweb.be/sites/default/files/guide/attachments/extrapolation_of_packaging_materials_201802.pdf** (March 2021)
- UK: Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protection products under regulation (EC) no. 1107/2009 of the EU parliament and council on placing plant protection products on the market (final draft) **https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/crd-guidance-document.pdf** (March 2021)
- Australia: Generation of storage stability data for agricultural chemical products **https://apvma.gov.au/node/44236** (March 2021)

- ECHA: Guidance on the Biocidal Products Regulation, Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C (Version 2.0, May 2018) **https://echa.europa.eu/documents/10162/23036412/bpr_guidance_vol_i_parts_abc_en.pdf/31b245e5-52c2-f0c7-04db-8988683cbc4b** (March 2021)

(5) FAO/WHO International Code of Conduct on Pesticide Management (FAO and WHO, 2014)
http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/en/ (March 2021)

(6) CropLife International, Technical Monograph, no. 19, Minor Changes of Formulants Contained in Formulations (Crop Protection Products) (CropLife International, August 2012)

11. GLOSSARY

Ambient temperature:

Common, prevailing, and uncontrolled atmospheric conditions in a room or place. A test described as conducted at ambient temperature was conducted at whatever conditions were prevailing at that time on that room or place.

Batch:

A batch is the result of the manufacturing process and represents one homogeneous amount of a formulation after release. Often, other descriptors such as lot may be used instead. An Expiry Date is set at batch level.

CIPAC methods:

Analytical and physical test methods published by CIPAC.

Co-formulant:

Also referred to as “inert” or “formulation inert”. A co-formulant is a substance or a mixture other that the active substance(s), added in the formulation during the formulation process in order to dilute and/or to bring a desirable property to the final formulated CPP.

CPP:

Crop Protection Product is defined by the formulation in its sales pack as placed on the market. Also referred to as formulated product or just product.

Dates:

Format and details of dates as defined by country-specific regulations.

Expiry date:

Date beyond which a batch of a product should not be used without further appropriate re-examination and the manufacturer cannot guarantee that it remains fit for intended use (no adverse effects on application, biological performance, operator/consumer and environmental safety). The date is calculated and based on the starting date of a batch. The Expiry Date is always related to a particular batch of a CPP.

FAO/WHO tolerances:

Tolerances established by FAO / WHO for the active ingredient content and outlined in the FAO/WHO manual, considering analytical and sampling errors and the manufacturing variance. The active ingredient content of a CPPs must stay within these tolerances during its entire Shelf Life.

Formulation:

Term to describe an unpacked preparation with defined composition containing active ingredient(s) and co-formulant(s).

No significant change:

Physical, chemical and technical properties of a CPP stay within the registration of the product, e.g. active ingredient content stays within FAO tolerances, and the product stays fit for use.

No significant weight change:

Criteria used to evaluate the suitability and tightness of a packaging containing the CPP upon storage. Weight changes can be caused either by uptake of humidity through the container walls (weight increase) or by loss of water or solvent from the formulation through the container walls (weight loss). In general, a weight change of equal or less that 2 % is acceptable. A weight change of more than 2% may also be acceptable if justified by the manufacturer.

Packaging:

Packing of a CPP is described by the type, material, size, etc.

Regulatory Shelf Life:

Result of accelerated and/or real time storage stability studies according to country specific regulations granted by the local authorities of a country based on the registration document submitted by the manufacturer. Within the Regulatory Shelf Life, the product stability and integrity must be assured.

(Commercial) Sales pack:

Container in which a batch of a CPP is placed on the market.

Seepage:

Criteria used to evaluate packaging compatibility. Seepage can be defined as no leakage of product through the container walls, no stickiness at the outside of the package, tight closure and pack, no significant ballooning or paneling, no significant weight change.

Shelf life:

Period during which the product remains suitable for use and complies with its registration, when stored in the unopened original sales pack under conditions recommended by the manufacturer. The Shelf Life is established for a formulated product in general (including its packaging) and applies to all its manufactured batches.

Starting date:

Also referred to as Manufacturing Date, Production Date or Release Date as used in different guidance documents, e.g. FAO / WHO Manual(1). Date on which a batch becomes the finished product as it is described by its specifications. Products normally have a shelf life of two years from the starting date.

Appendix 1: Options to establish the Shelf Life of CPPs (examples)

Storage conditions* (including accelerated storage)	Conditions (real time storage)	Supported Shelf Life claim
2 weeks / 54°C or equivalent conditions according to CIPAC MT 46.4 (e.g. 8 weeks / 40°C instead of 2 weeks / 54°C)	2 years ambient	2 years (standard)
3 weeks / 54°C or equivalent conditions derived from to CIPAC MT 46.4 (e.g. 12 weeks / 40°C instead of 3 weeks / 54°C)	3 years ambient	3 years
4 weeks / 54°C or equivalent conditions derived from to CIPAC MT 46.4 (e.g. 16 weeks / 40°C instead of 4 weeks / 54°C)	4 years ambient	4 years
1 year ambient temperature *plus* **2 weeks / 54°C**	3 years ambient	3 years
2 years ambient temperature *plus* **1 week / 54°C** or equivalent conditions derived from to CIPAC MT 46.4 (e.g. 4 weeks / 40°C instead of 1 week / 54°C)	3 years ambient	3 years
2 weeks / 54°C (1) *plus* **1 year ambient temperature**	3 years ambient	3 years
Note: According to Japan regulations storage at 40°C for any number of months is equal to a Shelf Life of the same number of years	*Not required*	e.g. 5 years (for 5 months at 40 °C)

*Other time / temperature combinations can be applied.

The information contained in this monograph is accurate to the best of the knowledge of CropLife International, but no liability can be accepted whatsoever in respect of the use of this information nor in respect of any advice contained herein.

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