

Unclassified

ENV/JM/MONO(2015)32

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

15-Dec-2016

English - Or. English

**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

Cancels & replaces the same document of 25 August 2015

**GUIDANCE DOCUMENT FOR STORAGE STABILITY TESTING OF PLANT PROTECTION AND
BIOCIDAL PRODUCTS - GUIDANCE USED IN SUPPORT OF PRE-REGISTRATION DATA
REQUIREMENTS FOR PLANT PROTECTION AND BIOCIDAL END-USE PRODUCTS**

**Series on Testing & Assessment
No. 223**

**Series on Biocides
No. 10**

JT03407205

Complete document available on OLIS in its original format

This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

ENV/JM/MONO(2015)32
Unclassified

English - Or. English

OECD Environment, Health and Safety Publications

**Series on Testing and Assessment
No. 223**

and

**Series on Biocides
No. 10**

**GUIDANCE DOCUMENT FOR STORAGE STABILITY TESTING OF PLANT PROTECTION
AND BIOCIDAL PRODUCTS – GUIDANCE USED IN SUPPORT OF PRE-REGISTRATION
DATA REQUIREMENTS FOR PLANT PROTECTION AND BIOCIDAL END-USE PRODUCTS**

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

**Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris 2016**

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 35 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in twelve different series: **Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides; Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; Safety of Manufactured Nanomaterials; and Adverse Outcome Pathways.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/chemicalsafety/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

This publication is available electronically, at no charge.

Also published in the Series on Testing and Assessment [link](#)

**For this and many other Environment,
Health and Safety publications, consult the OECD's
World Wide Web site (www.oecd.org/chemicalsafety/)**

or contact:

**OECD Environment Directorate,
Environment, Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16
France**

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

© OECD 2016

Applications for permission to reproduce or translate all or part of this material should be made to: Head of Publications Service, RIGHTS@oecd.org, OECD, 2 rue André-Pascal, 75775 Paris Cedex 16, France

FOREWORD

The work on the development of guidance for storage stability testing of plant protection and biocidal products started in 2012 within the Task Force on Biocides (TFB). The project was included in the work plan of the Test Guidelines Programme in April 2013. An Expert Group on Biocide Chemistry (EGBC) was established under the TFB; it was composed of experts from: Australia, Belgium, Canada, Ireland (chair), Germany, the Netherlands, Sweden, the United Kingdom, the United States, the European Commission and BIAC (Business and Advisory committee to the OECD).

A draft Guidance Document for *Storage stability testing of plant protection and biocidal products - guidance used in support of pre-registration data requirements for plant protection and biocidal end-use products* – was approved by the 27th Meeting of the Working Group of National Co-ordinators of the Test Guidelines Programme (WNT) in April 2015. The Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology agreed to its declassification on 10 July 2015.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

GUIDANCE DOCUMENT FOR STORAGE STABILITY TESTING OF PLANT PROTECTION AND BIOCIDAL PRODUCTS

Guidance used in Support of Pre-registration Data Requirements for Plant Protection and Biocidal End-Use Products

INTRODUCTION

1. Plant protection products (PPP) and biocidal products (BP) are designed to be efficacious and unchanged when stored for a period of time following production. This guidance document describes the general storage stability requirements and procedures relied upon when verifying a period of product stability and package integrity for PPP and BPs. The guidance document is not applicable to microbial PPP and BPs. The general storage stability requirements and procedures described in this guidance document are based on existing guidelines and procedures. This guidance document does not intend to give a detailed breakdown of storage stability requirements for product type/form (water dispersible granule, soluble concentrate, etc.). There are three principal types of storage stability studies that regulatory authorities may require for PPP and BPs:

- (1) Accelerated storage stability tests.
- (2) Ambient storage stability tests.
- (3) Low temperature storage stability tests.

2. It should be noted that there are a large number of storage stability parameters to consider when interpreting storage stability data such as test temperature, test duration, test material packaging, content of active ingredient (a.i.) and relevant impurities in the product after storage, test humidity, exposure to light, and physical and chemical properties of the product after storage etc.

3. The guidance document outlines the differences and similarities between storage stability requirements in the various regulatory jurisdictions and also aims to identify common key characteristics or requirements between those jurisdictions.

Note 1: The terms "active ingredient", "active substance" and "active constituent" are used in different jurisdictions. These three terms are considered equivalent and valid for purposes of this guidance document.

Note 2: The terms "product", "preparation" and "formulation" are also used in different jurisdictions. These three terms are considered to be equivalent for the purposes of this guidance document.

CONSIDERATION OF TEST PARAMETERS

4. Accelerated storage data can be used to provide an indication that the product will be stable for at least two years at ambient temperature. The FAO and WHO Pesticide Specifications Manual [1] recommends quantifying active substances(s) before and after accelerated storage at one of the six temperature and time regimes provided in CIPAC MT 46.3 [2]. The FAO/WHO Manual indicates storage at $54^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 14 days as the default test conditions. The other five temperature/time regimes provided for by CIPAC MT 46.3 are reported by the Manual as alternative test conditions "when the formulation is not suitable nor intended to be used in hot climates and is adversely affected by very high temperature". The FAO/WHO manual considers the accelerated testing as indicative of product stability for at least two

years under ambient storage conditions. CIPAC MT 46.3 specifies a glass container or a suitable container for accelerated testing. There is no humidity specification for MT 46.3. If there is the possibility of product instability at accelerated temperatures, ambient testing should be employed rather than accelerated testing. The EU applies the FAO/WHO and CIPAC test temperature and duration criteria as outlined above for accelerated storage stability testing for PPPs and BPs. ECHA's Guidance [3] for BPs in the EU, reiterates the FAO/WHO requirements with respect to test temperatures and duration for accelerated testing. It is important to note that CIPAC MT 46.3 was not developed for the testing of microbial pesticides, because microbial products may require specific conditions according to the actual product.

5. The APVMA 2005 storage-stability guideline [4] recommends $54 \pm 2^\circ\text{C}$ for 14 days but allows for two alternate testing temperatures and duration combinations listed in MT 46.3 for the two year claim. The applicant must also demonstrate (data or argument) no undue interaction between the product and packaging.

6. USEPA Memorandum 16 Nov 2012 [5] describes an optional protocol for accelerated testing at $54^\circ\text{C} \pm 2^\circ\text{C}$ for 14 days that may be used in lieu of 12-month ambient testing. The USEPA specifies 50% relative humidity in the accelerated study for permeable packaging material [5^{bis}]. For other packaging material there is no humidity specification but the humidity is to be reported. The USEPA Memorandum recommends commercial packaging or smaller packages of the same type of construction and material as the commercial packaging.

7. As of 2014, PMRA (Health Canada) [6] has revised its storage stability data requirements for end-use products and manufacturing concentrates. There is now the option of submitting either an accelerated storage stability study (54°C for 14 days) or a one-year study at ambient temperature/warehouse conditions.

8. Certain regulatory authorities (e.g. the USEPA, PMRA) only require ambient testing if the product fails the accelerated storage stability test, while ambient storage stability testing is required in addition to accelerated storage stability testing in certain regulatory jurisdictions (e.g. the EU) regardless of whether the latter storage stability is available. There is no specified requirement in the EU to conduct ambient storage for two years in the case of BP. Shelf life studies should reflect the shelf life claimed for BPs in the EU. For PPPs and BPs in the EU it should be noted that while a shelf life study should be conducted for ambient storage for two years it is possible to claim shorter shelf lives on the basis of the results from interim time periods if the active is shown to degrade. Accelerated storage stability data can be used to authorise PPP and BP products in the absence of two year ambient data in the EU. However, the ambient storage stability data needs to be provided to the relevant EU regulatory authority as soon as possible thereafter (three years in the UK). The FAO and WHO Pesticide Specifications Manual [1], APVMA 2005 storage-stability guideline [4], the USEPA guideline OCSPP 830.6317 [7], PMRA DIR98-03 [8], CropLife International [9] and ECHA [3] describe parameters for ambient or 'real time' stability testing. Some of these [4,7,8] include a humidity specification for permeable packages. Ambient testing temperatures include 20°C , 25°C , 30°C and actual warehouse temperature depending on the expected geographical conditions where commercial storage of the product will occur. Testing intervals are typically three months for the first year and then every six to twelve months thereafter. The ambient storage stability test should be conducted in commercial packaging. It is important to check if the packaging remains suitable for trade after storage. It is important to report any apparent corrosion, leakage, malformation of the material packaging and closure during and after storage. Extrapolation between different forms of commercial packaging may be accepted on a case by case basis in some OECD regulatory jurisdictions (EU). However other jurisdictions require that each commercial packaging is subjected to separate testing (USEPA, PMRA). For those regulatory jurisdictions that do accept extrapolations on a case by case basis, it is generally accepted that for ambient storage studies, the PPP and BP should be stored in the worst case commercial packaging, the stability of the packaging should be

assessed, and the relevance of different packaging types should be clearly explained [3]. Acceptable extrapolations for different packaging types with respect to BPs in the EU have been proposed by ECHA [3]. The OECD is not aware of any other formal guidance documents that are used by other regulatory jurisdictions for packaging extrapolation purposes for either PPP or BPs, other than those proposed by ECHA for BPs in July 2013.

9. The EU relies upon the FAO/WHO criteria and ECHA criteria outlined above for ambient stability testing for PPPs and BPs respectively. The FAO/WHO Manual recommends that PPP formulations should not be stored for more than two years. However, it should be noted that the EU and the APVMA will allow storage periods for longer than two years in the case of BPs but the storage period of greater than two years must be fully justified and will only be accepted on a case by case basis with the APVMA accepting a maximum of three years. In general, the EU requires an ambient storage study for two years together with relevant quality control data that assesses key parameters prior to and after storage for the required shelf life, in order to support shelf life claims longer than two years [3]. The methods of analysis used for active substance and relevant impurity content in the product should be fully validated; performance criteria should be fully documented. Monitoring the isomer ratio in the storage stability test is required by some jurisdictions (for example PMRA). Chiral methods of analysis may be required for storage stability testing depending on the technical active substance in question.

10. Following each testing interval the product is analysed for active substance content. Some regulatory jurisdictions such as the EU, the USEPA and PMRA also require an analysis of the content of any relevant impurities (impurities of toxicological, eco-toxicological or environmental fate relevance) in the product formulation after storage. EU BP regulatory authorities also require an analysis of the content of any 'substance of concern' (see definitions and abbreviations at the end of this document) in the product formulation after storage. The requirement to analyse for relevant impurities/substances of concern may be waived if no increase in the concentration of relevant impurities/substances of concern is expected upon manufacture/storage of the formulation.

11. PPP and BP regulatory authorities in the EU apply different acceptability criteria for active ingredient content after storage in end use products. The EU PPP regulatory authorities apply the FAO/WHO specification recommendations of 5% allowable decrease of active ingredient content after accelerated and ambient storage. The FAO/WHO Pesticide Specifications Manual [1] recommends that the active substance concentration following accelerated stability testing should not degrade by more than 5% from the concentration prior to testing. The FAO and WHO Manual states that if the active substance concentration decreases by more than 5% in comparison with the initially measured value, then information about possible degradation products should be provided. The FAO and WHO Manual refers to CropLife International Technical Monograph No. 17 [9] for a more "detailed consideration of shelf life and storage stability matters". The CropLife Technical Monograph states that a maximum 10% deviation with respect to the active nominal content is acceptable in shelf-life studies. The 5% degradation limit is the preferred criteria in EU PPP regulatory jurisdictions, however the $\pm 10\%$ value referred to by CropLife [9] has also been accepted by a number of EU PPP regulatory authorities. The CropLife degradation limit of $\pm 10\%$ is based on a nominal concentration starting point as opposed to time zero. The CropLife degradation limit is not applied by BP regulatory authorities in the EU. The EU BP acceptability criteria for maximum decrease of active ingredient content after storage is slightly different from that provided for by the FAO/WHO Manual and CropLife Technical Monograph. The BP regulatory authorities in the EU allow for a maximum general decrease of 10% active ingredient content from time zero (instead of the 5% from time zero provided for by the FAO/WHO Manual for accelerated studies and the $\pm 10\%$ deviation from nominal value suggested by CropLife for shelf life studies). EU BP regulatory authorities consider that a decrease in the active content of $\leq 10\%$ should not adversely affect the efficacy and risk assessment of the product. Where the decrease is $> 10\%$, or in specific cases where the degradation of $< 10\%$ will impact the efficacy or risk assessment, then the applicant should be asked to address the stability of the

active. The EU BP degradation limit of $\leq 10\%$ is applied to both accelerated and ambient storage stability tests [3].

12. The EU utilizes the PPP and BP criterion for both accelerated and ambient testing while other agencies like the APVMA utilize the FAO and WHO table of tolerances for technical concentrates and formulated products [1]. The USEPA and PMRA utilize a slightly different table of certified limits when deciding upon the acceptability of active ingredient degradation in the product [9]. Deviations from these certified limits may be justifiable on a case by case basis. It is significant to note that regulatory jurisdictions seem to diverge on the base reference point, for active ingredient content upon storage. The EU and FAO/WHO compare the level of active ingredient in the formulation after storage with the level of active ingredient in the formulation at time zero in the test sample (T₀). The remaining regulatory jurisdictions compare the level of active ingredient content in the formulation after storage with the nominal concentration (N) on the label.

13. USEPA Memorandum 16 Nov 2012 [5] and USEPA guideline OCSPP 830.6317 [7] state that at the end of each test period, the product should be evaluated for physical changes that include inhomogeneity, phase separation, clumping, and other changes that would interfere with the usefulness or safe handling of the product. Test containers should also be reweighed at the end of each test interval.

14. The APVMA 2005 storage-stability guideline [4], PMRA DIR98-03 [8] and USEPA guideline OCSPP 830.6320 [10] describe the visual-inspection procedure to evaluate the effects of the product formulation/preparation on the package/container during storage. Such a confirmation of no significant interaction between the product and packaging may be performed concurrently with ambient or accelerated stability testing. It should be noted that some regulatory authorities (EU) and the FAO/WHO require additional information in relation to the physical and chemical properties after accelerated or ambient storage that may have an adverse effect on the application and /or safety of the product (additional information in relation to the physical and chemical properties after accelerated storage are not required by APVMA, PMRA or USEPA). The exact physical and chemical properties that require testing after storage are based on product types (Croplife International formulation type codes). The EU requirements for these physical and chemical properties are in line with the requirements specified in the FAO/WHO Manual. It should be noted that in the case of BPs, EU, guidance is not yet available regarding specific Product Type (PT) regarding the physical and chemical properties required after storage.

15. If the active substance in the product is sensitive to light and the formulation/preparation is expected to be exposed to light in storage, some regulatory agencies require an assessment of light stability (e.g. required in the EU but not in the US). Exposure testing with actual sunlight or simulated sunlight is recommended. Testing protocols for active substances in aqueous media [11, 12] or pharmaceutical formulations [13] may be adapted to pesticidal and biocidal formulations/preparations.

16. Some regulatory jurisdictions and the FAO/WHO require low temperature stability testing for liquid preparations/formulations. The USEPA and the PMRA do not require low temperature stability testing. The EU and APVMA require that low temperature stability is addressed; however in both cases a label warning against cold storage will negate the need for low temperature stability testing. Procedures for assessing the stability (*i.e.* homogeneity, phase separation, stability of emulsion, etc.) of liquid preparations/formulations stored at low temperatures (*ca.* 0° C) have been described in CIPAC MT 39.3 [14].

17. For solid formulations/preparations in flexible packaging intended for the EU, the effects that stacking such packaging may have on physical and chemical properties during storage may be required. Some EU member states (e.g. UK) require that solid PPP formulations sold in a flexible pack should be stored under pressure for the entire shelf life study. Other EU member states (e.g. Germany) do not request

this information with respect to flexible packs. There should be no loss of granule integrity or caking on storage of flexible packs. The flexible packaging should remain stable. The stacking pressures applied should be typical of those in commercial practice and fully justified.

18. If there is concern that storage may render a product unsatisfactory for its intended use, the submitter may generate data that verifies that storage has not changed the performance and safety of the product. These tests may include full and complete dissolution of water-soluble packaging, palatability of baits, effectiveness of aversive agents, performance of delivery systems, performing application tests using practical relevant equipment, etc.

SUMMARY OF TEST CONDITIONS AND TOLERANCE LIMITS AFTER STORAGE

19. A summary of the storage stability test conditions and tolerance limits after storage are provided in Tables 1 to 4.

Table 1: Accelerated Testing Conditions

Jurisdiction/Agency	Temperature, Time, Package	Humidity
FAO/WHO	CIPAC MT46.3 in glass jars or commercial packaging (preference for 54°C for 14 days)	Not required.
USEPA	Optional. 54°C 14 days in commercial packaging or smaller packages of equivalent materials.	50% relative humidity if package is permeable
EU	CIPAC MT46.3 in glass jars or suitable containers (preference for 54°C for 14 days)*	Not required.
APVMA	54°C for 14 days or 45°C for 6 weeks or 40°C for 8 weeks in commercial packaging	May be required
PMRA	Optional. 54°C 14 days in commercial packaging or smaller packages of equivalent materials.	50% relative humidity if package is permeable

* The new EU PPP data requirements (valid from 2016), will require the accelerated storage testing to be done in commercial packaging.

Table 2: Active Substance Degradation Limits in the Product after Accelerated and Ambient Storage*

AI Nominal Concentration (N)	USEPA & PMRA	EU (PPP) & FAO/WHO APVMA	EU (BP)
N < 1.0%	N ± 10%	If there is a decrease of ≥5% in concentration of active ingredient from the test sample at time zero, then additional information will be required.*	If there is a decrease of ≥10% in concentration of active ingredient from the test sample at time zero, then additional information will be required.
1.0% < N ≤ 20.0%	N ± 5%		
20.0% < N ≤ 100%	N ± 3%		

* According to the FAO and WHO Manual "It is generally accepted that deviations of ± 10% of the nominal active ingredient content do not significantly influence the biological performance. Where the active ingredient is unavoidably subject to degradation during recommended storage, an overage ≤10% of the nominal content may be applied to compensate for degradation. Alternatively, a limit not less than 95% for active ingredient content after the storage stability test may be proposed". The CropLife suggested deviation of ±10% of the nominal active ingredient is also accepted by most EU PPP regulatory authorities, however the 5% degradation from time zero is the preferred criteria for accelerated and ambient testing with respect to PPPs. If degradation is > 5 % from time zero, then the breakdown products should be identified. Deviations from the EU degradation limits may be considered acceptable on a case by case basis.

Table 3: Ambient Testing Conditions

Jurisdiction/ Agency	Temperature, Tolerance, Interval and Duration	Humidity and Light	AI Degrad. Limits
USEPA	20°C or 25°C (no tolerance specified) or warehouse temperature conditions (measured and reported) in commercial packaging or smaller packages of equivalent materials. Assay at initial and at every 3 months for one year. Test may continue with intervals every 6 months thereafter for PPP and BP. (see Note below)	50% relative humidity if package is permeable	Table 2
EU	<p>20°C, 25°C or 30°C (mean temperature and extremes to be reported) in commercial packaging or smaller packages of equivalent materials. Assay at initial and 24 months for PPP.</p> <p>In the case of BPs in the EU, the ambient shelf life study should reflect the shelf life claimed for the BP. For BP in the EU shelf lives of 2+ years can be supported by a 2 year ambient storage study along with quality control (QC) data* for the BP stored for 2+ years**.</p> <p>Alternatively, the ambient testing may be conducted with shorter intervals (6, 12, 18 months, etc.) if the applicant feels that there may be a potential problem with storage stability of the product after two years or a shorter shelf life than two years is claimed by the applicant for BP and PPP.</p>	<p>Humidity to be reported.</p> <p>Exposure to light may be required if active is sensitive to light.</p>	Table 2
APVMA	At or above 25°C in commercial packaging or smaller packages of equivalent materials. Assay at initial, 6, 12, 18 and 24 months for PPP and BP.	May be required	Table 2
PMRA	20°C or 25°C (no tolerance specified) or warehouse temperature conditions (measured and reported) in commercial packaging or smaller packages of equivalent materials. Assay at initial and at every 3 months for one year. Test may continue with intervals every 6 months thereafter for PPP and BP. (see Note below)	50% relative humidity if package is permeable	Table 2

* The QC data should be accompanied by information on the packaging in which the BP has been stored, the length of storage, the storage conditions and a justification for the physical and chemical properties assessed in the QC data and how this supports the longer shelf life. The QC data can be further supported by an assessment of the degradation of the active ingredient with time.

** For the ambient storage study of two years, all the relevant physical and chemical properties prior to and after storage need to be determined.

Note : Each container should be weighed at the beginning of the test and at each of the test intervals, prior to and after sampling.

The FAO/WHO Manual has no specific requirements for ambient testing.

The USEPA and PMRA only require ambient testing in the event that the accelerated study fails.

Table 4: Sub-Ambient Testing Conditions

Guideline	CIPAC 39.3*
Product	Liquid
Test Temperature	0°C ± 2°C
Test Length	7 days
Report	Volume and nature of any separated material

* In certain cases (e.g. CS and formulation types containing capsules – ZC, ZE and ZW) it may be important to assess the effect of freezing and thawing cycles on the stability of the formulation. Adverse effects on retention of the active ingredient by capsules may occur (reference 1).

LITERATURE

- (1) Pesticide Specifications, *Manual on the development and use of FAO and WHO specifications for Pesticides*, second revision of the first edition, World Health Organization and Food and Agriculture Organization of the United Nations, Rome 2010.
- (2) *Collaborative International Pesticide Analytical Council, Ltd. (CIPAC) Handbook J*, “MT 46.3 Accelerated Storage Procedure” CIPAC Ltd. (<http://www.cipac.org>). CIPAC Publications available from: Marston Book Services Ltd.: (<http://www.marston.co.uk>).
- (3) ECHA’s Guidance on the Biocidal Products Regulation Volume I: Identity/ physico-chemical properties/ analytical methodology – Part A: Information Requirements: http://echa.europa.eu/documents/10162/15623299/bpr_guidance_ir_part_vol_i_part_a_en.pdf
- (4) Australian Pesticides & Veterinary Medicines Authority, “Guidelines for the Generation of Storage Stability Data of Agricultural Chemical Products,” Kingston ACT Australia 2604, December 2005.
- (5) Memorandum: Keigwin R., Harrigan J., Rossi L., Housenger J.; “Accelerated Storage Stability and Corrosion Characteristics Study Protocol”, To: Office of Pesticide Programs, USEPA, Washington D.C., 16 November 2012: <http://www.epa.gov/pesticides/regulating/final-signed-acc-ss-cc-memo.pdf>.
- (5^{bis}) Clarification to Memorandum: 23Oct2013 Communication with USEPA.
- (6) PMRA decision on accelerated storage stability study: http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/prod/_memo-note/stability-stabilite-eng.php
- (7) United States Environmental Protection Agency, Product Properties Test Guidelines OCSPP 830.6317 “Storage Stability,” EPA 712-C-02-026, Washington D.C, 2002.

- (8) Regulatory Directive Dir98-03: “Chemistry Requirements for the Registration of a Manufacturing Concentrate or End-use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products,” Pest Management Regulatory Agency.
- (9) CropLife International "Technical Monograph No. 17, 2nd Edition, Guidelines for Specifying the Shelf Life of PPP", June 2009
- (10) United States Environmental Protection Agency, Product Properties Test Guidelines OCSPP 830.1750 "Certified Limits", EPA 712-C-96-028, Washington D.C, 1996.
- (11) *Ibid.* OCSPP 830.6320 "Corrosion Characteristics".
- (12) United States Environmental Protection Agency, Fate, Transport and Transformation Test Guidelines OCSPP 835.2210 "Direct Photolysis Rate in Water By Sunlight" EPA 712-C-98-060, Washington D.C., 1998.
- (13) OECD Guidance Document on Direct Phototransformation of Chemicals in Water (1997). Environment, Health and Safety Publications – Series on Testing and Assessment, No. 7. <http://www.oecd.org/chemicalsafety/testing/seriesontestingandassessmentpublicationsbynumber.htm>
- (14) International Conference on Harmonisation (ICH), Guidance for Industry: ICH Harmonised Tripartite Guideline Stability Testing: Q1B Photostability Testing of New Drug Substances and Products, Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), 5600 Fishers Lane, Rockville, MD 20857, November 1996: <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073373.pdf>
- (15) *Collaborative International Pesticide Analytical Council, Ltd., (CIPAC) Handbook J*, “MT 39.3 Low Temperature Stability of Liquid Formulations.” CIPAC Ltd.: <http://www.cipac.org> CIPAC Publications available from: Marston Book Services Ltd.: <http://www.marston.co.uk>

DEFINITIONS AND ABBREVIATIONS

APVMA – Australian Pesticides and Veterinary Medicines Authority

BP – Biocidal Product

CIPAC-MT – Collaborative International Pesticides Analytical Council- Miscellaneous Techniques

ECHA – European Chemicals Agency

EU – European Union

FAO – Food and Agriculture Organisation of the United Nations

OCSPP – US EPA’s Office of Chemical Safety and Pollution Prevention

PMRA – Pest Management Regulatory Agency, a branch of Health Canada

PPP – Plant Protection Product

QC – Quality control

Substance of concern – any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect.

US EPA – United States Environmental Protection Agency

WHO – World Health Organization of the United Nations