CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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DISCUSSION PAPER ON MONITORING THE PURITY AND STABILITY OF CERTIFIED REFERENCE MATERIALS OF PESTICIDES DURING PROLONGED STORAGE

(Prepared by the Electronic Working Group chaired by India and co-chaired by Argentina and Iran)

Background

1. CCPR51(2019) considered an additional request related to shelf-life of certified reference materials (CRMs) raised by some delegations as follows:

   - CRMs were used for many purposes e.g., Good Agricultual Practice (GAP) supervised field trial data, monitoring of import/export samples, etc.
   - The limitation of the use of CRMs after the expiry date led to recurring high costs for laboratories, consideration should therefore be given to including guidance on monitoring of purity and stability of CRMs of multi-class pesticides during prolonged storage.

2. CCPR51 further agreed to request Argentina and India to prepare a discussion paper regarding monitoring of purity and stability of CRMs of multi-class pesticides during prolonged storage for consideration at CCPR52.[1]

3. At CCPR52(2021), India, also on behalf of Argentina, introduced the item, reminded CCPR of the background for the work, the work process followed in the development of the discussion paper and key issues discussed in the paper. The Delegation informed CCPR that further work was needed on this topic and recommended that the EWG be established to further develop the discussion paper for consideration by CCPR53.

4. CCPR noted the general support to continue and agreed to establish an Electronic Working Group (EWG) chaired by India, and co-chaired by Argentina and Iran, working in English and Spanish, with the following Terms of Reference (TORs):[2]

(i) To further develop the discussion paper to consider the need, feasibility and relevance:

   a) To develop harmonized guidelines/analytical protocol on the monitoring of purity and stability of CRMs and stock solutions of multi-class pesticides during prolonged storage, including intermediate and working standards.

   b) To develop harmonized criteria for the use of CRMs and stock solutions beyond the expiry date as per certified analysis.

(ii) Should there be support in the EWG to develop such work, to submit a project document for the new work proposal as an annex to the discussion paper for consideration by CCPR53.

Work process

5. The EWG received comments from Australia, Chile, South Africa, Uruguay and in the second round from Australia, Chile, South Africa, Uruguay, Canada, Thailand, United States of America (USA), India, Argentina, and Iran. All the EWG members supported the development of the discussion paper. Details of the Discussion paper are provided as per the following:

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1 REP19/PR51, paras. 182, 183 & 186

2 REP21/PR52, paras. 198-201

- Appendix I presents the project document proposal for new work on guidelines for monitoring the purity and stability of certified reference materials of pesticides during prolonged storage
- Appendix II presents the discussion paper on monitoring the purity and stability of certified reference materials of pesticides during prolonged storage
- Appendix III presents an outline the guidelines for monitoring the purity and stability of certified reference materials of pesticides during prolonged storage
- Appendix IV contains the list of participants in the EWG

Recommendation

6. CCPR is invited to consider the proposal for new work on guidelines for monitoring the purity and stability of certified reference materials during prolonged storage (Appendix I) based on the data and information provided in the discussion paper (Appendix II).

APPENDIX I

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON
GUIDELINES FOR MONITORING THE PURITY AND STABILITY OF CERTIFIED REFERENCE MATERIALS OF PESTICIDES DURING PROLONGED STORAGE

(For consideration by CCPR)

1. The purposes and the scope of the work

To develop guidelines for 'Monitoring the purity and stability of certified reference materials (CRMs) of pesticides during prolonged storage' to harmonize concepts and to develop criteria to recognize the expired/expiring CRMs with valid purity and stability to continue using them in analysis of multi-class pesticides, and pesticide residues in different food commodities and the environment (soil, air, water) samples. Thus, use of expired CRMs with validated purity and stability in the measurement systems will not only ensure continuity of their use in the laboratories but also have economic impact by saving the purchasing cost of fresh CRMs.

2. The relevance and timeliness of the work

The importing countries sometimes create non-tariff trade barriers by lowering maximum residue limits (MRLs) of a particular pesticide on a particular food commodity. For generating true and authentic pesticide residue data, validated analytical protocols and CRMs are of utmost importance for qualitative and quantitative determination of pesticide residues in foods.

High recurring acquisition cost and short expiry date of CRMs are some constraints in the analysis of pesticide residues in food commodities and in the environment. Many times, laboratories get CRMs with expiry period close to the expiration date, and sometimes the availability of CRMs from the suppliers is limited. This forces labs to buy new standards and prepare new stock solutions more frequently than necessary. Many poor and developing countries cannot afford to purchase high-cost CRMs for their pesticide residue and food safety work.

Recent studies have shown that if a laboratory maintains the CRM at storage conditions better than those recommended by the manufacturers, their rate of degradation is significantly minimized. Many CRMs stay stable even after the date of expiry mentioned in the the Certificate of Analysis (CoA). Under such conditions, the expiry date as recommended by the reference material producers (RMPs) may be extended and in such cases re-use of expired CRMs after verification of their purity as prescribed in can be highly useful for such poor and developing countries.

The proposed work on monitoring the purity and stability of certified reference materials of pesticides during prolonged storage is thus relevant and timely for consideration by Codex/Codex Committee on Pesticide Residues (CCPR).

3. The main aspects to be covered

Main aspect to be covered is to monitor and establish the purity and stability of certified reference materials of pesticides during prolonged storage (before and after expiry) and if the purity of CRM is found within the acceptable range as per the CoA, their use as CRM after expiry is continued to be allowed.

4. An assessment against the *Criteria for the Establishment of Work Priorities*

4.1 General criterion

From the point of view of consumer health protection and fair trade practices the proposed work contributes to identify an emerging issue~~s~~ relating to the development of relevant CRM standards and validate their purity after expiration to ensure their safe use by developing LC[3]/GC[4]/LC-MS[5]/GC-MS protocols for analysis of pesticide residues in different food matrices and in soil and water.

4.2 Criteria applicable to general subjects

4.2.1 Scope of work and establishment of priorities between the various sections of the work

While there is a general understanding that the issue of CRMs stability is important to CCPR, the lack of data on stability and purity of CRMs during prolonged storage, and absence of SOPs to determine their purity beyond the expiry period prevent the use of CRMs beyond the expiry period. These issues will be addressed as part of the scope of the work and prioritized between the various sections of the work (see sections 1 and 2).

[3] Liquid chromatography
[4] Gas chromatography
[5] Mass spectrometry

4.2.2 Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

Highly pure and stable CRMs are required for purity assessment and accurate analysis (trueness and/or precision) of technical materials, formulations, and analysis of pesticide residues in food commodities and environmental samples. A CRM is a specific class of reference material (RM) whose property values (purity, concentration, etc.) are determined and certified in accordance with metrological principles using international best practice protocols established as per ISO guidelines.

The requirements of their purity and stability of CRMs are met by adoption of standards and measurement quality systems as per International Organization for Standardization (ISO) and International Electro-technical Commission (IEC), ISO/IEC 17025, as well as in accordance with international standards ISO 17034 (2016), ISO Guide 30 (2015), ISO Guide 31 (2015) ISO Guide 35 (2017).

Except for FAO/WHO/JMPR, the pesticide residues and pesticide CRM related work is not undertaken by any other international inter-governmental bodies.

4.2.3 Amenability of the subject of the proposal to standardization

The proposal is considered amenable to standardization.-

The expiry period of pesticide CRM is determined based on their type, class, chemical structure, and storage conditions like temperature, humidity etc. At present no national legislations on extending the validity of CRMs beyond the expiry period are provided by regulatory agencies of different countries. In addition, no other work has been developed at international level on the use of expired CRMs (see section 4.2.3).

No impediment to international trade is foreseen by having an international agreed guidance on the use of verified expired CRMs in pesticide residue analysis in exportable food commodities.

The ISO guidelines and research reports in literature will be used as a reference to develop the Codex guidelines.

4.2.4 Consideration of the global magnitude of the problem or issue

No global document covers the core points related to CRMs and their possible use beyond expiration.

Since pesticides are used globally, the development of standard analytical protocols for the quantification of pesticide residues using expired CRMs is of global relevance to ensure food safety and fair-trade practices for agricultural commodities moving in international trade.

5. The relevance to the Codex strategic objectives

The Codex Strategic Plan 2020-2025 underpins the high priority that continues to be placed on food safety and quality by FAO and WHO and guides the Commission in carrying out its responsibilities to fulfill the mandate of protecting consumer health and ensuring fair practices in the food trade. The development of guidance on monitoring the purity and stability of CRMs during prolonged storage is relevant to these Codex strategic objectives.

6. Information on the relation between the proposal and other existing Codex documents as well as other ongoing work

No guidance from the Codex Alimentarius related to CRMs is currently available nor being considered.

7. Identification of any requirement for and availability of expert scientific advice

No provision of scientific advice is required for the development of these guidelines

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

For the elaboration of this document, the advice from FAO, WHO and the JMPR Secretariat will be taken as appropriate. Other documents issued by international organizations such as relevant ISO guides will be taken as reference e.g.

- ISO Guide 30 (2015) Reference materials–selected terms and definitions. International Organization for Standardization (ISO), Geneva
- ISO Guide 31 (2015) Reference materials–contents of certificates, labels and accompanying documentation. International Organization for Standardization (ISO), Geneva
- ISO GUIDE 33:2015 related to reference materials — Good practice in using reference materials

- ISO Guide 34:2009 which defines RM as material that is sufficiently homogenous and stable with respect to one or more specified properties, and which has been established to be fit for its intended use in a measurement process [ISO Guide 35:2017; ISO Guide 30:2015]
- ISO Guide 35 (2017) Reference materials–guidance for characterization and assessment of homogeneity and stability. International Organization for Standardization (ISO), Geneva
- ISO/IEC 17025 (2005) General requirements for the competence of calibration and testing laboratories. International Organization for Standardization (ISO), Geneva
- ISO 17034:2016 which outlines the general requirements to be met by a reference material producer (RMP)
- SANTE (2017) Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed. SANTE/11813/2017, 21–22 November 2017 rev.0, European Commission Directorate General for Health and Food Safety, Bruxelles/Brussels, Belgium. 1–46
- WHO (2006a) WHO Expert Committee on Biological Standardization? Recommendations for the preparation, characterization, and establishment of international and other biological reference standards (revised 2004). WHO technical report series 2006, No. 932
- WHO (2006b) WHO working group on stability of reference materials for biological medicines and in vitro diagnostics Geneva, Switzerland, 27–28 November 2006 1–15
- ISO 13528 (2015) Statistical methods for use in proficiency testing by inter–laboratory comparison. International Organization for Standardization (ISO), Geneva
- ISO/IEC 17043 (2010) Conformity assessment–general requirements for proficiency testing. International Organization for Standardization (ISO), Geneva

9. The proposed timeline for completion of the new work, including the start date and the proposed date for adoption by the Commission (the time frame for developing a standard should not normally exceed five years)

Subject to approval by the Codex Alimentarius Commission, the Guidelines will be considered at CCPR54 (2023) and should be finalized for adoption by CAC in 2025 or earlier.

APPENDIX II

DISCUSSION PAPER ON
MONITORING THE PURITY AND STABILITY OF CERTIFIED REFERENCE MATERIALS OF PESTICIDES DURING PROLONGED STORAGE

(For information)

INTRODUCTION

1. Pesticide residues in food commodities have become a worldwide agricultural trade-concern which has led to enforcement of strict pesticide regulations. Analyses of multi-class pesticides in the food chain with reliable measurement and accuracy require certified reference materials (CRMs) of known chemical purity and stability to ensure food safety, food quality and the safe environment (Reenie, 2015).

2. Since in a measurement quality system, reproducibility and metrological traceability of analytical results is of prime importance, a CRM of known chemical purity is required to determine the amount of reference chemical in the sample. This discussion paper provides the technical justification on the need for guidance for the harmonization of concepts and criteria to monitor the purity and stability of CRMs of pesticides during prolonged storage. Background information about CRMs is described in the paragraphs below

BACKGROUND

3. A CRM is a specific class of reference material (RM) whose property values (purity, concentration, etc.) are determined and certified in accordance with metrological principles using international best practice protocols established as per ISO guidelines. The determining property of a CRM is that it has metrological traceability and is accompanied by a certificate, which documents the property value(s) with its uncertainty, issued by the reference material producer (RMP) in accordance with international standards.

4. Reliable measurement of pesticides and their residues depends critically on the quality of CRMs, validated methods, comprehensive quality systems, and above all the competence of the staff operating the analytical equipment. These requirements are met by adoption of standards and measurement quality systems as per International Organization for Standardization (ISO) and International Electro-technical Commission (IEC), ISO/IEC 17025.

5. Unlike the RM, the CRM has metrological traceability and is accompanied by a certificate of analysis (CoA), which documents the property values and the uncertainty, issued by the RMP in accordance with international standards and best practice protocols (and ISO Guides 30:2015, 31:2015, and 33:2015. The ISO Guide 34:2009 defines RM as material that is sufficiently homogenous and stable with respect to one or more specified properties, and which has been established to be fit for its intended use in a measurement process. ISO Guide 35, 2017 describes use of CRMs in the calibration and assessment of a measurement system and procedure, that includes method development, validation, quality control and assurance, root-cause analysis, assignment of values to specified properties, proficiency testing (PT), inter-laboratory comparison and metrological traceability.

6. While ISO/IEC 17025:2005 outlines general requirements for the competence of calibration and testing laboratories, ISO Guide 17034:2016 outlines the general requirements to be met by an RMP to demonstrate its competence. The certification is carried out in accordance with the requirements of ISO Guides which are published by ISO REMCO (Reference Material Committee of the International Standardization Organization) to produce and certify RMs.

7. The highly pure and stable CRMs are required for purity assessment and accurate qualitative and quantitative analysis (trueness and/or precision) of pesticide active ingredient(s) in technical materials and formulations, stock solutions, working solutions, and for the analysis of pesticide residues in food commodities and the environmental samples. Indispensable to the accuracy and reliability of the analysis (Guimarães et al. 2014), these are routinely utilized in the calibration and assessment of a measurement system and procedure that includes method validation, quality control, quality assurance, root cause analysis, proficiency testing, inter–laboratory comparison, and metrological traceability to conventional scales, and assigning values to specified properties.

8. Accuracy of analytical results is reliant on sample preparation, calibrators used, as well as the method of analysis employed. Any ambiguity in its design, preparation, packaging, storage, as well as improper handling causing cross contamination may affect accuracy of concentration, stability, and uncertainty in the overall process of establishing RM/CRM purity during storage. Accuracy of data is reliant on accuracy in sample preparation, of calibrators used, as well as the method of analysis (Rettinger et al., 2010). Short–and long–term stability studies are generally conducted as a part of certification which covers a storage period of up to two years at different temperatures (Pauwels et al 1998).

9. Limited shelf life, diminishing purity with time, and high recurring cost are some major constraints generally faced by the laboratories especially in the developing countries for qualitative and quantitative determination of pesticide residues in foods. Moreover, the date of expiry recommended in the CoA limits the use of CRMs after their expiry. This leads to high recurring cost of procuring new CRMs by the laboratories working in the field of multi–pesticide residue analysis. This necessitates the need for continuous monitoring of purity and stability of CRMs. For expired CRMs, it is pre–requisite to re–validate its purity and stability for subsequent use to achieve reliable analytical results.

10. Since CRMs are susceptible to degradation by temperature, light, oxygen, humidity etc., it is therefore necessary to investigate their short– and long–term stability under different storage conditions of temperature and time [ISO Guide 35 (2017, Lamberty et al 1998)].

11. As per the international guidelines, if a laboratory maintains the CRM at storage conditions better than those recommended by the manufacturer (i.e., temperature lower than recommended without exposure to light and moisture), the rate of degradation of the CRM is significantly minimized. For example, in long–term storage study, the CRM are usually stored in a deep freezer at ≤ – 20 °C for a period of 2 or more years (Tahalan et al 2005, SANTE, 2017, WHO 2006a, 2006b). As per SANTE (2017), under such conditions, the expiry date as recommended by the RMPs may be extended as appropriate for a CRM by a date allowing for storage up to 10 years or as long as certified property values mentioned in CoA hold good (within ± 10 %).

12. The certified property values of CRMs can be established from analytical results of regular monitoring of their purity, stability, and z–scores acquired in various national/ international proficiency testing (PT) programmes along with their inter–laboratory comparison study [Thomson 2016, ISO 13528 (2015). The globally accepted criteria of z–scores have been successfully utilized by United States Food and Drug Administration (US FDA) for demonstrating the quality of results to re–verify non–certified RMs including expired RMs/CRMs of elements. According to US FDA, if z–score obtained in a PT programme with respect to the targeted analyte is in an acceptable range, then both non–certified RM as well as expired RM/CRM of that analyte is still fit for the intended purpose (Cunningham and Capar 2014).

13. Furthermore, Roelandts and Gladney had earlier mentioned that a non–certified RMs, including expired RMs/CRMs with established consensus values can be used to demonstrate repeatability in a measurement system.

14. Commercial suppliers of pesticide standards sell CRM standards with limited expiry dates. This forces laboratories to buy new standards and prepare new stock solutions more frequently than necessary. This leads to insurmountable extra work and increased laboratory costs, especially for compounds for which stability is normally not questionable.

15. Additionally, shipping of CRMs by the suppliers to laboratories in developing countries increase the acquisition cost and time for procurement to perform a sustainable pesticide residue control program. Many times, laboratories get material close to the expiration date, and sometimes the availability of reference materials from the suppliers is limited.

16. It has been observed that several CRMs even after expiry continue to retain their valid purity as per CoA and therefore entitled for continuous use in the laboratories as CRMs as long as meets the purity requirements. Besides ensuring continuity of their use, it also has economic impact by saving the purchasing cost of fresh CRMs.

17. The long-term intra-lab and inter-lab validation experiments conducted at the Pesticide Residue Laboratory (PRL) at ICAR-IARI, New Delhi, India to assess the purity of standards and stock solutions of 89 CRMs of multi-class pesticides stored at -25°C beyond their expiry revealed that when CRMs were stored in conditions better than those recommended by RMPs for longer period of 3 years, most of the CRMs remained optimally stable with respect to their observed purity and stability (Sharma et. al. 2020). The study reported that more than 96 % of the CRMs remained optimally stable with respect to their observed purity even after their expiry date as per CoA.

18. The performance of the valid and expired CRMs was evaluated through 44 z-scores for 15 expired and 29 valid CRMs obtained in 14 international and national PT programs conducted by the international PT sample providers namely EUPT-European Union Referral Laboratory, Spain; FAPAS-Food Analysis Performance Assessment Scheme, UK; and APLAC- Asia Pacific Laboratory Accreditation Cooperation, Australia. Inter-laboratory comparison of 6 randomly selected expired and valid CRMs was tested by liquid chromatography-mass spectroscopy (LC-MS/MS) at three different ISO 17025 accredited laboratories and the average % deviation between % purity ranged from -2.35 to +0.95% (Sharma et al. 2020).

19. Dorweiler et al. (2016) conducted simulated accelerated aging study of multi-component CRM mixes of 528 pesticides and their metabolites/degradation products in solution phase at stressed temperature of 50°C, and the samples analyzed at 0, 1.5, 3, and 6- day time period which simulated 0, 6, 12 and 24 months storage time. Study indicated that 65% of the CRMs remained stable up to 24 months, 19% exhibited borderline stability, and about 16% were significantly unstable. Thus, even in the solution phase, most of the CRMs retained their stability up to 24 months.

20. The long-term intra-laboratory and inter-laboratory validation experiments were also performed at the NVWA laboratory, Amsterdam, the Netherlands to assess the storage stability of standards and stock solutions of LC-pesticides (Andréde Kok et al. PO006pdf, 2019). The stability of CRM standards was assessed by continuously measuring old against new stock and calibration-mixture solutions, on a long-term basis. The study revealed that the stability of most of the pesticide reference standards is up to 15 years, and in stock solutions (in toluene or MeOH), at -18 °C is up to 10 years.

21. An outline of the guidelines is presented in Appendix III.

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APPENDIX III

GUIDELINES FOR MONITORING THE PURITY AND STABILITY OF CERTIFIED REFERENCE MATERIALS OF PESTICIDES DURING PROLONGED STORAGE

(An outline)

(For information)

INTRODUCTION

1. As a result of the impact of temperature, light, oxygen, humidity, etc., certified reference materials (CRMs) are liable to degradation during prolonged storage and during transport. Even at low temperature and without light, some CRMs may degrade before expiry period. Effective storage methods are thus needed to ensure the stability and purity of CRMs within and beyond their expiry date.

2. To avoid the degradation the CRMs vials must be placed in airtight capped tube/sealed pouch and immediately stored in the refrigerator at -25^{o}C.

3. For expired CRMs, it is pre-requisite to re-verify its purity and stability for subsequent use to achieve reliable analytical results.

4. Purity studies of the CRM include different storage conditions of temperature and time (ISO[6] Guide 35, 2017). For long-term stability studies, the CRMs are stored in a deep freezer at sub-zero temperature(≤-20°C) for a period of 2 or more years (WHO[7], 2006a, b; Tahlan et al. 2005) and analyzed initially at the time of procurement and thereafter proposed monitoring at regular intervals until expiration and 3-5 years after expiration.

5. Studies conducted in different laboratories indicated that when CRMs were stored at sub-zero temperature for longer period, most of the CRMs remained optimally stable up to 15 years with respect to their observed purity (WHO, 2006a, b; Tahlan et al., 2005). This is because at sub-zero temperature, the adverse effects of thermal degradation, photo-degradation, oxygen, humidity, transpiration, etc. are minimized thereby prolonging the shelf life of the CRMs.

6. According to international guidelines, laboratories must follow manufacturer's guidelines. However, if a laboratory maintains the CRM at storage conditions better than those recommended by the manufacturer (i.e., temperature lower than recommended without exposure to light and moisture), the rate of degradation of the CRM is significantly minimized. Under such conditions, the expiry date as recommended by the reference material producers (RMPs) may be extended as appropriate for a CRM by a date allowing for storage up to 10 years or as long as certified property values mentioned in the certificate of analysis (CoA) hold good (≤ ±10%) (SANTE[8], 2017).

ANALYTICAL PROTOCOL FOR DETERMINING THE PURITY AND STABILITY OF CRMS

7. The purity of CRMs whose validity had expired as per CoA should be compared with the purity obtained at the time of procurement under same analytical conditions by HPLC[9]/GC[10]/LC[11]-MS[12]/GC-MS in terms of retention time (RT in minutes) and peak area at the respective ultra-violet (UV) maxima.

8. The purity of the CRMs during prolonged storage is monitored periodically, by injecting 50-100 mgL^{-1} stock solution prepared in a suitable organic solvent, in HPLC/GC preferably as per the analytical conditions mentioned in the CoA. The peak area percent is taken into consideration for measuring the purity (%).

9. If its purity level after re-verification in the ISO 17025 accredited laboratory is found within the limits prescribed in the certificate of analysis, it implies that the analyte level(s) in the CRM are still within an acceptable range and therefore should be considered for continued use as CRMs.

10. The gravimetric records are maintained for the stock solutions stored in the deep freezer at -25 °C to minimize evaporation loss during storage. Quantitative measurement of the mass or concentration of the CRM in a weighing bottle is conducted at the time of its preparation of stock solution and later at different time intervals.

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[6] International Organization for Standardization
[7] World Health Organization
[8] Directorate-General for Health and Food Safety, European Commission (SANTE)
[9] High-performance liquid chromatography
[10] Gas chromatography
[11] Liquid chromatography
[12] Mass chromatography

LONG-TERM INTER-LABORATORY COMPARISON AND VERIFICATION OF PURITY BY PARTICIPATION IN THE PT PROGRAMME

11. Maintaining proper storage conditions and regular monitoring of % purity before and after their expiry, the expired CRMs retain their purity levels prescribed in their CoA. Such expired CRMs can continue to be used as valid CRMs by the laboratories as standard reference materials for testing, calibration, method validation, quality control, quality assurance, and other applications of measurements when re-verification is found within the limit (±10%) performed as per the international guidelines. Detailed protocols for re-verifying purity of expired CRMs are presented in this document.

12. An inter-laboratory and intra-lab comparison and re-verification of purity should be conducted in different ISO/IEC 17025 accredited laboratories at different places, at different times, by different people, and using different equipment (Armishaw, 2016) to verify the % purity of the expired and valid CRMs in different laboratories.

13. Proficiency testing (PT) programs in different food commodities should be conducted by PT providers which are accredited in compliance to ISO/IEC 17043 (2010). The purity and stability of the valid and expired CRMs can be verified through z-scores obtained through PT program which is a globally accepted procedure (Thompson, 2016; ISO 13528, 2015).

14. The criteria of z-score can be utilized to re-verify non-certified RMs including expired CRMs of elements. According to the Food and Drug Administration of the United States of America (USA FDA), if z-score obtained in a PT programme with respect to the targeted analyte is in an acceptable range, then both non-certified RM as well as expired RM/CRM of that analyte is still fit for the purpose (Cunningham and Capar 2014). A z-score of 2 or less is considered acceptable, a z-score between 2 and 3 is questionable, and beyond 3 is unacceptable (National Measurement Institute, 2016, Thompson, 2016).

APPENDIX IV

LIST OF EWG MEMBERS

Chair: India

Dr. Krishna Kumar Sharma
Former Network Coordinator
All-India Network Project on Pesticide Residues
ICAR- Indian Agricultural Research Institute, New Delhi

Co-Chairs

Argentina
Codex Contact Point
Agroindustry Secretariat

Iran
Roya Noorbakhsh
ISIRI

Australia
Karina Budd
Member Country
Department of Agriculture Water & the Environment

Belgium
Wibke Meyer
Observer Organization
Crop Life International

Stephanos Kirkagaslis
Observer Organization
European Commission

Canada
Jian Wang
Canadian Food Inspection Agency

Chile
Roxana Inés Vera Muñoz
Servicio Agrícola y Ganadero

Francis Alarcón
Instituto de Salud Pública de Chile (ISP)

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Servicio Fitosanitario del Estado-MAG

Ivania Morera Rodríguez
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Alejandro Rojas Leon
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Codex-India
Codex Secretariat
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Dr. Vandana Tripathy
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Dr. Rajesh Rangasamy
Export Inspection Council, New Delhi

Usharani Dandamudi
CSIR-Central Food Technological Research Institute, Mysore

Varsha Misra
Observer Organization
National Accreditation Board for Certification Body

Japan
Codex Japan, FAO/WHO,
Ministry of Health, Labour and Welfare

Republic of Korea
Hwang Kiseon
MAFRA

South Africa
Aluwani Alice Madzivhandila
Department of Health

South Korea
Park Yu-min
Ministry of Food and Drug Safety

Sweden
Niklas Montell
Swedish Food Agency

Thailand
Chonnipa Pawasut
ACFS

Namaporn Attaviroj
ACFS (Codex Contact Point of Thailand)

Uruguay
Susana Franchi
FAO/WHO,
Dirección General de Servicios Agrícolas /
M.G.A.P

Uruguay
Roberto Puentes
Laboratorio Tecnológico del Uruguay (LATU)

United States of America
Marie Maratos Bhat
USDA-US Codex Office

Alexander Domesle
U.S. Department of Agriculture

International Fruit and Vegetable Juice Association
John Collins
Observer Organization
International Fruit & Vegetable Juice Association