CODEX ALIMENTARIUS COMMISSION





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Agenda Items 4(a,b), 6, 7(a,b,c,d), 8, 9, 11, 12, 13, 15

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME **CODEX COMMITTEE ON PESTICIDE RESIDUES**

> 52nd Session (Virtual) 26-30 July and 3 August 2021

Comments submitted by Kenya

Kenya appreciates the opportunity to provide comments on the agenda items of CCPR52 as follows:

Agenda Item 4a

Agenda 4.1: Matters arising from FAO and WHO

Kenya would like to thank FAO and WHO sharing this information. Both the World Food Safety Day and UN Food System Summit 2021 are very important events for the country. Kenya participated both locally and internationally in World Food Safety day 2021 and looks forward to joining other member states in the UN Food Systems Summit 2021. Kenya appreciates involvement of FAO, WHO and other UN bodies (WFP, IFAN)

Kenya also takes note of the update of chapters of the environmental Health Criteria 240-Principles and method for risk assessment as such updates help to improve food safety risk assessment approaches.

Agenda Item 4b

Agenda 4.2: Matters arising from other international organizations (IAEA)

Kenya welcomes the report by the representative of IAEA. We thank IAEA for all the technical support it has been providing to most developing countries in strengthening both the human expertise and technical infrastructures of many analytical laboratories.

Kenya will be looking forward to support from IAEA in capacity building for analysis of contaminants, pesticide residues and residues of veterinary drugs in food.

Agenda Item 6

Agenda 6: Proposed maximum residue limits for pesticides in food and feed

Kenya would like to welcome the report of the evaluation by JMPR. Kenya would like to provide comments on the following proposed MRLs for the different food and feed items as follows:

Bifenthrin (178)

Kenya supports the proposed MRLs for the following commodities: Straw and fodder (dry) of cereal grains (1 mg/kg (dw)) and recommends advancement of these proposed MRL to the next Codex Step.

Buprofezin (173)

Kenya supports the proposed MRLs for the following commodities: Citrus pulp, dry (5 mg/kg), Citrus oil, edible (6 mg/kg), Olive oil, crude (20 mg/kg), Group of tree nuts (0.05 mg/kg), Almond hulls (3 mg/kg), Almond (W), Mammalian fats except milk fats (0.01 mg/kg), Eggs (0.01 mg/kg), Poultry, edible offal of (0.01 mg/kg), Poultry fats (0.01 mg/kg), Poultry meat (0.01 mg/kg)

Kenya recommends the advancement of the proposed MRLs to the next Codex Step and the withdrawal of the previous MRLs for Almond.

Metconazole (313)

Kenya supports the proposed MRLs for the following commodities: Wheat straw and fodder, dry [25 mg/kg (dw)] and recommends advancement to the next codex step

Azoxystrobin (229)

Kenya agrees with the previous recommendations for azoxystrobin in coffee bean.

Dicamba (240)- Registered

Kenya supports the proposed MRLs for the following commodities: Maize (0.01 mg/kg), Maize fodder (dry) [0.6 mg/kg (dw)], and recommends the advancement of the proposed MRLs to the next Codex Step.

Fosetyl-Al (302)

Kenya supports the proposed MRLs for the following commodities: Flowerhead Brassicas (subgroup) (0.2 mg/kg), Head Brassicas (subgroup) (0.2 mg/kg) and recommends the advancement of the proposed MRLs to the next Codex Step.

Agenda Item 7a

Agenda 7.11 Revision of the Classification of Food and Feed (CXA 4-1989): Class C - Primary Animal Feed Commodities including issues related to fodder commodities (At Step 4) (CX/PR 21/52/6)

Kenya would like to thank the EWG Chaired by the USA and co-chaired by the Netherlands for preparing document CX/PR.20/52/6: Revision of Classification of Food and Feed: Class C: Primary Animal Feed Commodities.

Kenya generally agrees with the current structure of Class C. The revision that has been made accommodates all the processed feed commodities which have been moved from class D to Class C. The revised structure of Class C is as was agreed during CCPR50 and CCPR51. It will ultimately improve the calculation of animal dietary burden, to support establishment of a maximum residue limits (MRLs), for animal commodities.

Kenya also agrees with:

- The revised Type 11 into three groups with subgroups which include an additional subgroup for miscellaneous processed product
- The group of grasses have been renamed as subgroup 051D: Grasses for Animal Feed to differentiate it from grasses listed Type 03 of Class A.
- Silage commodities have been moved from Subgroup 50C/51C to 50A/51A since it was a commodity with high water content. However, we would like to seek more clarity on the use of the letter code AS on silage, since it may be used on subgroups 051B to 051D.

Specific comments:

- a) Kenya seeks clarification on the use of code AM. We note the code AM belong to the subgroup 052B and 052C not to subgroup 052A. We propose to delete AM0165
- b) Kenya further proposes editing i.e. change the code "AM 3583 rape seed meal" to "AM 3578 rape seed meal" in the table in Appendix II of CX/PR 20/52/7
- c) Kenya would like to propose the inclusion of sweet potato (*ipomoea batatas*) vine, silage and Hull under miscellaneous commodities subgroup 052A. Sweet potato vine, hulls and silage are utilized as feed for cattle and pigs

Agenda Item 7b

Agenda 7.21: Revision of the Classification of Food and Feed (CXA 4-1989): Class D – Processed foods of plant origin. All types in Class D. Proposed groups in different types (at Step 4) (CX/PR 21/52/7)

Kenya welcomes the conclusions and the recommendations of the EWG on the Revision of Class D Chaired by United States and co-chaired by the Netherlands and would like to comment on each of these recommendations as follows:

Recommendation 1

Kenya agrees with the proposal to include flour commodities not originating from cereals separated from the flour from cereals and to classify them under group 69 (Miscellaneous derived products from plant origin).

Recommendation 2

Kenya agrees with the proposal to keep Group 78 Type 15 (Manufactured foods (multi-ingredients) of plant origin), however we are of the view that there should be more future discussion on how to include commodities meeting these criteria for multi-ingredients be put in the group and how MRLs for such commodities should be derived.

Recommendation 3

Kenya takes of note of the proposal not to create groups for wholemeal analogous to the group of flour from cereals and proposes that this recommendation be discussed further at CCPR52 with a view of deciding how residues of pesticides in these commodities are accommodated in the future.

Recommendation 4

Kenya agrees with the proposal to change the Group 070 "Fruit Juices" into "Fruit and vegetable juices" with consequential changes to the introduction text.

Recommendation 5

Kenya agrees with:

- (i) Proposed structure, location of commodities and other changes proposed for Group 066 Teas.
- (ii) Approach taken for herbal teas to mention the most important ones separately and to cover minor ones under two single codes DT 9999 Leaves and Flowers from other crops used for herbal teas, dried and DT 9998 Roots from other crops used for herbal teas, dried.

Recommendation 6

Kenya agrees with the relocation of commodities from Class D to Class C taking into account the working principles from the transferring of commodities from class D to C as agreed by CCPR and the corresponding revision made to Class C and Class D.

However, the following are the specific comments:

Kenya suggests the following rewording;

- i) Change see "DF 0013 Cherries dried" to DF 0013 Cherries subgroup of dried
- ii) Change see "Citrus dried DF 0001" to see "Citrus subgroup of dried"
- iii) And Change "DV 2084 Fungi dried" to "DV 2083 Group of edible fungi"

Agenda Item 7c

Agenda 7.31: Revision of the Classification of Food and Feed (CXA 4-1989): Tables on examples of representative commodities for commodity groups in different types under Class C and Class D (for inclusion in the Principles and Guidance for the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups (CXG 84-2012)) (at Step 4) (CX/PR 21/52/8)

Kenya would like to thank the EWG chaired by the United States of America and co-chaired by the Netherland for preparing the proposed list of representative commodities under Class C and Class D.

Kenya agrees with the list of representative commodities listed in Table 7. Examples of selection of representative commodities, Class C, Type 11 Primary Animal Feed Commodities.

We also agree with Table 8 Example of the selection of representative commodities Class D, Processed Foods of Plant Origin.

Agenda Item 7d

Agenda 7.4: Revision of the Classification of Food and Feed (CXA 4-1989): Impact of the revised types in Class C and Class D on CXLs (CX/PR 21/52/9)

Kenya would like to thank the EWG chaired by the United States and co-chaired by the Netherland for preparing the document CX/PR 20/52/9.

Kenya agrees with the earlier decision that no changes would be made to CXLs until a time when the JMPR reviews were complete as per the current procedure for establishing Codex schedules and priority list of pesticides.

Kenya also agrees with the proposed changes in Appendices I (Classes C) and II (Class D) to enable the implementation of changes to the Codex database.

Agenda Item 8

Agenda item 8.1: Proposed guidelines for compounds of low public health concern that may be exempted from the establishment of CXLs or do not give raise to residues: CX/PR 21/52/12

Kenya thanks the electronic working group led by Chile, India and United States of America and welcomes the work on the proposed guidance for compounds of low public health concerns that may be exempted from the establishment of CXLs.

Kenya would like to submit the following comments:

General Comment:

Kenya agrees with the overall structure of the proposed guideline and its readiness for adoption at step 5

Specific comments:

Criterion 1: Active substances without hazardous properties identified (very low or no toxicological concern)

Kenya agrees with this criterion which represents substances and their relevant metabolites for which it is not necessary to establish Human Health Guidance Values (ADI/ARfD), which includes basic substances, and other substances which are food components.

Substances and relevant metabolites that do not bioaccumulate or do not have the capacity to cause significantly toxic effects at environmentally relevant concentration (corrosive, sensitizing, neurotoxic, immunotoxin, carcinogenic, mutagenic, reproductive, developmental or endocrine disrupting effects, among others

Criterion 2: Substances for which it is not possible to differentiate between the exposure associated with its use as pesticide and its other uses in the food chain

Kenya proposes a differentiation of compounds in this criterion as follows:

- i) A grouping of plant/vegetable oils and plant essential oils and essential oils into one group. This is because this group of substances that are more associated with use in food items.
- ii) A grouping of substances that are traditionally used for their pesticidal properties, this group could include Pyrethrum (Pyrethrins), *Azadirachtin* (neem product), *Azadirachta indica* (Neem leaf and seed kernel oil) and *Annona spp.* (Annonins, Squamocin) among others.
- iii) A grouping of substances that are chemical in nature such as Soaps (fatty acid salts and sulphur to name a few.

The proposed group does not adequately separate the substances that are currently used as pesticides and those that whose exposure could be due to intended use as food items.

Criterion 3: Substances for which no consumer exposure linked to the mode of application is foreseen

Kenya agrees with this grouping of these substances, which are used for the purpose of disrupting mating.

These substances that include pheromones and other semiochemicals dispersed through dispensers for mating disruption purposes, and have no consumer exposure linked to the mode of application.

Criterion 4: Microorganisms which are not pathogenic and do not produce mammalian toxins or other potentially toxic secondary metabolites of human health concern

Kenya agrees with this grouping, which includes microbial pesticides, excluding microorganisms that are either primary mammalian pathogens or are taxonomically close relatives to microbes that are primary mammalian pathogens. Kenya supports the proposal that separate grouping could be provided for microorganisms that are closely related to known toxigenic human pathogens, evidence should be provided that toxins of concern are absent in final pesticide products and are not likely to be produced by the microorganism, following application, at levels on or in the treated crop that will either exceed natural background levels or potentially cause harm to public health.

Various microorganisms occur naturally in the different regions of the world and do not produce mammalian toxic that are harmful to human health.

Agenda Item 9

Agenda item 9: Discussion paper on the review of the mass spectrometry provision in the guidelines on the use of mass spectrometry for the identification, confirmation and quantitative determination of pesticide residues (CXG 56-20050 and the guideline for performance criteria for the method of analysis for the determination of pesticide residues in food and feed (CXG 90-2017): CX/PR21/52/13

Kenya would like to thank Iran and Costa Rica for leading the EWG on the preparation of the discussion paper on the review of mass spectrometry provisions in the two guidelines;

Kenya recommends the re-establishment of the EWG to continue work on TORs and submits report at the next CCPR Session. The EWG could not find common grounds to whether TOR (i) adequately addresses the issue at hand or whether there is a need to proceed to addressing TOR(ii).

Agenda Item 11

Agenda item 11: Review of the international estimate of the short term intake equation (IESTI) CX/PR 21/52/15 General Comment

Kenya would like to thank the EWG chaired by the European Union and co-chaired by Brazil and Uganda for preparing the document CX/PR 21/52/15. We would like to note that the IESTI equation is a very important element of the dietary exposures assessment when proposing MRL by JMPR.

Kenya would like to agree with the conclusion by JMPR that benchmarking assessment of the current deterministic IESTI equation to the probabilistic exposure assessment from all countries and population of interest has characterise conservatism of the current equation and allows exposure to actual distribution.

Kenya takes note of the recommendation of the EWG that there was need to review the WHO/FAO final published paper.

Kenya agrees that there is still need for further work to address the risk management and risk communication challenges and also acknowledge the fact that quantitative consumer protection goals have not been clearly formulated by CCPR and information on actual level of protection from the current IESTI equation has not been available in the past.

Kenya also agree that information in section 1-3 sufficiently addresses TOR (i) and we would like it to reside in the appendix to the report.

TOR (ii) Gather bulking and blending information and prepare an overview that will be discuss at CCPR52 to decide on how to conclude on or follow up on this matter.

Kenya would like to thank the 8 countries and 13 trade organisations who provided information on bulking and blending in repose to TOR (ii) of the EWG. We agree the information provided in section 4 and appendix 1 sufficiently TOR (ii) and it should be forwarded JMPR.

Agenda Item 12

Agenda item 12: Engagement of JMPR in parallel reviews of new compounds: Proposed procedures and principles: CX/PR 21/52/16

Kenya welcomes the formation of the EWG to propose principles and procedures to enable the participation of the JMPR in parallel reviews of a new compound to accelerate the setting of Codex MRLs and support MRL harmonisation.

Kenya notes that establishment of a successful parallel review process will require some flexibility to address challenges collaboratively and refine the process iteratively.

General Comments:

Comment on the content and timeframes: Kenya thanks the EWG for its work in preparing the document for consideration and the proposed approach for the parallel review. Kenya agrees with the proposed principles and procedures for the parallel review process to enable JMPR to engage in reviews of new compounds. Further Kenya agrees with the nomination process timelines and the nomination criterion and requirements and criteria for the prioritization and scheduling pesticides for evaluation by JMPR and the prioritization criterion.

Specific comments:

Section 2: Selection of pesticides for JMPR Review

Kenya understands that the parallel review would be undertaken on a pilot basis. If this is the case, Kenya seeks clarification on the need to make an inclusion of the proposed paragraph "...Only pesticides nominated for a parallel review will be exempted from the requirement for a national registration at the time of scheduling. In order for CCPR to agree to having a pesticide evaluated by the JMPR as part of a parallel review, the complete data package as required by JMPR must be made available at, or shortly after the CCPR meeting. This will allow JMPR to initiate the parallel review process as soon as the product nominations are approved by CAC in July of each year".

Kenya seeks clarification on whether the process will not be considered as a pilot but rather be a norm, and thus the reason for the editorial amendment to the procedural manual Risk analysis principles applied by CCPR.

Section 3: JMPR Call for Data

Kenya seeks clarification on the inter-relationship between this section and Section 2.2. However, Kenya agrees with the announcement of the data call as important for the success of the process.

Section 4: Parallel Review

Kenya agrees with the proposal in this section and also affirms the need for JMPR reviewers in this process of parallel review should not the same experts as the ones involved in the national registration process. This will avoid conflict of interest.

Section 5: Risk assessment methodology.

Kenya agrees with the proposal set out in this Section, and wishes to emphasize the need of using methodology published by the FAO/WHO. Kenya proposes that any differences in approaches in review of the data provided should be documented and communicated to enhance the transparency of outcomes of reviewers who review the same data to share with the CCPR. Kenya proposes inclusion of text to reflect this in Section 5 to request "Where consensus is not arrived at, the reason/rationale for dissension will be documented for communication to the CCPR".

Section 6: Submission of the final label

Kenya agrees with this proposal.

Section 7: Interaction between JMPR reviewers and third parties (national regulators, sponsor)

Kenya agrees on the need for interaction and communication between reviewers, whether JMPR or national, and the sponsor.

Kenya encourages that the "global project manager" responsible for the process should be independent of the national reviewers /registration authorities or the JMPR and proposes that the person could be the Chair of the EWG, so that the Chair can report back to the CCPR on the progress of the process.

Agenda Item 13

Agenda item 13: Discussion paper on the management of unsupported compounds without public health concern scheduled for periodic review: CX/PR 21/52/17

Kenya who participated in the discussion paper preparation, thanks the others Canada, Chile and India for leading the preparation of the discussion paper on the management of unsupported compounds without public health concerns;

Kenya submits the following comments to the various questions as follows:

TOR (i) Question 1: Investigate the circumstances that lead to unsupported compounds and obstacles that prevent providing support.

Kenya notes that some compounds remain in Table 2A and 2B for long without receiving the requisite support for reevaluation. It is noted that in many cases, the industry that initially provided the requisite data for evaluation do not submit data for periodic re-evaluation since the compounds' patents may have lapsed and therefore gone to generic companies. It is also noted that after 15 or 25 years, the industry still manufacturing the unsupported chemicals is not in a position to provide data to support periodic review, while noting that there could be a change in the toxicology data.

TOR (i) Question 2: Which are the obstacles that prevent providing support to these compounds

Kenya notes that the unsupported compounds sometimes remain in the Table 2A states that in many of the cases where the cases, this is due to lack of support from the agrochemical industry to generate data in support of periodic review; as well as limited funding in research institution to generate data to support period re-evaluation. Further in many Codex Members, a clear understanding of the data requirements and the possible data gaps required to support the review process is not clearly understood by the researchers.

TOR1/Question 3: Do you believe that all Codex members and observers participating in CCPR are sufficiently aware of what information and data are required to support a periodic review of a pesticide and existing CXLs?

Many Codex members and observers participating in CCPR are aware of the data and information required to support a periodic review. However, there should be a critical examination of the requirements for period review in light of this fact. Since some unsupported pesticides are still registered in some Codex members, a clearly defined survey should critically examine what limits the data submission process to support a periodic review. This should aim at providing a clear outcome on the understanding of Codex Members and observers on the need for submission of appropriate information to support period review.

TOR1/Question 4: Do you believe that all Codex members and observers participating in CCPR are sufficiently aware of the consequences that follow from lack of data support for certain compounds/uses?

Many Codex members and observers are generally aware of the need for data to support certain compounds and uses. However, the outcome from a lack of data submission may not be clear to all, especially leading to the loss of CXLs for these compounds and removal from the Codex database.

TOR2/Question 1: Do you believe it is possible that Codex members and observers participating in CCPR could efficiently collaborate to assist other Member states, currently lacking the capacity to independently support pesticides/uses important to their production systems, to develop data packages adequate for JMPR evaluation?

Kenya believes that it is possible for Codex Members participating in CCPR to collaborate through:

- Work sharing programs aimed at the generation of data to develop data packages adequate for JMPR evaluation.
- ii) Strengthening of existing capacities in Codex Members countries to support pesticide uses that are important for the production systems and trade in the member Countries,

TOR2/Question 2: What kind of collaborations activities you believe can be developed?

Kenya believes the following:

- i) Collaboration in Joint Review of data packages generated by Codex Members and observers.
- ii) Work sharing programs to generate data to support periodic review.
- iii) The Committee could explore mechanisms to enhance data pooling from various Codex members and observers to ensure completeness of data packages in support of periodic reviews.

With respect to the TOR2/Question 3: Do you consider that there is any possibility to reduce the minimum data requirements for a JMPR re-evaluation of a pesticide without a registered public health concern? If so, what are the minimum data requirements you consider appropriate?

Kenya considers that the requirements should be adhered to as required, hence a reduction of data requirements should not be encouraged.

TOR 3: Explore the advantages and challenges that arise from the options 2b and 3 as recommended by CCPR51

i) Option 2b: Only those CXLs for which there are registrations listed in the National Registration Database (NRD) will be retained.

Kenya has examined the proposed options for the two options and supports the provision of the National Registration Database to encourage Codex Members to provide information. The proposal in this option should however be further discussed at Committee level in light of the Risk analysis principles.

Advantage: This will facilitate the maintenance of CXLs for the registrations in the Codex Member countries for the uses noted, thus avoiding disruption of trade. The NRD would provide information on the current registrations of unsupported compounds. Providing information to the NRD should be simplified for Codex Members to provide information on the compounds in order to be considered.

ii) Option 3: Codex Members and observers are granted 4 years to fulfil the data requirements to maintain the CXLs. (i.e., 4-year rule). If Members or observers are unable to address the data requirements, all CXLs are to be revoked"

Kenya submits that the provision of the 4-year rule is in line with the Risk analysis principles applied by the CCPR. There should however be further discussion on the proposal to revoke CXLs if Members or Observers are unable to address the data requirements.

The collaborative approaches to enhance data generation through work sharing programs and joint reviews for collation for JMPR submission would ensure that pesticides needed in some Codex Member states that have limited resources and capacity to generate data to support pesticides of interest. Further, closer examination should be given to ensure that compounds with registered uses but are not supported, especially for countries that need a wide range of tools to manage pests should be considered and their CXLs maintained.

Agenda Item 15

Agenda item 15: establishment of priority lists of pesticides for evaluation by JMPR 2021: CX/PR 21/52/19

Kenya welcomes the outcome of the work of the EWG priorities chaired by Australia. Kenya takes note of the commodities pesticide combinations, under new uses and other evaluation; fludioxnil (211) for papaya (PH) and mango (PH),), Azoxystrobin (229) for papaya (PH) and mango (PH) and Bifenthrin (178) for okra, lettuce, avocado, etc., are of benefit to the continent.

Kenya looks forward to the periodic review for dimethoate (toxicology and residue) and chlorpyrifos (toxicology and residues). These compounds are widely used in African region and are a subject of concern due to differences in risk assessment outcomes.

Kenya generally agrees with the Priority list for evaluation by the 2021 JMPR Extraordinary meeting and the Priority list for evaluation by the 2021 JMPR Regular meetings to facilitate the evaluation of various compounds for elaboration of MRLs.

Most of the tropical crops scheduled for evaluation are grown in the African region and the numbers of compounds on the new and follow-up evaluations are registered for use on the continent.