DEVELOPMENT OF NEW WORK PROPOSALS AND PROJECT DOCUMENTS / DISCUSSION PAPERS

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CONTENT

Brief introduction of the 8-step procedures

Project documents / discussion papers (relationship)

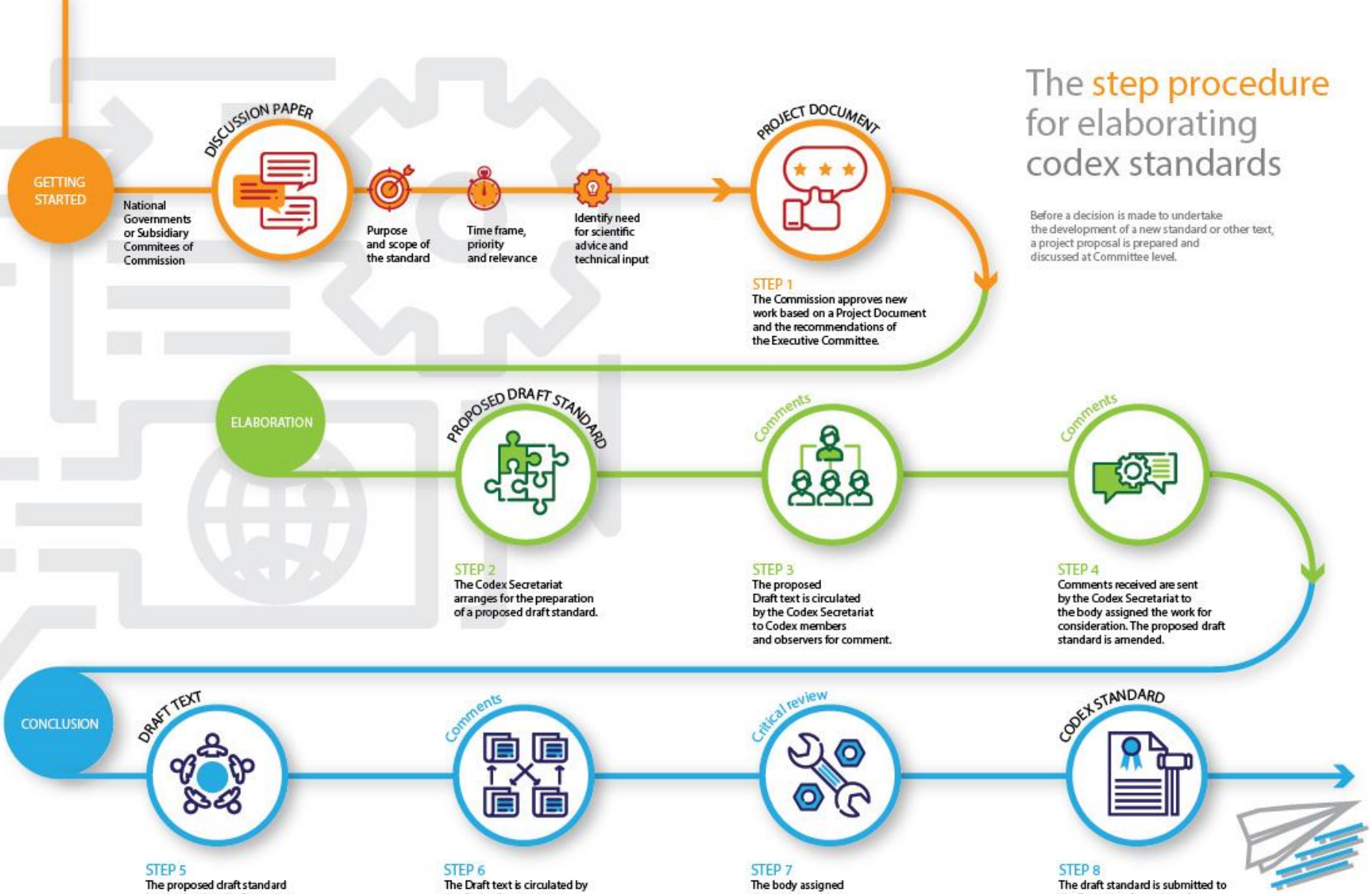
Critical review of proposals for new work

Examples

Benefits and challenges

The step procedure for elaborating codex standards

Before a decision is made to undertake the development of a new standard or other text, a project proposal is prepared and discussed at Committee level.



STEP 1
The Commission approves new work based on a Project Document and the recommendations of the Executive Committee.

STEP 2
The Codex Secretariat arranges for the preparation of a proposed draft standard.

STEP 3
The proposed Draft text is circulated by the Codex Secretariat to Codex members and observers for comment.

STEP 4
Comments received are sent by the Codex Secretariat to the body assigned the work for consideration. The proposed draft standard is amended.

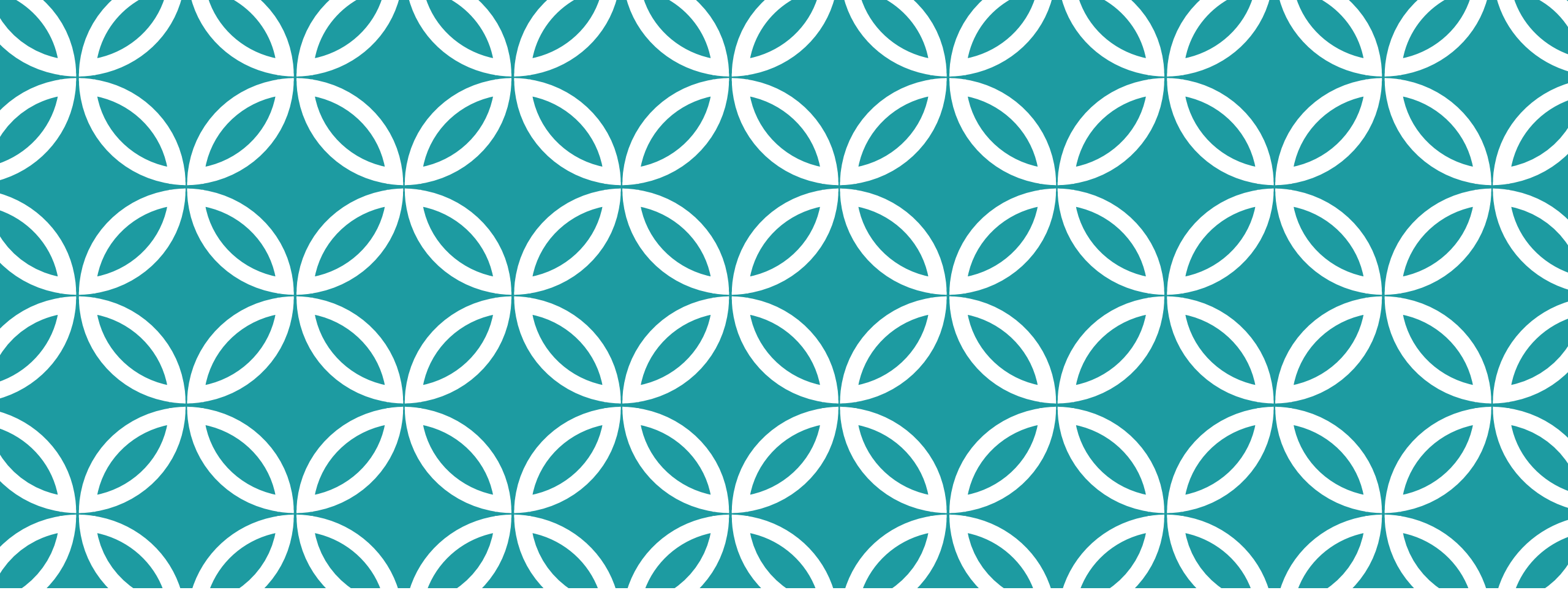
STEP 5
The proposed draft standard is submitted to the Executive Committee for critical review and to the Commission for adoption at step 5.

STEP 6
The Draft text is circulated by the Codex Secretariat to Codex members and observers for a another round of comments.

STEP 7
The body assigned the work considers the comments and amends the draft standard.

STEP 8
The draft standard is submitted to the Executive Committee for critical review and forwarded to the Commission for adoption as a Codex standard. It is then published on the Codex website.

Step 5/8:
Increasingly subsidiary bodies are utilizing a Step 5/8 procedure. This entails texts being submitted for adoption at Step 5 having a recommendation that Steps 6 and 7 be omitted and that the text also be adopted at Step 8. This practice substantially speeds up the adoption process.



DISCUSSION PAPER AND PROJECT DOCUMENT

DISCUSSION PAPER

- Preliminary step for starting new work
- Content:

  provides a background of the issues

  explains how the proposed new work: (i) intends to address the issue; (ii) fits in Codex work and strategic plan

  analyses gaps in Codex documents (if applicable)

  provides scientific data and identifies needs for scientific advice (if applicable)
- Purposes: verify interest of other members and support; identify partners to carry out the work; review the scope
- May or may not include a project document
- It is usually announced at the previous meeting under other business

PROJECT DOCUMENT

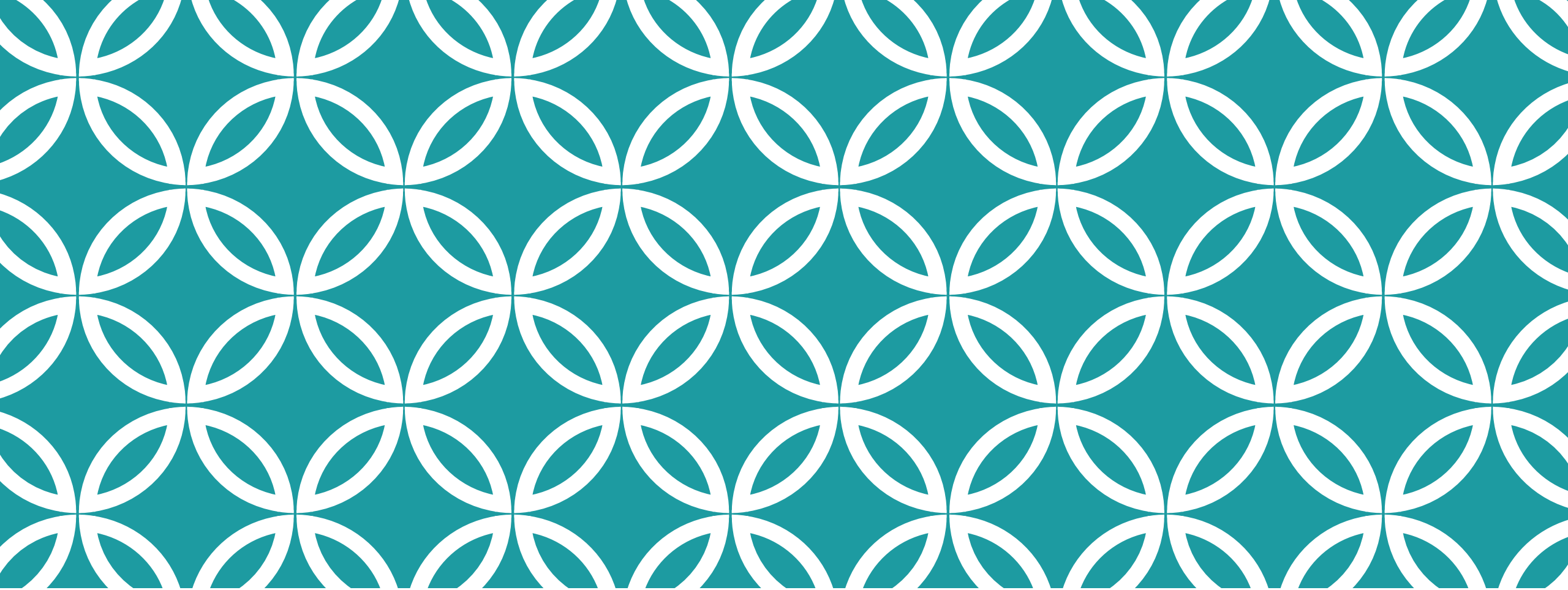
- the purposes and the scope
- its relevance and timeliness
- the main aspects to be covered;
- an assessment against the *Criteria for the establishment of work priorities*
- *relevance to the Codex strategic objectives*
- information on the relation between the proposal and other existing Codex documents
- identification of any requirement for and availability of expert scientific advice
- identification of any need for technical input to the standard from external bodies so that this can be planned for
- the proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

CRITICAL REVIEW

- Examination of proposals for development/revision of standards, taking into account the “Criteria for the Establishment of Work Priorities"
- The strategic plan of the Commission and the required supporting work of independent risk assessment
- Identifying the standard setting needs of developing countries
- Advice on establishment and dissolution of committees and task forces, including ad hoc cross-committee task forces (in areas where work falls within several committee mandates)
- Preliminary assessment of the need for expert scientific advice and the availability of such advice from FAO, WHO or other relevant expert bodies, and the prioritisation of that advice
- Exception: New work on numerical standards in accordance with criteria established by the relevant Committees, this includes MRLs for pesticides, veterinary drugs, GSFA, GSCTFF, INS.

EXCEPTIONS

The decision to undertake new work or revision of individual maximum residue limits for pesticides or veterinary drugs, or the maintenance of the General Standard on Food Additives, the General Standard on Contaminants and Toxins in Food and Feed, the Food Categorisation including related methods of analysis and sampling plans including related methods of analysis and sampling plans System and the International Numbering System, ***shall follow the procedures established by the Committees concerned and endorsed by the Commission.*** *(Codex Procedural Manual – Section II "Elaboration of Codex texts")*



EXAMPLES

CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 13

CX/CF 17/11/13
March 2017

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Eleventh Session
Rio De Janeiro, Brazil, 3-7 April 2017

DISCUSSION PAPER ON NON–DIOXIN LIKE PCBs IN THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXINS AND DIOXIN-LIKE PCBs

BACKGROUND

1. At its 80th meeting in 2015, the Joint FAO/WHO Expert Committee on Food Additives (JECFA80) assessed the toxicity of non-dioxin-like polychlorinated biphenyls (NDL-PCBs)[1]. JECFA concluded that none of the available studies on the NDL-PCBs known as the six indicator PCBs (PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180) and PCB 128, was suitable for derivation of health-based guidance values or for assessment of the relative toxic potency of the NDL-PCBs relative to a reference compound. Therefore, a comparative approach using the minimal effect doses was developed in order to estimate Margins of Exposure (MOEs) to provide guidance on human health risk. Owing to the long half-lives of these chemicals and to eliminate interspecies differences in toxicokinetics, JECFA considered it appropriate to estimate body burdens rather than using external dose (dietary exposure) for the risk characterization. Comparison of the human body burden estimates (derived from human milk concentrations) with the body burden estimates

APPENDIX I

(For consideration by CCCF)

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON THE "CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXIN AND PCB CONTAMINATION IN FOOD AND FEED"

(FOR CONSIDERATION BY CCCF AND APPROVAL BY CAC)

1. Purpose and Scope

The purpose of the proposed new work is to provide to member countries and the food and feed producing industry, guidance to prevent and reduce non dioxin-like (NDL) polychlorinated biphenyl (PCB) contamination in food and feed.

2. Relevance and Timeliness

At its 80th meeting in 2015, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) assessed the toxicity of NDL-PCBs[1]. JECFA concluded that based on the available data, dietary exposures to NDL-PCBs are unlikely to be a health concern for adults and children. For breastfed infants, the safety margins would be expected to be lower. However, based on present knowledge, the benefits of breastfeeding are considered to outweigh the potential disadvantages that may be associated with the presence of NDL-PCBs in breast milk.

Therefore it remains important that efforts are undertaken to reduce or prevent human exposure to NDL-PCBs by adherence to good agricultural practices and good animal feeding practices.

3. Main aspects to be covered

Review and update the *Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds* (CAC/RCP 62-2006) to include NDL-PCBs in its scope and rename as Code of Practice for the Prevention and Reduction of Dioxin and PCB Contamination in Food and Feed (CAC/RCP 62-2006).

DISCUSSION PAPER ON NON-DIOXIN LIKE PCBs IN THE *CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXIN AND DIOXIN-LIKE PCBs* (Agenda Item 13)[25]

144. The European Union, as Chair of the EWG, introduced the item and recalled that following JECFA80, CCCF10 had requested the development of a discussion paper to identify if the *Code of Practice for the prevention and reduction of dioxins and dioxin-like PCB contamination in Foods and Feed* (CAC/RCP 62-2006) could be revised to include measures also for non-dioxin like PCBs. The delegation informed the Committee that it was appropriate to revise the document as there were sufficient measures in place for such prevention or reduction as identified in paragraph 14a – e of CX/CF 17/11/13. In addition, additional measures had been identified for the prevention and reduction of dioxins and dioxin-like PCBs, e.g. cooking practice and carry-over from feed to food, and proposed that the revision of the COP also take up these measures.

145. The Committee agreed with the proposal and noted the comment of one delegation to take into account the needs of small enterprises.

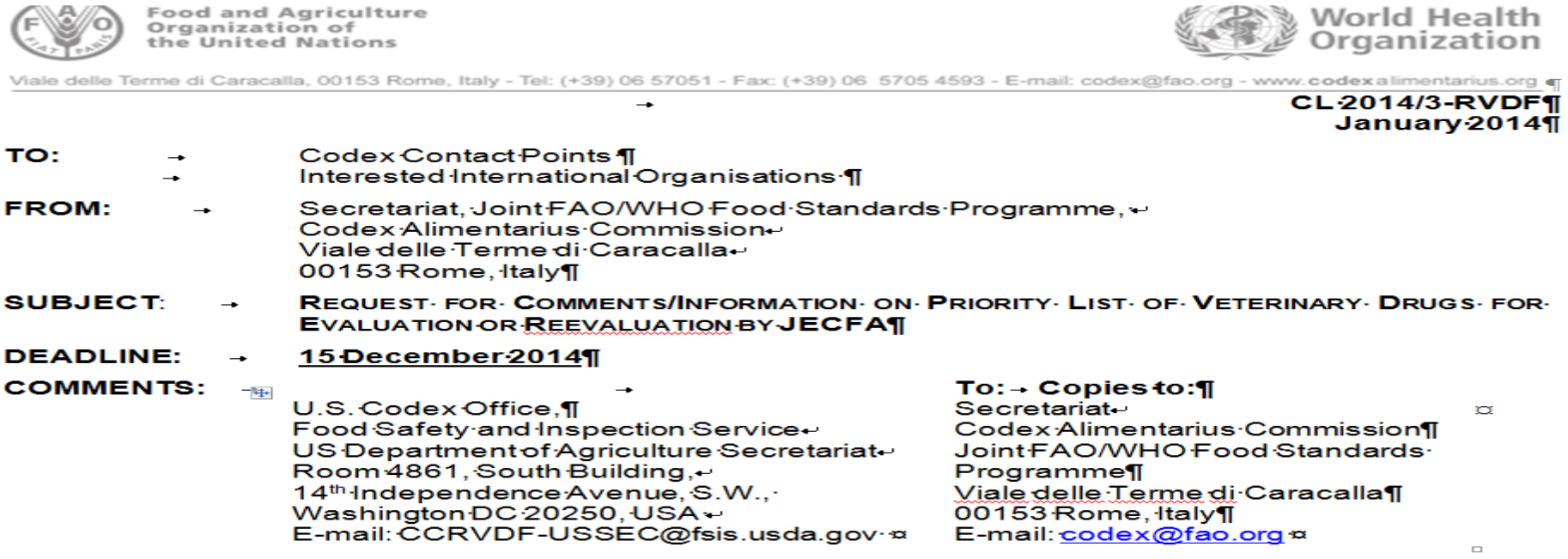
Conclusion

146. The Committee agreed to start new work and to forward the project document (Appendix IX) to CAC40 for approval.

147. The Committee further agreed to establish an EWG, chaired by the European Union, working in English only, to revise the COP for comments and consideration at its next session.

Member has proposed the compound

The mechanism for a Member to propose compounds for inclusion in the Priority List is to reply to the **Circular Letter on Priority**



Food and Agriculture Organization of the United Nations

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CL 2014/3-RVDF
January 2014

TO: Codex Contact Points
Interested International Organisations

FROM: Secretariat, Joint FAO/WHO Food Standards Programme,
Codex Alimentarius Commission
Viale delle Terme di Caracalla
00153 Rome, Italy

SUBJECT: REQUEST FOR COMMENTS/INFORMATION ON PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR REEVALUATION BY JECFA

DEADLINE: 15 December 2014

COMMENTS:

U.S. Codex Office,
Food Safety and Inspection Service
US Department of Agriculture Secretariat
Room 4861, South Building,
14th Independence Avenue, S.W.,
Washington DC 20250, USA
E-mail: CCRVDF-USSEC@fsis.usda.gov

To: Copies to:
Secretariat
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome, Italy
E-mail: codex@fao.org

- BACKGROUND
- 1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) at its 21st Session (August 2013) agreed to forward the Priority List of Veterinary Drugs for Evaluation or Reevaluation by JECFA to the 37th Session of the Commission Alimentarius Commission for approval.
- 2. The Committee also agreed to establish an electronic Working Group, chaired by Australia and working in English only, to consider the replies to the Circular Letter requesting comments and information on the Priority List of Veterinary Drugs requiring Evaluation or Re-evaluation by JECFA and report to the 22nd CCRVDF, scheduled in April 2015. The 21st CCRVDF noted that the deadline for the submission of proposals in response to the Circular Letter would be earlier than the current date to allow the electronic Working Group to prepare a proposal for the 22nd CCRVDF. The Committee noted the need to respect the deadline in order to allow the electronic Working Group to prepare a proposal for the Plenary. It further noted

Template for information necessary for prioritazation by CCRVDF

ADMINISTRATIVE INFORMATION

Member(s) submitting the request for inclusion

Veterinary drug names

Trade names

Chemical names and CAS registry number

Names and addresses of basic producers

PURPOSE, SCOPE AND RATIONALE

Identification of the food safety issue (residue hazard)

Assessment against the criteria for the inclusion on the priority list

RISK PROFILE ELEMENTS

Justification for use

Veterinary use pattern, including information on approved uses if available

Commodities for which Codex MRLs are required

RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS

Specific request to risk assessors

AVAILABLE INFORMATION

Countries where the veterinary drugs are registered

National/Regional MRLs or any other applicable tolerances

List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available

TIMETABLE

Date when data could be submitted to JECFA

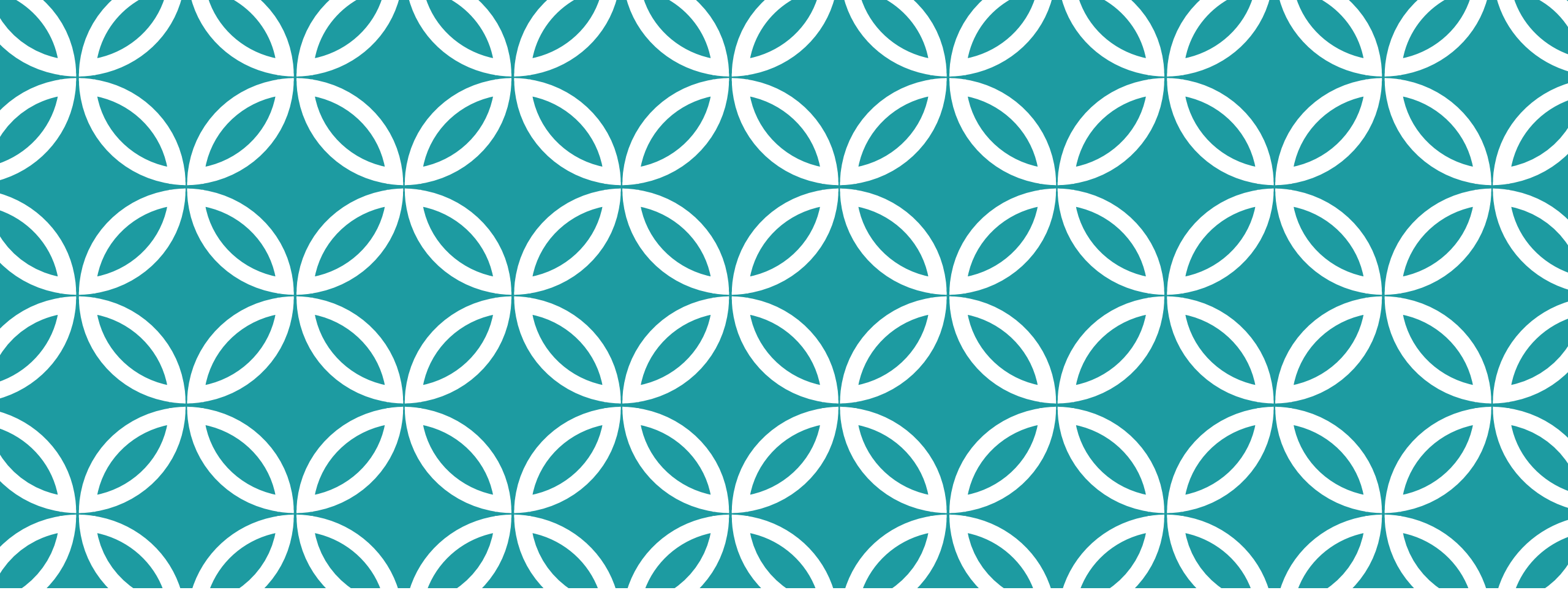
When preparing a preliminary risk profile, Member(s) should take into account the updated data requirement, to enable evaluation of a veterinary drug for the establishment of an ADI and MRLs, published by JECFA.

Appendix·X¶

PRIORITY·LIST·OF·VETERINARY·DRUGS·FOR·EVALUATION·OR·RE-EVALUATION· BY·JECFA¶

(for·approval)¶

Name·of·compounds¤	Questions(s)·to·be·answered¤	Data·availability/time¤	Proposed·by¤	Comments¤
Sisapronil· (formerly· known· as· phenylpyrazole)¤	Request· to· establish· ADI· and· recommend· MRLs· in· cattle· tissues· (liver,· kidney,· muscle· and·fat)¤	Data·available·¤	USA¤	¤
Ethoxyquin·↵ (feed·additive·use)¤	Request· to· establish· MRL· in· shrimp·muscle.¤	The· Delegation· of· the· Philippines· confirmed· that· relevant·data·are·available.¤	Philippines¤	To·be·confirmed·by·37th·CAC· that· it· is· appropriate· for· CCRVDF· to· deal· with· this· request.¤
Ivermectin¤	Establishment· of· an· MRL· in· bovine·muscle¤	Existing· JECFA· reports,· data· and·public·literature.¤	21st·CCRVDF¤	¤
Chlorpromazine¤	Update· the· toxicological· and· exposure·assessment¤	To· be· confirmed· through· a· JECFA·call·for·data¤	21st·CCRVDF¤	JECFA· Secretariat· agreed· to· provide· advice· to· the· 22nd. CCRVDF·on·the·availability·of· toxicological· and· exposure· data·and·possible·implication¤
Dimetridazole,· ipronidazole,· metronidazole·and·ronidazole¤	Update· the· toxicological· and· exposure·assessment·¤	To· be· confirmed· through· a· JECFA·call·for·data¤	21st·CCRVDF¤	JECFA· Secretariat· agreed· to· provide· advice· to· the· 22nd. CCRVDF·on·the·availability·of· toxicological· and· exposure· data·and·possible·implication·¤



BENEFITS AND CHALLENGES

BENEFITS

Discussion paper

- Identification of the issue / concern
- Verification of support and interest
- Identify partners in the elaboration
- Facilitate the preparation of the project document

Project document

- Part of the process
- Identification of timeframe (allow CCEXEC to monitor progress)
- Relationship with other texts
- Clarify scope and purpose of the work
- Assist in the development of work

CHALLENGES

Discussion paper

- Clarity and focus
- Provide evidence of the international relevance of the work
- Explain the relations with other documents

Project document

- Clarity of purpose and scope of the work
- Assessment against the criteria for new work (in particular for commodity standards)
- Relationship with other texts

Thank you for your attention

Now it’s your turn for making comments and asking questions