European Union comments on
Draft and Proposed Draft Principles and Guidelines for National Food
Control Systems

(Agenda item 4, CX/FICS 12/20/3)

Mixed Competence
European Union Vote

General comments

The European Union and its Member States (EUMS) would like to thank Australia for leading
the work on developing the guidance for national food control systems.

The EUMS consider Sections 1-3 (at Step 6) largely acceptable. However, the list of
principles is rather long and contains items which, while important, do not fit well under high
level core principles of a national food control system but would be better placed in Section 4.
This applies to principles 10-13, which could be moved under the relevant sections of Section 4
without undermining the importance of these topics.

Section 4 contains all the necessary elements for the design and operation of a national food
control system. However, it still requires significant work to make the structure more logical.
To this end, the EUMS have specific comments on the structure of sections 4.2, 4.3 and 4.4.

The EUMS also have a number of specific comments on individual paragraphs in Sections 3
and 4 to improve consistency and clarity and to fill gaps and remove duplication.

Specific comments on the structure of section 4.2

A simple framework should be established for this section. As drafted there are a number of
lists but none of them provides a clear way forward for structuring this section. For example,
the list in paragraph 40 is a mixture of things that should be considered in the process of
designing a system and elements of the design itself (components and prerequisites).
Distinction between design process and system design needs to be made. All the points from
paragraph 40 should be picked up in the appropriate sections and then delete it.

The paragraphs in this section as drafted could be grouped under the following headings (with
editing), which could be made into sub-sections:
• contextual considerations, to keep in mind during design phase (e.g. existing international and national standards and legislation);
• components of a national food control system (e.g. control programme); and
• underpinning prerequisites (e.g. data, resources).

By way of illustration, the existing paragraphs could be allocated to the most suitable headings as follows, though the text would need editing after rearranging the ideas to ensure that it flowed:

**Contextual considerations** that need to be kept in mind during the system design phase:
1. Existing international standards
   Paragraph 40, bullets 2, 3, final (modified).
2. Existing national standards and regulatory and legal frameworks
   Paragraph 40, bullets 1, 2, 4 (modified)

**Components** of a new or modified national food control system could be classified as follows:
1. Control programmes
   Paragraphs 47 – 51 (paragraph 47 could also be moved under section 4.3 Implementation)
2. Compliance and Enforcement
   Paragraphs 54 – 55
3. Food safety emergency preparedness and response
   Paragraphs 59 – 61
4. Evaluation systems
   Paragraphs 52 – 53

**Underpinning prerequisites** for a new or modified national food control system could be classified as follows:
1. Data capture and risk assessment
   Paragraphs 58, 41, 43 – 44
2. Documentation
   Paragraph 45
3. Resources
   Paragraphs 56 – 57
4. Communication systems
   Paragraphs 62 – 66

Uniform language should be used in this section. The current drafting implies that within a national food control system there are both ‘control programmes’ and ‘compliance and enforcement programmes’ and that these are different. 'Compliance and enforcement' could actually be considered an element of a control programme. The word ‘programme’ could be dropped from ‘compliance and enforcement’ to reduce confusion. Also definitions in footnotes would be desirable for 'control programme' and 'compliance and enforcement'.

**Definition of ‘Control Programmes’**
There appears to be no definition already in existence in the Codex documentation. It is suggested that a 'control programme' describes the collective activities in place to manage specific risks or issues. A form of words could be drawn from the FAO definition of 'Official Food Control':
'All mandatory activities necessary to assure the quality and safety of food' or it could be derived from the Codex definition of ‘Control Measure’ in CAC/RCP 1-1969:
'Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level'.

Drawing on these definitions the following definition is suggested for 'control programme':

**Control Programme is the collective actions and activities in place to manage specific food safety hazards and assure the quality and safety of food.**

**Definition of 'Compliance and enforcement'**
There appears to be no definition already in existence in the Codex documentation. The following definition is suggested 'Compliance and enforcement':

**Compliance and enforcement refers to the range of controls, procedures or other interventions undertaken by a competent authority [or third party on its behalf] when monitoring or verifying food business operator compliance with official [food and feed safety] requirements, including instigating any corrective measures to achieve compliance.**

The text in square brackets could be omitted.

**Specific comments on the structure of section 4.3**

Following paragraph 67 there should be a linking paragraph setting out the components of implementation. It should be spelled out that these are the things that need to be done to implement the components of the design set out in the previous section. Then sub-sections should follow, detailing these implementation components, which could be divided as follows:

1. **Legislation**, amendments or new
   Paragraphs 35 – 37
   Move paragraph 36 up to sit before paragraph 34.

2. **Guidance and instructions**, to competent authority and food business operators
   Paragraphs 68 – 70, 73 (contingency plans), 75, 76 – 77

3. **Training programmes and manuals**
   Paragraphs 71 - 74

4. **Communications**, including educational programmes
   Paragraphs 78 - 79

**Specific comments on the structure of section 4.4**

Paragraph 81 is largely about what might trigger a review. It should be revised and broken into two paragraphs as follows, to make that clearer:

81. **A national food control system should be regularly reviewed to contribute to the systems’ improvement.** Such reviews may take place at the level of system or program design or implementation as appropriate.

81bis. **Reviews could be triggered** in response to, for example, **data on foodborne illness and food safety incidents**, control programme data, non-compliances, food safety incidents, scientific research, and history of conformance, external and self-reviews of the system and changes to product risk or the production environment.
Paragraph 82 will then flow well from this.

Following paragraph 82, the ideas in the rest of the section need to be structured and ordered. A suggested approach could be to break it into those components of the system that should be subject to regular review (mirroring the components outlines in Section 4.2 System Design):

Components of the system that should be subject to regular review:
1. **Control Programmes**, including review of risk assessment capability, surveillance system
   Paragraphs 89, 86
2. **Compliance and Enforcement**, including review of legal basis
   No paragraphs fit this heading at the moment. Something about review of legal powers could be inserted for example:
   Evaluation of the suite of compliance and enforcement approaches (from advice, guidance and training to corrective actions, issuing sanctions and penalties) in securing compliance.
3. **Food Safety Emergency Preparedness and Response**
   Paragraphs 83, 84, 85

Then the section could finish with paragraphs 87 and 88.

**Specific comments on individual paragraphs**

Principle 2, paragraph 9:
Add the following footnote to the term 'entire food chain': *The entire food chain includes inputs such as animal feed, fertiliser, pesticides, veterinary drugs and any input of plant or animal origin.*
*Rationale: clarifies the concept of entire food chain.*

Principle 4, paragraph 12, footnote 4:
Add *food services providers and caterers* to the list in the footnote.
*Rationale: completes the definition of food business operators.*

Principle 4, paragraph 14:
Delete this paragraph.
*Rationale: This paragraph relates to consumer protection rather than a management role for consumers.*

Principle 6, title:
Delete the words ‘Incorporation of’ from the title.
*Rationale: these words are unnecessary.*

Paragraph 26, 2nd bullet point:
Reword as follows: *develops, implements, monitors, manages and reviews operates, evaluates and improves…*
*Rationale: to bring the terminology in line with paragraph 1, 1st sentence.*

Paragraph 28:
Insert ‘identification’ into second sentence, so the sentence will read: 'This should include the consistent application of a systematic framework for the **identification**, evaluation and, as necessary, control of food safety risks associated with the existing, new or re-emerging hazards.'

**Rationale:** identification of food safety risks is the first step in managing of them.

Paragraph 29:
Delete ‘national’ before ‘competent authority’.

**Rationale:** the term 'national' is unnecessary and its deletion allows maintaining consistent language throughout the document (where ‘competent authority’ is not generally prefixed with ‘national’).

Paragraph 29:
Delete wording 'which will reflect the principles of a national food control system' and add new paragraph 29bis after the diagram instead there is an additional paragraph after the diagram as follows:

'**29bis.** The principles of a national food control system, described in Section 3, will be reflected in both the process followed in designing and implementing the system and in the content at each stage of the process.'

It would then be possible to remove all further references to 'principles in section 3'.

**Rationale:** clarifies that the principles in section 3 should be followed, as appropriate, throughout the design and operation of a national food control system.

Paragraph 30:
The context of 'risk profile' is unclear.

Paragraphs 31 – 32:
Reverse the order of these paragraphs, with paragraph 32 coming before paragraph 31.

**Rationale:** for better flow of the text.

Section 4:
Arrange the elements of the diagram in a circular arrangement.

**Rationale:** the diagram currently gives the impression of a linear process, albeit there are small arrows feeding back from Monitoring and System review. A circular arrangement of the elements might better emphasise the cyclical nature of what we are trying to achieve. And also the fact that – depending on the development stage of a country – the starting point does not necessarily need to be the first element but rather any one of them, or several at the same time.

Paragraph 33:
Delete from the first sentence 'As a result of applying the guiding principles of Section 3 and the framework of Section 4'.

**Rationale:** this is unnecessary.

Paragraph 33:
Move the entire paragraph to Section 4.2 System Design.

**Rationale:** this paragraph is actually about design of a national food control system.

Paragraph 34:
Add period after 'mitigate'.
Paragraphs 34 – 37:
This section is very heavily focussed on legislation. As drafted it gives the impression that policy setting is mainly about making legislation, whereas legislation is actually an implementation step and it is only one tool for policy implementation. Policy setting is about what has been described in the preceding paragraphs, i.e. establishing national objectives about 'what' the country wishes to achieve with its national food control system. Paragraph 34 could be retained in Section 4.1 to provide a reference to legislation within this section about policy setting, but paragraphs 35-37 about legislation could be moved to Section 4.3 Implementation, because these describe the legislation that facilitates controls.

Paragraph 36, 5th bullet-point:
Modify as follows: 'enforce legislation and take proportionate, dissuasive and effective action in cases of unsafe or non-compliant food case of non-compliance with requirements, including, as appropriate, investigations, recall, safe disposal, and application of sanctions and penalties.'
Rationale: this bullet point should be expanded and made more generic.

Paragraph 36, 7th and 8th bullet-point:
These bullet points can be deleted if the 5th bullet point is expanded as proposed.

Paragraph 37:
Delete words 'penalties in the event of non-compliance'
Rationale: repetition, these are covered by paragraph 36.

Paragraph 38:
Modify the paragraph as follows: 'The competent authority should, engage with stakeholders including food business operators and consumers, in the development of new legislation policy and when making regulatory changes including new legislation.'
Rationale: to make it more generic.

Paragraph 38bis:
Add a new paragraph reading as follows: 'Policies should be documented clearly and made accessible to all interested parties, to ensure transparency.'
Rationale: it is important that policy is recorded and accessible to ensure transparency (Principle 3).

Paragraph 38:
Remove commas
Rationale: for clarity.

Paragraph 39:
Reword as follows: 'When designing a national food control system countries should ensure that the main objectives as defined in the policy are addressed as well as how to incorporate the and the principles in Section 3 are addressed.'
Rationale: for clarity.

Paragraph 40, 1st bullet point:
Although it depends where a country is starting and whether it is constrained by existing regulatory and legal frameworks, the regulatory and legal framework should follow the design of the system. Consideration of the existing framework, and whether amendment or new law is required, is an implementation step not a design point. It should be covered in Section 4.3.

Paragraph 40, 3rd bullet point:
It is unclear what ‘other’ refers to here. Does it mean the systems of countries to which the country might wish to export its food products? Or does it also mean nationally, in line with Principle 10?

Paragraph 47:
Combine the 1st and the 8th bullet point as follows: 'food safety hazards associated with different products and the risk to human health posed by the food or food related product'
Combine the 2nd and the 9th bullet point as follows: 'risk of unfair practices in the food trade associated with different products, such as potential fraud or deception of consumers'

Paragraph 47:
Change the footnote nr 9 to read: 'Effective use of these factors provides for system characteristics 1 and 2 as described in paragraph 33.'
Rationale: this list of factors provides additional guidance to the characteristics rather than the other way round.

Paragraph 50:
An additional bullet could be included on ‘provision of advice, guidance and training’. This could be via on-site visits but could be written material or industry guides, training days etc.

Paragraph 59:
Add sentence at the end: 'Robust traceability systems – providing for both forward and backward traceability – are essential in providing for timely identification of the sources for emergencies and allowing effective recall of affected products.'
Rationale: self-explanatory (expands on what has been said in paragraph 33 about traceability).

Paragraph 60:
Add the words 'from the market' at the end of the first sentence.
Add a new second sentence as follows: 'Food business operators have the primary responsibility to set up these procedures.'
Rationale: The primary responsibility of food business operators follows from Principle 4, paragraph 12.

Paragraph 61:
Replace in the first sentence ‘national government’ by 'competent authority'.
Rationale: for consistency.

Paragraph 62:
Add the following sentence at the end of the paragraph: 'Nevertheless, transparency should not undermine the effectiveness of the control programmes.'
Rationale: certain aspects of particularly compliance and enforcement programmes should probably not be published e.g. some targeting criteria which could compromise the element of surprise when deliberate non-compliance or fraud is to be detected.

Paragraph 63:
Modify the paragraph as follows: 'Communication among all stakeholders, including public health…'
Rationale: to make it more generic.

Paragraph 67:
Replace 'in keeping' with 'suitable'
Rationale: clarity and simplicity – 'in keeping with' is an idiom that may not be familiar to all non-native speakers.

Paragraph 68:
Move after paragraph 69.
Rationale: paragraph 69 is of a more general nature and leading into paragraph 68, which is describing the topic in further detail.

Paragraph 68:
Some editorial amendments are needed with changes to punctuation and presentation of the bullets. Also, if it is agreed that there are both ‘control programmes’ and ‘compliance and enforcement’, then the paragraph should amended as follows:

• Guidance and instructions relating to the national food control system, control programmes and compliance and enforcement, including legal requirements, should be developed for the competent authority staff and food business operators to ensure:
  • ensure all participants are fully aware of what is expected from of them (Principle 4);
  • ensure uniform application of legislation;
  • objectives are clearly communicated to them; and
  • that they have all the necessary resources are available to carry out tasks (human, material and financial resources) available to carry out their tasks.

Paragraph 69:
Modify the paragraph as follows: ‘The competent authority should implement a range of food control activities, including surveillance, inspections, verification and audit, verification and surveillance, to ensure that food business operators meet their responsibilities and are in compliance with requirements. Detailed procedures should be developed to articulate the key tasks and responsibilities of both competent authority and food business operators. for verification of compliance.
Rationale: clarity

Paragraph 70:
Remove colon from second sentence, after 'proportionate'.
Rationale: editorial

Paragraph 70:
Replace the third sentence with 'These may include:'
Rationale: to shorten and simplify the text.
Paragraph 71, the last bullet point:
Delete this bullet point. It is more appropriate for the monitoring and review section 4.4. If it remains, it could be reworded as follows: ‘formal review process of the national food control system, including audit programmes’

Paragraph 72:
Replace the words 'appointed officers (e.g. inspectors or verifiers), analysts and other individuals carrying out technical/professional duties' with ‘all staff carrying out / involved in official controls’.
Rationale: to shorten and simplify the text.

Paragraph 74:
Replace ‘industry’ with ‘food business operators’.
Rationale: for consistency.

Paragraph 78:
The context is unclear.

Paragraph 80:
Modify the first sentence of this paragraph as follows: 'The appropriateness and effectiveness of the national food control system should be regularly assessed against the objectives of the system, effectiveness of control programmes, as well as against legislative and other regulatory requirements.'
Rationale: The order of ‘appropriateness’ and ‘effectiveness’ should be reversed, as it has to at first be an appropriate system, and then effective. The second part of the first sentence should be deleted as it is unnecessary and is not logical. Effectiveness of the system is not assessed against the effectiveness of the control programmes. The control programmes effectiveness is necessary to make sure the system is effective. It is a necessary but not sufficient condition for overall effectiveness, but it is not something that the effectiveness of the whole system is measured against. The legislative and other regulatory requirements are part of the system that has to be assessed. These should be subject to review, as these are just tools to embed the system, they are not the end in itself.

Paragraph 80:
Regarding the second sentence of this paragraph, it should be fleshed out a bit with what the ‘criteria for assessment’ might be, what they might look like. Do we mean ‘what does effectiveness look like and how might it be measured’? Criteria for assessment might be the objectives of the policies, the outputs from the control programmes or the compliance measures within the underpinning control programmes.

Paragraph 81:
It should be spelled out what ‘control programme data’ is. This data can be drawn from the factors in paragraph 47. A cross-reference could be included. The word ‘conformance’ is used here. A general point is that the terms ‘non-conformance/ non-compliance/ non-conformity’ are used at different places in the document. It would be helpful to be consistent with the terminology used, unless there is a distinction, in which case this needs to be explained in a definition.

Paragraph 81:
Add the word 'control' before ‘programme design' in the last sentence.
Paragraph 84:
Add a bullet-point: **capability to trace back- and forwards across the food-chain**.
*Rationale: the timeliness of tracing back to the origin or from origin to products to be recalled often determines the effectiveness of Competent Authorities' response to emergency. Deficiencies in traceability should ideally be detected during a review – not in the middle of an emergency.*

Paragraph 87:
It may not be appropriate to single out the PVS tool as the veterinary element is very small in overall food control system

Paragraph 88:
Add a new sentence at the end of the paragraph reading as follows: **Following any review, all related documentation, procedures and guidance should be reviewed and updated if necessary to reflect any changes.**
*Rationale: self-explanatory*

Paragraph 89:
Break the 2nd bullet-point into two separate bullet-points at the 1st semi-colon
*Rationale: clarity*