



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX ALIMENTARIUS COMMISSION**  
**41<sup>st</sup> Session, FAO Headquarters, Rome, Italy, 2 - 6 July 2018**  
**PROPOSALS FOR NEW WORK<sup>1</sup>**

A list of proposals to elaborate new standards and related texts is presented below, including the reference of the project document in the relevant report. The Commission is invited to decide whether or not to undertake new work in each case, taking into account the critical review conducted by the Executive Committee, and to decide which subsidiary body or other body should undertake the work. The Commission is invited to consider these proposals in the light of its *Strategic Plan 2014-2019* and the *Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies*.

Codex Body	Text	Reference and project document
	The project document for new work on a standard for yam	REP18/FFV Para 60, Appendix V
CCFFV	The project document for new work on a standard for onions and shallots	REP18/FFV Para 60, See <b>Annex I</b> of this document
	The project document for new work on a standard for berry fruits	REP18/FFV Para 60, See <b>Annex II</b> of this document
CCFL	The project document for new work on the development of guidance on use of simplified nutrition information on the front of pack	REP18/FL Para 48, Appendix III
CCFH	The project document for new work on code of practice on food allergen management for food business operators	REP18/FH Para 48, See <b>Annex III</b> of this document
	The project document for new work on code of practice on guidance for the management of (micro)biological foodborne crises/outbreaks	REP18/FH Para 54, See <b>Annex IV</b> of this document

<sup>1</sup> Codex meetings held from March 2018, proposals for elaboration of new standards and related texts will be issued as Add. 1 to this document.

**REVISED PROJECT DOCUMENT****PROPOSAL FOR NEW WORK ON A CODEX STANDARD FOR ONION AND SHALLOTS**

(Prepared by Iran and Indonesia)

**1. Purpose and the scope of the standard**

The objective of the work is to develop a global standard that establishes the basic quality requirements for onions and shallots, to assure consumers of a safe, quality product. The standard would apply to the different commercial varieties and/or types of onion (*Allium cepa* L. cv. Common onion), shallot (*Allium cepa* L. cv. *Aggregatum*), and grey shallot grown from *Allium oschaninii* O. Fedtsch to be supplied to the consumer in the natural state after preparation and packaging. Green onion and shallots with full leaves and onion and shallots for industrial processing being excluded.

**2. Relevance and timeliness**

Due to the growing trend of worldwide onions and shallots production and trade, it is necessary to develop an international standard for the safety, quality and labeling of the product. The Standard for onion and shallots will help to protect consumers' health and to promote fair trade practices in accordance with the different international agreements. Onions and shallots are versatile vegetables adapted to wide range of climatic condition and can be grown throughout the year.

Onions and Shallots are one of the traded commodities in the world. The difference of interests between producers and consumers generate diversity of standards that causes difficulties in trade, especially in consumer protection. Therefore, the harmonization of standards becomes necessary and the standard will be used as reference standard among the world. Onions and Shallots became a universal commodities and consumed by million people as food ingredients or used by food industry. Therefore onions and shallots hygiene and quality standard are needed.

Harmonization will reduce the difference in standards between producer, re-exporter and consumer countries. Onions and Shallot's standard is very relevant to be developed into globally accepted standard through harmonization based on its characteristics. Harmonization of onions and shallots standard will be a reference in consumer protection and facilitate fair trade in accordance with international agreements as well as a reference internationally agreed through consensus between producer, consumer and trader countries.

**3. Main aspects to be covered**

The standard entails main aspects related to the definition of the produce, essential quality factors e.g. size and labeling requirements in order to provide certainty to the consumer on the nature and characteristics. The standard will supply high quality and safe products to protect consumer's health and against misleading practices by including all the necessary parameters such as weight, size, proper labeling, etc.

The most relevant items which may be considered are related to:

- Establish the minimum quality requirements and maturity of onion and shallots which shall be complied with, independently from the quality class.
- Define the categories to classify onions and shallots in accordance with their characteristics.
- Consider the sizing classes to commercialize onions and shallots.
- Establish the tolerance as regards quality and size that may be permitted of onions and shallots contained in a package.
- Include the provisions to be considered relating to the uniformity of the packaged product and the packaging used.
- Include provisions for the labeling and marking of the product in accordance with the general standard for the labeling of prepackaged Foods (CXS 1-1985).
- Include provisions for pesticides and contaminants with the reference to the general standard for contaminants and toxins in food (CXS 193-1995).
- Include provisions for hygiene with the reference to the general principles of food hygiene (CXC 1-1969) and other relevant codes of hygiene practices.

The most relevant points that can be considered are those related to the establishment of minimum quality requirements, maturity requirements, definition of quality classes and their tolerances and the section on marking or labeling.

#### 4. Assessment against the Criteria for the Establishment of Work Priorities General criterion

Developing an international standard for onions and shallots would be useful for all the nations' involved, producing, exporting, or consuming countries. The quality of the produce should comply with global commercial and marketing practices, in order to take into account the needs of consumers worldwide, as well as the food safety requirements.

##### Relevance to the Codex strategic objectives

- Protection of consumers by promoting fair trade practices relating to the identification, origin of produce, characteristics according to different regions,
- Standardization of quality parameters.

##### Criteria applicable to commodities

##### (a) Volume of production and consumption in individual countries and volume and pattern of trade between countries

There are many onions and shallots producing countries in the world. Around 190 countries produce onions and shallots for their domestic use, and many are also involved in international trade. It is estimated that over 9,200,000 acres of onions and shallots are harvested annually around the world. Onion and shallot is a highly traded vegetable involving more than 100 countries throughout the world. So it should come as no surprise that global sales from onions exports by country totaled an impressive US\$3.1 billion in 2016.

Overall, the value of onions exports were up by an average 20.8% for all exporting countries since 2012 when onions shipments were valued at \$2.6 billion. Year over year, the value of global onions exports retreated by -3.1% from 2015 to 2016. World export value on shallots had increased in average 10.49% per year. While world import value on shallot had increased as well in average 8.35% per year.

Among continents, Asian countries accounted for the highest dollar worth of exported onions during 2016 with shipments valued at \$961.1 million or almost a third (30.9%) of the global total. In second place were European Union exporters at 30.3% while 22.4% of worldwide onions shipments originated from North America. Smaller percentages came from Africa (8.4%), Latin America excluding Mexico (3.7%) and Oceania (mostly New Zealand and Australia) at 3.3%.

**Table 1: Onions world import value production (incl shallots)**

Source: COMTRADE, United Nations

Period	Trade value
2017	\$11,287,534
2016	\$2,726,787,853
2015	\$3,277,571,767
2014	\$3,030,325,026

**Table 2: Onions world export value (incl shallots)**

Source: COMTRADE, United Nations

Period	Trade value
2017	\$44,292
2016	\$3,203,853,586
2015	\$3,270,521,122
2014	\$3,012,905,735

**Table 3: Worldwide production in 1000 tons (incl. spring onions and shallots (2000-2013))**

Source: FAOSTAT

Bron: FAO	2000	2002	2004	2006	2008	2010	2012	2013
Total	49.948	52.653	62.524	68.317	74.501	78.925	82.498	85.795
China	14.105	16.545	18.047	19.598	20.823	21.748	22.245	22.345
India	4.721	4.210	7.761	10.847	13.565	15.118	16.813	19.299
Rest Asia	11.419	11.229	11.812	13.304	14.118	14.548	15.224	15.669
Africa	3.926	4.771	6.716	7.353	8.031	9.009	8.993	9.650
America	7.985	8.224	9.055	8.737	8.903	9.570	9.319	9.306
Europe	7.545	7.392	8.901	8.256	8.806	8.672	9.558	9.225
Rest Asia	247	283	233	222	254	260	347	302
USA	3.253	3.168	3.768	3.250	3.407	3.338	3.277	3.159
Iran	1.344	1.525	1.627	2.038	1.849	1.923	2.260	2.382
Russia	1.339	1.402	1.673	1.789	1.713	1.536	2.081	1.985
Turkey	2.200	2.050	2.040	1.765	2.007	1.900	1.736	1.905
Egypt	763	755	895	1.120	1.949	2.208	2.025	1.903
Pakistan	1.648	1.385	1.449	2.056	2.015	1.701	1.692	1.661
Brazil	1.142	1.222	1.158	1.346	1.367	1.753	1.519	1.539
Algeria	316	448	658	704	759	1.001	1.183	1.344
Nigeria	593	633	1.147	1.175	1.366	1.346	900	1.320
Netherlands	821	817	1.225	942	1.236	1.302	1.353	1.310
Korea	878	933	948	890	1.035	1.412	1.196	1.294
Mexico	905	1.131	1.241	1.238	1.252	1.266	1.239	1.270
Spain	960	1.022	1.030	1.100	1.063	1.105	1.170	1.187
Bangladesh	134	150	272	769	889	872	1.159	1.168
Myanmar	476	647	778	999	1.013	1.109	1.138	1.141
Japan	1.247	1.274	1.128	1.161	1.271	1.042	1.098	1.070
Uzbekistan	432	480	539	591	728	884	1.010	1.069
Sudan	168	499	1.207	1.405	938	1.116	1.036	1.037
Ukraine	563	514	722	869	1.049	909	1.141	1.020
Other	30.767	32.598	39.019	43.112	47.593	51.200	54.286	57.032

In order to determine which are the Onion production facts in high yielding countries relied on latest UN data.

**Table 4: Main onion importing countries (2012-2014)**

Source: COMTRADE, United Nations

Country	2012		2013		2014		%age growth in 2014	%age share in 2014
	Qty	Value	Qty	Value	Qty	Value		
U.S.A	3,85,353.48	269.73	4,36,979.16	340.45	5,00,380.56	344.70	1.25	11.71
United Kingdom	3,22,038.68	167.06	4,27,222.73	249.21	4,05,264.88	239.10	-4.06	8.12
Russian	2,30,191.78	107.27	2,43,912.33	124.81	3,61,737.28	180.94	44.97	6.15
Germany	2,15,561.14	137.17	2,45,123.67	186.70	2,53,857.23	179.13	-4.05	6.09
Japan	3,42,710.26	183.15	3,02,661.17	171.78	3,50,348.03	165.00	-3.95	5.61
Malaysia	4,42,494.68	137.65	4,59,873.71	213.29	4,19,302.75	145.94	-31.58	4.96
Canada	1,75,594.64	125.62	1,85,898.94	152.18	1,89,118.04	144.72	-4.90	4.92
Netherlands	1,98,186.10	92.15	2,03,637.51	131.95	2,34,271.09	122.01	-7.53	4.15
Saudi Arabia	3,05,788.00	113.57	2,79,323.65	101.11	3,15,129.45	116.20	14.92	3.95
France	1,15,267.70	69.22	1,39,401.97	98.90	1,33,535.03	93.24	-5.72	3.17
Belgium	1,29,861.77	68.23	1,35,279.12	92.42	1,29,065.09	84.87	-8.17	2.88
Indonesia	1,55,361.49	67.23	1,24,544.25	67.95	1,44,885.00	64.49	-5.09	2.19
Sri Lanka	1,52,928.97	32.41	1,49,490.43	81.73	1,62,373.46	47.05	-42.43	1.60
Mexico	34,542.67	15.49	56,719.66	33.26	77,451.74	44.17	32.80	1.50
Brazil	1,79,513.78	60.07	2,66,897.51	108.36	1,50,591.71	40.43	-62.69	1.37
Italy	67,925.40	28.67	86,319.10	48.07	71,537.93	36.73	-23.59	1.25
Kuwait	0.00	0.00	1,12,050.68	37.91	93,865.32	35.35	-6.75	1.20
Singapore	57,738.37	26.02	68,295.49	39.45	67,180.75	33.35	-15.46	1.13
Ireland	35,832.88	29.21	35,832.88	30.17	40,922.62	30.18	0.03	1.03

**Table 5: Main onion exporting countries (2012-2014)**

Source: COMTRADE, United Nations

Exporting Country	2014		2013		2012		%age growth in 2014	%age share in 2014
	QTY	Value	QTY	Value	QTY	Value		
Netherlands	9,31,726.64	356.15	10,39,011.75	491.17	10,59,648.80	477.66	-2.75	16.23
Mexico	3,18,406.25	257.75	3,45,143.72	324.75	3,61,692.99	301.89	-7.04	10.26
India	11,23,682.24	294.22	9,83,963.13	437.62	8,98,060.61	295.16	-32.55	10.03
China	4,52,491.13	224.78	5,84,462.21	280.91	5,88,536.57	244.42	-12.99	8.30
Egypt	2,91,923.12	164.29	3,15,293.01	190.24	3,62,649.69	212.38	11.64	7.22
Spain	2,80,595.16	120.65	3,50,824.41	191.10	3,87,156.55	186.15	-2.59	6.32
USA	2,47,501.85	143.30	2,68,299.17	173.94	2,78,419.10	173.66	-0.16	5.90
New Zealand	1,69,057.87	81.70	1,75,613.16	117.40	1,81,225.95	117.45	0.04	3.99
France	1,37,220.37	90.52	1,38,757.82	116.84	1,36,156.12	91.27	-21.88	3.10
Peru	1,90,512.86	65.28	2,36,892.32	78.55	2,71,116.76	90.35	15.02	3.07
Poland	1,27,529.66	42.96	1,43,862.04	61.60	1,35,988.89	66.11	7.32	2.25
Germany	1,16,747.43	44.82	1,15,888.94	59.12	1,16,966.70	60.84	2.91	2.07
Turkey	65,159.36	27.92	62,318.53	26.44	1,49,745.63	58.11	119.78	1.97
Pakistan	45,986.94	10.95	1,31,745.60	41.69	1,85,243.59	44.59	6.96	1.51
Italy	44,793.16	45.09	37,764.79	46.54	34,802.24	40.69	-12.57	1.38
Canada	38,734.31	21.85	50,742.57	31.12	58,261.53	36.24	16.45	1.23
Australia	68,656.62	43.36	59,385.13	43.60	46,577.89	35.56	-18.44	1.21
Argentina	1,51,713.53	54.14	2,26,874.99	91.53	1,38,708.81	35.40	-61.32	1.20
Chile	36,804.23	25.34	26,757.50	21.94	39,916.76	29.34	33.73	1.00

**Table 6: Top 20 import countries onion including shallots (2012-2014)**

Source: COMTRADE, United Nations

<b>Rank</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>
1	USA	USA	USA
2	United Kingdom	United Kingdom	Japan
3	Russia	Malaysia	United Kingdom
4	Germany	Germany	Malaysia
5	Japan	Japan	Germany
6	Malaysia	Canada	Canada
7	Canada	Netherlands	Saudi Arabia
8	Netherlands	Russia	Russia
9	Saudi Arabia	Brazil	Netherlands
10	France	United Arab emirates	France
11	United Arab emirates	Saudi Arabia	Indonesia
12	Belgium	France	United Arab emirates
13	Indonesia	Belgium	Brazil
14	Sri Lanka	Sri Lanka	Pakistan
15	Mexico	Indonesia	Sri Lanka
16	Brazil	Italy	Ireland
17	Italy	Pakistan	Italy
18	Kuwait	Singapore	Singapore
19	Singapore	Kuwait	Colombia
20	Ireland	Cote d'Ivoire	Indonesia

**Table 7: Onion production in countries during 2012 – 2014** Source: COMTRADE, United Nations

Region	Value (tone)		
	2012	2013	2014
China	22,244,986	22,351,234	22,610,915
India	16,813,000	19,299,000	19,401,680
United States of America	3,242,940	3,159,350	3,166,740
Russia	2,080,814	2,050,000	2,505,189
Egypt	2,024,881	1,984,937	2,109,197
Iran	1,938,000	1,904,846	1,994,253
Turkey	1,735,857	1,660,740	1,790,000
Pakistan	1,691,800	1,538,929	1,740,184
Brazil	1,519,022	1,359,492	1,646,498
Netherlands	1,353,000	1,310,000	1,589,957
Mexico	1,238,602	1,294,009	1,387,000
Republic of Korea	1,195,737	1,270,060	1,379,000
Algeria	1,183,268	1,214,501	1,368,184
Spain	1,169,721	1,204,900	1,364,633
Bangladesh	1,159,259	1,168,000	1,340,877
Myanmar	1,142,400	1,093,230	1,244,900
Ukraine	1,141,300	1,068,000	1,233,989
Japan	1,098,000	1,066,577	1,169,000
Sudan	1,036,000	1,037,000	1,108,610
Uzbekistan	1,009,520	1,019,900	1,068,348
Indonesia	964,221	1,010,773	1,065,000
Nigeria	899,700	929,866	985,400
Morocco	855,764	802,340	813,707
Peru	775,537	748,078	783,134
Argentina	721,141	736,271	758,233
Poland	642,169	727,380	733,619
South Africa	633,297	584,971	651,070

**Table 8: Top 20 exporting countries onion including shallots (2012-2016)**

Source: COMTRADE, United Nations

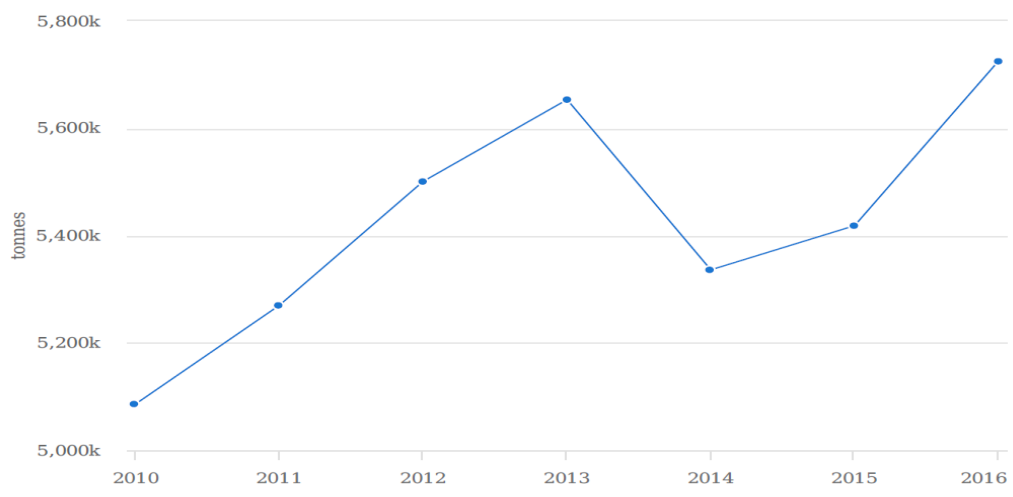
Rank	2016	2015	2014	2013	2012
1	Netherland	India	Netherland	Netherland	Netherland
2	Mexico	Netherland	Mexico	India	India
3	India	China	India	Mexico	Mexico
4	China	Egypt	China	China	China
5	Spain	Spain	Egypt	Spain	Egypt
6	USA	Mexico	Spain	Egypt	USA
7	Egypt	USA	USA	USA	Spain
8	New Zealand	Pakistan	New Zealand	New Zealand	France
9	Peru	Peru	France	France	New Zealand
10	France	New Zealand	Peru	Argentina	Peru
11	Germany	Afghanistan	Poland	Poland	Argentina
12	Poland	Germany	Germany	Germany	Italy
13	Canada	France	Turkey	Italy	Germany
14	Italy	Poland	Pakistan	Australia	Australia
15	Australia	Yemen	Italy	Pakistan	Poland
16	Belgium	Tajikestan	Canada	Canada	Turkey
17	Argentina	Iran	Australia	Turkey	Thailand
18	Pakistan	Argentina	Argentina	Yemen	Chile
19	Iran	Canada	Chile	Iran	Canada
20	Australia	Belgium	Iran	Poland	Yemen

**Table 9: Top 10 onion and shallots producing countries (2015-2016)**

Source: COMTRADE, United Nations

2015-2016		
Rank	Producing Country	Production (tone)
1	China	22,300,000
2	India	19,299,000
3	U.S.A	3,159,400
4	Iran	2,381,551
5	Russia	1,984,937
6	Turkey	1,904,846
7	Egypt	1,903,000
8	Pakistan	1,660,800
9	Brazil	1,536,300
10	Korea	1,411,650





**Graph 1: World production onions and shallots (2010-2016)**

Source: FAOSTAT

World export value on shallots had increased in average 10.49% per year. While world import value on shallot had increased as well in average 8.35% per year. As detail, the table below presents international trading of onions and shallots, including export, import and re-export.

**(b) Diversification of national legislation and apparent resultant or potential impediments to international trade:**

UNECE standard (FFV-25: onion-2010) developed a basic quality characteristic for onion and also a standard (FFV-56: Shallots-2013) that concerning the marketing and commercial quality control of shallots. The OECD has also produced an interpretative brochure for quality inspection / certification of onion. A Codex standard for onion can provide a comprehensive international standard covering quality and safety aspects of onion that will ensure the overall quality of the produce. The UNECE standards and OECD brochures can be taken as a starting point to develop into a more inclusive standard by including agreed provisions from all countries / regions in the world interested in this produce.

Due to lack of a worldwide standard for onions and shallots, international trade has been widely affected. Importers prefer to import fruits and vegetables based on a Codex standard. Therefore, the new work would provide internationally recognized specific standards in order to enhance international trade and to accommodate the exporter and importer requirements.

The elaboration of this global standard is being carried out in consonance with the legitimate objectives of the World Trade Organization and the statutes of the Codex Alimentarius Commission, which include protecting consumers' health and ensuring fair practices in the food trade.

**(c) International or regional market potential**

The import of onions and shallots by most countries is increasing. Commerce activity presents that the trend of export and import of onions and shallots had increased as well as the increase of world population and economic development. According the UN comtrade data, the total export value of shallots in 2015 was 3.338.282 US \$ (7.514.978 tones) while the total import value of it was 3.227.394 US \$ (7.305.371 tones). Onions and shallots come in different varieties and sizes. Generally, size is the only criteria taken into consideration. Therefore development of a quality standard that includes sizing requirements will help to enhance trade. See also point (a).

**(d) Amenability of commodity to standardization**

The characteristics of onions and shallots from their cultivation to retail sale e.g. cultivar varieties, composition, quality characteristics, packaging, presentation, labeling, storage, etc. all lead to adequate parameters for the standardization of the product. These parameters have been harmonized to certain extent at regional e.g. UNECE and group of countries e.g. OECD levels. Using UNECE and OECD brochures as the basis to develop a global harmonized standard by considering other countries / regions needs should therefore be amenable to consumer protection and facilitate worldwide harmonization.

Taking into account that technical information is available and certain degree of harmonization at regional levels has already been achieved on certain aspects, complementary work to come up with an inclusive standard on this worldwide traded produce should be amenable.

**(e) Coverage of the main consumer protection and trade issues by existing or proposed general standards**

The new work will improve the protection of the consumer and facilitate trade by establishing an internationally recognized marketing and quality control of standard for onion and shallots. The proposed standard will address those requirements described in point 3 e.g. minimum requirements, classes, size, color, uniformity, packaging, etc.

**(f) Number of commodities which would need separate standards including whether raw, semi-processed or processed**

A single standard for onions and shallots will cover all aspects of relevant to consumed raw varieties of red, white and yellow onion and also red and grey shallots that traded worldwide. The proposal gives recommendation for onion and shallots intended for long-term conservation and consumption in the fresh state.

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

The existing standards which may be considered while developing a codex standard for onion are:

- -UNECE Standard concerning the marketing and commercial quality control of onion, (FFV-25: onion-2010).
- UNECE Standard concerning the marketing and commercial quality control of shallot (FFV-56: Shallots-2013).
- OECD International brochures for fresh Fruits and Vegetables: onion, 2008.
- ASEAN Standard on Shallots (ASEAN stan. 14:2009).

This new work will consider these standards in formulating the Codex standard.

**5. Relevance to the Codex strategic objectives**

The elaboration of a Codex standard for onions and shallots will promote the maximum application of codex standards by countries in their national legislation and will consequently facilitate international trade. Likewise, the elaboration of this standard will help to protect consumer health against risks associated with these products. The new work contributes to state the essential quality requirements for onion and shallots for human consumption with the purpose of protecting the consumer's health and achieving fair practices in the food trade. This proposal is relevant to Strategic Goal 1 – Establish international food standards that address current and emerging food issues and its corresponding Objectives of the Strategic Plan 2014-2019 in particular objective 1.1: Establish new and review existing codex standard based on priorities of the Codex Alimentarius Committee.

**6. Information on the relation between the proposal and other existing Codex documents**

This proposal is for a new global standard and has no relation to any other existing Codex text on this item, except that this standard will make reference to relevant standards and related texts developed by general subject Committees.

The proposal concerning the preparation of a commodity standard for onions and shallots is part of the Terms of Reference of the Codex Committee on Fresh Fruits and Vegetables. See also points (e) and (f).

**7. Identification of any need for any requirements for and availability of expert scientific advice**

For the elaboration of this project document, the information generated by the research working group at national level for the characterization of onions and shallots have been taken as reference. Therefore, in case of requiring further information in the course of elaboration of the standard, this group of experts may be consulted including the expertise available in other importing / exporting countries participating in the CCFFV.

No expert scientific advice is foreseen at this stage. Published research documents by international bodies will be referred in the process of preparing the standard, if found necessary.

**8. Identification of any need for technical input to the standard from external bodies**

There is no need of technical input from external bodies.

**9. Proposed timeline for completion of the new work**

It is expected that the development of this standard to be conducted in three CCFFV meetings or less, depending on the agreement reached by CCFFV.

## PROJECT DOCUMENT

### PROPOSAL FOR NEW WORK ON A CODEX STANDARD FOR BERRY FRUITS

(Prepared by Mexico)

#### 1. Purpose and scope of the standard

This standardization project defines the specifications that the berry fruits must meet, as well as their basic requirements, to assure to the consumers of a safe and quality product.

The standard would apply to varieties of berries grown from:

- raspberry (*Rubus idaeus* L.)
- blackberries (*Rubus* sect. *Rubus*)
- loganberry (*Rubus loganobaccus* L. H. Bailey)
- white, red and black currants, (*Ribes rubrum* L., *Ribes nigrum* L.)
- European gooseberry or thorn grape (*Ribes uva-crispa* L.)
- bilberry or bilberry (*Vaccinium myrtillus* L.)
- blueberry or blueberry (*Vaccinium corymbosum* L., *Vaccinium formosum* Andrews)
- lowbush blueberry, (*Vaccinium virgatum* Aiton)
- red cranberry (*Vaccinium vitis-idaea* L.)
- American cranberry (*Vaccinium macrocarpon* Aiton)
- wild blueberries (*Vaccinium oxycoccos* L.)
- Cloudberry (*Rubus chamaemorus* L.)
- hybrids of these species such as boysena or bramble of boysen (*Rubus ursinus* Cham. And Schldl. X *Rubus idaeus* L.), blackberry tay (*Rubus* sect. *Rubus* x *Rubus idaeus* L.), hybrid gooseberry (*Ribes nigrum* L. x *Ribes grape* -spark L.).

The berry fruits will have to be supplied fresh to the consumer after preparation and packaging.

#### 2. Relevance and timeliness

Berry fruits are highly prized in worldwide for preparing various products such as juices, jams, sweets, fruit wine, etc. Therefore, it is necessary to establish a standard covering safety, quality and labeling, in order to have a reference that has been agreed internationally by consensus among the major producers and traders.

Berry fruits has become relevant in the food market, because they have increased their preferences for the average income consumers. Also, there are findings that relate the consumption of berry fruits with positive effects against different types of diseases.

Producers have adopted the use of new technologies to increase the efficiency of production processes due to the increase in global demand for these berry fruits.

In 2013, the main berry fruits producers in the world were, in descending order: United States (30 percent), Spain (21 percent) and Mexico (17 percent). Together, these countries contribute with 68 percent of the world production.

The world production of berry fruits reached a little more than 11 million tons in 2013, which represents an increase of 5.3 percent over 2012.

#### 3. Main aspects to be covered

This project for draft standard will include features related to the caliber, categories, quality, packaging and labeling.

These are the most important issues to consider:

- Establishing minimum requirements for berry fruits, regardless of the category of quality.
- Defining quality categories to classify berry fruits according to their characteristics.
- Provisions on presentation - the homogeneity of the packaged product from the same origin, quality, size, etc.
- Incorporating the provisions for marking or labeling in accordance with the General Standard for Prepackaged Foods Labeling.
- Establishing test methods for various berry fruits parameters.

#### 4. Assessment against the Criteria for the Establishment of Work Priorities

##### General criterion

Berry Fruits exist in different varieties, shapes and sizes. Therefore, marketing is made according to those characteristics.

The development of an international standard for berry fruits will protect consumers from fraudulent practices, while facilitating international trade. This standardization project will benefit consumers and producer/exporter countries.

##### Criteria applicable to the product

##### (a) Volume of production and consumption in various countries, and volume and trade between countries

According to the FAO, during the period 1995-2005, the value of world exports of fresh berries showed an increase of 158% from 111.27 million dollars in 1995 to 287.61 million in 2006, equivalent to an average rate of 14.4% annual growth.

The world production of berries in 2006, was close to 1238.2 thousand tons, compared with the production in 1995, which was 828.7 thousand tons, represented a growth of 49%, so it can be said that it has an annual growth rate of 4.5%.

Mexico was the world's leading exporter in value of exports of fresh berries, with a share, from 2004 to 2006, of 23% of the value of world exports, followed by the US with 22%, Spain 16%, Poland 10%, Chile 7%, Netherlands 4%, and 3% Belgium.

In 2010, the United States was the largest exporter of berries, with 42,952 tons. Mexico exported a volume of 41,259 tons, Argentina 14,912 tons, Spain 6839, and the Netherlands 3,800 tons in the same period.

**\*\*Figure 1 Leading exporters of berry fruits in the world**

(Thousands of US dollars)

Exporters	Exported value in 2011	Exported value in 2012	Exported value in 2013	Exported value in 2014	Exported value in 2015
United States of America	235039	272004	290402	307556	293570
Spain	159054	153507	204308	249726	276352
Mexico	131742	149888	162177	214497	259344
Netherlands	41950	53043	61460	75401	140343
Portugal	29181	36726	40653	89161	96314
Morocco	12582	9902	15933	28504	52801
Poland	21702	19240	31539	33991	42875
Belgium	21643	21931	32757	28909	27642
France	14751	18583	17074	18590	20877
World	740963	809802	943736	1154606	1309279

\*Source: Sistema Producto Zarzamora A.C.

\*\*Source: TradeMap

Product: 081020 Raspberries, blackberries, mulberries and loganberries, fresh

**\*\*Figure 2- Leading importers of berry fruits in the world**  
(Thousands of US dollars)

Importers	Imported value in 2011	Imported value in 2012	Imported value in 2013	Imported value in 2014	Imported value in 2015
United States of America	325037	404536	456747	619761	822025
Canada	208986	239882	259178	279110	264183
Germany	63627	78340	108583	138713	161607
United Kingdom	106254	111055	123584	135401	155585
Netherlands	38641	45377	46671	50740	100212
France	61442	69558	65354	71532	73795
Spain	6577	6149	11739	24040	46305
Belgium	20058	20884	32092	40058	39374
Switzerland	15473	19703	25691	29569	34766
World	981936	1164926	1344995	1639104	1918795

\*\*Source: TradeMap

Product: 081020 Raspberries, blackberries, mulberries and loganberries, fresh

**(b) Diversification of national legislation and resultant or potential impediments in international trade**

There is now a regional standard for berry fruits known as UNECE FFV-57, but there are no international standards for them, and those marketed worldwide are subject to different national laws.

To overcome the resulting or potential impediments to international trade, it is essential to incorporate the different standards into a single internationally accepted standard for importers and exporters.

**(c) International or regional market potential**

The production of berry fruits has increased, so trade can be improved by developing quality standards for these fruits. The main importing countries, which correspond to countries with high incomes, are motivated by a strong domestic demand. Canada is the second largest importer of blueberries, cranberries, and strawberries. In general, the Canadian and European markets have gained space in the exports and imports of berries.

**(d) Amenability of commodity to standardization**

It is important to standardize the characteristics of internationally marketed berries, which is feasible through the following general characteristics: size, maturity, quality and defects allowed, which are adequate parameters in the product.

**(e) Coverage of the main consumer protection and trade issues by existing or proposed general standards**

Currently there is no Codex product standard for berries, so the new work will facilitate the commercial trade of this product, establishing a quality standard agreed upon and accepted internationally.

**(f) Number of commodities that would need separate standards including whether raw, semi processed or processed**

The standard would be horizontal, and would apply to varieties of berries grown from:

- raspberry (*Rubus idaeus* L.)
- blackberries (*Rubus* sect. *Rubus*)
- loganberry (*Rubus loganobaccus* L. H. Bailey)
- white, red and black currants (*Ribes rubrum* L., *Ribes nigrum* L.)
- European gooseberry or thorn grape (*Ribes uva-crispa* L.)
- bilberry or bilberry (*Vaccinium myrtillus* L.)
- blueberry or blueberry (*Vaccinium corymbosum* L., *Vaccinium formosum* Andrews)

- lowbush blueberry (*Vaccinium virgatum* Aiton)
- red cranberry (*Vaccinium vitis-idaea* L.)
- American cranberry (*Vaccinium macrocarpon* Aiton)
- wild blueberries (*Vaccinium oxycoccos* L.)
- Cloudberry (*Rubus chamaemorus* L.)
- hybrids of these species such as boysena or bramble of boysen (*Rubus ursinus* Cham. And Schltld. X *Rubus idaeus* L.), blackberry tay (*Rubus sect. Rubus x Rubus idaeus* L.), hybrid gooseberry (*Ribes nigrum* L. x *Ribes grape -spark* L.).

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

Regional UNECE FFV-57 standard for berry fruits.

**5. Relevance to the Codex strategic objectives**

The development of the standardization project for berry fruits is in compliance with the Codex strategic objectives: 1.1 *Establishing new and revised Codex standards based on the priorities of the CAC*; and 3.1 *Increasing the effective participation of developing countries in the Codex*.

**6. Information on the relationship between the proposal and existing Codex documents and other ongoing Codex work**

The standardization project for berry fruits is a new work, and it has no relation to any existing Codex document on this subject.

**7. Identification of availability of expert scientific advice**

Expert scientific advice is not necessary.

**8. Identification of any need for technical help from external bodies**

No technical contributions from external bodies are required.

**9. Proposed program for the accomplishment of this work**

It is expected that the development of this standard to be conducted in three CCFFV meetings or less, depending on the contributions and the agreement of the members.

**10. General information concerning berry fruits**

**Origin and geographical distribution:**

Berry fruits are cultivated throughout different countries according to the climatic properties of each one.

**Uses:** Berry fruits have many different uses, can be consumed: (i) fresh or (ii) used as an input for a large number of products such as jams, purées, juices, wines, ingredients for pastry, cereals, flavorings, syrups, liqueurs, jellies, flavorings, medicinal uses, and (iii) also can be sell frozen.

**Nutrition:** Berry fruits are generally low in calories; fats and sodium but contain essential minerals, dietary fiber (including soluble fibers such as pectins) and vitamin C.

Most berry fruits contain sugars such as glucose, fructose and sucrose which contribute to their sweetness.

All berries contain carotenoids, including components that are precursors of vitamin A.

Berry fruits are best known for their accumulation of antioxidant components (mainly polyphenols, carotenoids and vitamin C) and have amongst the highest antioxidant capacity of commonly-eaten foods.

The amounts of these antioxidant components vary between berry species, between varieties and can be influenced by growing conditions.

**PROJECT DOCUMENT****PROPOSAL TO DEVELOP A CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS**

(Prepared by Australia and the United States of America)

**1. The purpose and the scope of the Code of Practice**

The purpose of the Code of Practice (CoP) will be to provide guidance to food business operators and competent authorities to manage allergens in food production, including controls to prevent cross-contact. Food allergen management also involves allergen labelling which is addressed by the *General Standard for Labelling of Prepackaged Foods* (CXS 1-1985).

The development of a CoP for allergen management will contribute to the health and safety of consumers in a globalised food supply chain. It will facilitate a proactive approach to managing allergens in food production, rather than a reactive response once a food safety hazard is identified

The scope of the CoP will cover allergen management throughout the supply chain including during manufacturing, as well as at retail and food service end points. It will address good hygiene practice (GHP) in manufacturing and food preparation practices in food service.

Most food allergies are caused by an adverse immune reaction (hypersensitivity) to certain food proteins. In addition there may be other reasons why a consumer needs to avoid certain foods, such as intolerance, which does not cause anaphylaxis but can significantly impact quality of life.

Allergy to food can be classified by their immune mechanism:

- immunoglobulin E (IgE)-mediated (immediate hypersensitivity),
- non-IgE mediated (cell-mediated or delayed hypersensitivity), and
- mixed IgE and non-IgE mediated.

The scope of this CoP will cover IgE-mediated and cell-mediated food allergies (e.g., celiac disease) that can be provoked by low doses of the offending food (thus requiring attention of GHPs in addition to labelling). It will not cover intolerances such as lactose intolerance and sulphite-sensitivity, which can be addressed by labelling strategies alone.

**2. Main aspects to be covered**

The main aspects of this code of practice for the management of allergens in processed food include:

*Scope* - The application of the CoP, the points in the food supply chain covered, and the allergenic foods identified as highest priority risk.

*Definitions* – what are food allergens requiring management and what is allergenic contamination (e.g., “cross-contact”).

*Role of competent authorities, food business operators and consumers* - Enforcement agencies, food businesses and consumers all have a role in the risk management of food allergens. Understanding the nature of this issue, the appropriate control measures and the information needs of consumers, informs requirements for compliance and enforcement to deliver safe food outcomes.

*Training and supervision* – best practice allergen management and awareness for employees.

*Raw materials* – allergen management practices to minimise risk.

*Storage and distribution* – identification and segregation of allergens.

*Manufacturing and food service* – control measures, including equipment, process design and cleaning.

*Formulation and labelling* – ensuring all allergens in the food are included on the label.

*Testing and analysis* – validation and verification of allergen control.

*Risk management tools* – Consumer complaints, corrective actions, recalls.

**3. Assessment against the Criteria for the establishment of work priorities**

*General criterion - Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.*

The protection of consumer health and the safety of food is a Codex priority. Food safety, as defined in the *General Principles of Food Hygiene* is an ‘assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use’ (CXC 1-1969).

While food allergies may affect a relatively small proportion of the population, an allergic reaction can be life threatening or fatal. Allergens are an ongoing food safety concern for both allergic consumers and food business operators.

The proposed CoP will meet this criterion by:

- Raising the importance of food allergen management for consumers, noting that food allergies are an increasing food safety issue globally.
- Establishing internationally agreed principles and controls for the management of allergenic contamination in foods
- Providing greater assurance that allergen management is understood and can be implemented consistently by all food business operators.

**(a) Diversification of national legislations and apparent resultant or potential impediments to international trade**

With the increasing health burden posed by food allergens, comes the expectation that food business operators and competent authorities take steps to manage allergenic contamination. In a global market it is crucial that there is international understanding of this issue and of the measures required to address it. An internationally developed guidance document for best practice allergen management will facilitate this outcome.

**(b) Scope of work and establishment of priorities between the various sections of the work**

The scope of the work will be allergen management throughout the supply chain including during manufacturing, as well as at retail and food service end points. It will address good hygiene practice (GHP) in manufacturing and food preparation practices in food service.

The revision of the *General Principles of Food Hygiene* includes allergenic contamination as a key hygiene control measure, noting that the allergenic nature of some foods should be part of hazard identification and should be managed with appropriate controls to prevent their presence in food where they are not labelled. The increased recognition of allergens as a potential food safety hazard means that there is an expectation for food business operators and competent authorities to consider allergen management in a hygiene control system.

The development of a CoP will provide additional support to both food business operators and competent authorities and facilitate the implementation of the revised *General Principles of Food Hygiene*.

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

This proposal was developed following the proposed inclusion of allergen contamination as a key hygiene control measure in the revised *General Principles of Food Hygiene* (CXC 1-1969).

The Codex *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) specifies that specific foods and ingredients which are known to cause hypersensitivity always be declared.

**(d) Amenability of the subject of the proposal to standardization**

While current practices in allergen management have increased the allergenic safety of food products, risk management approaches remain divergent. A risk management approach based on a common agreed set of principles in a CoP would lead to consistent and well-understood management across the food industry.

**(e) Consideration of the global magnitude of the problem or issue**

Food allergies have been an increasing food safety issue globally and have emerged as a major public and personal health burden.

In the USA it is estimated that 2 percent of adults and about 5 percent of infants and young children suffer from food allergies. Approximately 20,000 consumers require emergency room treatment and a number of Americans die each year because of allergic reactions to food (USFDA, 2016a).

In Europe, the cases of food allergies have doubled and the number of hospitalisations caused by severe allergic reactions has increased 7-fold over the last decade (EAACI, 2015).

In Australia, food allergy is estimated to occur in 10 percent of Australian infants, 4 to 8 percent of children under five years of age, and around 2 percent of the adult population. Hospital admission rates for anaphylaxis have been increasing. While the highest rates are in children under five, there has also been a doubling in admission rates for older children (aged 5-14 years). Between 2005 and 2012 there was a 50 percent increase in food allergy related anaphylaxis admissions, compared to the previous seven years (Mullins *et al.*, 2015).



Australia analyzed its recall data for the last ten years and found that the most common reason for recalls in Australia is undeclared allergens, accounting for approximately one third of all recalls. During this period, undeclared milk was the most common reason for an allergen-related recall followed by peanut. Undeclared allergen was the most common reason for recalls involving imported food (53%).

A root cause analysis for recalls in 2016 to early 2017 identified the following key reasons for how food safety issues with allergens occurred:

- Lack of skills and knowledge of labelling requirements
- Supplier verification issues
- Packaging errors
- Accidental cross contact

Similarly, in the United States, unlabeled allergens continue to be a leading cause of recalls and the leading cause of reportable foods for FDA-regulated foods (reportable foods are foods that pose a risk of serious adverse health consequences or death to consumers.) Reports of foods with undeclared allergens to FDA's Reportable Food Registry increased from about 30 percent of reports in the first year of the registry (September 8, 2009 to September 7, 2010) to 47 percent of reports in year 5 (September 8, 2013 to September 7, 2014) (USFDA, 2016b). Milk was the most common specific undeclared major food allergen. Root causes were similar to those identified by Australia (Gendel *et al.*, 2014).

Processed foods including multiple ingredients are primarily involved with undeclared allergen recalls.

#### **4. An assessment against the Criteria for the evaluation and prioritizing of new Work by the Codex Committee on Food Hygiene**

The US recently promulgated new regulations for preventive controls under the FDA Food Safety Modernization Act. The regulation specifically addresses the need for food allergen controls (appropriate labelling and prevention of allergen cross-contact) in facilities handling food allergens. The requirements apply to all domestic facilities and to foreign facilities that manufacture, process, pack or hold food for consumption in the US. The US is developing guidance on how to comply with the requirements; however, the need for allergen controls is global. In fact, because of the need to protect consumers, allergen labelling is required by many countries.

Of particular concern is the need for guidance on the controls to ensure that the label lists allergens and the product bears the correct label. While the labelling requirements for allergens is addressed by the *General Standard for Labelling of Prepackaged Foods* (CXS 1-1985), the management of the labels to ensure that the food bears the necessary information for allergic consumers is addressed primarily through GHPs. Thus, the scope of work will focus on these types of controls, along with the controls to prevent the inadvertent addition of an allergen in a product that does not list the allergen on the label (cross-contact) resulting when the same equipment, utensils, etc. are used for foods with different allergen profiles without proper GHPs. These types of controls are broadly applicable by countries.

#### **5. Relevance to the Codex strategic objectives**

This proposal is consistent with the Strategic Plan of the Codex Alimentarius Commission 2014-2019.

##### Strategic goal 1 - Establish international food standards that address current and emerging food issues

The development of a code of practice for allergen management in processed foods has been identified by Members – therefore meeting Objective 1.2 Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards. The presence of undeclared allergens is a major food safety issue, particularly in developed countries where there have been increasing cases where food is a causative agent for anaphylaxis, and death from anaphylaxis.

##### Strategic goal 2: Ensure application of risk analysis principles in the development of Codex Standards

The development of a Codex code of practice for allergen management is consistent with Objective 2.3 to increase scientific input from developing countries, in particular 2.3.3, Encourage sustained and continuous participation of technical and scientific experts from developing countries in the work of Codex. Existing allergen control guidance has been prepared without input from developing countries. This offers the opportunity to get input from these countries.

### Strategic goal 3: facilitate the effective participation of all Codex Members

With the increasing health burden posed by food allergens comes the expectation that food business operators and competent authorities take steps to manage allergenic contamination, therefore this affects all members. In a global market it is crucial that there is international understanding of this issue and of the measures required to address it. In particular competent authorities of developing countries may benefit from this guidance since they may not have the resources to develop such guidance themselves. We therefore anticipate electronic working groups and physical, adjacent to CCFH meeting, when possible, and providing translation in the official languages of the Commission to the extent possible.

### Strategic goal 4: Implement effective and efficient work management systems and practices

During the development of the guidance, all working documents and electronic discussions will be distributed in a timely and transparent manner through the e-forum at <http://forum.codex-alimentarius.net/>. As the revision progresses, the latest versions of the texts will be translated to the official languages of the Commission ahead of the annual Committee meetings.

## **6. Information on the relation between the proposal and other existing Codex documents**

This proposal was developed following the proposed inclusion of allergen contamination as a key hygiene control measure in the revised *General Principles of Food Hygiene* (CXC 1-1969).

The Codex *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) specifies that the following foods and ingredients, which are known to cause hypersensitivity, always be declared:

- Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
- Crustacea and products of these;
- Eggs and egg products;
- Fish and fish products;
- Peanuts, soybeans and products of these;
- Milk and milk products (lactose included);
- Tree nuts and nut products; and
- Sulphite in concentrations of 10 mg/kg or more.

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

Expert scientific advice from FAO/WHO or other relevant expert bodies is not needed as input to start this work. The hazard is already known and the focus will be describing control measures to minimise allergen contamination.

## **8. Identification of any need for technical input to the standard from external bodies**

Technical input from FAO/WHO is not anticipated but may be needed from food allergy experts in Member countries. Member countries will be responsible for obtaining relevant input from within their countries, recognising that there are a number of established bodies providing technical expertise including experts from organisations such as the Food Allergy Research & Resource Program (FARRP) in the US, the European Academy of Allergy and Clinical Immunology (EAACI) and consumer groups such as Allergy & Anaphylaxis Australia.

## **9. Time-line for completion of the new work (the time frame for developing a standard should not normally exceed five years.)**

- CCFH49 (2017): Endorsement of the new work proposal by CCFH
- CAC41 (2018): Approval of new work by CAC
- CCFH50 (2018): Start date - discussion paper and draft CoP at step 3
- CCFH51 (2019): Adoption at Step 5
- CCFH52 (2020): Finalize CoP
- CAC42 (2021): Adoption at Step 8

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## PROJECT DOCUMENT

### Development of a Guidance Document for the Management of (Micro)biological Foodborne Crisis/Outbreaks

(Prepared by the EU)

#### 1. Purpose and Scope of the Guidance Document

The purpose of the new work is to provide guidance to competent authorities on the management of foodborne outbreaks/crises, including the communication between national programs with "INFOSAN. The guidance intends to address preparedness, detection, response and recovery with the intent of limiting the extent of such events. The scope is limited to biological hazards. This guidance intends to provide a supplement and a link to documents developed by FAO/WHO and Codex texts, as appropriate. The document will define the role of competent authorities and collaboration with food business operators and other stakeholders during foodborne outbreaks/crises.

#### 2. Relevance and Timeliness

Most Codex Standards provide guidelines on general or sector-specific good hygiene practices, good manufacturing practices, etc. intended to prevent contamination and exposure of humans to hazards through the consumption of food. Unfortunately, exposure cannot always be prevented and sporadic cases or multiple cases linked to the same food source (outbreak, possibly crisis if very severe or extended) can occur. The proposed risk management guidance document therefore supplements the existing standards in cases where prevention was not fully effective.

#### 3. Main aspects to be covered

The guidance will address recommendations on preparedness for outbreaks and on their management.

Preparedness will focus on recommendations to have a structured approach in place and maintained before an outbreak occurs. It will address the following aspects, but may not be limited to these:

- alert networks for public health and food safety,
- the use of molecular typing data of pathogens facilitating the detection of links between human cases and food,
- structures and tools to ensure exchange of information between public health and food safety authorities,
- the establishment of permanent management and crisis communication networks,
- traceability provisions,
- simulation exercises and trainings.
- As regards outbreak/crisis management, recommendations will focus on the following aspects, but may not be limited to these:
  - investigations in humans in order to identify the likely food source,
  - (rapid) risk assessments,
  - tracing back and forwards of the affected food,
  - robustness of information (such as molecular typing analyses, environmental and epidemiological investigations),
  - communication to consumers and trade partners.

#### 4. Assessment against the Criteria for the establishment of work priorities

##### (a) Ensuring fair practices in food trade and taking into account the identified needs of developing countries

Food-borne outbreaks/crises have a direct effect on public health (morbidity and sometime mortality). They are often accompanied by disproportionate reactions by consumers and trade partners, not only the affected batches. Guidelines on a structured approach for outbreak/crisis management and communication may limit these effects and result in a better preparation for such events in developing and developed countries.

##### (b) Diversification of national legislation and apparent resultant or potential impediments to international trade

Legislation on food safety focuses on prevention, monitoring and corrective actions (if required). In case of a foodborne outbreak or crisis, the lack of a coordinated approach, e.g. between public health and food safety authorities, and of a communication strategy might create confusion and uncertainties, causing impediments to domestic consumption and international trade. The introduction of a approach, agreed at global level, could reduce the impact on trade.

**(c) Scope of work and establishment of priorities between the various sections of the work**

See 4.7.

**(d) Work already undertaken by other international organisations in the field and/or suggested by the relevant international intergovernmental bodies**

A number of works undertaken by FAO and/or WHO, and Codex texts are relevant for this initiative. The new standard will refer to them in the appropriate sections, supplement them and indicate how they should be addressed within the specific context of (micro)biological crisis/outbreak preparedness and management. The standard should provide an integrated approach linking the existing work and enhancing the awareness of the existing documents. Details are given in the Table below.

**Table**

<b>Works undertaken by FAO and/or WHO, and Codex texts</b>	<b>Link with proposed new Codex Standards</b>
FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies <sup>2</sup>	The FAO/WHO guide is generic. The new standard should provide a more integrated approach including links with data from investigations in humans towards the source and elaborating the tracing back and forward of affected consignments. Information on some new tools (e.g. molecular testing) should also be given, which contribute to the investigations and are specific for microbiological hazards.
The WHO "Foodborne disease outbreaks: Guidelines for investigation and controls" <sup>3</sup>	The WHO document focuses mainly on investigations in humans cases and provides a summary of preliminary risk assessment data (for all hazards and useful for reference purposes). Within the remit of a Codex Standard, there will be more focus on (micro)biological outbreaks, food investigations, how to handle historical and emerging analytical data from humans and food with information from epidemiological investigations, finding gaps in the investigation, tracing forwards, etc.
FAO training handbook on "Enhancing Early Warning Capacities and Capacities for Food Safety" <sup>4</sup>	The development of early detection and warning systems are an essential part in outbreak preparedness. Apart from referring to the FAO handbook, the proposed guidelines will also propose examples of tools to detect specifically biological outbreaks (e.g. by linking results of molecular testing) and include alert networks in humans (as the starting point is often human cases) and the integration of human and food safety alert networks.
FAO/WHO framework for developing national food safety emergency response plans <sup>5</sup>	The existing document provides a very generic basis for preparedness. The purpose is to supplement it by providing guidelines on the practical and more specific implementation of microbiological outbreak preparedness.

<sup>2</sup> [http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474_eng.pdf?ua=1)

<sup>3</sup> [http://www.who.int/foodsafety/publications/foodborne\\_disease/outbreak\\_guidelines.pdf](http://www.who.int/foodsafety/publications/foodborne_disease/outbreak_guidelines.pdf)

<sup>4</sup> <http://www.fao.org/3/a-i5168e.pdf>

<sup>5</sup> <http://www.fao.org/docrep/013/i1686e/i1686e00.pdf>

Principles and guidelines for the conduct of microbiological risk assessment (CXG-30-1999) <sup>6</sup>	The proposed guidance will only refer to existing risk assessments and to the need to have a structure in place to carry out rapid risk assessment if a newly emerging risk. It will be recommended to do this according to the principles and guidelines of CXG-30-1999.
Principles and Guidelines for an exchange of information in food safety emergency situations (CXG 19-1995) <sup>7</sup>	Exchange of information is just one part of the crisis/management preparedness and management. This part can be kept short referring to the recommendations in CXG 19-1995.
The FAO/WHO "Risk Communication applied to food safety handbook" <sup>8</sup>	The handbook deals with food safety risk communication in general and will be referred to in the section on risk communication which is essential in the proposed draft guidelines. The proposed draft guidelines will provide the key issues on risk communication related to a specific outbreak situation (including communication if uncertainty on the source) and biological hazards.
The WHO "Outbreak Communication. Best practices for communicating with the public during an outbreak" <sup>9</sup>	The WHO document is general and does not address communication on the food as possible source, while there is a need to provide specific guidance related to such communication during specific foodborne (micro-)biological outbreak.
The FAO "Food Traceability Guidance" <sup>10</sup>	The FAO guidance addresses how to implement a traceability system and how to use it for recalls, which are an essential part of outbreak/crisis preparedness and management. Tools to analyse traceability information from different sources in order to detect hotspots and give orientation to further investigations and to the source are not addressed and will be included in the proposed guidance document.
INFOSAN <sup>11</sup> , including the draft Template for INFOSAN/IHR communication: National protocol for information sharing with national and international partners during food safety events and outbreaks of foodborne illness <sup>12</sup>	Reference to INFOSAN is essential in outbreak/crisis management as the way to exchange information with trade partners, being a part of outbreak/crisis preparedness and management. The INFOSAN draft template addresses when (decision tree) and how (template for notification) to use INFOSAN. The proposed guidance will integrate INFOSAN into a comprehensive approach, but also will provide a guidance on how the countries should coordinate and share information at National level, taking into account central and regional governance.
FAO/WHO guide for development and improving national food recall systems <sup>13</sup>	Recalls might be part of outbreak management. The proposed guidelines will not address in detail how to organise such recalls but refer to the existing FAO/WHO guide. They will include how to identify the consignments to be recalled as a result of the foodborne outbreak investigations.

<sup>6</sup> [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B30-1999%252FCXG\\_030e\\_2014.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B30-1999%252FCXG_030e_2014.pdf)

<sup>7</sup> [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/fr/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B19-1995%252FCXG\\_019e.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/fr/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B19-1995%252FCXG_019e.pdf)

<sup>8</sup> <http://www.fao.org/3/a-i5863e.pdf>

<sup>9</sup> [http://www.who.int/csr/resources/publications/WHO\\_CDS\\_2005\\_32web.pdf](http://www.who.int/csr/resources/publications/WHO_CDS_2005_32web.pdf)

<sup>10</sup> <http://www.fao.org/3/a-i7665e.pdf>

<sup>11</sup> [http://www.who.int/foodsafety/areas\\_work/infosan/en/](http://www.who.int/foodsafety/areas_work/infosan/en/)

<sup>12</sup> Not published yet.

<sup>13</sup> <http://www.who.int/foodsafety/publications/recall/en/>

**(e) Amenability of the subject of the proposal to standardization**

Although food-borne outbreaks/crises are caused by a large range of hazards and circumstances might be different, a guidance document is needed providing a structured approach for the management of foodborne outbreaks/ crises in order to be well prepared, to limit the public health and trade impact and to act efficiently in a situation which requires immediate action.

**(f) Consideration of the global magnitude of the problem or issue**

Food-borne outbreaks/crises occur everywhere in the world. As examples, in 2015 over 4 300 (micro-)biological foodborne outbreaks were reported in the EU, involving more than 36 000 human cases, over 3 800 of which were hospitalised and 17 died, despite the presence of relatively high preventive food safety standards.

**5. Criteria for the evaluation and prioritizing new Work by the Codex Committee on Food Hygiene****(a) Currency of information: Yes**

Collecting and sharing experiences in order to enhance preparedness all over the world may reduce the public health and trade impact of future outbreaks/crises.

In addition, more and more data become available from new molecular analytical methods (e.g. whole genome sequencing), facilitating the identification of clusters human cases and the food source. This information allows earlier detection of outbreaks, an improved management of such incidents and enables to, better narrow the identification of involved batches, and hence reduce the impact of actions taken.

There is a need to deal with these new and complex data in an appropriate risk management and risk communication framework.

**(b) Positive impact on public health – foodborne risk to public health: Yes, high rating (20)**

There are numerous descriptions of the public health impact of foodborne outbreaks. See also 4.6. In 2011, a single outbreak of STEC O104:H4 from sprouted seeds caused disease in at least 4 000 humans of which 55 died. Listeria in deli meat caused disease in 57 people, of which 24 died, in Canada in 2008. Better preparedness and management have a high potential to gain a positive impact on public health.

**(c) Impact on trade due to public health risk: Rating of 10**

The guidance is relevant for all food. Food outbreaks may result in reluctance of consumers to buy the specific culprit food or even other foods not directly associated with the outbreak. Consumers' confidence may further reduce by premature and inappropriate communication on the source of the outbreak. Restoring consumers' confidence is usually difficult and lengthy, putting food business operators in dire situations. During the 2011 STEC outbreak, farmers' losses in the fruit and vegetable sector were estimated at 812 Mio € in the first 2 weeks only. Export bans constituted an annual value of 600 Mio €. The lawsuit in Ontario was claiming damages of \$350 million for the 2008 Listeria outbreak.

**6. Relevance to the Codex strategic objectives****Strategic goal 1: Establish international food standards that address current and emerging food issues**

(Micro-)biological outbreaks occur every day. Due to new analytical methods it is expected that the number of identified outbreaks will increase. This does not indicate an increased public health risk *per se*, as they were just not identified in the past, but it does enhance the need to manage outbreaks properly since they may have a significant economic impact (impact on consumption and on trade).

**Strategic goal 2: Ensure application of risk analysis principles in the development of Codex Standards**

The guidance document will not address a specific hazard or food commodities. It is intended to be relevant to all micro-biological hazards in all kinds of food causing an outbreak. The guidance document will include the three components of risk analysis in a distinct way: it will provide recommendations on preliminary risk management activities, including an initial, quick risk assessment within an outbreak situation, on what risk management measures should be in place to be well prepared and to limit the extent of an outbreak and on how communication should try to re-assure consumers and trade partners on the safety of food produced.

**Strategic goal 3: facilitate the effective participation of all Codex Members**

As outbreaks can occur anywhere in the world, the proposed guidance is of relevance for all members. In particular competent authorities of developing countries may benefit from this guidance since they may not have the resources to develop such guidance themselves. We therefore anticipate electronic working groups and physical, adjacent to CCFH meeting, when possible, and providing translation in the official languages of the Commission to the extent possible.

#### Strategic goal 4: Implement effective and efficient work management systems and practices

During the development of the guidance, all working documents and electronic discussions will be distributed in a timely and transparent matter through the e-forum at <http://forum.codex-alimentarius.net/>. As the revision progresses, the latest versions of the texts will be translated to the official languages of the Commission ahead of the annual Committee meetings.

#### **7. Information on the relation between the proposal and other existing Codex documents**

The guidance will supplement the existing Codex standards that focus on the prevention of foodborne hazards and outbreaks. The proposed guidance provides recommendations in cases where prevention failed.

#### **8. Identification of any requirement for and availability of expert scientific advice**

Expert scientific advice is not needed as input to start this work since many different hazards and food commodities might be involved, for which risk assessments often already exist. The WHO "*Foodborne disease outbreaks: Guidelines for investigation and controls*" provide an overview of the epidemiology and methods of control and prevention of most important foodborne diseases.

#### **9. Identification of any need for technical input in the standard from external bodies so that this can be planned for**

No additional need is identified at this stage.

#### **10. The propose 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**

An initial draft can be drafted by an electronic working group (EWG), after the meeting of CCFH49 and subject to its agreement on the new work and its terms of reference; the outcome of the EWG would be presented at CCFH50. The intention is to propose it at step 5 at CCFH52 in 2020 and to aim for the final adoption by the CAC in July 2021.