E

CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5 **CX/PFV 14/27/7**
June 2014

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES

27th Session
Philadelphia, Pennsylvania, United States of America,
8 – 12 September 2014

PROPOSED DRAFT STANDARD FOR GINSENG PRODUCTS
(conversion of the *Regional Standard for Ginseng Products* to a worldwide standard)

(Prepared by the Electronic Working Group
chaired by Republic of Korea and co-chaired by Canada)

(Step 3)

Codex Members and Observers wishing to submit comments on this proposal should do so in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (Codex Alimentarius Procedural Manual) as presented in Annex I before **31 July 2014**. Comments should be addressed:	
to: US Codex Office, Food Safety and Inspection Service, US Department of Agriculture, Room 4861 South Building, 1400 Independence Ave., S.W., Washington, D.C. 20250-3700 USA E-mail: uscodex@fsis.usda.gov; ccpfv2014@fsis.usda.gov	with copy to: Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy E-mail: codex@fao.org
Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in Annex IV to this document.	

BACKGROUND

1. The 26th Session of the Committee on Processed Fruit and Vegetables (CCPFV) (October 2012) agreed to establish an electronic Working Group (EWG), led by the Republic of Korea and co-chaired by Canada, open to all Members and Observers, and working in English, to develop a proposed draft Standard for Ginseng Products for circulation for comments and consideration at its next session.[1]

2. In March 2013, the Codex Secretariat sent out a kick-off message to all Codex member countries and observers inviting them to participate in the EWG. A total of 26 participants from 9 member countries, including Korea and Canada serving as co-chairs of the EWG, the European Union and an observer expressed their interests in the EWG. The list of participants is presented in Annex II.

FIRST ROUND OF COMMENTS (EWG)

3. The 36th Session of the Codex Alimentarius Commission (July 2013) approved new work for the conversion of the *Regional Standard for Ginseng Products* (CODEX STAN 295R-2009) to a worldwide standard.[2] Accordingly, the EWG commenced full-scale work for the development of new worldwide standard.

4. The worldwide standard for Ginseng Products shall be elaborated on the basis of the current Regional Standard for Ginseng Products and according to Procedural Manual of the Codex Alimentarius Commission (refer to (b)(i) of Part 5, *Subsequent Procedure Concerning Publication and Possible Extension of Territorial Application of the Standard*, Section II, Procedural Manual). Hence, all participating countries were asked to submit their comments and/or opinions on each section of the standard so that the current Regional Standard for Ginseng Products may be applied worldwide.

[1] REP13/PFV, para 138, Appendix VIII.
[2] REP13/CAC, para 118, Appendix VI.

5. Comments were submitted by Canada, China, the European Union, the Republic of Korea, Switzerland, and the United States of America. The first draft was prepared after expert groups deliberated the submitted comments based on scientific grounds. Annex II describes the comments submitted by the participating countries of the e-WG and the Chair's suggestion concerning them in preparation of the 1st Working Draft Standard for Ginseng Products.

SECOND ROUND OF COMMENTS (EWG)

6. The first draft prepared in the first round of the EWG's work was circulated among all EWG's members. The United States of America, Canada, the European Union, and IADSA presented their opinion on the draft. The United States and Canada responded that they have no further comments on the first draft at this point. The EU and IADSA, on the other hand, submitted comments concerning the methods of sampling and analysis, the title of the Standard, pesticide residues and quality factors (ginsenoside Rg1) for ginseng products. The Chair's suggestions in respect of the proposals by the EU and IADSA are described in Annex II.

7. In addition, the Codex Secretariat submitted suggestions regarding provisions and format that generally apply to Codex standards for processed fruits and vegetables especially for those that have recently been revised by CCPFV in the course of simplifying and updating the standards.

SUBMISSION OF THE PROPOSED DRAFT STANDARD

8. The EWG presents the proposed draft Standard for Ginseng Products (Annex I) for consideration at the next session of CCPFV.

9. The proposed draft Standard was prepared in the manner of revising the current regional standard and reflecting the opinions gathered from the first and second rounds of the EWG and the proposals made by the Codex Secretariat. In addition to making editorial corrections, parts of the phrases and provisions of the current Regional Standard were revised and/or inserted.

10. Key issues and pending points highlighted in the process of preparing the proposed draft Standard are as follows.

SOME MATTERS FOR CONSIDERATION

Scope

11.The footnote to "ginseng products" in the third sentence of Section 1.1 was moved to the "labelling section" as its content is more appropriate and valuable to the product labelling.

Food Additives

12. Since ginseng products covered by this standard are those prepared from ginseng roots alone and do not use any food additives, the standard does not include a section on "food additives". The Codex Secretariat noted that the absence of a section on food additives does not mean necessarily that food additives are not permitted for use in the products covered by the standard and suggested to clarify their use in the standard. Therefore, in order to be clear about the use of food additives, a new section on food additives (Section 4) was introduced including the following sentence: "No additives are permitted in the products covered by this standard."

Method of Analysis

13. This standard includes methods of analysis for six items. The Codex Secretariat noted that methods of analysis should be in conformity with the *General Criteria for the Selection of Methods of Analysis* and preferably refer to validated methods developed by recognized international organizations. Hence, the EWG recommends that the proposed draft Standard refers to the AOAC methods for moisture, solids and ash, while stating in the Annexes the methods for water-insoluble solids, water-saturated n-butanol extracts, and ginsenosides that are yet to be developed by international organizations. In this connection, the Republic of Korea plans to conduct an inter-laboratory validation test on the methods of analysis presented in this draft standard with the involvement of at least 8 institutions according to the requirements of the Committee on Methods of Analysis and Sampling and will submit the test results to CCMAS.

Quality Factors

14. Section 3.2.2.1 "Dried Ginseng" (d). Ginsenoside Rg1 should be identified as well. As the two most representative components of ginseng products, ginsenoside Rb1 and Rg1 had been both suggested as quality factors in the course of developing the Regional Standard. Considering the matter of identifying ginsenoside Rg1 as well in terms of analysis, there is no problem in doing so because both components can be identified in one chromatogram (one trial of analysis). However, since some member countries have expressed concerns about analysis expense and suggested that identifying Rb1 is sufficient for ginseng products, the FAO/WHO Coordinating Committee for Asia concluded ginsenoside Rb1 as a quality factor to alleviate the burden of expense. Nevertheless, if member countries agree to adding identifying ginsenoside Rg1 as a quality factor, this may be applied to the Standard.

REQUEST FOR COMMENTS

15. Codex members and observers wishing to comment on Annex I are kindly requested to bear in mind that the standard attempts to define the identity and essential composition and quality factors of ginseng products intended *for consumption* as foods *therefore*, *quality characteristics linked to pharmacological uses of ginseng products are out of the scope of the standard and the work of the Codex Alimentarius Commission.*

16. The clarifications provided by the Chair of the EWG in reply to comments made by the EWG participants are provided in Annex II ***and are for information purposes hence they are not subject to comment***. They have been retained in this document as considered useful to explain some key points relating to the revision of the standard.

ANNEX I

PROPOSED DRAFT STANDARD FOR GINSENG PRODUCTS

1. SCOPE

This Standard applies to ginseng products as defined in Section 2 below, and offered for direct consumption, including for catering purposes or for repacking if required. This standard applies to ginseng products used as a food or food ingredient and does not apply to products used for medicinal purposes.

2. DESCRIPTION

2.1 PRODUCT DEFINITION

Ginseng product is the product:

(a) prepared from all part of fresh and sound ginseng roots, derived from *Panax ginseng* C.A.Meyer and *P. quinquefolius* L., cultivated for commercial purposes and used for foods;

(b) packaged in such a manner as to safeguard the safety and nutritional and quality characteristics of the products;

(c) processed in an appropriate manner, undergoing operations such as drying, steaming, cutting, powdering, extraction and concentration in conformity with Section 2.2.

2.2 TYPES OF GINSENG PRODUCTS

Ginseng products covered by this standard may be as follows:

2.2.1 Dried Ginseng

2.2.1.1 Dried Raw Ginseng

Dried Raw Ginseng is manufactured when ginseng roots defined in Section 2.1(a) are dried in an appropriate manner such as sun drying, hot air drying or other recognized drying methods. The product may be classified into one of such product types that have the main root and/or lateral roots or that are powdered or sliced.

2.2.1.2 Dried Steamed Ginseng

Dried Steamed Ginseng is manufactured when ginseng roots defined in Section 2.1(a) are prepared using the steaming method and the drying method stated in Section 2.2.1.1. The product may be classified into one of such product types that have the main root and/or lateral roots or that are powdered or sliced.

2.2.2 Ginseng Extract

2.2.2.1 *Raw Ginseng Extract*

Raw Ginseng Extract is manufactured when soluble components of ginseng roots defined in Section 2.1(a) or *Dried Raw Ginseng* defined in Section 2.2.1.1 are extracted by using water, ethanol or their mixture filtered and concentrated. This product has a dark brown colour and a high viscosity. The product may be also presented as a powdered type through spray- or freeze-drying.

2.2.2.2 *Steamed Ginseng Extract*

Steamed Ginseng Extract is manufactured when soluble components of *Dried Steamed Ginseng* defined in Section 2.2.1.2 are extracted by using water, ethanol or their mixture filtered and concentrated. This product has a dark brown colour and a high viscosity. The product may be also presented as a powdered type through spray- or freeze-drying.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 COMPOSITION

3.1.1 Basic Ingredients

Ginseng roots as defined in Section 2.1(a).

3.2 QUALITY FACTORS

3.2.1 Flavour, Colour, Taste and Ginsenoside Pattern

Ginseng products shall have normal flavour, colour, taste and a ginsenoside pattern[1] unique to specific species ginseng as well as be free from foreign matters.

---

[1] The unique constituents of ginseng are found to be a complex mixture of saponins often referred to as ginsenosides, and more than 30 ginsenosides are known. Ginsenoside Rb1 or ginsenoside Rf is one of the major ginsenosides. Ginsenoside Rb1 is identified in all ginseng species in quantities, while ginsenoside Rf is identified mainly in *Panax ginseng* C.A. Meyer.

3.2.2 **Chemical and Physical Characteristics**

3.2.2.1 ***Dried Ginseng***

(a) Moisture: no more than 14.0% (Powdered type: no more than 9.0%)

(b) Ash: no more than 6.0%

(c) Water-saturated n-butanol extracts: no less than 20 mg/g

(d) Ginsenoside Rb1 [and Rg1]: to be identified

In addition, in case of the product manufactured from *P. ginseng* C.A. Meyer, ginsenoside Rf should be also identified.

3.2.2.2 ***Ginseng Extract***

3.2.2.2.1 *Ginseng Extract (liquid form)*

(a) Solids: no less than 60.0%

(b) Water-insoluble solids: no more than 3.0%

(c) Water-saturated n -butanol extracts: no less than 40 mg/g

(d) Ginsenoside Rb1 [and Rg1]: to be identified

In addition, in case of the product manufactured from *P. ginseng* C.A. Meyer, ginsenoside Rf should be also identified.

3.2.2.2.2 *Ginseng Extract (powdered form)*

(a) Moisture: no more than 8.0%

(b) Water-insoluble solids: no more than 3.0%

(c) Water-saturated n -butanol extracts: no less than 60mg/g

(d) Ginsenoside Rb1 [and Rg1]: to be identified

In addition, in case of the product manufactured from *P. ginseng* C.A. Meyer, ginsenoside Rf should be also identified.

3.3 **DEFINITION OF DEFECTS**

The following defects shall be applied to the dried ginseng.

(a) *Insect-damaged ginseng*: Ginseng that is visibly damaged by insects or contains dead insects

(b) *Mouldy ginseng*: Ginseng that is visibly affected by mould

3.4 **CLASSIFICATION OF "DEFECTIVES"**

A container that fails to meet one or more of the applicable quality requirements, set out in Section 3.2 and 3.3, should be considered a "defective".

3.5 **LOT ACCEPTANCE**

A lot should be considered as meeting the applicable quality requirements referred to in Section 3.2 and 3.3, when the number of "defectives", as defined in Section 3.4, does not exceed the acceptance number (c) of the appropriate sampling plan with an AQL of 6.5.

4 FOOD ADDITIVES

No additives are permitted in the products covered by this standard.

5. CONTAMINANTS

5.1 The products covered by this Standard shall comply with the maximum levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX/STAN 193-1995).

5.2 The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

6. HYGIENE

6.1 It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969), and other relevant Codex texts, such as codes of hygienic practice and codes of practice.

6.2 The products should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria to Foods* (CAC/GL 21-1997).

7. LABELLING

The products covered by this Standard shall be labelled in accordance with the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985). Any health claims should comply with the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997), if necessary.

In addition, the following specific provisions apply:

7.1 NAME OF THE PRODUCT

The name of the products defined in subsections 2.2.1.1, 2.2.1.2, 2.2.2.1 and 2.2.2.2 shall be *Dried Raw Ginseng, Dried Steamed Ginseng, Raw Ginseng Extract* and *Steamed Ginseng Extract*, respectively. In this case, the products manufactured with *P. ginseng* C.A. Meyer can be named *White Ginseng, Red Ginseng, White Ginseng Extract* and *Red Ginseng Extract*.

7.2 NAME OF THE GINSENG SPECIES

All ginseng products shall be labelled with the scientific or common name of the ginseng that is used as raw material. The common names of the ginseng species shall be declared in accordance with the law and custom of the country where the products are distributed.

7.3 COUNTRY OF ORIGIN

The country of origin of ginseng root used as raw material of the product shall be declared.

7.4 LABELLING OF NON-RETAIL CONTAINERS

Information about non-retail containers shall be given on the container or in accompanying documents, except that the name of the product, lot identification and the name and address of the manufacturer, packer or distributor, as well as storage instructions, shall appear on the container. However, lot identification, and the name and address of the manufacturer, packer or distributor may be replaced by an identification mark, provided that such a mark is clearly shown in the accompanying documents.

7.5 OTHER LABELLING REQUIREMENTS

Except when otherwise specified by the national legislation, the products should have a clear marking to indicate that they are not intended for medicinal purposes, including other labeling requirements stipulated by the country where ginseng products are distributed.

8. METHODS OF ANALYSIS AND SAMPLING

8.1 SAMPLING PLANS

Sampling shall be in accordance with the *General Guidelines on Sampling* (CAC/GL 50-2004).

8.2 PREPARATION OF TEST SAMPLE

Dried ginseng is pulverized using a grinder to make approximately 3-mm-sized particles for the experiment. Ginseng extract is used in the experiment as is.

8.3 METHODS OF ANALYSIS

PROVISION	METHOD	PRINCIPLE	TYPE
Moisture	AOAC 925.45 *B** * Quantity of sample - Dried Ginseng: 2 g - Ginseng Extract: 1.5 g (mixing with 20 g of sea sand)	Gravimetry	I
Solids	AOAC 925.45 *B* and calculated by subtracting the content of moisture from 100%	Calculation	I
Ash	AOAC 923.03	Gravimetry	I
Water-insoluble Solids	described in Annex A	Gravimetry	I

PROVISION	METHOD	PRINCIPLE	TYPE
Water-saturated n-butanol extracts	described in Annex B	Gravimetry	I
Identification of ginsenosides Rb1, [Rg1] and Rf	described in Annex C	TLC or HPLC	I

References

1. Standard Operation Procedure (SOP) for Determination of Moisture (*attached to the standard*)

2. Standard Operation Procedure (SOP) for Determination of Ash (*attached to the standard*)

Sampling Plans

The appropriate inspection level is selected as follows:

Inspection level I - Normal Sampling

Inspection level II - Disputes, (Codex referee purposes sample size), enforcement or need for better lot estimate

SAMPLING PLAN 1

(Inspection Level I, AQL = 6.5)

NET WEIGHT IS EQUAL TO OR LESS THAN 1 KG (2.2 LB)		
Lot Size (N)	**Sample Size (n)**	**Acceptance Number (c)**
4,800 or less	6	1
4,801 - 24,000	13	2
24,001 - 48,000	21	3
48,001 - 84,000	29	4
84,001 - 144,000	38	5
144,001 - 240,000	48	6
more than 240,000	60	7
NET WEIGHT IS GREATER THAN 1 KG (2.2 LB) BUT NOT MORE THAN 4.5 KG (10 LB)		
Lot Size (N)	**Sample Size (n)**	**Acceptance Number (c)**
2,400 or less	6	1
2,401 - 15,000	13	2
15,001 - 24,000	21	3
24,001 - 42,000	29	4
42,001 - 72,000	38	5
72,001 - 120,000	48	6
more than 120,000	60	7
NET WEIGHT GREATER THAN 4.5 KG (10 LB)		
Lot Size (N)	**Sample Size (n)**	**Acceptance Number (c)**
600 or less	6	1
601 - 2,000	13	2
2,001 - 7,200	21	3
7,201 - 15,000	29	4
15,001 - 24,000	38	5
24,001 - 42,000	48	6
more than 42,000	60	7

SAMPLING PLAN 2

(Inspection Level II, AQL = 6.5)

NET WEIGHT IS EQUAL TO OR LESS THAN 1 KG (2.2 LB)		
Lot Size (N)	**Sample Size (n)**	**Acceptance Number (c)**
4,800 or less	13	2
4,801 - 24,000	21	3
24,001 - 48,000	29	4
48,001 - 84,000	38	5
84,001 - 144,000	48	6
144,001 - 240,000	60	7
more than 240,000	72	8
NET WEIGHT IS GREATER THAN 1 KG (2.2 LB) BUT NOT MORE THAN 4.5 KG (10 LB)		
Lot Size (N)	**Sample Size (n)**	**Acceptance Number (c)**
2,400 or less	13	2
2,401 - 15,000	21	3
15,001 - 24,000	29	4
24,001 - 42,000	38	5
42,001 - 72,000	48	6
72,001 - 120,000	60	7
more than 120,000	72	8
NET WEIGHT GREATER THAN 4.5 KG (10 LB)		
Lot Size (N)	**Sample Size (n)**	**Acceptance Number (c)**
600 or less	13	2
601 - 2,000	21	3
2,001 - 7,200	29	4
7,201 - 15,000	38	5
15,001 - 24,000	48	6
24,001 - 42,000	60	7
more than 42,000	72	8

Annex A

Determination of water-insoluble solid content

1. **Scope of application**

This method can be applied for the analysis of ginseng extract (liquid form).

2. **Principles**

Samples are dissolved in distilled water and centrifuged. The supernatant is removed, and the remaining solid is precipitated and dried. Its weight is determined to be the water-insoluble solid content.

3. **Equipment & Apparatus**

3.1 Centrifuge (temperature controllable)

3.2 Centrifuge tubes for centrifugation

3.3 Serum separation tube or micro-pipette

3.4 Drying oven with a thermostat (±1℃ temperature control)

3.5 Electronic balance (measurable down to 0.1 mg)

3.6 Desiccator (silica gel)

3.7 Tongs

4. **Experimental procedures**

4.1 Dry a centrifuge tube in a drying oven at 105℃ for 3 hours. After drying, place the centrifuge tube in a desiccator, let it stand at room temperature for 30 minutes, and then record its weight.

4.2 Repeat procedure step 4.1 until a constant weight is obtained for the centrifuge tube. Note, however, that the drying time should be 1-2 hours.

4.3 Precisely weigh out approximately 1 g of sample and place it in the centrifuge tube with known constant weight[2].

4.4 Add 15 ml of distilled water to the centrifuge tube containing the sample to dissolve the sample.

4.5 Centrifuge the tube at room temperature at 1000×g[3] for 15 minutes and then remove the supernatant immediately using a serum separation tube while trying not to touch the separated precipitate. The supernatant may not be able to be completely removed due to the necessity of leaving a small amount of the supernatant to prevent the loss of suspended solids.

4.6 Repeat procedural steps 4.4 and 4.5 two more times with the solid that remains in the centrifuge tube.

4.7 Dry the centrifuge tube with the remaining sample in a drying oven at 105℃ for 5 hours.

4.8 After drying, place the centrifuge tube in a desiccator, let it stand at room temperature for 30 minutes, and then measure its weight.

4.9 Repeat procedures step 4.7 and 4.8 until a constant weight is obtained for the centrifuge tube containing the sample. Note, however, that the drying time should be 1-2 hours.

4.10 The water-insoluble solid content is calculated as follows:

$$\text{Water-insoluble solid content (\%)} = \frac{W_1 - W_0}{S} \times 100$$

W_0: Weight of the centrifuge tube (g)

W_1: Weight of the centrifuge tube with the solid residue after drying (g)

S: Weight of the sample (g)

---

2 The constant weight is the smaller value among weights measured successively when the weight difference between the current weight measurement and the previous weight measurement is less than 2 mg.

3 $g = G\frac{M}{R^2}$ (g: gravity acceleration, G: gravity constant, R: radius, M: mass)

Annex B

Determination of water-saturated n-butanol extracts

1. **Scope of application**

This method can be applied for the analysis of dried ginseng and ginseng extracts (liquid and powder forms).

2. **Principles**

Crude saponin is extracted from ginseng products using water-saturated n-butanol as the solvent after the removal of the nonpolar lipids and carbohydrates using diethyl ether and distilled water.

3. **Equipment & Apparatus**

3.1 Separatory funnel (250 mL)

3.2 Round flat flask (200-300 mL)

3.3 Erlenmeyer flask (200-300 mL)

3.4 Standard sieve (No. 80)

3.5 Filter paper (No. 2)

3.6 Glass funnel

3.7 Funnel Shaker

3.8 Rotary evaporator

3.9 Constant-temperature water bath

3.10 Electronic balance (measurable down to 0.1 mg)

3.11 Drying oven with a thermostat (±1℃ temperature control)

3.12 Desiccator (silica gel)

3.13 Grinder

3.14 Tongs

4. **Reagents**

4.1 n-butanol (over EP grade)

4.2 Diethyl ether (over EP grade)

4.3 Distilled water

5. **Preparation of the water-saturated n-butanol solution**

5.1 Mix n-butanol and distilled water at a ratio of 70:30.

5.2 Shake the mixture sufficiently and let it stand so that the upper layer (water-saturated n-butanol layer) and the lower layer (water layer) separate completely.

5.3 After complete separation is achieved, the water-saturated n-butanol layer is stored in a container and capped until further use.

6. **Pretreatment of samples**

Dried ginseng samples are pulverized using a grinder and sifted through an 80-mesh sieve for experimental use. The ginseng extract is used in the experiment as is.

7. **Experimental procedures for dried ginseng**

7.1 Precisely weigh out approximately 5 g of sample and place it in a round flat flask (A). Then, add 50 ml of the water-saturated n-butanol solution. Perform reflux extraction in a constant-temperature water bath at 75-80℃ for 1 hour and then let it stand for 30 minutes.

7.2 Transfer the solution obtained in step 7.1 into a separatory funnel after filtering it through filter paper.

7.3 Repeat procedures step 7.1 and 7.2 two more times for the solid remains in the round flat flask (A).

7.4 Add 50 ml of distilled water to the mixed solution obtained in step 7.2-7.3 and then **shake the solution using a funnel shaker (approximately 15 minutes)**. Let it stand until the upper layer (water-saturated n-butanol layer) and the lower layer (water layer) are completely separated.

7.5 Transfer the upper layer (water-saturated n-butanol layer) into a previously weighed flat bottom flask (B) and vacuum-concentrate and dry (60℃) the sample until the liquid is completely removed.

7.6 Add 50 mL of diethyl ether to the round flat flask (B) containing the precipitates and reflux the sample again in a constant-temperature water bath at 46℃ for 30 minutes.

7.7 Discard the diethyl ether in the flat bottom flask (B) by filtering the sample through filter paper and then collect the precipitates on the filter paper in a flat bottom flask (B) by dissolving them with methanol.

7.8 Concentrate the contents in the round flat flask (B) until the odors of diethyl ether and methanol disappear.

7.9 After drying the round flat flask (B) **in a drying oven at 105℃ for 1 hour**, place it in a desiccator at room temperature, **let it stand for 1 hour, and then measure its weight**.

7.10 The water-saturated n-butanol content of dried ginseng is calculated as follows:

$$\text{Water-saturated n-butanol extract (mg/g)} = \frac{W_1 - W_0}{S}$$

W_0: Weight of the flask (mg)

W_1: Weight of the flask after concentration and drying (mg)

S: Weight of the sample (g)

8. **Experimental procedures for ginseng extracts**

8.1 Precisely weigh out approximately 2 g of sample in an Erlenmeyer flask, add 60 mL of distilled water to dissolve the sample, and then transfer it to a separatory funnel (A).

8.2 Add 60 ml of diethyl ether, shake the funnel several times, and then remove the gas by opening the cork. Repeat the above procedure step 8.2, 2-3 times.

8.3 Shake the separatory funnel sufficiently **in a funnel shaker (approximately 15 minutes)** and then let it stand until the upper layer (diethyl ether layer) and the lower layer (water layer) are completely separated.

8.4 Transfer the lower portion (water layer) to a different separatory funnel (B), add 60 ml of the water-saturated n-butanol solution, **shake the funnel under the same conditions as described in step 8.3,** and let it stand until the layers are completely separated. The supernatant (water-saturated n-butanol layer) is collected (collected from above of the boundary surface) and transferred to another flask.

***** At this time, the lower layer (water layer) is considered the emulsion layer in the next two separation stages but not in the final separation stage.

8.5 Repeat procedure step 8.4 two more times on the lower layer (water layer) left in the separatory funnel (B). At the final separation stage, the supernatant including the emulsion is slowly removed, leaving only the upper layer, by opening the spout of the separatory funnel.

8.6 Collect the solution (supernatants from each separation stage) obtained from procedures step 8.4-8.6 into the separatory funnel (B), add 50 ml of distilled water, and shake the funnel under the same conditions as described in (c). Then, let it stand **until the upper layer (n-butanol layer) and the lower layer (water layer) are completely separated.**

8.7 Transfer the supernatant (n-butanol layer) into the previously weighed flat bottom flask and **vacuum-concentrate (60℃)** it until the liquid is completely removed.

8.8 Dry the flat-bottomed flask **in a drying oven at 105℃ for 1 hour** and then place in a desiccator at room temperature. **Let it stand for 1 hour** and then measure its weight.

8.9 Calculate the water-saturated n-butanol content in the ginseng extract using the same method as described in step 7.10.

Annex C

Identification of ginsenosides [Rg_1,] Rb_1, and Rf

Ginsenosides in ginseng products can be identified by thin-layer chromatography (TLC) or high-performance liquid chromatography (HPLC).

1. **Sample solution preparation**

The dried 1-butanol extract obtained according to the method for the measurement of the water-saturated n-butanol extract in Annex B is completely dissolved in 10 ml of methanol and then filtered through a 0.45-μm membrane filter.

2. **Standard solution preparation**

Reference substances for ginsenoside [Rg_1,] Rb_1 and ginsenoside Rf are dissolved in methanol to concentrations of 0.2%, and then the solutions are filtered through a 0.45-μm membrane filter.

3. **Identification**

3.1 **Thin-Layer Chromatography (TLC)**

3.1.1 **Preparation of the developing solvent**

(a) Mix n-butanol:ethyl acetate:water at a ratio of 50:10:40 (A), or chloroform:methanol:water at a ratio of 65:35:10 (B) in a separatory funnel.

(b) Shake the funnel sufficiently and let it stand until the solvent is completely separated.

(c) Collect only the upper layer when using solvent (A) as the developing solvent and only the lower layer when using solvent (B) and store the layers for further use. Collect from above (A) or below (B) the boundary surface of the relevant solvent when each solvent is separated and stored to increase the purity of the developing solvent.

3.1.2 **Developing chamber**

(a) Use a developing chamber with a cover (the developing chamber is completely sealed by applying glycerin, etc.).

(b) Attach filter paper to the sides and back of the inside of the developing chamber and soak them with the developing solvent.

(c) Place the developing solvent slowly into the developing chamber (approximately halfway up to the starting line of the TLC plate).

(d) Place the cover on and let it stand until the inside of the developing chamber is sufficiently saturated (30 minutes).

3.1.3 **TLC preparation**

(a) The TLC plate is cut into appropriate pieces over 10 cm in length and wide enough to accommodate the number of samples needed for identifying the ginsenosides.

(b) Place the plate in a clean drying oven and dry it at 110℃ for 10-15 minutes before use.

(c) Draw a line (starting line) 1 cm from the bottom of the TLC plate and mark the spots for dropping the samples. Then, draw a line (ending line) at exactly 8 cm from the starting line.

3.1.4 **TLC identification**

(a) Five-microliter samples of the ginsenoside references and the sample solutions prepared as described above are dropped while drying using a dryer. Each 5-μl sample is dropped by dividing it into several drops carefully without scraping off the silica gel of the TLC plate and not by using one drop.

(b) After the dropping is completed, dry the TLC plate with a dryer.

(c) Place the TLC plate in the developing chamber with its starting line at the bottom and develop the samples.

(d) When the developing solvent reaches the ending line, the TLC plate is taken out and dried with a dryer.

(e) Spray a 10% sulfuric acid solution evenly on the TLC plate.

(f) Place the plate in a dryer at 110℃ for 5-10 minutes for the development of the colors.

(g) Compare the R_f values and colors of the substances separated from the sample with those of the ginsenoside references to identify the relevant ginsenosides in the ginseng products.

$$R_f = \frac{distance\ sample\ solution\ migrated}{distance\ developing\ solvent\ migrated}$$

3.2 **High-Performance Liquid Chromatography (HPLC)**

The sample solution prepared according to the description above and the ginsenoside references are analyzed using HPLC under the conditions described below. Ginsenosides in the sample solutions can be identified by comparing their retention times with the peaks shown by the ginsenosides in the reference substances.

<Operating conditions>

(a) Column: ODS column

(b) Detector: UV (203nm) or ELSD

(c) Eluent

- UV: acetonitrile:water (30:70, v/v)-
- ELSD: acetonitrile:water:isopropanol (94.9:5.0:0.1, v/v/v)

(d) Flow rate: 1.0 ml/min~2.0 ml/min

※ The analytical conditions can be adjusted depending on the laboratory conditions, but the peaks of [Rg_1,] Rb_1, and Rf in the chromatogram should NOT be located in the first 5 minutes NOR in the last 5 minutes of the retention time.

Reference 1

Standard Operation Procedure for Determination of Moisture

1. **Scope of application**

This method can be applied for the analysis of dried ginseng and ginseng extract.

2. **Principles**

It is assumed that the moisture is the only volatile component in food. When the pressure of the water vapor in food is increased by heating, that of the surroundings is reduced relative to that of the food. The moisture in a food sample can be completely evaporated during heating at 105℃ without the occurrence of any chemical change.

3. **Equipment & Apparatus**

3.1 Weighing bottle with a lid

3.2 Glass rod (It should protrude at least 1.5 cm from the surface of the sea sand when inserted at a 45° angle into a weighing bottle containing 20 g of sea sand.)

3.3 Drying oven with a thermostat (±1℃ temperature control)

3.4 Electronic balance (measurable down to 0.1 mg)

3.5 Sea sand (20-35 mesh)

3.6 Desiccator (silica gel)

3.7 Grinder

3.8 Tongs

4. **Pretreatment of samples**

Dried ginseng samples are pulverized using a grinder to make approximately 3-mm-sized particles for the experiment. The ginseng extract is used in the experiment as is.

5. **Experimental procedures - dried ginseng and ginseng extract (powder form)**

5.1 Dry a weighing bottle and a lid separately in a drying oven at 105℃ for 5 hours. Afterwards, place the weighing bottle capped tightly with the lid in a desiccator, let it stand at room temperature for 30 minutes, and then measure its weight.

5.2 Repeat procedure step 5.1 until a constant weight is obtained for the bottle and lid. Note, however, that the drying time should be 1-2 hours.

5.3 Precisely weigh out approximately 2 g of sample, and place it into the weighing bottle with known constant weight.

5.4 Dry the weighing bottle containing the sample in a drying oven at 105℃ for 3 hours. The lid is placed slightly ajar to dry the sample in the weighing bottle.

5.5 Place the weighing bottle capped tightly with the lid in a desiccator, let it stand at room temperature for 30 minutes, and then measure its weight.

5.6 Repeat procedures 5.4 and 5.5 until a constant weight is obtained for the bottle containing the sample. Note, however, that the drying time should be 1-2 hours.

5.7 The moisture content is calculated as follows:

$$\text{Moisture content in the sample (\%)} = \frac{S-(W_1-W_0)}{S} \times 100$$

W_0: Weight of the weighing bottle (g)

W_1: Weight of the weighing bottle with the sample after drying (g)

S: Weight of the sample (g)

6. **Experimental procedures - ginseng extract (liquid form)**

6.1 Dry the weighing bottle containing 20 g of sea sand and a glass rod in a drying oven at 105℃ for 5 hours.

6.2 After drying, place the weighing bottle in a desiccator, let it stand at room temperature for 30 minutes, and then measure its weight.

6.3 Repeat procedures 6.1 and 6.2 until a constant weight is obtained for the bottle containing the sea salt and the glass rod. Note, however, that the drying time should be 1-2 hours.

6.4 Precisely weigh out approximately 1.5 g of sample and place it into the weighing bottle with a known constant weight. Then, mix the sample well with the sea sand and evenly spread the mixture on the surfaces of the weighing bottle walls using the glass rod.

6.5 The remaining analytical steps and calculations are the same as for step 5.4 and 5.5 of section 5 above.

Reference 2

Standard Operation Procedure for Determination of Ash

1. **Scope of application**

This method can be applied for the analysis of dried ginseng samples.

2. **Principles**

Samples are collected in a container (crucible) for ash analysis and burned at 525-600℃ to remove the organic substances. The total mineral weight of the remaining sample is considered the ash content.

3. **Equipment & Apparatus**

3.1 Porcelain crucible with a lid

3.2 Electric heating plate

3.3 Electric furnace with a thermostat (±1℃ temperature control)

3.4 Electronic balance (measurable down to 0.1 mg)

3.5 Desiccator (silica gel)

3.6 Grinder

3.7 Tongs

4. **Pretreatment of samples**

Dried ginseng samples are pulverized using a grinder to make approximately 3-mm-sized particles for the experiment.

5. **Experimental procedures**

5.1 Heat a clean porcelain crucible in an electric furnace at 550℃ for 3 hours. Let it stand at room temperature for 1 hour, and then measure its weight.

5.2 Repeat procedure step 5.1 until a constant weight is obtained. Note, however, that the ashing time should be 1-2 hours.

5.3 Precisely weigh out approximately 3 g of sample in the porcelain crucible with known constant weight.

5.4 Place the porcelain crucible containing the sample in an electric furnace at 550℃ and ash the sample by heating the crucible with the lid on it until white or bright grayish white ash is formed.

5.5 After ashing is complete, place the porcelain crucible containing the sample in a desiccator, let it stand at room temperature for 1 hour, and then measure its weight.

5.6 Repeat procedures step 5.4 to 5.5 until a constant weight is obtained for the crucible containing the sample. Note, however, that the ashing time should be 1-2 hours.

5.7 The ash content is calculated as follows:

$$\text{Ash content in the sample (\%)} = \frac{W_2 - W_1}{S} \times 100$$

W_1: Weight of the porcelain crucible before ashing (g)

W_2: Weight of the porcelain crucible after ashing (g)

S: Weight of the sample (g)

ANNEX III
ORIGINAL LANGUAGE

FIRST ROUND

to prepare the Proposed Draft Standard for Ginseng Products
Comments submitted by the participating countries of e-WG
in response to the request for comments on the current regional standard,
and Chair's suggestion to coordinate

TITLE

Current Regional Standard		REGIONAL STANDARD FOR GINSENG PRODUCTS (Asia)
Comments from participating countries	China	Proposal: STANDARD FOR GINSENG ~~PRODUCTS~~ AND GINSENG EXTRACT
Chairs' suggestion		This proposed standard deals with dried ginseng and ginseng extracts. The scope of this standard already states, "This standard applies to the products defined in Section 2(*dried ginseng and ginseng extracts*)." Therefore, it is not necessary to amend the name of the standard. Moreover, the name of the standard should be inclusive because other product types will be possibly added later. Therefore, the name of the worldwide standard remains unchanged, as in the current regional standard, with the regional indication deleted. ~~REGIONAL~~ STANDARD FOR GINSENG PRODUCTS ~~(Asia)~~

1. SCOPE

Current Regional Standard		1.1 This standard applies to the ginseng products as defined in Section 2 below and offered for direct consumption, including for catering purposes or for repacking if required. It does not apply to the product when indicated as being intended for further processing. This standard applies to ginseng products[1] used as a food or food ingredient and does not apply to products used for medicinal purposes. 1.2 This Standard applies only in those jurisdictions where products defined in 2.1 are regulated as foods.
Comments from participating countries	Canada	**Issue.** need to further redefine the scope as it specifies, "It does not apply to the product when indicated as being intended for further processing". Ginseng extract as defined in Section 2.2.2 are considered products from further processing (eg. Extraction process), however the scope indicates it does not apply to products as being intended for further processing. **Proposal.** "…or for repacking if required. ~~It does not apply to the product when indicated as being intended for further processing.~~ This standard applies…"
	China	**Proposal.** 1.2 This Standard applies only in those jurisdictions where products defined in 2.1 are regulated as foods. This Standard should follow the laws and regulations of each country.

[1] Any health claims should comply with the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)

	Korea	**Proposal.** Delete the section 1.2 ~~1.2 This Standard applies only in those jurisdictions where products defined in 2.1 are regulated as foods.~~ **Rationale.** This section is overlapped with the sentence 'This standard applies to ginseng products used as a food or food ingredient' in section 1.1. And if this standard is applied only in the jurisdictions where ginseng products are regulated as a food, it will contravene the original purposes of the establishment of CODEX standards. In other words, the CODEX standard shall be applied to any countries which have regulations on ginseng products under the conditions stipulated in section 1.1 or which do not. Therefore, this section is unnecessary and should be deleted.
	USA	**Comment.** The U.S supports retaining the current Scope of the Draft Standard and the deletion of Section 1.2.
Chairs' suggestion		**Comment 1.** In order to assure the clarity of the scope and avoid duplicated meanings, the second sentence in section 1.1 and the whole section 1.2 are deleted. **Comment 2.** According to Paragraph 3 "*Nature of Codex Standards*" of the *General Principles of the CODEX Alimentarius(Codex Procedural Manual, 21st ed.)* [2], it is considered that adding the sentence, as is requested by China, is not necessary. Therefore, amendments to the current standard are made in the following manner. ~~1.1~~ This standard applies to the ginseng products as defined in Section 2 below and offered for direct consumption, including for catering purposes or for repacking if required~~. It does not apply to the product when indicated as being intended for further processing.~~ This standard applies to ginseng products used as a food or food ingredient and does not apply to products used for medicinal purposes. ~~1.2 This Standard applies only in those jurisdictions where products defined in 2.1 are regulated as foods.~~

2. DESCRIPTION

Current Regional Standard		DESCRIPTION
Comments from participating countries	USA	COMMENT: The United supports retaining this paragraph unchanged

2.1 PRODUCT DEFINITION

Current Regional Standard		**2.1 PRODUCT DEFINITION** The compulsory ingredient of ginseng product is fresh ginseng roots suitable to eating, derived from *Panax ginseng* C.A. Meyer and *P. quinquefolius* L., cultivated for commercial purposes and used for foods. Ginseng products should be packaged in such a manner as to safeguard the hygienic, nutritional, technological and organoleptic quality of the products.
Comments from participating countries	Canada	**Issue.** Need to further clarify as the scope indicates this standard applies to ginseng products as defined as "fresh" whereas the rest of the document is devoted to dried and further processed ginseng (ginseng extract). **Proposal.** "The compulsory ingredient of ginseng product is ~~fresh~~ ginseng roots suitable to eating, derived from <u>fresh</u> *Panax*…"

[2] 3. Codex standard and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.

	Switzerland	**Issue 1.** The wording «suitable to eating» related to fresh ginseng roots needs further clarification. Can fresh ginseng roots be eaten like vegetables? If not, the wording «suitable to eating» should be deleted. **Issue 2.** Further clarification is also needed concerning «cultivated for commercial purposes». Is a wild ginseng root as a raw material intended for use in foodstuffs not covered by this standard? **Issue 3.** Switzerland proposes to mention the compulsory ingredient under section «3 ESSENTIAL COMPOSITION AND QUALITY FACTORS» and uses under this section the following wording in order to be in line with other standards of this committee. **Proposal.** Ginseng product is the product: (a) prepared from fresh ginseng roots suitable to eating, derived from *Panax ginseng* C.A.Meyer and *P.quinquefolius* L.; (b) packaged in such a manner as to safeguard the hygienic, nutritional, technological and organoleptic quality of the products; (c) processed in an appropriate manner, undergoing operations such as steaming, drying, cutting, powdering, extracting in conformity with Section 2.2
Chairs' suggestion		**Comment 1.** In order to be in line with the other standards elaborated by this committee (CCPFV), amendments are made in the following manner. **Comment 2.** Since fresh ginseng roots can be eaten like vegetables, deleting the wording 'suitable to eating' is not necessary. The international trade volume of wild ginseng is very little, and collecting wild ginseng is illegal in some countries. Therefore, 'cultivated for' is appropriate here. In order to minimize a misunderstanding about ginseng extract manufacturing processes, inserting the word of 'concentrating' is proposed. Therefore, amendments to the current standard are made in the following manner. 2.1 PRODUCT DEFINITION ~~The compulsory ingredient of ginseng product is fresh ginseng roots suitable to eating, derived from Panax ginseng C.A. Meyer and P. quinquefolius L., cultivated for commercial purposes and used for foods. Ginseng products should be packaged in such a manner as to safeguard the hygienic, nutritional, technological and organoleptic quality of the products.~~ Ginseng product is the product: (a) prepared from fresh ginseng roots suitable to eating, derived from *Panax ginseng* C.A.Meyer and *P.quinquefolius* L., cultivated for commercial purposes and used for foods; (b) packaged in such a manner as to safeguard the hygienic, nutritional, technological and organoleptic quality of the products; (c) processed in an appropriate manner, undergoing operations such as drying, steaming, cutting, powdering, extracting and concentrating in conformity with Section 2.2

2.2 TYPES OF GINSENG PRODUCTS

Current Regional Standard		2.2. TYPES OF GINSENG PRODUCTS
Comments from participating countries	China	**Proposal.** TYPES OF GINSENG ~~PRODUCTS~~ AND GINSENG EXTRACT
	Switzerland	**Proposal.** Insert the following sentence under the title of Section 2.2. "Ginseng products covered by this standard may be proposed as follows:"

Chairs' suggestion	In order to describe this standard in the same manner as in the other standards developed by CCPFV, the following sentence is inserted under the title of Section 2.2. 2.2 TYPES OF GINSENG PRODUCTS Ginseng products covered by this standard may be proposed as follow:

2.2.1 Dried Ginseng

2.2.1.1 Dried Raw Ginseng

Current Regional Standard		2.2.1.1 Dried Raw Ginseng *Dried Raw Ginseng* is manufactured when fresh ginseng roots are sun dried or hot air dried or dried using other recognized methods. The product may be classified into one of such product types as have the main root and/or lateral roots, or as are powdered or sliced.
Comments from participating countries	Canada	**Issue.** The word "raw" creates confusion. Canada suggests removing the word "raw". **Proposal.** 2.2.1.1 Dried ~~Raw~~ Ginseng *"Dried ~~Raw~~ Ginseng* is manufactured….."
	Korea	**Proposal.** First sentence. Revise as follows, *Dried Raw Ginseng* is manufactured when fresh ginseng roots defined in 2.1 are sun dried or hot air dried or dried using other recognized methods. **Rationale.** to ensure that the raw material of Dried Raw Ginseng is explained more clearly.
	Switzerland	**Issue.** If the ginseng roots without processing before drying should be covered, the indication of «raw» is not necessary in our opinion. Therefore Switzerland proposes to delete «raw». **Proposal.** *Dried ~~Raw~~ Ginseng* is manufactured when fresh ginseng roots defined in Section 2.1 are dried in an appropriate manner such as sun dried, hot air dried or ~~dried~~ using other recognized methods.
Chairs' suggestion		Dried ginseng has two product types: a steamed and dried one and a non-steamed but dried one. It is recognized that dried raw ginseng is not the best expression. However, if dried ginseng is described without using the word of 'raw,' dried ginseng may be confused with dried steamed ginseng. In parallel with the wording of 'dried steamed ginseng,' dried raw ginseng is recommended. So, till an appropriate expression to discriminate between the two (dried ginseng and dried steamed ginseng) is suggested, the wording in the current draft should be maintained. Therefore, amendments to the current standard are made in the following manner. 2.2.1.1 Dried Raw Ginseng *Dried Raw Ginseng* is manufactured when ~~fresh~~ ginseng roots defined in Section 2.1(a) are dried in an appropriate manner such as ~~sun dried or hot air dried~~ sun drying, hot air drying or ~~dried using~~ other recognized drying methods. The product may be classified into one of such product types that have the main root and/or lateral roots, or that are powdered or sliced.

2.2.1.2 Dried Steamed Ginseng

Current Regional Standard	2.2.1.2 Dried Steamed Ginseng *Dried Steamed Ginseng* is manufactured when fresh ginseng roots are prepared using the steaming method or other recognized methods, and dried. The product may be classified into one of such product types as have the main root and/or lateral roots, or as are powdered or sliced.

Comments from participating countries	Canada	**Issue.** Further clarification is needed as to how "Dried Steamed Ginseng is dried". **Proposal.** *Dried Steamed Ginseng* is manufactured when fresh ginseng roots are prepared using the steaming method or other recognized methods, and dried using the acceptable methods mentioned in 2.2.1.2(2.*2.1.1?*).
	EU	**Comment.** The meaning of "other recognized methods" is not clear, assumingly they should also be steaming methods as the name of the product is "dried steamed ginseng". Perhaps the reference to other recognized methods is redundant in this case and could be deleted?
	Korea	**Proposal.** First sentence. Revise as follows, *Dried Steamed Ginseng* is manufactured when fresh ginseng roots defined in 2.1are prepared using the steaming method or other recognized methods, and dried. **Rationale.** to ensure that the raw material of Dried Steamed Ginseng is explained more clearly.
	Switzerland	**Proposal.** *Dried Steamed Ginseng* is manufactured when fresh ginseng roots defined in section 2.1 are prepared using the steaming method or other recognized methods, and appropriate recognized drying methods ~~dried~~.
Chairs' suggestion		In order to clarify a drying method for streamed ginseng, amendments are made in the following manner. 2.2.1.2 Dried Steamed Ginseng *Dried Steamed Ginseng* is manufactured when ~~fresh~~ ginseng roots defined in Section 2.1(a) are prepared using the steaming method ~~or other recognized methods,~~ and ~~dried~~ the drying method stated in Section 2.2.1.1. The product may be classified into one of such product types that have the main root and/or lateral roots, or that are powdered or sliced.

2.2.2 Ginseng Extracts

2.2.2.1 Raw Ginseng Extract

Current Regional Standard		2.2.2.1 Raw Ginseng Extract *Raw Ginseng Extract* is manufactured when soluble components of fresh ginseng roots or *Dried Raw Ginseng* are extracted, using water, ethanol or their mixture and then, they are filtered and concentrated. This product has a dark brown color and a high viscosity when much of the water is removed from it. The product may be also presented as a powdered type through spray- or freeze-drying.
Comments from participating countries	Canada	**Issue 1.** The word "Raw" creates confusion. Canada suggests removing the word "Raw". **Proposal 1.** 2.2.1.1 ~~Raw~~ Ginseng Extract "~~*Raw*~~ *Ginseng Extract* is manufactured….." **Issue 2.** Also, extracts prepared from fresh and dried ginseng are quite different in yield and characteristics. Canada suggests separating them into a different category when defining their composition and quality factors.
	Korea	**Proposal.** First sentence. Revise as follows, *Raw Ginseng* Extract is manufactured when soluble components of fresh ginseng roots defined in 2.1 or Dried Raw Ginseng defined in 2.2.1.1 are extracted~~,~~ by using water, ethanol or their mixture and then, they are filtered and concentrated. **Rationale.** to ensure that the raw material of Raw Ginseng Extract is explained more clearly and to make editorial correction.

	Switzerland	**Proposal.** 2.2.2.1 ~~Raw~~ Ginseng Extract ~~*Raw*~~ *Ginseng Extract* is manufactured when soluble components of fresh ginseng roots defined in Section 2.1 or Dried ~~Raw~~ Ginseng are extracted, using water, ethanol or their mixture ~~and then, they are~~ filtered and concentrated.
	USA	**Issue.** The United States believes that prescribing the two methods of extraction of soluble components in the first sentence is limiting and short sighted. This does not take into consideration other possible methods. Therefore the following addition is proposed. **Proposal.** *Raw Ginseng Extract* is manufactured when soluble components of fresh ginseng roots defined in 2.1 or *Dried Raw Ginseng* defined in 2.2.1.1 are extracted, by using water, ethanol or their mixture and other approved methods of extraction. These extracts are then filtered and concentrated.
Chairs' suggestion		**Comment 1.** According to editorial suggestions, amendments are made in the following manner. **Comment 2.** USA requests that the phrase 'other approved methods of extraction' should be inserted, but data to demonstrate that extracting methods by using other substances than water and ethanol should be applied has not yet been shared. When there is a full history of the use of the substances, the sentence may be amended. Therefore, amendment to the current standard are made in the following manner 2.2.2.1 Raw Ginseng Extract *Raw Ginseng Extract* is manufactured when soluble components of ~~fresh~~ ginseng roots defined in Section 2.1(a) or *Dried Raw Ginseng* defined in Section 2.2.1.1 are extracted, by using water, ethanol or their mixture, ~~and then, they are~~ filtered and concentrated. This product has a dark brown colour and a high viscosity ~~when much of the water is removed from it~~. The product may be also presented as a powdered type through spray- or freeze-drying.

2.2.2.2. Steamed Ginseng Extract

Current Regional Standard		2.2.2.2 Steamed Ginseng Extract *Steamed Ginseng Extract* is manufactured when soluble components of *Dried Steamed Ginseng* are extracted, using water, ethanol or their mixture and then, they are filtered and concentrated. This product has a dark brown colour and a high viscosity when much of the water is removed from it. The product may be also presented as a powdered type through spray-or freeze-drying.
Comments from participating countries	Korea	**Proposal.** First sentence. Revise as follows, *Steamed Ginseng* Extract is manufactured when soluble components of *Dried Steamed Ginseng* defined in 2.2.1.2 are extracted~~,~~ by using water, ethanol or their mixture and then, they are filtered and concentrated. **Rationale.** to ensure that the raw material of Steamed Ginseng Extract is explained more clearly and to make editorial correction.
	Switzerland	**Issue.** The first sentence mentions that the extract is mandatorily filtered and concentrated. Therefore it is not necessary to repeat that «much of the water is removed». **Proposal.** *Steamed Ginseng Extract* is manufactured when soluble components of Dried Steamed Ginseng are extracted, using water, ethanol or their mixture ~~and then, they are~~ filtered and concentrated. This product has a dark brown color and a high viscosity ~~when much of the water is removed from it~~.

Chairs' suggestion	The clarity of raw materials and the unnecessary expressions are amended in the following manner. 2.2.2.2 Steamed Ginseng Extract *Steamed Ginseng Extract* is manufactured when soluble components of *Dried Steamed Ginseng* defined in Section 2.2.1.2 are extracted~~,~~ by using water, ethanol or their mixture~~, and then, they are~~ filtered and concentrated. This product has a dark brown color and a high viscosity ~~when much of the water is removed from it~~. The product may be also presented as a powdered type through spray- or freeze-drying.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 INGREDIENTS

Current Regional Standard		3.1 INGREDIENTS Fresh ginseng roots as defined in Section 2.1.
Comments from participating countries	Canada	**Issue.** The word fresh should be removed as this section refers to dried ginseng and ginseng extracts. **Proposal.** ~~Fresh g~~Ginseng roots as defined in Section 2.1.
	Switzerland	**Issue.** «Fresh» is still mentioned under 2.1 and does not have to be repeated in this Section. **Proposal.** ~~Fresh g~~Ginseng roots as defined in Section 2.1.
Chairs' suggestion		Since the word "fresh" is not required, amendments are made in the following manner. 3.1 INGREDIENT ~~Fresh g~~Ginseng root as defined in Section 2.1(a)

3.2 QUALITY FACTORS

Current Regional Standard		3.2 QUALITY FACTORS Ginseng products shall have normal flavour, colour, taste and a ginsenoside pattern[3] unique to ginseng as well as be free from foreign matters.
Comments from participating countries	Canada	**Issue.** Canada suggests to further clarify this sentence to ensure different species of ginseng are captured. **Proposal.** Ginseng products shall have normal flavour, colour, taste and a ginsenoside pattern unique to specific species of ginseng as well as be free from foreign matters.
Chairs' suggestion		Since this standard applies to the species of *Panax ginseng* C.A. Meyer and *P. quinquefolius* L. only, inserting 'specific species' is accepted. Moreover, the numbering of 3.2.1 should be placed in front of this sentence so that a new sub-title(Chemical and Physical Characteristics) may be given to Section 3.2.2. Therefore, amendments to the current standard are made in the following manner. 3.2 Quality Factors 3.2.1 Ginseng products shall have normal flavor, colour, taste and a ginsenoside pattern unique to specific species of ginseng as well as be free foreign matters

[3] The unique constituents of ginseng are found to be a complex mixture of saponins often referred to as ginsenosides, and more than 30 ginsenosides are known. Ginsenoside Rb1 or ginsenoside Rf is one of the major ginsenosides. Ginsenoside Rb1 is identified in all ginseng species in quantities, while ginsenoside Rf is identified mainly in *Panax ginseng* C.A. Meyer.

3.2.1 Dried Ginseng

<table>
<tr><td colspan="2">Current Regional Standard</td><td>3.2.1 Dried Ginseng
(a) Moisture: no more than 14.0% (Powdered type: no more than 9.0%)
(b) Ash: no more than 6.0%
(c) Water-saturated 1-butanol extracts: no less than 20 mg/g
(d) Ginsenoside Rb1: to be identified
In addition, in case of the product manufactured from P. ginseng C.A. Meyer, ginsenoside Rf should be also identified.</td></tr>
<tr><td rowspan="2">Comments from participating countries</td><td>China</td><td>Proposal:Proposal.
(c) Water-saturated 1-butanol extracts: no less than 20 mg/g(There is not relevant data in China, so please offer relevant department this data)
(d) Ginsenoside Rb1: <s>to be identified</s> no less than 0.3%
(e) Ginsenoside Rg1 add Ginsenoside Re: no less than 0.3%</td></tr>
<tr><td>Switzerland</td><td>Issue 1. Switzerland proposes to mention the chemical and physical characteristics of all products under the same title.
Proposal 1.
3.2.1 Chemical and physical Characteristics
3.2.1.1 Dried Ginseng
Issue 2. The mention «to be identified» concerning the substances Ginsenoside Rb1 respectively Ginsenoside Rf needs further clarifications. Switzerland proposes to mention the observed quantity content (average) of Ginsenoside Rb1 respectively Rf presented in these products, based of the natural content and the processes. The content of the ginsenosides could be relevant in view of the quality of the final product as well as because these substances are pharmacological active compounds.</td></tr>
<tr><td colspan="2">Chairs' suggestion</td><td>Comment 1. The new sub-title (3.2.1 Chemical and Physical Characteristic) proposed by Switzerland is accepted.
Comment 2. Ginsenoside is an essential functional compound of ginseng products. From the pharmacological perspective, ginsenoside is an important index to qualitative value. There is a big difference in the value depending upon the ginseng species, product type, and producing country.
However, we are discussing a standard for ginseng used as a food not as a drug, there is no reason to focus on the quantity of individual ginsenoside. Therefore, crude saponin (water-saturated 1-buthanol extracts) can be appropriate as a qualitative index to ginseng products as a food.
Comment 3. On account of similar reasons, other ginsenosides than Rb1 and Rf need not be detected. As mentioned during previous meetings of CCASIA, such an extra work will be an increased burden for ginseng producers.
Therefore, the current regional standard remains unchanged while the sub-title (3.2.2) is inserted and the section number (3.2.2.1) is amended in this section.
3.2.2 Chemical and Physical Characteristics
<s>3.2.1</s> 3.2.2.1 Dried Ginseng
(a) Moisture: no more than 14.0% (Powdered type: no more than 9.0%)
(b) Ash: no more than 6.0%
(c) Water-saturated 1-butanol extracts: no less than 20 mg/g
(d) Ginsenoside Rb1: to be identified
In addition, in case of the product manufactured from P. ginseng C.A. Meyer, ginsenoside Rf should be also identified.</td></tr>
</table>

3.2.2 Ginseng Extracts

3.2.2.1 Ginseng Extracts (liquid form)

Current Regional Standard		3.2.2.1 Ginseng Extracts (liquid form) (a) Solids: no less than 60.0% (b) Water-insoluble solids: no more than 3.0% (c) Water-saturated 1-butanol extracts: no less than 70 mg/g (d) Ginsenoside Rb1: to be identified In addition, in case of the product manufactured from *P. ginseng* C.A. Meyer, ginsenoside Rf should be also identified.
Comments from participating countries	China	**Proposal.** (b) Water-insoluble solids: no more than ~~3.0%~~5.0% (c) Water-saturated 1-butanol extracts: no less than 70 mg/g*(There is not relevant data in China, so please offer relevant department this data)* (d) Ginsenoside Rb1: ~~to be identified~~ no less than 0.2% (e) Ginsenoside Rg1 add Ginsenoside Re: no less than 0.3%
	Korea	**Proposal.** Delete (c) ~~(c) Water-saturated 1-butanol extracts: no less than 70 mg/g~~ Or, amend as follows; (c) Water-saturated 1-butanol extracts: no less than ~~70~~40mg/g **Rationale.** The current content criterion was established at initial steps of the elaboration of the regional standard and on the base of Ginseng Extracts used as a functional food or a drug in some countries. However, almost all the countries do not have a content criterion for this quality factor. Moreover, as is defined in sections 2.2.2.1 and 2.2.2.2, Ginseng Extracts are manufactured using Dried Ginseng as a material. So, since a criterion (≥20 mg/g) for Dried Ginseng is already provided in (c) of section 3.2.1, a separate criterion for Ginseng Extracts, which are manufactured using Dried Ginseng, is not required. If such a criterion is necessary at all, one much lower than the current criterion shall be provided. Ginseng Extract distributed in the market and used as a food is a product manufactured by concentrating Dried Ginseng about two times. Accordingly, given the criterion for Dried Ginseng, it is logically more reasonable that the criterion for Ginseng Extract which is manufactured using Dried Ginseng shall be '≥40mg/g'. Coincidentally, the deletion or amendment of this section may be a scheme to remove a concern expressed by a certain member country during the 26th session of CCPFV and the 36th session of CAC, i.e., 'Ginseng extracts might have concentrated bioactive components that were more related to drugs.'
	Switzerland	**Issue.** Comments concerning Ginsenoside Rb1 respectively Ginsenoside Rf are mentioned under 3.2.1.1. Dried Ginseng **Proposal**: ~~3.2.2 Ginseng Extracts~~ 3.2.~~2.1~~1.2 Ginseng Extracts (liquid form)

Chairs' suggestion	**Comment 1.** Criteria for quantifying individual ginsenoside and detecting other ginsenosides than Rb1 and Rf are the same as in the comments to Section 3.2.1(Dried Ginseng). **Comment 2.** It would be advisable to provide such data as demonstrate that the water insolubility of 5.0 proposed by China is proper. **Comment 3**. Ginseng extracts come in the process of manufacturing dried ginseng. According to a usual manufacturing process (processing method), the crude saponin (water-saturated 1-buthanol) content in ginseng extracts is two times as much as that of dried ginseng; so, it is proposed that the criterion for water-saturated 1-buthanol extracts should be 40 mg/g. Therefore, amendments to the current standard are made in the following manner. ~~3.2.2~~ 3.2.2.2 Ginseng Extracts ~~3.2.2.1~~ 3.2.2.2.1 Ginseng Extracts (liquid form) (a) Solids: no less than 60.0% (b) Water-insoluble solids: no more than 3.0% (c) Water-saturated 1-butanol extracts: no less than ~~70~~ 40mg/g (d) Ginsenoside Rb1: to be identified In addition, in case of the product manufactured from *P. ginseng* C.A. Meyer, ginsenoside Rf should be also identified.

3.2.2.2 Ginseng Extracts (powdered form)

Current Regional Standard		3.2.2.2 Ginseng Extracts (powdered form) (a) Moisture: no more than 8.0% (b) Water-insoluble solids: no more than 3.0% (c) Water-saturated 1-butanol extracts: no less than 70 mg/g (d) Ginsenoside Rb1: to be identified In addition, in case of the product manufactured from *P. ginseng* C.A. Meyer, ginsenoside Rf should be also identified.
Comments from participating countries	China	**Proposal.** (c) Water-saturated 1-butanol extracts: no less than 70 mg/g*(There is not relevant data in China, so please offer relevant department this data)* (d) Ginsenoside Rb1: ~~to be identified~~ no less than 0.2% (e) Ginsenoside Rg1 add Ginsenoside Re: no less than 0.3%
	Korea	**Proposal.** Delete (c) ~~(c) Water-saturated 1-butanol extracts: no less than 70 mg/g~~ Or, amend as follows; (c) Water-saturated 1-butanol extracts: no less than ~~70~~60mg/g **Rationale.** It is a logical contradiction that the content criterion for (c) Water-saturated 1-butanol extracts is the same in sections 3.2.2.1 Ginseng Extract (liquid type) and 3.2.2.2 Ginseng Extract (powdered type) of the current regional standard. Consequently, due to the same rationale mentioned for section, 3.2.2.1 in the above, this criterion should be deleted. If such a criterion is necessary at all, one higher than that for liquid type shall be provided, because the solid content criterion is different for liquid type (Solids≥60%) and powdered type (Moisture≤8% means Solids≥92%)). Therefore, given the amended criterion (≥40 mg/g) for liquid type, it is logically more reasonable that the criterion for powdered type shall be '≥60mg/g(exactly≥61.3mg/g)'

Chairs' suggestion	**Comments 1**. The same position in Section 3.2.2.1(Ginseng Extracts/liquid form) should be maintained. **Comments 2.** When the water-saturated 1-buthanol content of a liquid form of ginseng extracts is 40mg/g, this value is equivalent to the water-saturated 1-buthanol 60mg/g of a powdered form. Therefore, amendments to the current standard are made in the following manner. ~~3.2.2.2~~ 3.2.2.2.1 Ginseng Extracts (powdered form) (a) Moisture: no more than 8.0% (b) Water-insoluble solids: no more than 3.0% (c) Water-saturated 1-butanol extracts: no less than ~~70~~ 60 mg/g (d) Ginsenoside Rb1: to be identified In addition, in case of the product manufactured from *P. ginseng* C.A. Meyer, ginsenoside Rf should be also identified.

3.3 Definition of Defects

Current Regional Standard		3.3 DEFINITION OF DEFECTS The following defects shall be applied to the dried ginseng. (a) *Insect-damaged ginseng* : Ginseng that is visibly damaged by insects or contains dead insects (b) *Mouldy ginseng* : Ginseng that is visibly affected by mould
Comments from participating countries	China	**Proposal.** 3.3 DEFINITION OF DEFECTS (a) *Insect-damaged ginseng*: Ginseng that is visibly damaged by insects or contains dead insects (b) *Mouldy ginseng*: Ginseng that is visibly affected by mould (c) *Sick ginseng* : Ginseng that is visibly broken or has obvious scar (d) *Off-color ginseng* : Ginseng that had lost original color from the skin
	Switzerland	**Issue.** Needs further clarifications; is the dried steamed ginseng product included or excluded?
Chairs' suggestion		Defects should be applied to dried ginseng only. And dried ginseng includes dried steamed ginseng. China proposed definition of sick ginseng but dried ginseng may be also distributed in the broken type; therefore, it is advisable to provide reasonable (visual) data to comprise sick ginseng and off-colour ginseng as well. Therefore, this section remains unchanged for the time being, as stated in the current regional standard. 3.3 DEFINITION OF DEFECTS The following defects shall be applied to the dried ginseng. (a) *Insect-damaged ginseng* : Ginseng that is visibly damaged by insects or contains dead insects (b) *Mouldy ginseng* : Ginseng that is visibly affected by mould

3.4 CLASSIFICATION OF "DEFECTIVES"

A container that fails to meet one or more of the applicable quality requirements, set out in Sections 3.2 and 3.3, shall be considered a "defective".

No comments

3.5 LOT ACCEPTANCE

A lot can be considered as meeting the applicable quality requirements referred to in Sections 3.2 and 3.3, when the number of "defectives", defined in Section 3.4, does not exceed the acceptance number (c) of the appropriate sampling plan.

No comments

4 CONTAMINANTS

Current Regional Standard		**4. CONTAMINANTS** The products covered by this Standard shall comply with the maximum levels of the *Codex General Standard for Contaminants and Toxins in Foods* (CODEX/STAN 193-1995). The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.
Comments from participating countries	China	**Proposal.** The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission. <u>If there is not relevant regulations by the Codex Alimentarius Commission, the products covered by this Standard shall comply with the levels of regulation in Section 4.1.</u> 4.1 Maximum residue limit <u>(a) HCH: no more than 0.10 mg/kg</u> <u>(b) DDT: no more than 0.10 mg/kg</u> <u>(c) Quintozene: no more than 0.10 mg/kg</u> <u>(d) Heptachlor no more than 0.02 mg/kg</u> <u>(e) Aldrin & Dieldrin no more than 0.02 mg/kg</u> <u>(f) Cypermethrin no more than 0.20 mg/kg</u> <u>(g) Malathion no more than 0.50 mg/kg</u> <u>(h) Parathion no more than 0.05 mg/kg</u> <u>(i) Azodrin no more than 0.02 mg/kg</u> <u>(j) Dimethoate no more than 0.05 mg/kg</u> <u>(k) Methamidophos no more than 0.05 mg/kg</u> <u>(l) Carbofuran no more than 0.10 mg/kg</u> <u>(m) Dursban no more than 0.50 mg/kg</u>
Chairs' suggestion		Establishing MRL for pesticides is entrusted to CCPR. CCPR is establishing pesticide MRL for ginseng and has already adopted MRL for two pesticides (difenoconazole and azoxystrobin). Still, many pesticides are waiting for their evaluation conducted by JMPR. Therefore, this section remains unchanged, as stated in the current regional standard.

5. HYGIENE

5.1 It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the ~~*Recommended International Code of Practice -*~~ *General Principles of Food Hygiene* (CAC/RCP 1-1969), and other relevant Codex texts, such as Codes of Hygienic Practice and Codes of Practice.

5.2 The products should comply with any microbiological criteria established in accordance with the *Principles <u>and Guidelines</u> for the Establishment and Application of Microbiological Criteria ~~for~~ <u>Related to</u> Foods* (CAC/GL 21-1997).

No comments

6. LABELLING

The products covered by this Standard shall be labelled in accordance with the *Codex General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985). In addition, the following specific provisions apply:

No comments

6.1 NAME OF THE PRODUCT

Current Regional Standard		6.1 NAME OF THE PRODUCT The name of the products defined in subsections 2.2.1.1, 2.2.1.2, 2.2.2.1 and 2.2.2.2 shall be *Dried Raw Ginseng*, *Dried Steamed Ginseng*, *Raw Ginseng Extract*, and *Steamed Ginseng Extract*, respectively. In this case, the products manufactured with *P. ginseng* C.A. Meyer can be named *White Ginseng*, *Red Ginseng*, W*hite Ginseng Extract*, and *Red Ginseng Extract*.
Comments from participating countries	Switzerland	**Issue.** Further clarification concerning the names «white» and «red» ginseng is needed. On which bases should these names be used? Are they used as synonyms and of which product names – products with or without steaming process?
Chairs' suggestion		White or Red is a term referring to the color of products based on the steaming process. *White ginseng* and *Red ginseng* are names used for thousands of years to discriminate between products manufactured with *P. Ginseng* C.A. Meyer and the ones with the other ginseng species.

6.2 NAME OF THE GINSENG SPECIES

Current Regional Standard		6.2 NAME OF THE GINSENG SPECIES All ginseng products shall be labelled the scientific or common name of the ginseng that is used as raw material. The common names of the ginseng shall be declared in accordance with the law and custom of the country where the product is consumed, in a manner not to mislead the consumer.
Comments from participating countries	Switzerland	**Proposal.** "All ginseng products shall be labelled <u>with</u> the scientific or common name of the ginseng that is used as raw material. The common names of the ginseng <u>species</u> shall be declared in accordance with……"
Chairs' suggestion		Editorial amendments are made in the following manner. 6.2 NAME OF THE GINSENG SPECIES All ginseng products shall be labelled <u>with</u> the scientific or common name of the ginseng that is used as raw material. The common names of the ginseng <u>species</u> shall be declared in accordance with the law and custom of the country where the product<u>s</u> ~~is~~ <u>are</u> ~~consumed~~ <u>distributed,</u> in a manner not to mislead the consumer.

6.3 COUNTRY OF ORIGIN

Current Regional Standard		6.3 COUNTRY OF ORIGIN The country of origin of the product and/or raw material shall be declared if its omission is likely to mislead or deceive the consumer.
Comments from participating countries	EU	**Proposal.** Provision 6.3 (Country of origin) should be deleted as it is contained in section 4.5 of the *Codex General Standard for the labelling of Prepackaged Foods*(CODEXSTAN1-1985).

Chairs' suggestion	~~Since Section 4.5 of General Codex Standard for the Labeling of Prepackaged Foods already has the sentence of "if its omission is likely to mislead or deceive the consumer," so it is not necessary to repeat. Yet, deceiving the country of origin for raw ginseng takes place frequently in the international ginseng market.~~ Section 4.5 of GSLPF(*General Codex Standard for the Labeling of Prepackaged Foods*) concerns the labeling of the country of origin of the product. However, in the international market of ginseng, deceptions are occurring as frequently in connection with the country of origin of the product itself as with the country of origin of raw materials for the product. Consequently, this section need be amended in such a manner that the country of origin of not the product but raw materials should be mandatorily labeled. Therefore, amendments should be made in such a manner as to label the country of origin for raw ginseng. 6.3 COUNTRY OF ORIGIN The country of origin of ~~the product and/or~~ ginseng root used as raw material of the product shall be declared ~~if its omission is likely to mislead or deceive the consumer.~~

6.4 LABELLING OF NON-RETAIL CONTAINERS

Current Regional Standard		6.4 LABELLING OF NON-RETAIL CONTAINERS Information about non-retail containers shall be given on the container or in accompanying documents, except that the name of the product, lot identification and the name and address of the manufacturer, packer or distributor, as well as storage instructions, shall appear on the container. However, lot identification, and the name and address of the manufacturer, packer or distributor may be replaced by an identification mark, provided that such a mark is clearly shown in the accompanying documents.
Comments from participating countries	Switzerland	**Proposal.** "However, lot identification, and the name and address of the manufacturer, packer or distributor may be replaced by an identification mark, provided that ~~such a mark~~ this is clearly shown in the accompanying documents."
Chairs' suggestion		Editorial amendment proposed by Switzerland is accepted.

6.5 OTHER LABELLING REQUIREMENTS

Except when otherwise specified by national legislation, the products should have a clear marking to indicate that they are not intended for medicinal purposes, including other labelling(s) stipulated by any country where ginseng products are distributed.

No comments

7. METHODS OF ANALYSIS AND SAMPLING

Current Regional Standard	7.1 DETERMINATION OF MOISTURE According to AOAC 925.45. 7.2 DETERMINATION OF SOLID According to AOAC 925.45 and calculated by subtracting the content of water from 100%. 7.3 DETERMINATION OF ASH According to AOAC 923.03. 7.4 DETERMINATION OF WATER-INSOLUBLE SOLIDS According to the method described in Annex A. 7.5 DETERMINATION OF WATER-SATURATED 1-BUTANOL EXTRACTS According to the method described in Annex B. 7.6 IDENTIFICATION OF GINSENOSIDES Rb1 AND Rf According to the method described in Annex C.

<table>
<tr><td rowspan="2">Comments from participating countries</td><td>EU</td><td>Comment. The methods of analysis should be presented in the standard table format with the four columns: Provision, Method Principle and Type. Preferably methods elaborated by international organizations should be used. Normally, there should be AOAC or ISO methods available for moisture, solids, ash and water insoluble solids. For butanol extracts and ginsenosides probably specific methods for ginseng need to be developed.
Finally, the standard tables for sampling plans need to be attached to the standard.</td></tr>
<tr><td>Korea</td><td>Issue. The section of Methods of Analysis in the current standard was endorsed in the 29th session of CCMAS. AOAC methods are proposed for the determination of moisture, solids and ash; and the methods of analysis stated in the Annexes are proposed for the determination of water-insoluble extracts, water-saturated 1-butanol and the identification of ginsenosides.
Nevertheless, CCMAS approved all these methods of analysis as type-IV because AOAC methods are for sugar and flour and the methods of analysis stated in the Annexes have insufficient test results for verifying their validity.
Proposal. It is necessary for a worldwide standard to suggest an analysis method which meets the criteria required by CCMAS. To do that, Korea has prepared Standard Operating Procedure for Analysis for each quality factor on the basis of the methods of analysis suggested in the current regional standard and is conducting a preparatory validation test on the Standard Operating Procedure in cooperation with domestic institutions specializing in ginseng.
A draft amendment of the methods of analysis is to be suggested around the coming March and April when the preparatory validation test will be completed. Based on the amendment, an inter-laboratory test among member countries for verifying its validity will be carried out in which at least 8 institutions shall attend, according to the requirements of CCMAS.
In this connection, Korea expects that participants in the e-WG will attend the inter-laboratory test as well.</td></tr>
<tr><td colspan="2">Chairs' suggestion</td><td>Comment 1. Since a sampling plan is described in the guidelines below (CAC/ GL 50-2004), the following section shall be newly established.
Comment 2. The analysis method of the current regional standard was approved as Type-IV; in order for the method to be approved as Type-I, inter-laboratory tests among member countries are required. In order to minimize errors between laboratories, SOP(Standard Operating Procedure) will be offered in the next month(May 2014) and we ask many countries to participate in the validation tests.
<*Current Regional Standard*>
<table>
<tr><th>PROVISION</th><th>METHOD</th><th>PRINCIPLE</th><th>TYPE</th></tr>
<tr><td>Moisture</td><td>AOAC 925.45</td><td>Gravimetry, drying at atmospheric pressure</td><td>IV</td></tr>
<tr><td>Solids</td><td>AOAC 925.45 and calculated by subtracting the content of water from 100%</td><td>calculation</td><td>IV</td></tr>
<tr><td>Ash</td><td>AOAC 923.03</td><td>Gravimetry, after ashing at 550℃</td><td>IV</td></tr>
<tr><td>Water-insoluble Solids</td><td>described in Annex A</td><td>Gravimetry</td><td>IV</td></tr>
<tr><td>Water-saturated 1-butanol extracts</td><td>described in Annex B</td><td>Gravimetry</td><td>IV</td></tr>
<tr><td>Identification of ginsenosides Rb1 and Rf</td><td>described in Annex C</td><td>TLC or HPLC</td><td>IV</td></tr>
</table>
</td></tr>
</table>

<*Worldwide Standard*>

7. METHODS OF ANALYSIS AND SAMPLING

7.1 METHODS OF SAMPLING

Sampling shall be in accordance with the *Codex General Guidelines on Sampling* (CAC/GL 50-2004)

7.2 METHOD OF ANALYSIS

PROVISION	METHOD	PRINCIPLE	TYPE
Moisture	described in Annex A	Gravimetry, drying at atmospheric pressure	I
Solids	described in Annex B	calculation	I
Ash	described in Annex C	Gravimetry, after ashing at 550℃	I
Water-insoluble Solids	described in Annex D	Gravimetry	I
Water-saturated 1-butanol extracts	described in Annex E	Gravimetry	I
Identification of ginsenosides Rb1 and Rf	described in Annex F	TLC or HPLC	I

SECOND ROUND

to prepare the Proposed Draft Standard for Ginseng Products

Comments submitted by EU and IADSA

in response to the request for comments on the 1st working draft,

and Chair's suggestion to coordinate

EU

Proposal 1

Concerning the methods of analysis, I get the impression from chair's comments and the latest version of the draft standard that commodity specific methods will be recommended in separate annexes for all parameters. However, in accordance with the General Criteria for the Selection of Methods of Analysis in the Procedural Manual, official methods developed by international organisations should be preferred. So I continue to think that we should make an effort to refer to the relevant AOAC and/or ISO methods at least for moisture, ash and solids.

Chair's suggestion
In the current Regional Standard, methods of analysis for moisture, solids and ash adopts that of AOAC while analysis methods for water-insoluble solids, water-saturated n-butanol extracts and ginsenosides are stipulated in the annexes, since these methods have not yet been developed by international organizations. The analysis methods in the Proposed Draft Standard are suggested in the same way as in the current Regional Standard. But the annexes for analysis methods for water-insoluble solids, water-saturated n-butanol extracts and ginsenosides have been prepared in the form of SOP(Standard Operation Procedure) with concrete and detailed descriptions on each method in order to raise its accuracy (reproducibility, repeatability, etc.). Also, references for moisture and ash analysis are attached. For reference, the Republic of Korea will conduct an inter-laboratory validation test on the methods of analysis with the involvement of at least 8 institutions and submit the test results to CCMAS.

Proposal 2

Concerning the methods of sampling, the last session of CCMAS concluded as follows (first bullet point of paragraph 83 of the report of 35th CCMAS):

"Commodity committees should be discouraged from simply referencing the Guidelines on Sampling (CAC/GL 50-2004), but be encouraged to develop their own sampling plans and in doing so should use CAC/GL 50-2004 and the Principles for the Establishment or Selection of Codex Sampling Procedures (Procedural Manual). Should commodity committees not be in a position to do so, CCMAS would be able to elaborate such sampling plans provided that the commodity committees provided information on the AQL or LQ. In cases where committees were no longer active, CCMAS could undertake the development of sampling plans where necessary."

So CCMAS may send the draft standard back to us if we simply refer to CAC/GL 50-2004 without proposing any sampling plan. Isn't the sampling plan that we have inserted in other PFV commodities not suitable for ginseng?

Chair's suggestion
Sampling plans that are commonly used in other product standards developed by CCPFV will be included in the Proposed Draft Standard.

IADSA

TITLE OF THE STANDARD

IADSA notes that while the 1st Working Draft of the Proposed Draft Standard for Ginseng Products refers in its title to '"Ginseng Products", it focuses only on *Panax ginseng* C.A.Meyer and *P.quinquefolius* L. However, other existing *Panax* species of Ginseng, such as *Panax japonicus* or *Panax notoginseng*, are not included in the Standard. Furthermore, *Eleutherococcus senticosus* (also known as 'Siberian Ginseng') is also not included in the Standard.

IADSA also notes however that *Panax japonicus* and *Panax notoginseng* would be traded internationally in lower volumes than *Panax ginseng* C.A.Meyer and *P.quinquefolius* L. On the other hand, it is understood that *Eleutherococcus senticosus* is traded in potentially significant volumes. However, although members of the same family (*Araliáceae*), Ginseng and 'Siberian Ginseng' are plants of two different plant genera: genus Ginseng (*Panax* L.) and genus Eleutherococcus(*Eleutherococcus*).

IADSA would therefore like to suggest to the eWG to consider the following amendment to the title of the Standard in order to avoid any potential trade barriers:

~~Regional~~ Standard for Ginseng Products based on Panax Ginseng C.A. Meyer and Panax quinquefolius L.

Chair's suggestion

In the course of developing the Regional Standard, trade volume of *P. japonicas* could not be verified nor was it suggested as necessary. Nevertheless, if standards for this species are proved to be necessary for international trade and its quality factor is properly presented, the species may be included in the Proposed Draft Standard.

P. notoginseng was also reviewed in the process of developing the Regional Standard. However, it was not included in this Standard based on the statement from China (the main producer of this species) that while this species is traded in the international market, it is only used medically and not as food.

Eleutherococcus senticosus is species completely different from that the genus *Panax*. Although it is distributed in some countries in the name of Siberian ginseng, it is misleading the consumers to group genus *Eleutherococcus* as ginseng since the origin of the word 'ginseng' is '*Panax*.' Besides, covering different genus of plants in a same standard goes beyond the principles of establishing standard as well as all botanical reason.

Therefore, the title of the Standard should be comprehensive as the current title so as to cover all species under the genus *Panax*. If it should be necessary to include other species besides *P. ginseng* and *P. quinquefolius* and their quality factors are properly presented, it will be possible to include other ginseng products of the genus *Panax* in the Standard through future revision of the standard.

2.1 PRODUCT DEFINITION

IADSA notes that section 2.1 Product Definition refers to ginseng roots. However, since in different parts of the world the use of specific parts of roots (such as rootlets and hair-roots) and the use of leaves is also allowed, IADSA proposes that all parts of roots and the use of leaves of Ginseng are incorporated in the product definition and across the Standard.

IADSA would therefore like to propose to the eWG to amend the definition in section 2.1 "Product Definition" as follows:

The compulsory ingredient of ginseng product is all parts of fresh ginseng roots and leaves suitable for eating, derived from Panax ginseng C.A. Meyer and P. quinquefolius L., cultivated for commercial purposes and used for foods.

Chair's suggestion

Although the use of 'ginseng leaves' as food material is allowed in some parts of the world, the history of using them for food or the study results validating such use are inadequate to universally apply the use of 'ginseng leaves' for food to all countries.

Types of ginseng products covered in this Standard are dried ginseng and ginseng extracts that are made only from 100% pure ginseng roots. However, ginseng leaves are mainly used as supplementary materials for secondary ginseng processed foods and are not used for products covered in this Standard. If products made from ginsengs leaves (as basic or optional ingredients) and distributed under the sole Standard, as dried ginseng or ginseng extract, this will be a practice deceiving the consumers.

Therefore, while it is acceptable to insert the phrase, 'all parts of,' in the Standard, inserting 'leaves' requires more careful deliberation.

3.2 QUALITY FACTORS

IADSA would like to propose that in section 3.2.2.1 "Dried Ginseng" (d). Ginsenoside Rg_1 should be identified too.

Chair's suggestion

As the two most representative components of ginseng products, ginsenoside Rb1 and Rg1 had been both suggested as quality factors in the course of developing the Regional Standard. Considering the matter of identifying ginsenoside Rg1 as well in terms of analysis, there is no problem in doing so because both components can be identified in one chromatogram (one trial of analysis). However, since some member countries have expressed concerns over the analysis expense and suggested that identifying Rb1 is sufficient for ginseng products, CCASIA concluded ginsenoside Rb1 as a quality factor to alleviate the burden of expense.

Nevertheless, if the member countries agree to adding identifying ginsenoside Rg1 as a quality factor, this may be applied to the Standard.

4. CONTAMINANTS

IADSA proposes that the applicable maximum limits for pesticides residues for ginseng products are explicitly referenced in the Proposed Draft Standard for Ginseng Products.

In this regard, IADSA proposes that the Codex Committee on Pesticides Residues is consulted taking into account the current discussions in this area.

Chair's suggestion
For many years, CCPR has been working on establishing criteria for pesticides residues for ginseng products and have already set the MRLs for two types of pesticides, difenoconazole and azoxystrobin. (Please refer to the Chair's suggestion on Section 4 in the email sent to you on April 8.)

ANNEX III

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

CHAIR
Dr. Kyujai HAN
Senior Research Scientist
Korea Food Research Institute
Republic of Korea
Phone: +82-31-780-9120
Email: hankj@kfri.re.kr

Mr Kangkook Kim
Codex contact point of the Republic of Korea
General Division of International Cooperation
Ministry for Food, Agriculture, Forestry and Fisheries
Republic of Korea
Phone: +82-44-201-2021
Email: codex1@korea.kr

Dr. Jeonghae Rho
Associate Professor
School of Culinary Arts
College of Hotel and Curinary Arts
Woosong University
Republic of Korea
Email: drno@wsu.ac.kr

CO-CHAIR
Kevin Smith
National Manager
Processed Products Program
Agrifood Division
Agrifood, Meat & Seafood Safety Directorate
Canadian Food Inspection Agency
Canada
Phone: +1 (613)773-6225
Email: Kevin.Smith@inspection.gc.ca

ARGENTINA - ARGENTINE

Punto Focal - Contact Point
Codex Alimentarius - ARGENTINA
Direccion Nacional de Relaciones Agroalimentarias Internacionales
Ministerio de Agricultura, Ganaderia y Pesca
Buenos Aires
Phone: +54 11 4363-6290/4363-6329
Email: codex@minagri.gob.ar

CHINA - CHINE

Mr Guiling Yang
China Codex Contact Point
Ministry of Agriculture
Beijing, 100044
Phone: +86-10-59199375
Fax: 86-10-59199377, 59193315
Email: codex@agri.gov.cn

Mr Lianxue Zhang
Jilin Agricultural University
South of East Ring Rd.
Changchun, 130118
Phone: +86-13844847715
Email: zlxbooksea@163.com

Mr Jia Feng
Jilin Ginseng and Antler office
Jilin Agricultural Commission
Changchun, 130118
Phone: +86-13756066110
Email: srbfj@163.com

Mr Yingping Wang
Institute of Special Animal and Plant Sciences of China Academy of Agricultural Sciences (CAAS)
No.12 Zhongguancun South St., Haidian District Beijing
Phone: +86-13843241005
Email: yingpingw@126.com

Dr. Yueru Li
Centre of Quality Standard and Testing Technique for Agri-Product
Jilin Agricultural University
Changchun, 130118
Phone: +86-18643107215
Email: lyrcszx6407@126.com

EUROPEAN UNION
UNION EUROPÉENNE
UNIÓN EUROPEA

Mr Risto Holma
European Commission
Health and Consumers Directorate-General
Brussels - Belgium
Phone: +32-2-299 86 83
Email: risto.holma@ec.europa.eu

Ms Bernadette Klink-Khachan
EU CODEX Contact Point
European Commission
DG Health and Consumers Directorate-General
Unit G06: Multilateral International Relations
Rue Froissart 101
1049 Brussels
Phone: +32 2 295 79 08
Email: codex@ec.europa.eu

GHANA

Ms Joyce Okoree
Manager
Codex Contact Point
Ghana Standards Authority
P.O. BOX MB 245
Accra
Phone: + 233 244 381 351
Email: codex@gsa.gov.gh

INDONESIA - INDONÉSIE

Ms Enny Ratnaningtyas
Director of Beverage and Tobacco Industry
Ministry of Industry, Indonesia
Phone: +62 21 5747043
Email: codex_kemenperin@depperin.go.id

SERBIA - SERBIE

Mrs Zorica Knezevic
Senior Advisor
Division of International Cooperation and European Integration
Institute for Standardization of Serbia
Phone: +381 11 6547 096
Email: iss-international@iss.rs

SWITZERLAND - SUISSE - SUIZA

Ms Franziska Franchini
Scientific Officer
Federal Office of Public Health (FOPH)
CH-3003 Bern
Phone: +41 31 324 93 71
Email: franziska.franchini@bag.admin.ch

Mr Martin Müller
Swiss Codex Contact Point, Scientific Advisor
Division of International Affairs
Federal Office of Public Health
CH-3003 Bern
Phone: +41 31 3249316
Fax: +41 31 3221131
Email: martin.mueller@bag.admin.ch

UNITED STATES OF AMERICA
ÉTATS-UNIS D'AMÉRIQUE
ESTADOS UNIDOS DE AMÉRICA

Mr Dorian Lafond
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250
Email: Dorian.lafond@usda.gov

Mr Paul South
Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD 20740
Phone:301 436-1640
Email: Paul.south@fda.hhs.gov

Ms Jasmine Curtis
Program Analyst
USDA/FSIS/USCODEX OFFICE
Room 4865
Phone: +1-202-690-1124
Email: Jasmine.Curtis@fsis.usda.gov
Doreen.Chen-Moulec@fsis.usda.gov
Uscodex@fsis.usda.gov

INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS
ORGANISATIONS NON-GOUVERNEMENTALES INTERNATIONALES
ORGANIZACIONES INTERNACIONALES NO GUBERNAMENTALES
INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS

Ms Cynthia Rousselot
Director of Scientific and Technical Affairs
Rue de l'Association 50
1000, Brussels
Belgium
Phone: +32 2209 1155
Email: cynthiarousselot@iadsa.org

Mr David Pineda Ereño
IADSA Expert
Rue de l'Association 50
1000, Brussels
Belgium
Phone: +32 2 209 11 55
Email: Davidpineda@iadsa.org

ANNEX IV

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in underlined/bold font and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied/pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.