CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 12 **CAC/39 CRD/10**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

39th Session

FAO Headquarters, Rome, Italy, 27 June – 1 July 2016

MATTERS REFERRED TO THE COMMISSION BY CODEX COMMITTEES AND TASK FORCES

COMMENTS

B. MATTERS FOR INFORMATION

Codex Committee on General Principles (CCGP)

(Comments of India)

INDIA

Para 4: JEMNU as the primary source of scientific advice

India supports considering JEMNU as the primary source for seeking scientific advice in the Codex Committee in Nutrition and Foods for Special Dietary Uses (CCNFSDU).

Rationale: FAO and WHO expert bodies are generally recognised as being transparent, and unbiased in their approach, and are largely acceptable to Codex member countries world over. These scientific bodies of FAO/WHO involve experts from different countries to participate in risk assessment process and developing appropriate scientific opinion on issues. Besides, other committees of the Codex requiring scientific advice for standards development primarily seek such information from FAO/WHO scientific bodies like JECFA, JMPR, JEMRA etc. Therefore, the scientific issues under consideration of CCNFSDU should primarily be referred to JEMNU for risk assessment/soliciting scientific information.

B. MATTERS FOR ACTION

Codex Committee on Fish and Fishery Products (CCFFP)

(Comments of Kenya and Nigeria)

KENYA

The Committee agreed to suspend physical meetings of the Committee and to continue working by correspondence.

COMMENT: We support the bulk of the work to be done electronically to minimize physical meetings. There is need to have at least one physical working group to finalize the work before submission to CAC for adoption.

NIGERIA

Nigeria does not support the CCFFP decision to suspend physical meetings of the Committee and to continue working by correspondence.

Rationale

Not all countries have the same level of technological development and organization of their Codex Committee. Alternatively CCFFP should consider hosting its sessions biennially.

Codex Committee on Milk and Milk products (CCMMP)

Information on the technological justification of the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content (Analysis of the replies to CL 2015/26-CAC)

(Comments of Kenya, India and the United States)

KENYA

Information on the technological justification of the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content (Analysis of the replies to CL 2015/26-CAC) is presented in the annex to this document.

COMMENT: Kenya proposes Option 2 which states as follows: " To request CCFA to address this matter in the context of its work on alignment of the food additive provisions of commodity standards and relevant provisions of the *General Standard for Food Additives* (GSFA)".

INDIA

Para 17:

Option 1: India agrees with option 1, that the matter should be forwarded to CCMMP to prepare a proposal for amendment of the Standard for Mozzarella.

Rationale:

The Codex Alimentarius Procedural Manual, in the Section 'Relations between Commodity Committees and General Subject Committees' says 'When an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the Committee on Food Additives for endorsement and inclusion in the General Standard for Food Additives'.

Option 2: India is of the view that the technological justification for the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content should, therefore, be ascertained by the Codex Committee on Milk and Milk Products which is the relevant commodity committee in this case. The recommendations of the CCMMP may then be sent to the CCFA for endorsement as per the above Codex procedure.

UNITED STATES OF AMERICA

We appreciate the opportunity to provide the following recommendation relative to CX/CAC 16/39/13, specific to the section on: Information on the technological justification of the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content.

The preferred option outlined at the conclusion of this document is Option 1: To request CCMMP to consider this matter and prepare a proposal for amendment of the *Standard for Mozzarella*. Furthermore, we also recommend that the scope of this work be limited to resolution of this particular issue and not include a re-opening of the entire standard.

Report and analysis of responses to CL 2016/6-MMP: Draft General Standard for Processed Cheese

(Comments of Costa Rica/Dominican Republic/ Uruguay and India)

Costa Rica, Dominican Republic and Uruguay

English

1. BACKGROUND

In 2012, at its 35th session the Codex Alimentarius Commission (CAC) agreed to circulate a letter asking Members to identify the gaps in the safety and quality provisions of Codex texts that would justify new work on processed cheese.

In 2013, the CAC agreed to establish an electronic Working Group, co-chaired by New Zealand and Uruguay to conduct a feasibility study and prepare a document on a new draft standard for processed cheese. In 2014, the CAC agreed to initiate new work on this standard, reactivate the CCMMP to work initially correspondence and create a working group (PWG) led by New Zealand and co-chaired by Uruguay, in order to prepare a draft standard for circulation and comment at Step 3.

In July 2015 the CAC, recognizing the progress made in the field, consumer information and labeling, agreed to adopt the draft at Step 5 and requested New Zealand to convene a PWG and consider the possibility of organizing a physical working group to study the outstanding issues identified in the CL 2015/15.

The PWG met in Montevideo, Uruguay in December 2015 with the participation of 19 member countries, a member organization and two organizations as observers. Among the most important agreements, we can mention that there was agreement on the fact that only cheese must be the main ingredient in all three categories of raw materials; categorize the melted / processed cheese according to the raw materials used and place these categories in the section of raw materials; maintain a table in the specifications of composition, in accordance with similar provisions in other standards for dairy products; notifiable percentage of cheese variety denomination; mandatory declaration of cheese (section 7.3) for the products included in the categories indicated in sections 3.1.1, 3.1.2 and 3.1.4. (Para. 10, 11, 16, 18, 28 and 30. CL 2015/34-MMP-Appendix II. It is important to note that the only point of the scope of the standard on which an agreement could not be reached, was the one regarding stabilizers, which remained between brackets.

In response to CL 2015/34-MMP Request for Comments at Step 6 response from 21 countries, one member organization and one observer organization was received. The answers to that circular letter were compiled by the Secretariat in New Zealand for CCMMP, who analyzed the comments received. The report and recommendations were sent on a new circular letter (CL 2016/6-MMP April 2016) with a deadline for comments until May 13, 2016, on the understanding that during the 39th session of the Commission the report and the comments received in response to this Circular Letter will be discussed.

These observations were again compiled by New Zealand, who prepared the report contained in document CX / CAC 16/39/13 Add. 1 to make it available to countries on June 2 in its English version.

2 - CONSIDERATIONS

In CX / CAC 16/39/13 Add. 1 New Zealand made the following key questions, about which we transmit our view.

(I) Is "processed cheese" a product that is amenable to standardization?

Yes. There were standards that sustained the manufacture of this product; these were revoked by the CAC in 2012. Nowadays, there are products with different percentages of melted cheese, and products with non-dairy ingredients using the name, which compete in the market with the product and do not meet the definitions of the standard on Use of Dairy Terms. This situation misleads consumers because of their ignorance about cheese content of the products, also creating unfair competition between manufacturers and competitive disadvantages for those manufacturers who do use cheese in the development of these products.

In addition, the progress made to date shows that processed cheese is a product that could be subject of standardization.

(II) What would be the rationale and justification for continuing the work, taking into account:

- **difficulties on securing consensus on core issues;**

It is true that some differences remain, but they decreased significantly when the scope of the standard was limited, giving more opportunities for a future agreement. The highlight of the discussion regarding composition was only for one of the four categories defined at the last meeting of the physical group, in which it was proposed to include high humidity spreadable cheese (category 3.1.3 of Section 3 of the Circular Letter CL2015 / 34-MMP). We can note that there was consensus on the remaining three categories (3.1.1, 3.1.2 and 3.1.4), demonstrating the progress made.

- **lack of evidence of trade problems**

The reasons for trade problems were already discussed. If we compare the expressions made in the opportunity of the discussion of this standard and the expressions used in documents justifying the development of other standards, they are similar. For example, the need of a clear definition and description (labeling) in order to prevent unfair trade practices and consumer confusion - CX / CAC 14/37/9 - Annex 2.

Products under the same name may include, depending on the country, products with non-dairy ingredients, food preparations, cheese spreads, etc. This inclusion, prejudices products with high content of cheese, with respect to those who are not, being both offered to the consumer under the same labeling without more information, not allowing a clear distinction between them. This may represent unfair competition in trade.

A similar argument was made in the document referred to in paragraph 1, for which the justification seeks to differentiate a new product from an existing one which previously traded. In this case, new products compete unfairly with a traditional dairy product of better nutritional characteristics.

- **absence of any food safety issues relating to this product;**

It has been expressed from the beginning of the request that the need of the standard is not a food safety issue. We understand that identity and quality standards not only seek to solve problems of food safety of products, but they allow to define the identity and quality of the products with which we work, and in this sense, new jobs and revisions continue to be approved in Codex Product Committees. If we analyze the work being carried out at present, there are studies that have been approved solely for the purpose of reviewing parameters that lead to distinguish between two different qualities grades of safe products. The identity of the products is as relevant in the field of Codex standards that in some of them sensory parameters are included to define two qualities of a safe product.

• the Commission's broader commitment to give priority to food safety related work

The CAC has in its target two key priorities that are at the same level: ensure food safety and fair practices in trade; in this case, the justification of the need for this standard relates to fair practices in trade.

In this line of working in both safety and identity and quality of products, to facilitate trade is that it has been recently approved the establishment of the Commodity Committee "Committee of Spices and Culinary Herbs" and other works in identity and quality standards of products in various Codex Commodity Committees and even in CCMMP.

• the Commission's recognition of the need to make a "final effort" to determine if the development of international standard(s) for processed cheese would be feasible; and

Based on the arguments raised to the above questions, we consider that the need for this standard is justified. Analyzing the comments in the report, only two countries expressed their view to discontinue work on the standard.

• the resources required for any further physical working group or committee meetings

The CCMMP is working electronically on this standard and other standards presented in Step 5 at this meeting. In the work plan, it was indicated that the two jobs would end in 2016. Both standards have some points in dissent that deserve further work.

It is important to consider that participation through electronic means is accessible to a greater number of countries, therefore we should urge countries to use of this tool. Physical work limits participation to countries with lower incomes and higher cost or participation by citizen. If we consider the economy of the countries concerned in the standard, they are mostly developing countries, where the possibility of being present at meetings of the Codex becomes more difficult.

Electronic work might be slower as it require more time for exchange.

(III) If there were to be no international standard, what are the alternative options open to members to deal with the diverse national preferences with regard to product composition and use of stabilizers and thickeners, bearing in mind the wide range of products in trade?

Establishing clearly the minimum percentage of cheese that processed cheese must contain, there would not be need of additional regulation for other products, since they could not be called this way. This would solve the problem of unfair practices in trade and would avoid misleading consumers.

The use of stabilizers and thickeners is ruled by Codex Stan 192-1995. To define the stabilizers and thickeners that can be used in processed cheese, we can consult IDF, taking advantage of its valuable experience on the subject. This organization could make a proposal with the stabilizers and thickeners to be used in these products.

In addition, the proposed standard would not restrict the development of products, it only seeks to clarify the cases in which the products can be named according to the use of dairy terms standard.

CONCLUSION:

While the CAC at its meeting of 2015 confirmed that the deadline for completion of work is 2016, currently only two points remain to be solved. We understand based on the points outlined above, the need for the standard is sufficiently explained and justified, and does not differ from justifications used for other standards, which have not been questioned at the time of approval.

The work done electronically, the level of participation and response is similar to other standards being submitted in Step 5 and for which no physical work is requested.

Being the Codex an organ that bases its decisions on science, the evaluation process and criteria to be taken into account by the Executive Committee to make recommendations to the Commission and the latter decision by the Commission should be done homogeneously in all cases.

Moreover, we understand that continuing the work in electronic form by the Committees is feasible. Although it will require more time to reach consensus, it would allow participation of a greater number of countries (just analyze the availability of Internet access, for sending and receiving documents electronically, and the availability and cost of traveling to send a delegate to a meeting).

Finally, Objective 4.1 of the Strategic Plan 2014-2019 proposes within its implementation, the use of new technologies to improve member participation in Codex activities. It is therefore an opportunity for the Commission to enable the Committee of Milk and Milk Products to continue working in the two standards in this way. We understand this also would give the possibility to analyze various aspects of electronic work on two standards whose major interest in their creation arise from different regions.

RECOMMENDATION

The main point of the remaining discussion is the one on stabilizers. To facilitate discussion of it, it could be requested the valuable support of the IDF, so that, from its experience it could make a proposal regarding the stabilizers to be used in processed cheese.

In addition, and given that an agreement on the composition of "high humidity spreadable cheese" has not been reached, this product may be excluded from the scope of the standard, or could be subject of a specific standard for it.

Español

1 - ANTECEDENTES

En la 35ª sesión de la Comisión del Codex (CAC) celebrada en el 2012 se acordó circular una carta circular para solicitar a los Miembros que identificaran las lagunas existentes en las disposiciones sobre inocuidad y calidad de los textos del Codex que justificarían la conveniencia de emprender nuevos trabajos sobre el queso fundido. En el 2013, la CAC acordó establecer un Grupo de trabajo electrónico, copresidido por Nueva Zelandia y Uruguay para realizar un estudio de factibilidad, y que prepararía un documento relativo a un nuevo proyecto de norma para el queso fundido; en 2014 la CAC acordó iniciar un nuevo trabajo sobre dicha norma, reactivar el CCMMP para que trabajase, inicialmente, por correspondencia y crear un grupo de trabajo presencial (GTp) dirigido por Nueva Zelandia y copresidido por Uruguay, con el fin de preparar un anteproyecto de norma para distribuirlo y recabar observaciones en el trámite 3.

En julio 2015 la CAC, tras reconocer los avances realizados respecto al ámbito, información al consumidor y etiquetado, convino en adoptar el anteproyecto en el trámite 5 y solicitó a Nueva Zelandia que convocara un GTp y examinara la posibilidad de organizar una reunión presencial para estudiar las cuestiones pendientes señaladas en la circular CL 2015/15.

El GTP se reunió en Montevideo, Uruguay en diciembre de 2015 en el que participaron 19 países miembros, 1 organización miembro y 2 organizaciones en calidad de observadores. Entre los acuerdos más importantes se puede mencionar: Hubo acuerdo con respecto a que el queso deberá constituir el único ingrediente principal en las tres categorías de materias primas; categorizar el queso fundido/procesado de acuerdo con las materias primas utilizadas y colocar dichas categorías en la sección de materias primas; mantener una tabla en las especificaciones de composición, de conformidad con disposiciones similares en otras normas para productos lácteos; declaración obligatoria del porcentaje de queso con denominación de variedad; declaración obligatoria del contenido de queso (sección 7.3) para los productos incluidos en las categorías indicadas en las secciones 3.1.1, 3.1.2 y 3.1.4. (párr. 10, 11, 16, 18, 28 y 30. CL 2015/34-MMP-Apendice II. Es importante mencionar que el único punto de la norma que no se pudo consensuar en el ámbito de la reunión fue lo referente a estabilizantes, que quedó entre corchetes.

En respuesta a la CL 2015/34-MMP- Solicitud de observaciones en el Trámite 6, se recibió respuesta de 21 países, una organización miembro y una organización observadora. Las respuestas a dicha carta circular fueron compiladas por la Secretaría de Nueva Zelandia para el CCMMP, quien analizó las observaciones recibidas. El informe y las recomendaciones se enviaron en una nueva carta circular (CL 2016/6-MMP de abril de 2016) con plazo para recibir observaciones hasta el 13 de mayo de 2016, en el entendido que durante el 39 º periodo de sesiones de la Comisión, se debatiría el informe y las observaciones recibidas en respuesta a la presente Circular.

Estas observaciones fueron nuevamente compiladas por Nueva Zelandia, quien elaboró el informe que consta en el documento CX/CAC 16/39/13 Add. 1 que se puso a disposición de los países el 2 de junio en su versión en inglés.

2 - CONSIDERACIONES

En el documento CX/CAC 16/39/13 Add. 1 se realizan por parte de Nueva Zelandia los siguientes planteos, de los cuales trasmitimos nuestro punto de vista.

- **Se considera que el "queso fundido/procesado" se presta a la normalización**?

Sí. Existieron normas que sustentaban la elaboración de este producto, mismas que fueron revocadas por la CAC en el 2012. Actualmente existen productos con diversos porcentajes de queso fundido, y productos con ingredientes no lácteos que utilizan la denominación, los cuales compiten con el producto, y no cumplen con las definiciones establecidas en la norma sobre Uso de Términos Lecheros. Situación que induce a error a los consumidores por desconocimiento frente al contenido de queso, creando además una competencia desleal entre los fabricantes y desventajas competitivas en aquellos fabricantes que sí emplean queso en la elaboración de estos productos.

Asimismo; el avance alcanzado a la fecha demuestra que es un producto que se presta a la normalización.

(II) ¿Cuál sería el fundamento y justificación para continuar el trabajo teniendo en cuenta

- **Dificultades en conseguir un consenso sobre cuestiones fundamentales;**

Si bien es cierto que se mantienen algunas diferencias, éstas disminuyeron considerablemente al limitar el alcance de la norma, lo que da más oportunidades a un acuerdo futuro.

El punto álgido de la discusión con respecto a la composición, se produjo sólo para una de las 4 categorías que se definieron en la última reunión del grupo físico, en la que se propuso incluir queso fundido untable de alta humedad (la categoría 3.1.3 de la sección 3 de la carta circular Cl2015/34-MMP). Hay que destacar que sí se llegó a un acuerdo en las restantes tres categorías (3.1.1, 3.1.2 y 3.1.4), lo que demuestra el avance logrado.

- **la falta de pruebas con respecto a problemas en el comercio**

Las razones de problemas al comercio fueron ya expuestas en su momento. Si comparamos las expresiones realizadas en el debate de la oportunidad sobre esta norma y expresiones utilizadas en documentos que justificaron la elaboración de otras normas, son similares. Ej: la necesidad de una definición y denominación (etiquetado) clara con el fin de evitar prácticas comerciales desleales y la confusión de los consumidores - CX/CAC 14/37/9 – anexo 2

Productos bajo una misma denominación pueden incluir, según el país, productos con ingredientes no lácteos, preparaciones alimenticias, productos untables de queso, etc. Esta inclusión, perjudica los productos con alto contenido de queso, con respecto a aquellos que no lo son, pero al consumidor se le ofrece bajo el mismo rotulado y sin mayor información, no permitiendo una clara distinción entre ellos. Esto puede representar una competencia desleal en el comercio.

Similar planteo se realizó en el documento mencionado en el párrafo 1, en el que la justificación busca diferenciar un producto nuevo de uno existente que se comercializaba anteriormente. En este caso, los productos nuevos compiten deslealmente con un producto lácteo tradicional de mejores características nutritivas.

- **Ausencia de problemas de inocuidad con este producto**

Se ha manifestado desde el inicio del planteo de la necesidad de la norma que no es un problema de inocuidad. Entendemos que las normas de calidad e identidad no solo buscan solucionar problemas de inocuidad de los productos si no que permiten definir la identidad y calidad de los productos con los que se trabaja, y en este sentido, se siguen aprobando nuevos trabajos y revisiones en el ámbito de los Comités de Producto del Codex. Si analizamos los trabajos que se vienen realizando en la actualidad, existen trabajos que han sido aprobados con el único fin de revisar parámetros que conducen a distinguir entre dos calidades de productos inocuo. La identidad de los productos es tan relevante en el ámbito de las normas Codex que en alguna de ellas se incluyen parámetros sensoriales para definir dos calidades de un producto inocuo.

- **el compromiso de la Comisión a priorizar temas de inocuidad,**

La CAC tiene en su objetivo dos prioridades fundamentales que están al mismo nivel: garantizar la inocuidad de los alimentos y las prácticas equitativas en el comercio; en este caso, la justificación de la necesidad de esta norma se relaciona con las prácticas equitativas en el comercio.

En esa línea, de trabajar tanto en la inocuidad como en la identidad y calidad de productos, para facilitar el comercio es que se ha aprobado recientemente la creación del Comité de Productos "Comité de Especias y Hierbas Culinarias" y distintos trabajos en normas de calidad e identidad de productos, en varios comités de productos e incluso en CCMMP.

- **Reconocimiento de la Comisión de la necesidad de hacer un "último esfuerzo" para determinar si el desarrollo de la norma internacional (s) para el queso fundido sería factible; y**

Con base en los argumentos planteados en las preguntas anteriores, se considera que se justifica la necesidad de contar con esta norma. Observando los comentarios en el informe, solo dos países expresaron la opinión de discontinuar la norma.

- **Recursos necesarios para las reuniones adicionales del grupo de trabajo o comité físicas?**

El Comité de CCMMP está trabajando en forma electrónica en esta norma y en otra norma que se presenta en trámite 5 en la presente reunión. En el plan de trabajo se indicaba que los dos trabajos finalizarían en el año 2016. Ambas normas tienen algunos puntos en disenso que ameritan seguir trabajando.

Es importante tomar en consideración que la participación en forma electrónica es accesible para un mayor número de países, por lo tanto debe instar a los países en el uso de esta herramienta. El trabajo presencial limita la participación a los países de mayores ingresos, y o menores costo de participación por habitantes. Si consideramos la economía de los países interesados en la norma, son en su mayoría países en desarrollo, donde la posibilidad de estar presente en reuniones del Codex se hace más difícil.

El trabajo en forma electrónica podría ser más lento al requerirse un mayor tiempo para el intercambio.

(III) Si no se produjera ninguna norma internacional, ¿cuáles son las opciones alternativas abiertas a los miembros para hacer frente a las diversas preferencias nacionales con respecto a la composición del producto y el uso de estabilizantes y espesantes, teniendo en cuenta la amplia gama de productos en el comercio?

Definiendo claramente el porcentaje mínimo de queso que debe tener el queso fundido para denominarse de esta manera, no se requeriría regulación adicional para el resto de productos, dado que éstos no podrían denominarse de esta manera. Esto resolvería el problema de prácticas no equitativas en el comercio y se dejaría de confundir o inducir a engaño a los consumidores.

El uso de estabilizantes y espesantes se rige por la norma Codex Stan 192-1995. Para definir los estabilizantes y espesantes a utilizar en el queso fundido, aprovechando la valiosa experiencia de la FIL en la temática, se podría consultar a este organismo para que haga una propuesta con los estabilizantes y espesantes a emplear en este tipo de productos.

La propuesta de norma no restringiría el desarrollo de productos, solamente pretende clarificar los casos en que se pueden denominar según lo dicta la norma de uso de términos lecheros.

CONCLUSIÓN:

Si bien es cierto la CAC en su sesión del 2015 confirmó que el plazo para la finalización de los trabajos es el 2016, actualmente solo restan dos puntos a resolver. Entendemos en base a los puntos expuestos anteriormente, que la necesidad de la norma está suficientemente explicada y justificada, y no se diferencia de justificaciones utilizadas para otras normas, que no han sido cuestionadas en el momento de su aprobación.

El trabajo realizado en forma electrónica, el nivel de participación y de respuesta es similar al de otras normas que están siendo remitidas en trámite 5, y para las cuales no se plantean trabajos presenciales.

Siendo el Codex un órgano que basa sus decisiones en la ciencia, el proceso de evaluación y los criterios a tomar en cuenta por parte del Comité Ejecutivo para efectuar recomendaciones a la Comisión y la toma de decisiones por parte de ésta debería realizarse de forma homogénea en todos los casos.

Por otra parte, entendemos que continuar el trabajo en forma electrónica por parte de los Comités es viable, a pesar que requieran de mayor tiempo para lograr un consenso, ya que permiten la participación de un mayor número de países (basta analizar la disponibilidad de acceso a internet, recepción y envío de documentos en forma electrónica, y disponibilidad y costos de traslado de técnicos).

Finalmente, el Objetivo 4.1 del Plan Estratégico 2014-2019 plantea dentro de sus actividades implementar nuevas tecnologías para mejorar la participación de los miembros. Es por lo tanto una oportunidad para la Comisión, permitir al Comité de Leche y Productos Lácteos continuar trabajando en esta forma en las dos normas. Entendemos, además que esto permitiría analizar diversos aspectos del trabajo electrónico en dos normas cuyo interés mayoritario para su creación surgen de regiones diferentes.

RECOMENDACIÓN

El punto principal que resta discutir es el relativo a los estabilizantes. Para facilitar la discusión del mismo, se podría solicitar el valioso apoyo de la FIL, para que, desde su experiencia haga una propuesta en cuanto a los estabilizantes a emplear en el queso fundido.

Asimismo y dado que no se ha logrado consensuar la composición para el “queso fundido untable de alta humedad”, este producto podría excluirse del alcance de la norma, o podría considerarse en otra norma específica para el mismo.

INDIA

Specific Comments:

India recommends that the work on the General Standard for Processed Cheese should be continued.

Codex Committee on Sugars (CCS)

Draft Standard for Non-Centrifuged Dehydrated Sugar Cane Juice

(Comments of Costa Rica, Ecuador and Sudan)

COSTA RICA

Costa Rica agradece la oportunidad para expresar sus comentarios en el trámite 6 del procedimiento ya que considera de suma importancia que se realice una norma Codex para lo que en nuestro país se conoce como "Tapa Dulce".

Asimismo, Costa Rica desea destacar que no coincide con Colombia en lo explicado en el informe respecto a los niveles bajos de azúcares reductores, porque al igual que sugieren varios países (Brasil, Japón y Costa Rica) un nivel bajo de azúcares reductores (1.5 %m/m sugerido) sí permite alcanzar un nivel máximo de sacarosa (91% propuesto); con lo cual no contravendría el producto originalmente propuesto. De igual manera, Costa Rica sigue apoyando la posición enviada en respuesta a la CL 2015/19-CS.

En relación con la propuesta establecida en el informe, a Costa Rica le preocupa que no se observa un avance en el proyecto de norma respecto del año pasado, en el cual se ha trabajado de manera electrónica; entonces pareciera que una reunión presencial podría ser útil, pero también preocupa las posibilidades reales de los países en desarrollo para poder participar.

Dado lo anterior, Costa Rica solicita que el tema se mantenga en agenda y no se vaya a suspender hasta agotar todas las vías para lograr un consenso.

ECUADOR

Ecuador agradece a Colombia la oportunidad de comentar el documento: "PROYECTO DE NORMA CODEX PARA EL JUGO DE CAÑA DE AZÚCAR DESHIDRATADO NO CENTRIFUGADO", sin embargo apoyamos la recomendación de Colombia de realizar una reunión presencial del Comité de Codex sobre Azucares.

De acuerdo a lo mencionado Ecuador desea realizar las siguientes observaciones específicas:

- **Capítulo 1; Párrafo 1**

  ÁMBITO DE APLICACIÓN

  Esta norma se aplica al jugo de caña de azúcar deshidratado no centrifugado, según se define en la sección 2 que está destinado al consumo directo, inclusive para fines de hostelería o para reenvasado en caso necesario, como también al producto cuando se indique que está destinado a una elaboración ulterior. Esta norma no se aplica a los productos obtenidos a partir de la reconstitución de sus componentes.

  Ecuador:

  No especifica las presentaciones de jugo de caña de azúcar deshidratado a las que se aplica esta normativa.

  Se sugiere aumentar en el párrafo 1 lo siguiente:

  Esta norma se aplica al jugo de caña de azúcar deshidratado no centrifugado, **"en sus dos presentaciones: bloque y granulado"**, según se define en la sección 2 que está destinado al consumo directo, inclusive para fines de hostelería o para re-envasado en caso necesario, como también al producto cuando se indique que está destinado a una elaboración ulterior. Esta norma no se aplica a los productos obtenidos a partir de la reconstitución de sus componentes

- **Capítulo 2; Párrafo 1**

  DEFINICIÓN DEL PRODUCTO

  Se entiende por "jugo de caña de azúcar deshidratado no centrifugado", al producto obtenido por la evaporación del jugo de caña de azúcar Saccharum officinarum L., que contiene microcristales amorfos no visibles al ojo humano, que mantiene sus elementos constitutivos como sacarosa, glucosa, fructosa y minerales.

  Ecuador:

  a.- No existe nombre común para el producto.

  Incluir los nombres comunes para los países, como es el caso de Ecuador el nombre de **"Panela".**

b.- No existe un término que evidencie la procedencia del jugo de caña de azúcar.

Además, Ecuador propone aumentar dentro del párrafo lo siguiente:

Se entiende por jugo de caña de azúcar deshidratado no centrifugado, al producto obtenido por la evaporación del jugo de caña de azúcar **"proveniente de cualquier variedad de la planta gramínea"** Saccharum officinarum L., que contiene microcristales amorfos no visibles al ojo humano, que mantiene sus elementos constitutivos como sacarosa, glucosa, fructosa y minerales.

- **Capítulo 2; Subcapítulo 3.2; Tabla Características físicas y químicas**

Requisito	COMPOSICIÓN EN BASE SECA	
	Valor	
	Mínimo	Máximo
Cenizas (% m/m)	0,9	--
Sacarosa (% m/m)	--	91
Azucares reductores (% m/m)	4,5	--
Proteínas en % (N X 6,25)	0,2	--

La norma no especifica los tipos de Azucares Reductores.

Ecuador:

a) Respecto al contenido de Cenizas se solicita proporcionar información que evidencie la procedencia del valor mínimo propuesto en la tabla.

b) En cuanto a % de Proteína presente en el producto se recomienda no establecer un valor mínimo, debido a que en el proceso de elaboración se utiliza altas temperaturas las cuales desnaturalizan la mayoría de proteínas presentes en la caña de azúcar, adicionalmente este proceso permite obtener un producto inocuo ya que disminuye la carga microbiana.

c) Solicitamos especificar cuáles azucares reductores se encuentran contenidos (dentro del término azucares reductores).

SUDAN

Sudan Support the recommendation made by USA that the term "non-centrifugal" is the appropriate standard English term rather than non-centrifugated, also we support the comment made by Philippine with the following rationale:

Non-centrifugated is not a standard term use in the sugar industry worldwide, at least in English speaking countries. Moreover, we would like to note again, that we are developing standard for sugar, not for sugar cane juice; hence delete the word "juice." "Non-centrifugal" clearly describes the distinguishing characteristic of this type of sugar compared to other sugars. "Cane sugar" will specifically identify the commodity in development and its primary source. Ergo, "Non-centrifugal cane sugar" may appropriately be used.

The product maybe a different form of sugar, but it is still sugar even the proposed value for sucrose content is 91% maximum.

Specific Comments:

The Table below shoes the result of analysis of Sudanese Sugar and comparison of the result within the received Codex standard:

Jaggary analysis Method used:

Provision	Method	Principle
Moisture	ICUMSA	Loss on drying
Ash %	ICUMSA	Volumetric /Conductivity
Sucrose %	Untied molasses	Volumetric Lane and enynon
Reducing sugars %	Untied molasses	Volumetric Lane and enynon

Protein % (N*6.25	Kjeldehal	Raw protein

2- Jaggary bench marking

Requirement	**Composition on Dry Basis**	
	Value	
	Minimum	**Maximum**
Ash % (m/m)	-	4.00
Sucrose %	65.50	80.50
Reducing Sugar %(m/m)	5.50	11.00
Protein % (Nx6.25)	0.90	7.80

* The figures are acceptable and within the ranges shown by different countries. The processes of the product are free from any additive. Just heating the juice in open pans. The analysis of reducing sugar is high and that was attributed to the prolong heating under atmospheric pressure and high temperature and with such condition in addition to low PH of the juice (5.00 to 5.50)the inversion rate increases to figure shown above.

Name of the Product: Jagguary

Product Definition:

Non-centrifugated dehydrated sugar cane juice" is the product obtained from the evaporation of sugar cane juice *Saccharum officinarum L.* which contains amorphous micro crystals invisible to the naked eye, which maintains its constituent elements, such as saccharose, glucose, fructose and minerals.

3.2 Quality factors

3.2.1 Colour

In addition to above color formation enhanced by heating juice to high temperature.

Chemical characteristic: S**ucrose and Reducing Sugar**

It is well known there is no any additive is allowed, but nevertheless without neutralization of juice sucrose inversion will occur once the three factors of inversion are available i.e. low PH of juice, high temperature during processing and time.

With such condition ultimately the amount of sucrose decreases accompanied with increase in reducing sugar level.

Codex Committee on Food Labelling (CCFL)

(Comments of Egypt)

EGYPT

Based on 36th session of the Codex Alimentarius Commission, Egypt has been requested to prepare a proposal for new work aiming to revise the General Guidelines for Use of the Term "Halal" "CAC/GL 24-1997".

- On CCFL 43; Egypt has prepared a proposal to review and revise Codex General Guidelines for Use of the Term "Halal", to be discussed as per agenda item 8.
- Through CCFL 43th; A few delegates mentioned that Halal standard should be updated on SMIC level as the right platform for discussing Halal by only Muslim countries (see the final report)
- Egypt would like to clarify the Following points: According to the Codex procedural manual, section 1 (Rules of procedure of the Codex Alimentarius Commission) (Rule viii voting and procedure) (item 3. At the request of a majority ……)
- It is apparent that Codex Guidelines for Use of the Term "Halal", CAC/GL 24-1997 is International standard and doesn't belong to region or group of countries. Based on the foregoing, who claimed that this standard belongs to only Muslim countries, This is not accepted as the Halal standards is very widely used in International trade , so private standards can negatively impact fair trade & cause challenges to International trade.

- Egypt recognizes that regional standards other than Codex are " private Standards" that do not cover many issues specially:
    - Transparency/ Involvement of key stakeholders in decision-making
    - Stringency of requirements as compared with Codex
    - Costs of certification/ Requirement for multiple certifications
    - Impact on access to markets

Therefore, the Codex Committee on Food Labelling assumes its responsibility to clear those challenges.

The proposed Discussion paper by CCFL to cover consumer preference claims should not include Halal as Halal is a separate issue & not a claim, Halal is a group of procedures which upon fulfilment should be reflected on the labels.

The recommendation to review Codex Halal Guidelines comes originally from Codex Near East committee & was also recognized by Codex Commission

Egypt still highlights the importance of Halal updates in Codex platform as the only International platform to discuss this & clear the challenges for fair trade.

Codex Committee on Methods of Analysis and Sampling (CCMAS)

Protein conversion factors

(Comments of Kenya, India, American Oil Chemists' Society and European Vegetable Protein Federation)

KENYA

ISSUE: The Committee on CCMAS noted that it was not in a position to reply to the question posed by CAC38 on the appropriate protein conversion factors for soy products as this was in the remit of other Codex Committees; and noted that it might be timely for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors.

COMMENT: Kenya is in agreement that FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factor .This is to harmonize the Protein Conversion Factors to facilitate.

INDIA

The recent publication of the International Dairy Federation (IDF) (IDF Bulletin 482/2016) supports Protein Conversion Factor of 5.71 for soy proteins. Nevertheless, India agrees to the formation of an expert panel to review available scientific literature, should the Commission deem it of additional use, with the understanding that the protein conversion factors (PCF) should be based on science.

AMERICAN OIL CHEMISTS' SOCIETY

Position on the Nitrogen Conversion Factor for Soy Protein

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List of Tables

I. Executive Summary

We hereby submit that the 6.25 nitrogen conversion factor for soy protein is supported by international consensus of the following scientific and regulatory experts and organizations:

- Codex Alimentarius
  - Codex Standard 175-1989 Codex General Standard for Soy Protein Products
  - Codex Standard 174-1989 Codex General Standard for Vegetable Protein Products (VPP)
  - Codex CAC/GL 2-1985 Guidelines on Nutrition Labelling (as amended by the 29th Session of the Commission, 2006)
  - Codex Standard 234-1999 Recommended Methods of Analysis and Sampling (as amended by the 30th Session of the Commission, 2007)
- National and Regional Government Nutrition Labeling Regulations
  - Argentina
  - Brazil
  - China
  - European Union

- India
- Japan
- Korea
- United States
- Mexico
- Malaysia
- South Africa

- Globally Recognized Analytical Sciences Associations
  - American Oil Chemists Society (AOCS)
  - AOAC International (AOAC)
  - AACC International (AACC)
  - International Organization for Standardization (ISO)

The proposed 5.71 nitrogen conversion factor for soy protein is based on outdated and inaccurate data originally reported in 1931. These data have since been discredited with improvements in analytical methods and technology, as well as an increased understanding of the chemical composition of proteins and the effects of amino acids and protein on human health:

- Analytical data of amino acids for over 50 samples of various soy products conducted by the United States Department of Agriculture, independent laboratories, and an independent university researcher show a nitrogen conversion factor in a range of 6.24-6.37

Furthermore, the literature exploring approaches to calculating nitrogen to protein conversion factors present inconsistent outcomes, highlighting the uncertainties with trying to establish a “precise” conversion factor. Human nutrition research, however, continues to demonstrate that soy is a high-quality protein that supports growth and maintenance when consumed as a sole source protein and 6.25 is used to calculate the protein content of diets.

Changing the nitrogen conversion factor for soy protein from 6.25 to 5.71 will represent a departure from internationally recognized analytical methods, established nutrition clinical research procedures, as well as widely embraced trade and regulatory practices. Changing from the 6.25 to 5.71 conversion factor will result in an almost 10% reduction in the calculated protein content of soy foods without any change to the product itself. Potential impacts include:

- Elimination of isolated soy protein as a food ingredient from the marketplace as it will be impossible to meet the product standard 90% protein minimum using a 5.71 nitrogen to protein conversion factor
- Significant costs to food manufacturers due to expensive label changes
  - “Isolated soy protein” would have to be removed from product ingredient lists
  - Changes to protein nutrition labelling
  - Potential requirement for product formula changes
- Confusion for food manufacturers seeking to make products containing isolated soy protein
- Confusion for consumers seeking products containing isolated soy protein
- Impacts on presentation and interpretation of data from nutritional research for both scientific and lay audiences (which generally use 6.25)
- Significant cost increases for animal production facilities using soy as source of protein in feed rations

We therefore, support the continued use of the 6.25 nitrogen conversion factor for the measurement of protein in soybeans and soy products.

II. Introduction

We hereby submit that the 6.25 nitrogen conversion factor (NCF) for soy protein is supported by international consensus of scientific and regulatory experts and organizations. The World Health Organization (WHO) and the Food & Agriculture Organization of the United Nations (FAO)[1-5], as well as several national and regional governments recognize the 6.25 NCF for soy protein for purposes of trade, nutritional labeling, and the promotion of public health. The proposed 5.71 conversion factor is based on outdated and inaccurate data originally reported in 1931 by D.B. Jones, a USDA researcher[6]. These data were based on the 1898 publication of Osborne and Campbell[7] whose report did not claim that their values represented the nitrogen content of the whole bean, merely the fraction that they isolated. The Jones' factor of 5.71 has been disputed by other researchers who cite improvements in analytical methods and technology, as well as an increased understanding of the chemical composition of proteins[8-11] and the effects of amino acids and protein on human health. Changing the NCF for soy protein from 6.25 to 5.71 will represent a departure from internationally recognized analytical methods, established nutrition clinical research procedures, as well as widely embraced trade and regulatory practices. This position document will cover four important viewpoints that support a 6.25 NCF for soy, namely: published literature covering proposed approaches to calculating NCFs and human nutrition studies assessing a source of protein's impact on human health, the scientific analytical environment, analytical data on a variety of soy products based on a direct method of analysis recommended by the FAO (2003) for the measurement of protein[5], and the current regulatory environment.

In response to the proposal to explore the appropriate NCF for soy, we request a definition of the need to change the NCF: what pressures, scientific or economic, are driving the need for a new conversion factor? What public health or other benefits will justify the significant investment in time and money required to conduct this exploration? Further, if the consensus is that there is a critical need to conduct further assessment of the appropriate NCF for soy protein, in the interests of protecting the health of consumers, we believe the same exercise should be conducted for **all** commonly consumed proteins and the results of this work should be released and implemented into the appropriate Codex Standards simultaneously to ensure the ensuing impact on all proteins will be equally felt. To this end, a recent publication by Angell, et al., 2016[12] made the case that a specific NCF should be made for all seaweed products, and that doing so when the seaweed industry (as a protein source) is in its infancy will prevent potential economic losses (obviously not to the seaweed industry but more so to protein ingredient competitors), since they recommend a value lower than 6.25 for seaweed. Koletzko and Shamir[13] noted, in a commentary about a standard for infant formula, that a newsletter from the German dairy industry suggested that "the application of a NCF of 6.25 instead of 6.38 for all dairy products would lead to a loss of some €80m" for the dairy industry in Europe alone". There will be increasing pressure, then, in the face of increased efforts to introduce novel dietary protein sources to the global commercial market[14] to develop new NCFs for these proteins. Therefore, it is imperative that a global consensus as to how to measure protein for all human dietary proteins be established rather than to continue to depend on efforts driven by disparate motivations to derive NCFs which has led to different methods and approaches – we recognize that an NCF is an operational definition, a change in the procedure for measuring those factors that are used in deriving the NCF produces different values.

The issue of identifying appropriate nitrogen conversion factors has arisen in the Codex Committee on Fish and Fishery Products (CCFFP) at their 34th session. The committee requested FAO to develop a table of nitrogen factors for fish species and the FAO has issued a call for data for "Elaboration of a table of nitrogen factors for quick frozen fish sticks, fish portions and fish fillets including procedure for determining nitrogen factors"[15]. This additional example speaks not only to the need to continue to generate NCFs for proteins if it is determined that nitrogen determinations will remain the method of choice for food protein quantitation, but that there is no current consensus method for developing the NCFs.

The critical nature of establishing a consensus on the procedure to calculate NCFs is most evident in the recently published Standard Tables of Food Composition in Japan (STFCJ) 2015[16] where none of the NCFs calculated by sum of the anhydrous amino acids for any of the foods were equal to 6.25. In fact, virtually all the foods measured by this method were significantly lower than 6.25, including dairy proteins. Thus, while the currently commonly used 6.25 NCF may be erroneous, it is equally erroneous for **all** proteins. In fact, this was noted by Marriotti, et al., 2008[17] and a ***corrected default value for all proteins of 5.6 was proposed.***

The Kjeldahl method, the modified Kjeldahl method, and the combustion methods continue to be widely used for analytical measurement of protein. Direct analysis of amino acids to quantitate protein, however, provides more accurate and nutritionally relevant values. We believe devoting time and resources to the validation of improved methods for measurement of protein, such as direct analysis of amino acids discussed in FAO Food and Nutrition Paper 77[5] or by alternate methods that are being evaluated[18], and the dissemination of these data for public use would be more aligned with the Codex Alimentarius Commission's Procedural Manual[19] on determining priorities and initiating new work than initiating work to determine the "precise" NCFs for widely consumed proteins.

III. Published Literature Relevant to Nitrogen Conversion Factors

A review of published literature exploring approaches to calculating NCFs was published in 2006 by the International Dairy Federation[20]. An updated version of the 2006 review by the International Dairy Federation was published in 2016 [21] with little new data. The papers cited in these reviews present inconsistent outcomes, highlighting the uncertainties with trying to establish a "precise" NCF (Table 1). Many of the papers do not deal with the issue of non-protein nitrogen, which is present in soy and dairy proteins to varying degrees. Furthermore, investigators disagree as to what constitutes non-protein nitrogen. Some investigators believe that amino acids and peptides account for non-protein nitrogen[22] while others believe these should be considered as part of the protein content since the purpose of the developing these calculations are for nutritive purposes and all organisms utilize proteins in their hydrolyzed form of amino acids and peptides[17, 23].

Table 1. Publications on Methods to Calculate Nitrogen Conversion Factors

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
Osborne TB and Campbell GF (1898) J Am Chem Soc 20: 419-428[7]	Soy (Glycine hispida)	This paper did not propose a N to P conversion factor	17.5%	The authors of this paper did not claim that their values of %N represented the nitrogen content of the whole soybean, merely the fraction(s) that they separated; the authors claimed that glycinin was the major protein in the soybean but did not state the percent of glycinin typically found in soybeans Although not specifically cited by Jones, 1941[6] it is evident that Jones used this paper to arrive at the 5.71 NCF for soy.
Jones DB (1941) United States Department of Agriculture, Circular No.183 (Original version 1931)[6]	Soy (Glycine max)	5.71	17.51	This citation bases the NCF for soy protein on the nitrogen content of only one of the storage proteins (glycinin),presumably based on the 1898[7] report above While citing 5.71 for soy protein, the Jones paper does not provide any data to show how this calculation was derived; only 1 sentence in the report is dedicated to soy protein The NCF for other crops is discussed in more detail but the 2006 IDF report[20] does not cite the Jones paper for the following crops: wheat (5.83), rye (5.83), barley (5.83) or oats (5.83)
Tkachuk R (1969) Cereal Chem 46: 419-423[23]	Defatted soybean	5.69		This paper derives NCFs for cereals and oilseeds based on data published in an earlier publication (Tkachuk, 1969 Cereal Chem 46: 206-218[24]) and derives glutamine and asparagine values from the content of ammonia (assumes all ammonia is derived from these 2 amino acids and simply divides the total ammonia by 2 and assigns the resultant values to asparagine and glutamine); this is based on Tkachuk's 1966 work in wheat (Tkachuk, 1966 Cereal Chem 43: 207-222[25]) where glutamine and asparagine values are directly measured by comparing enzymatically digested protein to acid hydrolyzed wheat protein; it is on this work *alone* in wheat that the assumption that free ammonia only comes from asparagine and glutamine; note that in the work on wheat, accurate estimates of the relative proportions of asparagine or glutamine were possible by direct measurement; errors would have resulted in NCF if one assumed equal proportions of both amino acids as subsequent investigators have done who cite this method Note also that this paper the author points out the errors and assumptions made in the Jones 1941[6] paper (i.e. not accounting for non-protein nitrogen), calling into question the NCF proposed by Jones[6]

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
DeRham O (1982) Lebensm. Wiss. Technol 15, 226-231[23]	Soy Isolate Soy (Glycine max)	5.6-5.8 5.75-5.8	17.54 17.24	DeRham points out that amino acid analytic methods do not routinely measure asparagine and glutamine, so in his analysis he ***assumed*** 50:50 or 75:25 amide:acid ratios when calculating the conversion factors from the listing of amino acid compositions of food in the FAO 1970 report[24] Soy protein has a ratio closer to 25:75 which would raise the calculated conversion factor from what deRham actually calculated DeRham points out that other investigators may have used different assumptions of amide:acid ratios (e.g. Jones 1941[6] and Morr 1981[9]) which may explain why conversion values in his report differ from those DeRham also questions Jones' stated values (Jones 1941[6]) and mentions that Jones used an arbitrary method to establish some of the conversion factors; DeRham also suggests that there are some errors in the Jones report, e.g. deRham suggests the conversion values reported in Jones 1941[6] for wheat flour and wheat bran should be inverted DeRham concludes his paper by saying that nutritional studies should continue to use the traditional 6.25 conversion factor until more precise conversion factors are available
Morr CV (1982) J Food Sci 47, 1751[28]	Soy (Glycine max)	5.76	17.36	Morr's 1982 paper is a follow-up of his 1981 paper (Morr, 1981 J Food Sci 46, 1362[9]); follow-up was in response to personal communications Morr received from Posati and de Rham and the follow-up paper was to try to "minimize the magnitude of the discrepancies within the N conversion factors" determined by the Kjeldahl method and Factor Method (the latter was proposed by Morr, 1981[9] and involves calculating the NCF based on residual weights of amino acids determined by amino acid analyses) The 1981[9] paper states that the Factor Method is "recommended to provide the most accurate conversion factor". In that paper, Morr calculates an average NCF of 6.77 and 5.93 for 4 different soy protein preparations analyzed using the Factor Method and Kjeldahl Methods, respectively; calculations for 4 soy proteins whose compositions had been published previously averaged 6.58 In the 1982 paper cited in the 2006 IDF report[20], Morr *uses the same amino acid compositional data* he derived in the 1981[9] paper for 2 soy protein preparations, but then "computes" the asparagine and glutamine contents according to the method of Tkachuk 1966[25], 1969[24]; meaning that the content of ammonia was used to *derive* the values for asparagine and glutamine based on the assumption that only these amino acids give rise to the ammonia; the total mole content of ammonia is subtracted from the total moles of asparagine and glutamine to *derive* the value of the carboxylic acid forms of these amino acids which are assumed to be in equal proportion Thus, values for asparagine and glutamine are not consistent with currently known relative proportions of glutamine and asparagine in soy protein
Boisen S, Bech-Andersen S and Eggum BO (1987) Acta Agric Scan 37, 299-304[29]	Soy Meal Soy Meal Soy Meal	6.30 (No Amides) 5.65 (With Amides) 5.49	15.87 17.7 18.21	NCFs calculated by even a single research group for a single sample can vary significantly (5.49 to 6.30 for soy meal) and 3 different factors are quoted in this report Note that the 2006 IDF repor[20] cites this same paper to support a conversion factor range of 6.34 to 6.38 for milk and milk products; this citation provides three different skim milk powder conversion factors: 5.75,

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
				6.13 (corrected for amides) and 6.9; ***The first two factors clearly are not in line with supporting a 6.34-6.38 conversion factor for milk and again demonstrate the problem with consistency in calculation and potential application of different NCFs*** As for the three NCFs provided for soy, 6.3 was calculated based on amino acid composition and protein nitrogen, 5.65 was calculated based on indirect and inaccurate estimates of amidation (measures of ammonia release after acid hydrolysis and *the assumption that all of the ammonia came from asparagine and glutamine*) and 5.49 was calculated based on amino acid nitrogen over total nitrogen, which always gives the lowest value (e.g. 5.75 for skim milk powder using this method)
Mosse J (1990) J Agric Food Chem 38, 18-24[30]	Soy (Glycine max) Soy (Glycine max)	5.38-5.67 5.76	18.18 17.36	The objective of this paper was "to show that in the absence of perfectly accurate values of the conversion factor, it is still possible to accurately determine its upper and lower limits" Mosse questions Jones ,1941 paper[6] by stating "...so that the questionable values he suggested remain still widespread today, in spite of various improvements successively made by Heathcote (1950), Kutscher and Langnau (1965), Tkachuk (1966a,b, 1969, 1977), Tkachuk and Irvine (1969), Ewart (1967), Holt and Sosulski (1979), Sosulski and Holt (1980) and Morr (1981, 1982)". Mosse provides a detailed mathematical approach to determining NCFs (3 possible values k_A k_P and k, depending on calculation method) for 10 cereals and 6 legumes/ oilseeds and shows that the conversion factors that he calculates based on residual amino acids weights change as the nitrogen contents of the samples increased (not always in the same direction depending on the sample type) *providing more evidence for the difficulty in calculating and assuring that analysts use appropriate accurate nitrogen to protein conversion factors* Mosse also pointed out that other researchers have provided NCFs that were in error if they omitted to correct for the amide nitrogen values (coming from asparagine and glutamine); however, his corrections (calculations for k_A) were based on measures of ammonia release after acid hydrolysis and *were based on the assumption that all of the ammonia came from these 2 amino acids only* Mosse's earlier paper (Mosse, 1985 J Cereal Sci 3: 115-130[31]) in wheat cites Tkachuk, 1969[24] as being the only published literature to indicate that all NH3 comes from Gln and Asn alone, however only wheat, not soy, was studied by Tkachuk Despite Mosse's claim in current paper that "...the AA compositions used here probably represent the most complete analyses of the total proteins of cultivated seeds" *no amino acid data are provided in the paper, appendices or supplemental data, so the reader is not able to replicate or verify the calculations made in the paper* Amino acid data for non-soy proteins are available (other published papers), *but the data used for soy protein in this paper are "unpublished" and unavailable to view*
Sosulski FW and Holt NW (1980) Can J	Soybean	5.58		In this paper only NCFs for grain legumes were calculated exactly as per Tkachuk, 1969[23] using amino acid analyses; thus one would expect similar values to those Tkachuk reported

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
Plant Sci 60: 1327-1331[32]				It should be noted that using the SAME METHODS, Sosulski and Imafidon (Sosulski and Imafidon, 1990 J Ag Food Chem 38: 1351-1356[33]) reported NCFs of 6.02 to 6.15 for dairy products and 5.61 to 5.93 for egg, meat and fish products
Marriotti F et al. (2008) Crit Rev Food Sci Nutr 48: 177-184[16]	Soybean	5.5		This paper is a review of the issues in calculating NCFs and argues that an NCF of 6.25 is incorrect for **all** major human dietary protein Authors admit addressing this issue has been avoided "because scientists fear opening the Pandora's box" Marriotti et al point out the flaws with the Jones factors (Jones, 1941[6]) were due to assumptions made and the technology available in 1941 and that amino acid analyses are the preferred method to calculate NCFs, when other additional factors are also taken into account (e.g. non-protein nitrogen). With regard to concerns that amino acid measures have an inherent increased variability compared with measures of nitrogen, Marriotti, et al. point out that the variability of amino acid measures would not significantly impact NCF measures (calculated CV of 2%) and that improvements in amino acid analyses are occurring An interesting point raised by Marriotti, et al. that warrants consideration, is that for proteins with a lower NCF than 6.25, measures of protein content decrease WHILE THE CHEMICAL SCORE (PROTEIN QUALITY) increases (compared to proteins with higher NCFs); example calculations show that more amino acids to meet nutritional requirements are provided in less protein for the protein with lower NCF; this can be avoided if the amino acid requirements are also adjusted for the same NCF
Sriperm N et al. (2011) J Sci Food Agric 91: 1182-1186[34]	Soy meal	5.64		The purpose of this paper was to get to specific NCFs for feedstuffs "to minimize the feeding of excess nitrogen (N) and to reduce N pollution". Calculations were based on the methods reported by Mosse, 1990[30] so not surprising that soy meal NCF was similar to that of Mosse Interestingly, if the purpose of the paper was to get to specific NCFs to reduce feeding excess N, then one must consider how this information will be used; if the currently used NCF of 6.25 for soy meal in feed is reduced to 5.64, does the feed formulator add more soy meal to get to the required protein levels and potentially harm the environment by increasing the excreted N in feces? OR should all the existing requirements be lowered in view of the fact that all protein content in feedstuffs, previously based on a NCF of 6.25, should be now considered lower by 5.64/6.25 (reduction of 10%). If the latter, then there would be NO CHANGE to actual formulations *per se* only a paper exercise to change the nutritional composition for protein.
Maubois J-L and Lorient D (2016) Dairy Sci and Technol 96, 15-25[22]	Soy (Glycine max)	5.61-5.79		This paper, published in a journal devoted to dairy research, is a review that attempts to provide a scientific basis for the nitrogen to protein conversion factors of 6.38 for cow milk protein and 5.71 for soy protein but does not provide primary data to support these NCFs The authors point out the difficulty in obtaining accurate or 'true' nitrogen to protein conversion (NCF) factors; they point out that "…scientists have turned to determining the NCF from the amino acid composition" Interestingly these authors consider low molecular weight peptides and free amino acids as non-protein nitrogen (NPN) but in an earlier paper Mariotti, et al.[17]

Citation	Product Name/ Class	NCF Proposed	%N in Protein	Comments
				indicate that there are different objectives when using a NCF and for nutritional considerations all amino acids should be considered in the NCF; this further points out the controversies that arise when using NCFs in general Maubois and Lorient propose that the amino acid sequence of proteins or primary structure of proteins be used to calculate the NCF; this requires a thorough knowledge of the primary structure of proteins which is NOT available for most proteins, but is available for milk proteins; while the major soy protein sequences are known, the overall number of proteins contributing to total protein from soybean[35] is higher than that of milk protein[36] ; therefore it is unlikely that this method would offer any advantages as the relative amounts of the different proteins would need to be known with some certainty and assumed not to change with different lots of protein to develop an accurate NCF This paper cites Utsumi, 1992[34] as being the source of the sequence data on which the calculations of the soy proteins □-conglycinin and glycinin NCF shown in Table 3 are based; Utsumi, 1992[37] does not provide direct sequence data but Utsumi, 1997[38] does provide sequences for these 2 proteins only; since the sequences are listed for the different subunits and their ratios vary, it is not clear how the NCFs were calculated by the authors (this is not shown); if one uses the amino acid compositions of □-conglycinin[39] and glycinin[40] to calculate the NCF (using residual weights of the amino acids and weight of nitrogen) for these subunits one obtains 6.31 and 6.36, respectively Similarly when Maubois and Lorient attempt to calculate the soy protein NCF based on relative ratios of □□conglycinin (7S) to glycinin (11S) and the latters' respective sequences , they do not provide a clear explanation as to how the NCFs are calculated and how they take into account soy hemagglutinin and 7S glycosylation Maubois and Lorient also have a section in the paper on "Processing and anti-nutritional factors" which are not related to the topic of nitrogen to protein conversion factors; this section is simply added to discount soy protein as a high quality protein for infant formulas and cites very outdated publications and information With regards to suitability for infant formula, the authors attempt to make a case that soy protein is not suitable for infant formula; their unsubstantiated arguments are meaningless in view of the data emerging from the laboratory of Dr. Tom Badger and his Beginnings Study which show that soy protein based formulas promote normal growth and development comparable to cow milk based formulas[41-43]. A recent meta-analysis by Vandenplas et al.[44] also confirms the safety and normal growth promoting properties of soy-based infant formulas. Authors also claim that proposal to use 6.25 NCF for soy protein is unacceptable because it forgets the enormous work conducted over the past 50 years; the same can be said for the Jones' factor of 5.71 for soy protein which is still quoted for more than 50 years despite it being based on a faulty logic

Human nutrition research, however, continues to demonstrate that soy is a high-quality protein that supports growth and maintenance when consumed as a sole source protein and 6.25 is used to calculate the protein content of diets.

Table 2. Human Nutrition Studies Assessing Impact of Dietary Soy Protein on Health Outcomes

Citation	Product Name/ Class	NCF used for soy protein	Type of Study & Subjects	Comments
Rand WM et al. (2003) Am J Clin Nutr 77: 109-127[45]	Soy protein	6.25	Meta-Analysis of Nitrogen Balance studies in Adults	This meta-analysis was conducted in response to a request from the FAO/WHO/UNU to assess the protein requirements in healthy adults and tested a variety of animal or plant-based proteins or mixtures of these Protein requirement in adults defined as "the continuing intake of dietary protein that is sufficient to achieve body nitrogen equilibrium (zero balance)" Despite the known limitations of N balance studies, this method remains the primary approach for determining protein requirement in adults because there is no validate or accepted alternative Studies tested soy protein (7 as sole source and 2 as mixed sources) using an NCF of 6.25 as the basis for determining the quantity of protein intake There were various factors that contributed to the variability in nitrogen balance response due to differences in studies, differences between subjects and differences within subjects day to day; however, there was no significant difference between studies classified as to whether the dietary protein was predominantly from animal, vegetable or mixed-protein sources For the soy studies, the authors concluded: "These original soy studies showed clearly that the well-processed soy proteins were equivalent to animal protein, whereas wheat proteins were used with lower efficiency than were animal protein (beef)" The authors noted that the major source of dietary protein was found to have an insignificant effect on the median requirement, slope or intercept for nitrogen balance versus nitrogen intake plots One would expect that if the NCF of 6.25 applied to each of the studies led to an overestimation of the actual protein intake, ***then one would expect a lower N balance in the soy protein studies, but this was not observed*** Thus, it can be concluded from these studies that the use of a NCF of 6.25 for soy does not lead to erroneous estimations of protein requirements
Jing H et al. (2010) Early Hum Devel 86: 199-125[41]	Soy protein	6.25	Infant Formula Study to assess effects of breastmilk compared with formula feeding on brain activity in developing infants	Development of brain activity during infancy differs between those who are breastfed compared to with those fed either cow milk or soy protein-based formula, but was generally similar for the formula-fed infants
Andres A et al. (2013) J Pediatr 163: 49-54[42]	Soy protein	6.25	Infant formula study to assess effects of breastmilk compared with formula feeding on body composition and bone mineral content in developing infants	Anthropometric data were similar in soy-formula-fed and cow milk-formula-fed infants; however soy-fed infants were significantly leaner with greater fat-free mass compared with cow-milk formula-fed and breast-fed infants during the first 6 months of life Bone mineral content (BMC) was higher in breast-fed infants compared with cow-milk or soy-formula-fed infants at 3 months, but by age 9 and 12 months BMC was higher in cow-milk and soy-formula-fed infants, with the highest bone mineral accretion occurring in the cow-milk formula fed group
Pivik RT et al.	Soy	6.25	Infant formula	Although subtle effects of diet and gender were

(2013) Intl J Psychophysiol 90: 311-320[43]	protein		study to assess effects of breastmilk compared with formula feeding on cardiovascular development in infants	observed, there were no atypical findings with regard to cardiovascular development Differences observed were generally greater between breast-fed and formula-fed groups than between formula-fed infants

The studies summarized in the Table above indicate that the intake of soy protein, when based on a NCF of 6.25, resulted in similar nitrogen balance in adults and similar growth and development of infants when compared to animal and dairy protein. It is worthy to consider how these results may be interpreted should the NCF of soy protein be changed from 6.25 to 5.71. It could then be considered retrospectively, that 9% less soy protein resulted in similar nitrogen balance and similar infant growth characteristics to that observed with milk protein. Another consideration may be that changing the NCF for soy protein to 5.71 would require reformulating the infant formula to contain more soy protein by weight to meet the infant formula protein requirements. However, that could meet with considerable resistance, since there is a growing body of data that suggest that high dietary protein intakes in infancy and in growing children can induce adverse effects on the risk of obesity and associated diseases[46]. In a multicenter European study, over a thousand healthy term infants were randomly assigned to receive cow milk-based formulas and follow-on formulas with lower (1.77 and 2.2 g protein/100 kcal, respectively) or higher (2.9 and 4.4 g protein/100 kcal, respectively) protein levels[47]. At 2 years of age, the adjusted *z* score for weight-for-length was found to be 0.20 greater (P = 0.005) in the higher- than in the lower-protein formula group[47] and in a follow up of these children at 6 years of age, the high protein group had a significantly higher BMI (by 0.51, P = 0.009) compared to the low protein group [48]. The study investigators also demonstrated that long-term mental performance of children on the low protein intervention was unimpaired compared to the high protein intervention[49] allaying any concerns that reducing protein intake in infancy would have led to any adverse developmental effects. This and other studies then indicate that lowering protein intake in infants, rather than raising protein intake levels, would be associated with a reduced rate of obesity.

Use of the 5.71 factor instead of 6.25 in the calculation of protein content for soy-based follow-up formula could result in excessive protein intake. If grams of protein for a follow-up formula are calculated using a 5.71 nitrogen to protein conversion factor are compared to what the gram amount would be using a 6.25 conversion factor, the protein range would actually be 3.28 – 6.01 g per 100 kcal of FUF (assumes 9.2% reduction in protein content with use of 5.71 vs 6.25), instead of the 3 – 5.5 g/100 kcal range that is listed in the Codex FUF Standard[50].

Table 3. Follow Up Formula Calculations: Protein content using 5.71 vs. 6.25

N Conversion Factor	3 g protein/100 kcal	5.5 g protein/100 kcal
5.71 (6.25)	3 g (3.28 g)	5.5 g (6.01 g)

It should be noted that the US FDA published their revised nutrition and supplement facts labels and rules for serving sizes in May 2016[51]. In their final rule, they have reduced the RDI for protein for infants from 14 g/day to 11 g/day and for children 1-3 years of age the DRV was reduced from 16 g/day to 13 g/day[51]. Since the trend in regulations appears to be in reducing protein requirements, changing the conversion factor for soy from 6.25 to 5.71 would require adding more soy protein to food products, counter to the most recent scientifically driven trends in nutrition recommendations.

With regard to adults, Heidelbaugh ND et al.[52] showed that variations in calculating the protein content of menus or diets using different NCFs derived by different methods, minimally affect the values obtained for total protein contents, since any errors resulting from using 6.25 or specific NCF factors (e.g. Jones' factors) tend to be randomly distributed among any variety of foods when an overall menu containing healthy foods is analyzed. Heidelbaugh ND et al. (1975)[52] demonstrated that the protein content of menus designed for Skylab astronauts, which consisted of 68 different foods, differed by less than 3% when calculated using a NCF of 6.25, using Jones' factors or using derived NCFs based on amino acid composition of the foods. Therefore, it can be said for adult diets which contain a variety of healthy foods, there is no need, based on nutritional considerations, for specific NCFs to calculate protein content for individual foods.

IV. Scientific/Analytical Methodological Environment

Analytical Methods Support a 6.25 Conversion Factor

The Kjeldahl method, the modified Kjeldahl method, and the combustion method (known as the Dumas method) are commonly used for analytical measurement of protein. These methods measure protein in foods indirectly by assessing the quantity of nitrogen that can be released from a protein and captured as ammonia. Nitrogen from all nitrogenous compounds, including proteins and non-protein material, are typically included in this total. In the early 1880s, when the Kjeldahl method was invented, proteins readily available for testing (serum albumin and globulin from blood, casein from milk) contained about 16% nitrogen. Dividing 100 by 16% gave a nitrogen conversion factor of 6.25 and it was believed that this factor applied to all proteins. Although it has since been discovered through further scientific research that few foods contain precisely 16% nitrogen, use of the 6.25 conversion factor for measurement of protein sources has been maintained to allow for a measure of international harmonization in the expression of protein levels. It should be noted that Wolf, et al.[53] reported on the nitrogen content of soybean protein and several fractions of these proteins along with purified proteins. These preparations contained from 16.2 to 16.51% nitrogen[53] (NCF would be 6.05 to 6.17). Wolf, et al.[53] reported that a cold insoluble fraction contained 17.46% nitrogen which was probably very similar to the soy sub-fraction used by Osborne and Campbell in their measures[7], which is the citation that Jones used to support an NCF of 5.71 for soy.

By way of comparison, the NCF for dairy has been based on the nitrogen content of acid-precipitated casein published in a report in 1883 by Hammarsten[54] which was found to be 15.67% (NCF = 6.38). This is also the citation used by the IDF to support an NCF of 6.38 for dairy in their recent Bulletin[21] despite the fact that dairy protein contains whey and other proteins that individually vary in their NCF values[55].

Application of the 6.25 nitrogen conversion factor to measure soy protein analyzed by Kjeldahl, modified Kjeldahl, and combustion methods is widely recognized by international organizations, such as Codex Alimentarius and FAO[4,5], and technical associations, such as the American Oil Chemists Society (AOCS), AOAC International (AOAC), AACC International (AACC), and the International Organization for Standardization (ISO).

The Codex Standard 234-1999 “Recommended Methods of Analysis and Sampling” (as amended by the 30th Session of the Commission, 2007)[4] lists AOAC 955.04D method that recognizes 6.25 for soy protein, as the recommended protein measurement method for soy and vegetable protein products. Furthermore, Codex Standard 234-1999[4] specifically states the 6.25 conversion factor should be applied to nitrogen values for soy and vegetable protein products obtained using AOAC 955.04D.

AOCS, AOAC, AACC, and ISO analytical methods are widely recognized by regulatory agencies in enforcement of national regulations, as well as by university and government researchers. The current protein analytical methods approved by membership consensus in these technical associations list 6.25 as the nitrogen conversion factor for soy protein (Table 4).

Table 4. Official AOCS, AOAC, AACC, and ISO Soy Protein Analytical Methods

Current Protein Analytical Method	Recommended Nitrogen Conversion Factor
AOCS Ac 4-91[56](Revised 2011)	6.25
AOCS Ba 4d-90[57] (Revised 2011)	6.25
AOCS Ba 4e-93[58] (Revised 2011)	6.25
AOCS Ba 4f-00[59] (Revised 2011	6.25
AOCS Ba 4a-38[60] (Revised 2011)	6.25
AOCS Ba 10-65[61] (Reprinted 2009)	6.25
AOCS Ba 10a-05[62] (Reprinted 2009)	6.25
AOAC 992.23[63] (Revised 2005)	6.25
AACC 46-10.01[64] (Reapproval 1999)	6.25
AACC 46-11.02[65](Reapproval 1999)	6.25
AACC 46-16.01[66] (Reapproval 1999)	6.25
AACC 46-30.01[67] (Reapproval 1999)	6.25
ISO 16634-1:2008[68]	6.25

Newer Protein Analysis Methods Provide More Accurate Protein Data and Prove 5.71 Conversion Factor for Soy is Incorrect

The 5.71 nitrogen conversion factor for soy protein is based on analytical data generated by D.B. Jones, Principal Chemist of the United States Department of Agriculture (USDA) in a Circular (1931, slightly revised 1941)[6]. In this Circular[6], Jones hypothesized that not all nitrogen in foodstuffs was protein nitrogen and not all proteins contained 16% nitrogen; therefore, a universal conversion factor of 6.25 was not always appropriate. In support of his theory, Jones reported nitrogen contents for several plant and animal proteins from a variety of sources. He also reported a wide variation in the nitrogen content across these protein sources. Jones justified the 5.71 factor for soybeans by stating the major protein in soybeans is glycinin, a globulin composed of 17.5% nitrogen. From these data, he designated a conversion factor for soy protein of 5.71 (100 divided by 17.5 results in a factor of 5.71).

This 5.71 conversion factor for soy protein, based on Jones' logic, is false.

Research[8, 10, 11] has shown, however, that there can be wide variations in the levels of the major proteins in soybeans, glycinin and ß-conglycinin, which could result in widely different nitrogen conversion factors if Jones' logic were carried out. Murphy and Resurreccion (1984)[8] found glycinin/ß-conglycinin ratios varied significantly, depending on the soybean variety and differences in seasonal growing conditions. Roberts and Briggs (1965)[10] and Koshiyama (1968)[11] found that soy proteins typically consist of about 35% ß-conglycinin and contain between 15.5%[9] - 15.9%[10] nitrogen, respectively, translating to a conversion factor of 6.45 – 6.29. Utsumi et al.[38] reported that the ratio of 11S to 7S globulins in soybean cultivars varies from 0.5 – 1.7, making it apparent that the concept of a single specific and accurate NCF for soy would be difficult to know with any confidence. This is true for any naturally occurring protein ingredient, including milk protein, which can show variations in composition[69].

In recognition of the inconsistencies and inaccuracies inherent in analytical methods that measure protein indirectly through nitrogen content, other methods for measuring protein have been developed. In December of 2002, FAO convened the "Technical Workshop on Food Energy: Methods of Analysis and Conversion Factors". Outcomes of this workshop were published in FAO Food and Nutrition Paper 77[5]. One of the significant outcomes of this workshop was the recommendation by the expert panel for a superior and more accurate method using the sum of the anhydrous amino acids to measure protein. That is:

To measure protein as the sum of individual anhydrous amino acids, rather than the measurement of nitrogen by the Kjeldahl and other indirect methods.

Further, the workshop participants recommended that food composition tables should express protein content by the sum of anhydrous amino acids whenever possible, so these data may be used globally[5]. Using this recommended method, analytical product data supports a 6.25 nitrogen conversion factor as discussed below.

V. Analytical Product Data Using FAO's 2003 Recommendation

Analytical Product Data Supporting 6.25 Nitrogen Conversion Factor

The FAO Food and Nutrition Paper 77[5] recommended protein measurement by amino acid analyses. Heidelbaugh et al.[52] also proposed that the most accurate way to calculate NCFs for dietary purposes was based on amino acid composition. This method has been used by others to calculate NCFs for algae[12] and fish[70] in recent studies. If one applies this method to calculating the nitrogen conversion factors for defatted soybean meal, soy protein concentrate, and isolated soy protein one obtains values that range from 6.24 – 6.37 (Tables 5-7). The amino acid content of various soy ingredients produced from 1993-2007 were measured using the method described in Angell et al.[12] and Diniz et al.[70]. The anhydrous amino acid content was calculated as the amino acid molecular mass minus the molecular weight of water.

In addition, application of the FAO method to isolated soy protein amino acid data from 1982, isolated soy protein data currently available on the USDA National Nutrient Database for Standard Reference[71], and to amino acid data independently published in the scientific literature by Morr, 1981[9] yield a 6.30-6.31 conversion factor for soy protein. Application of the FAO method to amino acid values to commonly consumed foods, like soymilk[72] and tofu[73], published in the USDA National Nutrient Database for Standard Reference yields a 6.30 conversion factor. The USDA National Nutrient Database for Standard Reference lists these with an NCF of 6.25 using the approved AOCS and AOAC standards listed in Table 4.

The nitrogen conversion factors calculated using data from a fifteen year span of amino acid data demonstrate an overall average value of 6.33 (Tables 5-7). With the exception of one data point at 6.24 for one lot of defatted soy meal, the remaining nitrogen conversion factor values vary from 6.29 – 6.37. It is well recognized by experts in the field that plant products exhibit natural year-to-year differences and product-to-product differences, which are to be expected due to different growing conditions and variations in manufacturing

processes. The data for isolated soy protein ingredients presented in this document demonstrate stability of the protein nitrogen conversion factor over a 15 year period of time (Tables 5-7).

Amino acid analyses were performed on 55 soy protein samples (flakes and flour, isolated soy protein (ISP) or soy protein concentrates (SPC) according to conventional methods[74]. Samples were subject to acid hydrolysis at 110°C for 24 hours and the amino acids were separated by ion exchange chromatography and detected with ninhydrin. Each amino acid was quantitated against a standard known concentration for aspartic acid, threonine, serine, glutamic acid, proline, glycine, alanine, valine, methionine, isoleucine, leucine, tyrosine, phenylalanine, histidine, lysine and arginine. Methionine and cysteine were also quantitated after performic acid oxidation and tryptophan was quantitated after sodium hydroxide hydrolysis[74]. Values for amino acid weights were used to calculate a nitrogen conversion factor essentially as described by Angell et al.[12] and Diniz et al.[70].

The data in Tables 5-7 are based on analytical data from daily production samples analyzed by a single independent laboratory and show a nitrogen to protein ratio that is greater than the value, 6.25. Amino acid data used to calculate values for NCF of Isolated Soy Protein (2004-2007), soy protein concentrate, and soy flakes shown in Tables 5, 6, and 7, respectively, can be found in the Appendix as Tables 11-13.

Very importantly, it is noteworthy that these data are much more consistent with a nitrogen conversion factor of 6.25 than 5.71.

Table 5. 1993-2007 Isolated Soy Protein Industry Data*, **

Year	N Conversion Factor
1993	6.31
1994	6.33
1994	6.31
1995	6.33
1995	6.32
1997	6.35
1997	6.34
1998	6.36
1998	6.36
2002	6.33
2002	6.33
2002	6.32
2002	6.33
2003	6.34
2003	6.35
2004	6.35
2004	6.33
2004	6.36
2004	6.34
2004	6.34
2005	6.36
2005	6.35
2005	6.37
2005	6.34
2006	6.31
2006	6.35
2006	6.36
2006	6.34
2006	6.36
2006	6.33
2006	6.36
2007	6.31
2007	6.30
2007	6.31
2007	6.32
Mean	6.34
Standard Deviation	0.02

*Analytical method adapted from original method of Morr, 1981[9] and as described in Angell et al.[12] and Diniz et al.[70]

** NPAL Analytical Laboratories (St. Louis, MO, USA)

Table 6. 2004-2007 DuPont Soy Protein Concentrate Product Data*, **

Year	N Conversion Factor
2004	6.31
2004	6.29
2004	6.34
2004	6.32
2005	6.35
2005	6.37
2005	6.32
2006	6.32
2006	6.32
2007	6.29
Mean	6.32
Standard Deviation	0.03

*Analytical method adapted from original method of Morr, 1981[9] and as described in Angell et al.[12] and Diniz et al.[70]

** NPAL Analytical Laboratories (St. Louis, MO, USA)

Table 7. 2005-2007 DuPont Soy Flake & Flour Product Data*, **

Year	N Conversion Factor
2005	6.30
2005	6.31
2005	6.31
2004	6.34
2005	6.31
2005	6.32
2005	6.31
2005	6.24
2006	6.31
2007	6.29
Mean	6.30
Standard Deviation	0.03

*Analytical method adapted from original method of Morr, 1981[9] and as described in Angell et al.[12] and Diniz et al.[70]

** NPAL Analytical Laboratories (St. Louis, MO, USA)

In order to perform amino acid analysis on intact protein, it is necessary to release the constituent amino acids using hydrolysis. This is most commonly done via acid hydrolysis in 6N HCl over a period of time. Acid hydrolysis results in the conversion of amidated amino acids (glutamine and asparagine) to their acidic counterparts (aspartate and glutamate). Thus, during analysis, glutamine and glutamate are quantitated together, as are asparagine and aspartate. Since the amidated amino acids contain two nitrogen molecules and the acidic forms one, one cannot accurately calculate a NCF using amino acid analysis data alone, since one cannot accurately determine amidated amino acid content.

There is currently no method for direct quantitation of both glutamine and asparagine from protein. In 1966, Tkachuk[25] described two separate methods for estimating the amounts of amidated amino acids in protein samples. In the first method, amide ammonia released during hydrolysis is measured at several time points, then extrapolated to zero to estimate the concentration of amidated amino acids present in the starting sample. This method assumes linearity throughout the hydrolysis process, and is an extrapolation from only three time points. In 1982, Morr[28] published a research note in which he recalculated nitrogen conversion factors for soy products using the ammonia estimation method of Tkachuk[23]. In this note, Morr reduced the factors to 5.66-5.79 for four soy products based on an estimation of the amount of glutamine and asparagine present in each product[28]. Given that Tkachuk's method[25] is based on estimation of amide content in wheat, one cannot conclude that those factors calculated by Morr, 1982[28] are accurate.

In the second method referenced in Tkachuk, 1966[25], he attempts to determine amidated amino acid concentrations using three separate hydrolytic enzymes prepared in his laboratory using published methods. It should be noted that any side activities in these preparations had not been measured; it was assumed that no asparagine or glutamine deamidase activity was present that would lead to inaccurate results. In order to obtain concentrations for glutamine and asparagine, Tkachuk[25] performed both enzymatic and acid hydrolyses on samples, separated the resultant amino acids by chromatography, then compared the two chromatograms to determine differences. It should be noted that glutamine and asparagine were presumed by Tkachuk[25] to

co-elute with serine (based on retention times measured using pure standards). Thus, he could only estimate the amount of each by measuring differences in the serine peak between acid hydrolyzed and enzymatically hydrolyzed samples. Direct measurement of asparagine and glutamine released by this method was not possible. In addition, amino acid recoveries using the enzymatic method were poor, reaching only approx. 80% compared to >90% for the acid hydrolysis method. Thus, although valiant, Tkachuk's second method[25] can only be viewed as means of approximating the levels of asparagine and glutamine present in intact proteins.

Recently, a method was published using derivatization with [bis(trifluoroacetoxy)iodo]benzene (BTI) to measure glutamine levels in intact proteins[75]. Under the appropriate conditions, this reagent converts bound glutamine to acid-stable L-2,4-diaminobutyric acid (DABA). Thus, one can quantitate glutamine by measuring the DABA released following acid hydrolysis. BTI also converts asparagine to L-2,3-diaminopropionic acid (DAPA). However, Kuhn, et al.[75] have reported poor recovery of DAPA upon hydrolysis, so were unable to use this method for asparagine quantitation.

In conclusion, use of the Morr Factor method[28] to determine NCFs from anhydrous amino acid data can only approximate the factor, because it is not currently possible to measure asparagine and glutamine concentrations using direct methods. Therefore, use of NCFs derived from amino acid analysis data can only be viewed as estimates, until such time when validated, quantitative methods for determination of all amino acids present in a given sample are developed.

Use of the 5.71 Conversion Factor Conflicts with Mass Balance Calculations

As part of a quality assurance program, soy protein ingredient manufacturers generally analyze protein, moisture, fat, and ash for each lot of product. These proximates are all measured by direct analysis. Carbohydrates are not directly analyzed. Carbohydrate values are calculated by difference[4]: 100 minus the sum of protein, moisture, fat, and ash. Therefore, proximates must always add up to 100%. Isolated soy protein typically contains <1% carbohydrate, as determined by calculation[4]. Typical proximate values (on dry matter basis) for isolated soy protein using 6.25 as the conversion factor generate proximate data that can be supported by direct analysis (Table 8). Typical values for isolated soy protein using 5.71 as the conversion factor, however, generate proximate data that cannot be supported by direct analysis (Table 9). Use of the 5.71 factor results in 8% "missing mass". This 8% fraction cannot be properly classified as a nutrient by analytical methods, as the proximate values do not add up to 100% .

Table 8. 6.25 Factor: Typical Macronutrient Data for Isolated Soy Protein

Macronutrient	Typical Value
Protein (dry matter basis)	91%
Fat	4%
Ash	4%
Carbohydrate	1%

Table 9. 5.71 Factor: Typical Macronutrient Data for Isolated Soy Protein

Macronutrient	Typical Value
Protein (dry matter basis)	83%
Fat	4%
Ash	4%
Carbohydrate	1%
Missing Mass	**8%**

VI. Regulatory Environment

International Product Standards and Nutrition Labeling Recommendations and Regulations

Use of the 6.25 nitrogen conversion factor for soy protein is widely recognized as the appropriate method to determine compliance with product standards and nutritional labeling regulations by international organizations, such as Codex Alimentarius, and government regulatory agencies in India, Japan, Korea, the European Union, the United States, Argentina, Brazil, Mexico, Malaysia and South Africa (Table 10). Although an exhaustive list of regulations from around the globe is not provided in this document, the data provided represent the nutrition labeling regulations for countries ranked in the top 50 for population, hence a large portion of the global population[76].

The 2007 FAO/WHO Compendium of Codex Standards for Cereals, Pulses, Legumes, and Vegetable Proteins[77] and current Codex standards specifically state the 6.25 conversion factor should be applied to calculate protein values for soy and vegetable protein products. Namely:

- 175-1989 "Codex General Standard for Soy Protein Products"[1]

- 174-1989 "Codex General Standard for Vegetable Protein Products (VPP)[2]
- CAC/GL 2-1985 "Guidelines on Nutrition Labelling" (as amended by the 29th Session of the Commission, 2006)[3]

Codex Standard 175-1989[1] is widely accepted and followed by the isolated soy protein industry. Additionally, the 90% minimum protein level stated in Codex Standard 175-1989[1] serves as an important product standard to help identify high value isolated soy protein.

The nutrition labeling regulations of many major trading blocs list the 6.25 nitrogen conversion factor. For example, Argentina[78], Brazil[79], China[80], the European Union[81], India[82], Japan[83], Korea[84], the United States[85], Mexico[86], Malaysia[87] and South Africa[88] all require a 6.25 nitrogen conversion factor for soy protein ingredients. In addition, these nations recognize the Codex General Standard for Soy Protein Products STAN 175-1989[1], which requires a minimum 90% protein content.

Table 10. Current Soy Protein Conversion Factors from Around the Globe

Organization/Country/Region	Standard/Regulation	N Conversion Factor
Codex	Codex General Standard for Soy Protein Products STAN 175-1989[1]	6.25
Codex	Codex General Standard for Vegetable Protein Products (VPP) STAN 174-1989[2]	6.25
Codex	Guidelines on Nutrition Labelling CAC/GL 2-1985[3]	6.25
Argentina	Laws for the Labeling and Advertising of Food: Resolution in Conjunction with SPRyRS 149/2005 y SAGPyA 683/2005[78]	6.25
Brazil	Brazil National Health Surveillance Agency (ANVISA). Resolution – RDC No. 268, September 22, 2005[79]	6.25
China	China Ministry of Health "GB5009.5 Determination of Protein in Food"[80]	6.25
European Union	Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers[81]	6.25
India	Lab. Manual 3, Manual of Methods of Analysis of Foods, Cereal and Cereal Products, Directorate General of Health Services Ministry of Health and Family Welfare, Government of India[82]	6.25
Japan	Japanese Agricultural Standard for Vegetable Protein and Seasoned Vegetable Protein[83]	6.25
Korea	Nitrogen Conversion Factors for Protein Calculation, Korea Food Code[84]	6.25
United States	Title 21 Code of Federal Regulations Part 101.9[85]	6.25
Mexico	Norma Oficial Mexicana NOM-051-SCFI/SSA1-2010, Especificaciones generals de etiquetado para alimentos y bebidas no alcoholicas preenvasados[86]	6.25
Malaysia	Laws of Malaysia P.U. (A) 437 of 1985; Food Act 1983; Food Regulations 1985 (amended 2015); Malaysian Ministry of Health's 2010 Guide to Nutrition Labelling and Claims[87]	6.25
South Africa	Regulations No 146 Labelling and Advertising to food stuffs – Guidelines (2010)[88]	6.25

VVII. Implications of the Change from 6.25 to 5.71 Nitrogen Conversion Factor

Changing the nitrogen conversion factor for soy protein from the widely accepted 6.25 to 5.71 could have significant implications:

- Elimination of isolated soy protein as a food ingredient from the marketplace as it will be impossible to meet the product standard 90% protein minimum using 5.71 factor
- Significant costs to food manufacturers due to expensive label changes
    - "Isolated soy protein" would have to be removed from product ingredient lists

  - Changes to protein nutrition labelling
  - Potential requirement for product formula changes
- Confusion for food manufacturers seeking to make products containing isolated soy protein
- Confusion for consumers seeking products containing isolated soy protein
- Impacts on presentation and interpretation of data from nutritional research for both scientific and lay audiences (which use 6.25 for protein calculations)
- Significant cost increases for animal production facilities using soy as source of protein in feed rations
- Trade and product labelling logistical difficulties presented with multiple nitrogen conversion factors for various protein sources

Current isolated soy protein production methods generate product with a typical protein range of 90-92%, using 6.25 as the conversion factor. Occasionally, protein levels can reach 93-94%. Use of the 5.71 conversion factor for soy protein would artificially eliminate the isolated soy protein category, as protein levels will not reach the 90% minimum for the product standard. Product that is currently labeled as "isolated soy protein" would now be identified as "soy protein concentrate" (Codex STAN 175-1989 defines protein levels for soy protein concentrate as <90%, but ≥65%[1]). When 5.71 is applied, typical protein values would change to 82-84%, with occasional levels of 85-85.9%. Resulting replacement of the terminology "isolated soy protein" with "soy protein concentrate" in the ingredient list as a result of the use of a 5.71 conversion factor would require costly label changes for any product formula currently containing isolated soy protein.

In addition, products containing soy protein imported from countries utilizing the 6.25 conversion factor would require significant label changes. These significant label changes could generate confusion amongst consumers seeking products made with isolated soy protein, as well as products with specific protein levels. Furthermore, the use of a 5.71 factor for soy protein and the indirect measurement of protein via nitrogen content could inadvertently encourage adulteration of protein containing soy foods with substances that deliver nitrogen, as food processors may wish, for example, to continue to produce product with similar nutritional profiles and similar product standards of identity.

Soy protein has long been recognized for its beneficial health effects. As a result, soy protein has been extensively used in pre-clinical and clinical nutrition research. An important aspect of reporting data from nutrition studies for publication in international scientific research journals is the quantification of dietary protein intake. If the 5.71 factor is utilized to assess dietary soy protein intake while other countries use 6.25, the data may reflect artificially, yet significantly lower protein intakes in studies that utilize soy protein and the incorrect 5.71 factor. These artificially lower protein intakes in studies could conflict with soy research data generated from dietary intervention trials from other parts of the globe, making comparability of results across studies a challenge.

Animal production facilities that utilize soy as a significant protein source will face increased costs for feed if current feeding rates and amounts were maintained, due to the fact that measurement of protein levels in soy using the 5.71 factor will result in feed with 8.6% lower protein than levels calculated using the 6.25 NCF. Increasing the soy protein in animal feeds (if the NCF was reduced to 5.71) will also most certainly increase the nitrogen released in the feces of the monogastric animals which is harmful to the environment as pointed out by Mosse, et al.[30].

Finally, if the 5.71 conversion factor were to be applied to soy protein based on the 1931 research conducted by Jones[6], it should follow that the NCFs should be revisited for ALL major food proteins. Jones cited several NCFs for various proteins. As is the case with soy protein, it is likely that several of the NCFs reported by Jones are potentially incorrect due to the lack of sophisticated analytical techniques in 1931 compared to more recent technological advancements, as has already been pointed out by several researchers including Mosse, et al[30]. Determination of unique NCFs for all proteins from different sources that may be found in the food supply will be extremely laborious and will require consensus on a single method of calculating this NCF. Even if this is realized, implementing the agreed upon NCF for all proteins globally will be most difficult. It would appear more prudent to spend resources to develop methods that are based on amino acids themselves (as the nutritionally relevant moiety of the protein) rather than continue the decades long debate as to which NCFs are appropriate for different proteins.

VIII. Conclusions

In conclusion, this position document has carefully documented both regulatory and scientific support for the validity of 6.25 as the soy protein NCF. Additionally, as recommended by the FAO in 2003 and in the interests of continued advancement of analytical testing technology and food safety and quality, we also respectfully submit for consideration the measurement of protein via the sum of anhydrous amino acids or through the development and validation of other protein-specific measurements, rather than the indirect measurement of

protein obtained from the Kjeldahl method. Recent efforts to improve the measures of protein quality assessment are based on amino acid analyses[89], so it is reasonable to expect that amino acid methods will be standardized and more readily accessible globally. In addition, credible and valid analytical data on a variety of ingredients has been included that further support 6.25 as the soy NCF. We therefore, respectfully request the continued use of the 6.25 NCF for the measurement of protein in soy products. Harmonization of nutritional labeling and product standards, across professional organization and governments, is best served by continuing the 6.25 NCF for soy protein.

IX. References

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X. Appendix

Acronyms

AACC	AACC International (previously known as American Association of Cereal Chemists)

AOAC	AOAC International (previously known as Association of Official Analytical Chemists)
AOCS	American Oil Chemists Society
FAO	Food & Agriculture Organization of the United Nations
ISP	Isolated Soy Protein
ISO	International Organization for Standardization
SPC	Soy Protein Concentrate
USDA	United States Department of Agriculture
WHO	The World Health Organization

Table 11: Calculation of Nitrogen Conversion Factors for Soy Protein Isolate from anhydrous amino acid data

	g anhydrous AA residue/100 g sample																		
AA	**2004**	**2004**	**2004**	**2004**	**2005**	**2005**	**2005**	**2005**	**2006**	**2006**	**2006**	**2006**	**2006**	**2006**	**2007**	**2007**	**2007**	**2007**	**Averages**
lys	5.54	5.51	5.37	5.45	5.43	5.51	5.36	5.44	5.35	5.38	5.33	6.37	5.44	5.44	5.50	5.37	5.39	5.36	**5.47**
Hist	2.11	2.09	2.04	2.05	2.06	2.08	2.02	2.07	2.04	2.02	2.04	2.02	2.12	2.09	2.11	2.09	2.07	2.08	**2.07**
Arg	6.86	6.80	6.71	6.76	6.75	6.84	6.84	6.74	6.58	6.79	6.72	6.70	6.80	6.72	6.72	6.68	6.57	6.62	**6.73**
Asp	10.26	9.74	9.70	9.84	10.15	10.23	10.19	9.77	9.66	9.97	10.03	10.06	9.82	10.05	9.77	9.62	9.66	9.77	**9.90**
Thr	3.19	3.06	3.05	3.10	3.17	3.15	3.11	3.04	3.11	2.95	3.06	3.05	3.04	3.12	3.01	3.01	3.02	3.06	**3.07**
Ser	4.34	4.16	4.11	4.23	4.26	4.26	4.22	4.10	4.19	4.16	4.20	4.22	4.18	4.09	4.08	4.03	4.01	4.04	**4.16**
GlutA	18.29	18.10	17.90	18.12	18.41	18.74	18.67	18.21	16.25	18.63	18.17	17.91	19.21	18.38	16.73	16.42	16.45	16.45	**17.84**
Pro	4.36	4.77	4.48	4.40	4.54	4.49	4.50	4.48	4.60	4.58	4.73	4.55	4.64	4.79	4.50	4.50	4.33	4.45	**4.54**
Glyc	3.17	3.08	3.04	3.09	3.13	3.13	3.08	3.08	3.08	3.05	3.06	3.08	3.09	3.12	3.06	3.02	3.05	3.04	**3.08**
Ala	3.56	3.32	3.36	3.41	3.45	3.40	3.35	3.37	3.40	3.24	3.38	3.39	3.36	3.40	3.34	3.29	3.34	3.37	**3.37**
Cyst	1.03	1.14	1.06	1.05	1.08	1.05	1.08	1.03	1.08	1.11	1.06	0.99	1.02	1.05	1.03	1.06	1.02	1.05	**1.06**
Val	4.16	4.15	4.13	4.06	4.15	4.13	4.15	4.09	3.99	3.88	4.07	4.08	4.10	4.40	4.17	4.20	4.18	4.24	**4.13**
Meth	1.12	1.27	1.23	1.19	1.15	1.11	1.13	1.13	1.16	1.16	1.10	1.09	1.14	1.14	1.11	1.14	1.15	1.14	**1.15**
Isolu	3.98	3.73	3.74	3.79	3.87	3.82	3.87	3.74	3.74	3.76	3.89	3.94	3.78	3.93	3.87	3.83	3.81	3.91	**3.83**
Leu	7.20	6.77	6.83	6.93	6.94	6.89	6.92	6.75	6.85	6.68	6.97	7.08	6.90	6.88	6.77	6.70	6.75	6.84	**6.87**
Tyr	3.57	3.41	3.35	3.49	3.46	3.41	3.48	3.40	3.46	3.36	3.45	3.51	3.44	3.45	3.43	3.33	3.37	3.37	**3.43**
PhenylA	4.82	4.50	4.46	4.60	4.69	4.66	4.69	4.47	4.45	4.45	4.73	4.81	4.57	4.55	4.51	4.42	4.40	4.53	**4.57**
Trypto	1.09	1.11	1.14	1.09	1.06	1.07	1.02	1.07	1.09	1.06	1.07	1.05	1.05	1.12	0.99	1.09	1.12	1.11	**1.08**
g protein/100g sample	88.65	86.72	85.69	86.63	87.74	87.96	87.66	85.98	84.09	86.22	87.07	87.89	87.71	87.72	84.71	83.81	83.69	84.43	**86.36**
Total g N /100 g sample	13.96	13.69	13.52	13.65	13.8	13.85	13.77	13.57	13.32	13.58	13.68	13.87	13.79	13.8	13.43	13.3	13.26	13.36	**13.62**
NCF	6.35	6.33	6.34	6.35	6.36	6.35	6.37	6.34	6.31	6.35	6.37	6.34	6.36	6.36	6.31	6.30	6.31	6.32	**6.34**

Standard Amino Acid Analysis was performed as described in the text (see Section V above). Anhydrous amino acid weights were calculated by subtracting the MW of water (18 Da) from each amino acid, and the resultant weights tallied to determine percent protein content in a 100 gm sample. Total sample nitrogen was determined by tallying the N present in each AA residue based on percent nitrogen values. NCF was determined by dividing protein content by total nitrogen.

Table 12: Calculation of Nitrogen Conversion Factors for Soy Protein Concentrates from anhydrous amino acid data

	g anhydrous AA residue/100 g sample							
AA	**2004**	**2004**	**2004**	**2004**	**2005**	**2005**	**2005**	**Averages**
lys	5.59	5.52	5.58	5.60	5.51	5.54	5.51	**5.55**
Hist	2.14	2.10	2.09	2.10	2.09	2.07	2.11	**2.10**
NH#	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**
Arg	6.71	6.59	6.56	6.56	6.57	6.67	6.57	**6.61**
Asp	9.87	9.72	9.96	9.81	10.14	10.33	9.80	**9.95**
Thr	3.25	3.18	3.22	3.24	3.25	3.18	3.23	**3.22**
Ser	4.25	4.21	4.28	4.20	4.23	4.32	4.19	**4.24**
GlutA	17.55	17.23	17.88	17.55	17.95	18.75	17.63	**17.79**
Pro	4.41	4.34	4.56	4.43	4.55	4.66	4.39	**4.48**
Glyc	3.15	3.76	3.19	3.13	3.21	3.18	3.12	**3.25**
Ala	3.48	3.42	3.48	3.45	3.49	3.48	3.41	**3.46**
Cyst	1.30	1.30	1.29	1.28	1.19	1.12	1.29	**1.25**
Val	4.02	3.97	4.19	4.11	4.18	4.17	3.96	**4.09**
Meth	1.34	1.30	1.29	1.31	1.25	1.23	1.29	**1.29**
Isolu	3.67	3.68	3.74	3.67	3.81	3.86	3.64	**3.73**
Leu	6.76	6.75	6.81	6.68	6.85	7.00	6.57	**6.78**
Tyr	3.22	3.19	3.23	3.21	3.28	3.33	3.18	**3.23**
PhenylA	4.38	4.39	4.45	4.34	4.57	4.73	4.26	**4.45**
Trypto	1.09	1.08	1.10	1.09	1.10	1.05	1.07	**1.08**
g protein/100g sample	86.18	85.75	86.93	85.77	87.24	88.67	85.23	**86.54**
Total g N /100 g sample	13.65	13.63	13.71	13.56	13.74	13.91	13.48	**13.67**
NCF	6.31	6.29	6.34	6.33	6.35	6.37	6.32	**6.33**

NCFs were calculated as described above for Soy Protein Isolates

Table 13: Calculation of Nitrogen Conversion Factors from Soy Flake anhydrous amino acid data

	g anhydrous AA residue/100 g sample					
AA	**2005**	**2005**	**2004**	**2005**	**2005**	**Averages**
lys	5.62	5.48	5.27	5.63	5.58	**5.52**
Hist	2.15	2.17	2.09	2.17	2.16	**2.15**
Arg	6.82	6.82	6.38	6.68	6.81	**6.70**
Asp	9.99	10.38	9.74	10.09	10.13	**10.06**
Thr	3.29	3.20	3.19	3.32	3.24	**3.25**
Ser	4.15	4.17	4.18	4.21	4.23	**4.19**
GlutA	17.55	17.72	17.75	17.79	18.08	**17.78**
Pro	4.47	4.26	4.23	4.41	4.45	**4.36**
Glyc	3.17	3.15	3.10	3.22	3.19	**3.17**
Ala	3.50	3.37	3.41	3.53	3.50	**3.46**
Cyst	1.30	1.34	1.23	1.26	1.21	**1.27**
Val	4.09	4.04	3.96	4.11	4.10	**4.06**
Meth	1.30	1.25	1.29	1.23	1.18	**1.25**
Isolu	3.67	3.68	3.64	3.66	3.70	**3.67**
Leu	6.58	6.58	6.56	6.62	6.69	**6.60**
Tyr	3.29	3.15	2.99	3.22	3.31	**3.19**
PhenylA	4.41	4.46	4.34	4.44	4.50	**4.43**
Trypto	1.11	1.07	1.13	1.19	1.10	**1.12**
g protein/100g sample	86.46	86.28	84.49	86.76	87.15	**86.23**
Total g N /100 g sample	13.72	13.67	13.32	13.74	13.8	**13.65**
NCF	6.30	6.31	6.34	6.31	6.32	**6.32**

NCFs were calculated as described above for Soy Protein Isolates

EUROPEAN VEGETABLE PROTEIN FEDERATION

The European Natural Soy and Plant-based food Manufacturers Association (ENSA) and the European Vegetable Protein Association (EUVEPRO), as key stakeholders in soyfoods and in soy protein products, support the recommendation from CCMAS37 "… *that it might be timely for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors and to possibly update the report of the joint FAO/WHO/UNU expert consultation, Protein and Amino Acid Requirements in Human Nutrition (2002).",* and hereby ask for its endorsement by CAC39.

CAC38 and the Codex Committee on Nutrition and Foods for Special Dietary Uses CCNFSDU37 requested the Codex Committee on Methods of Analysis and Sampling CCMAS to

- assess the appropriateness of the use of the conversion factor of 5.71 to determine protein content in soybean products in general
- assess the accuracy and appropriateness of 5.71 as the nitrogen factor for soy protein isolates used in formula for infants and young children and to take into account the amino acid profile of the isolate

The CCMAS addressed the above questions regarding the Nitrogen Conversion Factor applicable to Soy protein during its last session in February 2016, and the discussions resulted in the following outcome:

Protein conversion factors

12. *The Committee agreed that it was not in a position to reply to the questions posed by CAC38 and CCNFSDU37 as the determination of conversion factors was in the remit of other Codex committees. The Committee agreed to inform the CAC and CCNFSDU accordingly.*

13. *The Committee agreed that conversion factors are scientifically based and that these factors should be harmonized between different Codex standards. The Committee noted that it might be timely for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors and to possibly update the report of the joint FAO/WHO/UNU expert consultation, Protein and Amino Acid Requirements in Human Nutrition (2002).*

The physical Working Group preceding the CCMAS37 session discussed the issue in more detail and, in addition to the conclusions here above, acknowledged that *"… there was no consensus on the nitrogen factors"*, and at the same time recognized that "*the conversion factors have severe economic aspects".*

A nitrogen conversion factor of 6.25 for soy products is consistent with current Codex Standards, the guidelines of globally recognised scientific organisations and agencies, national regulations, European Union legislation:

- Codex Alimentarius STAN 175-1989 Codex general standard for soy protein products
- Codex Alimentarius CAC/GL 2-1985 Guidelines on nutrition labelling
- Codex Alimentarius STAN 234-1999 Recommended Methods of Analysis and Sampling
- European Union Regulation 1169/2011 on the provision of food information to consumers Annex I
- European Commission delegated Regulation (EU)2016/127 supplementing Regulation 609/2013 regarding compositional requirements of infant formula and follow-on formula Annex 2 ('protein content = nitrogen content x 6.25')
- European Food Safety Agency EFSA Scientific Opinion on the essential composition of infant and follow-on formulae [EFSA Journal 2014;12(7):3760]
- European Food Safety Agency EFSA Scientific Opinion on Dietary Reference Values for protein [EFSA Journal 2012;10(2):2557]
- recommendations from the Analytical Sciences Associations (AOAC),
- many national and regional governmental nutrition and labelling regulations

If the value of 5.71 as NCF for soy protein were to replace the widely accepted 6.25, soy would inappropriately be challenged as a high quality protein source, resulting in confusion among consumers and health professionals. This would adversely impact public health programs that rely on soy protein as a staple commodity.

Applying different factors in different Codex standards would be inconsistent, have an impact on international trade, and would bring additional costs to food business operators, some of which are small and medium sized enterprises. Applying a conversion factor of 5.71 instead of 6.25 would result in an almost 10% reduction in the calculated protein content without any change to the composition of the products. This would mean that products would no longer be able to meet certain product requirements, which would entail changes to ingredients lists and food labels.

As stated by CCMAS in its report, protein conversion factors should be harmonised across the different Codex standards.

For the above reasons, we call upon CAC39 to endorse the recommendation of the CCMAS37 and to request FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors, and to possibly update the report of the joint FAO/WHO/UNU expert consultation, Protein and Amino Acid Requirements in Human Nutrition (2002).