



Association des Amidonneries
de Céréales de l'Union Européenne

43, av. Des Arts – B 1040 Brussels
Tel: +32-2-289 67 60 Fax: +32-2-513 55 92
e-mail: aac@aac-eu.org
Website : www.aac-eu.org



International Wheat Gluten Association

2918 5 AUG -8 A11 :43

G. Peter Bunn, III
General Counsel
Ferree, Bunn, O'Grady & Rundberg, Chtd.
9300 Metcalf Avenue, Suite 300
Overland Park, Kansas 66212 USA
Email: pbunn@fbolaw.com
Tel: (913) 381-8180 Fax: (913) 381-8836
www.iwga.net

August 2, 2005

Via email to <http://www.fda.gov/dockets/ecomments>.
And U.S. Postal Service

Mrs Marcia L. Moore
Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comment to CFSAN Threshold Working Group Draft Report Docket No. 2005N-0231

Dear Mrs Marcia L. Moore,

The authors of this letter are the Managing Director of the European Cereal Starch Industry Association (AAC) and the General Counsel of the International Wheat Gluten Association (IWGA). We are jointly submitting this comment to you concerning the Draft Report "Approaches To Establish Thresholds For Major Food Allergens and Gluten".

The members of our respective organizations comprise a super majority of producers of wheat gluten and wheat starch both in the EU, North America, and other geographic regions around the world. Accompanying this letter is a list of the membership of the AAC and the IWGA respectively.

We would be most grateful if these comments were taken into consideration by your committee in evaluating the thresholds for major food allergens and gluten in food.

2005N-0231

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Division of Dockets Management
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If we can be of help in this matter in any other way, please don't hesitate to contact either of us at your convenience.

Yours truly,



Lorenza Squarci
Managing Director
AAC



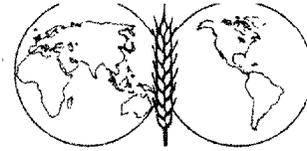
G. Peter Bunn, III
General Counsel
IWGA

GPB: bmb
Enc.



Association des Amidonneries
de Céréales de l'Union Européenne

43, av. Des Arts – B 1040 Brussels
Tel: +32-2-289 67 60 Fax: +32-2-513 55 92
e-mail: aac@aac-eu.org
Website : www.aac-eu.org



International Wheat Gluten Association

G. Peter Bunn, III
General Counsel
Ferree, Bunn, O'Grady & Rundberg, Chtd.
9300 Metcalf Avenue, Suite 300
Overland Park, Kansas 66212 USA
Email: pbunn@fbolaw.com
Tel: (913) 381-8180 Fax: (913) 381-8836
www.iwga.net

JOINT IWGA AND AAC COMMENT TO THE CFSAN DRAFT REPORT « APPROACHES TO ESTABLISH THRESHOLDS FOR MAJOR FOOD ALLERGENS AND GLUTEN IN FOOD »

The International Wheat Gluten Association (IWGA) and the European Cereal Starch Industry Association (AAC) would like to submit a comment to the draft report of the Threshold Working Group of the Center for Food Safety and Applied Nutrition on “Approaches to Establish Thresholds for Major Food Allergens and Gluten in Food”, more specifically with relation to gluten-free definition and limits.

As concluded under part IV-D of the report, the quantity and quality of the data needed to establish a definition for the term “gluten-free” for food labeling, are limited at the current time. This was reflected also in the final statement of the National Institute of Health conference on celiac disease of June 2004.

Nevertheless, we believe that recent data that became available from the Italian Microchallenge Study and from dietary survey studies in Finland, as referred to also in the draft report, are valuable in this context and may allow to conclude on a provisionally threshold for labeling of gluten-free foods, to be reconsidered when more scientific knowledge and chemical finding will become available. We would like to comment however on certain conclusions that are being drawn from both studies.

The Italian Microchallenge Study

A double blind, placebo-controlled challenge study is currently in progress in Italy, in which the daily exposure during 3 months to either 10 or 50 mg gluten is evaluated in biopsy proven celiac disease patients of min 18 years age. Preliminary results (Catassi et al., 2004) do not show a significant change as far as the clinical situation and the results of serological tests are concerned. Morphometric analysis of the small intestinal biopsies shows no difference among the placebo and 10 mg group, while a slightly lower average value for the vh/cd and a slightly higher average value for the IEL count is found for the 50 mg group, but not statistically significant however. The authors conclude that the results suggest that 10 mg should be considered as the maximum tolerable daily intake of gluten in treated celiacs.

Catassi et al. (2003) had reported earlier that children on a gluten-free diet showed a significant increase of the IEL count at a daily intake of 100 mg gliadin during 4 weeks, while at 500 mg gliadin daily also marked histological changes were noted. However, the study had important limitations due a.o. to the limited number of subjects and the lack of a control group.

The value of a well designed challenge study, including a control group and a sufficient number of patients in each group, is a.o. in the statistical evaluation of the results. While awaiting the completion of the study, we believe that the provisional conclusion from the results of the currently ongoing microchallenge study is that there is no statistically significant difference in the different test groups between the pre- and post-challenge situation for all parameters evaluated.

The dietary survey studies in Finland

The Department of Medicine and the Medical School of the University of Tampere have published during recent years results from dietary survey studies in Finland, comparing wheat starch-based and naturally gluten-free diets.

In a randomized study, Peräaho et al. (2003) found that a wheat starch-based and a naturally gluten-free diet result in a similar histological and clinical recovery in adult patients with newly diagnosed celiac disease.

Collin et al. (2004) determined the gluten content of a range of naturally and wheat starch-based gluten-free flours and baked products, and estimated the daily use of gluten-free flours from food records of celiac patients. While the majority of naturally gluten-free products contained no detectable gluten (<10 ppm, R5 ELISA), a number of naturally gluten-free products and most of the wheat starch-based gluten-free products contained between 10 and 100 ppm gluten. Some samples in both product groups contained between 100-200 ppm gluten. The daily use of gluten-free flours ranged from 10-300 g in adults (median 80 g) and 20-140 g in children (median 60 g). No correlation was found in adults between the level of consumption of the gluten-free products and the mucosal morphology and antiendomysial antibodies of the celiac patients.

Based on these data, the daily gluten uptake in function of the daily use of gluten-free foods and of their gluten content can be calculated (see also table III-1 of the draft report). The maximal values measured for daily consumption (300 g) and for gluten content (200 ppm) of the gluten-free products, would result in 60 mg daily gluten intake. As most values for consumption of gluten-free foods are below 150 g and for gluten content below 100 ppm, a realistic value for the daily gluten intake through the use of wheat starch-based gluten-free foods is 15 mg or below. Within these limits of gluten content and intake of gluten-free foods, the long-term treatment of celiac disease in Finland has been successful.

The range of safe gluten intake as calculated from the data reported in the context of the dietary survey studies in Finland, is in line with the preliminary results reported in the context of the Italian Microchallenge Study discussed above.

Kaukinen et al. (2004) in considering the above data from Finland, concludes that irrespective of whether wheat starch-based or naturally gluten-free products are used, the clinical and histological recovery is evident. The most important issue is that the adherence to the gluten-free

diet is good. It is recognized however that some individuals may be extremely sensitive to trace amounts of gluten.

Gluten-free limits

The revision of the Codex Standard for Gluten-Free Foods was put on hold in 2001 until a reliable method for the determination of gluten and scientific data on the tolerable intake of gluten by celiac people, become available. In the current proposal at Step 6, two levels of gluten are considered for gluten-free foods: maximum 200 ppm/ds for products containing derivatives of gluten-containing cereals, and maximum 20 ppm/ds for naturally gluten-free foods.

A maximum level of 200 ppm gluten is already commonly used in the market for wheat starch-based gluten-free foods, and the same limit value is used also for the wheat starch ingredient used in these foods.

Recent data on the gluten content of wheat starch-based gluten-free foods show that these products generally contain about 100 ppm gluten or less, with some products at 100-200 ppm gluten.

As indicated above, Collin et al. (2004) showed that with this range of gluten content, taking into account the daily intake of gluten-free foods, the long-term treatment of celiac disease in Finland has been successful.

The authors also conclude that since apparently this level can be achieved by the industry, the threshold for gluten in wheat starch-based gluten-free foods can be set at 100 ppm. The data on gluten content of gluten-free foods however are the result of the use in the market of the 200 ppm threshold value for wheat starch-based gluten-free foods, and are in line also with a 200 ppm limit value for wheat starch since:

- Wheat starch-based gluten-free flours and baked products contain maximally 70-80 % wheat starch;
- The gluten content of industrial wheat starch is mainly between 50 and 150 ppm, with maximum values measured up to 250 ppm (AAC, 2004)

The International Wheat Gluten Association and the European Cereal Starch Industry Association therefore believe that the maximum level of gluten for wheat starch-based gluten-free foods can be safely set at 200 ppm, as proposed also in the draft revised Codex Standard for Gluten-Free Foods. This will confirm the actual situation in the market of wheat starch-based gluten-free products generally containing 100 ppm gluten or less, which will result in a daily exposure level to gluten acceptable for a large majority of celiac people.

A second category of naturally gluten-free products, with guaranteed lower gluten content, will fulfill the needs also for the most sensitive celiac people.

One category of gluten-free foods with a low level of gluten acceptable also for the most sensitive people, or a further reduction of the maximum gluten content in wheat starch-based gluten-free foods, will exclude the use of wheat starch in gluten-free foods or substantially increase the cost of wheat starch-based gluten-free foods, and thus unnecessarily reduce the availability of gluten-free foods that can be safely used by the majority of celiac people, and decrease also their quality of life.

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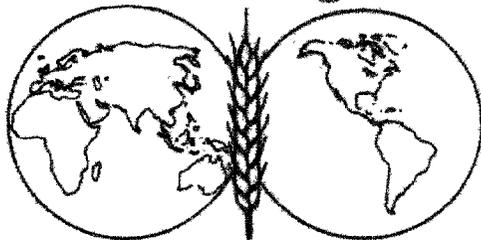
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G. Peter Bunn, III
General Counsel
Ferree, Bunn, O'Grady & Rundberg, Chtd.
9300 Metcalf Avenue, Suite 300
Overland Park, Kansas 66212 USA
Email: pbunn@fbolaw.com
Tel: (913) 381-8180
Fax: (913) 381-8836
www.iwga.net

International Wheat Gluten Association

MEMBERSHIP LIST

ARCHER DANIELS MIDLAND CO.

4666 Faries Parkway
Decatur, IL 62526

BM LLC

7 Sovetskaya Str., Zhalpak-Tyube
Zhambyl area, Zhambylskaya obl.
485124
REPUBLIC OF KAZAKHSTAN

CARGILL BV

Lelyweg 29
4600 AA Bergen op Zoom
Holland

CHAMTOR

Route de Pomacle, BP 20
F-51110 Bazancourt, FRANCE

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Ibbenbüren GERMANY

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JAPAN

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Nanyang City, Henan Province
P.R. China 473000

HERMANN KRÖNER GmbH

Postfach 1354,
D-49463 Ibbenbüren
Im Bocketal 21, D-49479
Ibbenbüren, GERMANY

JÄCKERING MÜHLEN UND NAHRMITTELWERKE GMBH

Vorsterhauserweg 49, D-59067 Hamm
GERMANY

LATENSTEIN B.V.

Waalbandijk 22
P.O. Box 392
6500 AJ Nijmegen
The Netherlands

MANILDRA MILLING CORP.

4210 Shawnee Mission Pkwy.,
Suite 312A
Shawnee Mission, KS 66205 USA

MGP INGREDIENTS, INC.

1300 Main Street, P. O. Box 130
Atchison, KS 66002 USA

PENFORD AUSTRALIA LTD.

170 Epping Road
Lane Cove NSW 2066
AUSTRALIA

ROQUETTE FRÈRES

Lestrem 62136, FRANCE

SEDAMYL S.P.A.

Via Monviso, 24
12037 Saluzzo (Cn)
ITALY

SYRAL

Zi Portuaire, BP 32
67390 - Marckolsheim
FRANCE

TATE & LYLE N.V.

Burchtsraat 10
B-9300 Aalst, Belgium

U.S. ENERGY PARTNERS, LLC

1030 East 15th Street
Russell, KS 67665 USA



Association des Amidonneries
de Céréales de l'Union Européenne

MEMBERSHIP LIST - AAC

1. AGRANA
Donau-City Strasse 9
A-1220 Wien
tel : 0043 1 211 370
fax : 0043 1 211 372998
www.agrana.com
2. ALTIA CORPORATION
P.O. Box 350
00101 Helsinki
tel : 00358 (9) 133 11
fax : 00358 (9) 133 32 78
www.altiagroup.fi
3. AVEBE - GROUP
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Cargill/Cerestar
Office Park Mechelen
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tel : 0032 (2) 15 40 04 11
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Cargill/Cerestar
Lelyweg 31
4600 AA Bergen op Zoom
The Netherlands
tel : 0031 (16) 428 22 00
fax : 0031 (16) 425 44 89

Cargill/Cerestar
Port of Tilbury
Tilbury
UK - Essex RM18 7PU
tel : 0044 (137) 585 11 22
fax : 0044 (137) 585 06 65

Cargill/Cerestar Benelux BV
Nijverheidsstraat 1
NL - 4551 LA Sas Van Gent
tel : 0031 (11) 545 90 00
fax : 0031 (11) 545 10 33

Cargill/Cerestar Deutschland GmbH
Cerestarstrasse 2
D - 47809 Krefeld
tel : 0049 (2151) 57 50 1
fax : 0049 (2151) 57 25 83

Cargill /Cerestar France SA
7, Rue du Marechal Joffre
F-59482 Haubourdin - Cedex
tel : 0033 (3) 20 44 35 35
fax : 0033 (3) 20 44 35 67

- | | | |
|-----|---|--|
| | Cargill/Cerestar France
18-20, Rue des Gaudines
BP 8215
78108 St Germain-en-Laye – Cedex | tel : 0033 (1) 30 61 35 00
fax : 0033 (1) 30 61 36 88 |
| | Cargill/Cerestar Iberica SA
Calle Marie Curie 6
E - 08760 Martorell (Barcelona) | tel : 0034 (93) 773 38 00
fax : 0034 (93) 775 59 50 |
| | Cargill/Cerestar UK Ltd
Trafford Park Plant
UK - Manchester M17 1PA | tel : 0044 (161) 872 59 59
fax : 0044 (161) 848 90 34 |
| | Cargill/Cerestar Scandinavia A/S
Ordrupvej 101, 2nd
DK – 2920 Charlottenlund | tel : 0045 (45) 46 90 00
fax : 0045 (45) 46 90 40 |
| | Cargill/Cerestar Italia
Via Cerestar 1
45035 Castelmasa (Ro) | tel : 0039 (04) 25 84 81
fax : 0039 (04) 25 84 07 84 |
| 5. | COPAM
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S. Joao da Talha
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fax 00351 2 (1) 955 86 89
www.copam.pt |
| 6. | CRESPEL & DEITERS
Postfach 16 61
D - 49466 Ibbenbüren | tel : 0049 (5451) 5000 0
fax : 0049 (5451) 5000 300
www.crespel-deiters.de |
| 7. | EMSLAND-STÄRKE
Postfach 11 40
D - 49824 Emlichheim | tel : 0049 (5943) 810
fax : 0049 (5943) 81205
www.emsland-staerke.de |
| 8. | FINNSUGAR Ltd
Sokeritehtaantie 20
SF-02460 Kantvik | tel : 00358 (9) 29 741
fax : 00358 (9) 2974234
www.daniscosugar.de |
| 9. | HUNGRANA KFT
Ipartelep
H-2432 Szabadegyháza | tel : 0036 25 578 101
fax : 0036 25578 112 |
| 10. | JÄCKERING
Postfach 17 33
D - 59007 Hamm | tel : 0049 (2381) 42 20
fax : 0049 (2381) 42 21 36
www.jaeckering.de |
| 11. | KRÖNER
Postfach 13 54
D - 49463 Ibbenbüren | tel : 0049 (5451) 94 47 0
fax 0049 (5451) 94 47 39
www.kroener-staerke.de |

12. NATIONAL STARCH
Prestbury Court
Greencourts Business Park
333, Styal Road
UK - Manchester M22 5LW
tel : 0044 (161) 435 32 00
fax: 0044 (161) 435 33 00
www.nationalstarch.com
13. PFEIFER & LANGEN/CHAMTOR
Linnicher Str. 48
D - 50933 Köln
tel : 0049 (221) 49 80 0
fax : 0049 (221) 498 03 71
www.pfeifer-langen.de
14. REMY INDUSTRIES
Remylaan
B-3018 Wijgmaal-Leuven
tel : 0032 (16) 24 85 11
fax : 0032 (16) 44 01 44
www.remy-industries.be
15. ROQUETTE FRERES
www.roquette.fr
Roquette Frères
F - 62136 Lestrem
tel : 0033 (3) 21 63 36 00
fax : 0033 (3) 21 63 38 50
Roquette Italia S.p.A.
Casella Postale 1
I - 15063 Cassano Spinola (Aless)
tel : 0039 (0143) 77 41
fax : 0039 (0143) 47 72 95
Roquette Laisa Espana SA
Avda Diagonal 440, 6º
E - 08037 Barcelona
tel : 0034 (93) 228 48 00
fax : 0034 (93) 228 48 18
Roquette UK
Sallow Road
Corby
Weldon Industrial Estate
UK Northants NN 17JX
tel : 0044 (153) 627 30 00
fax : 0044 (153) 626 38 73
16. SYRAL S.A.
B.P. 32
F-67390 Marckolsheim
tel : 0033 (3) 88 58 60 60
fax : 0033 (3) 88 58 60 61
www.syral.com
17. TATE & LYLE GROUP
www.tateandlyle.com
Tate & Lyle Europe
Burchtstraat 10
B - 9300 Aalst
tel : 0032 (53) 73 33 33
fax : 0032 (53) 73 30 33
Tate & Lyle France
Rue de Nesle 46 BP 7
F - 80190 Mesnil St Nicaise Cedex
tel : 0033 (1) 53 64 71 00
fax : 0033 (1) 53 64 71 99
Tate & Lyle Hellas
52, Georgkikis Scholis
P.O. Box 10018
GR - 541 10 Thessaloniki
tel : 0030 (31) 47 31 02
fax : 0030 (31) 47 38 47

Tate & Lyle Spain
San Juan de la Pena, Km 2
E - Zaragoza

tel : 0034 (976) 73 81 00
fax : 0034 (976) 73 81 28

Tate & Lyle Netherlands
Postbus 170
NL - 1540 AD Koog aan de Zaan

tel : 0031 (75) 653 21 11
fax : 0031 (75) 616 48 41

Tate & Lyle UK
Tunnel Avenue
Thames Bank House
UK - Greenwich-London SE10 OP

tel : 0044 (208) 853 72 00
fax : 0044 (208) 305 09 81

Sedamyl SpA
Via Monviso 24
I - 12037 Saluzzo

tel : 0039 (0175) 21 04 00
fax : 0039 (0175) 21 04 99

Associate Members

B.S.I.A.
British Starch Association
6, Catherine Street
UK - London WC2B 5JJ

tel : 0044 (171) 836 24 60
fax : 0044 (171) 836 05 80
www.fdf.org.uk

FACHVERBAND DER STÄRKE
INDUSTRIE EV
An der Elisabethkirche 26
D - 53037 Bonn

tel : 0049 (228) 91 42 30
fax : 0049 (228) 914 23 20
Info@verbaende-hees.de

FINNISH STARCH
MANUFACTURERS' ASSOCIATION
P.O. Box 115, Pasilankatu 2
FIN-00241 Helsinki

tel : 00358 (9) 1488 7217
fax : 00358 (9) 1488 7201
www.etl.fi

HUMAIZ
San Hermengildo 28 - 2ºB
E - 28015 Madrid

tel : 0034 (91) 711 45 99
fax : 0034 (91) 518 09 99
albertf@teleline.es

USIPA
Union des Syndicats des Industries des Produits
Amylacés et de leurs dérivés
4, place d'Estienne d'Orves
F - 75009 Paris

tel : 0033 (1) 48 78 51 00
fax : 0033 (1) 40 16 11 32
Usipa@wanadoo.fr

VNFG
Vereniging van Nederlandse Fabrikanten van Graanzetmeel
C/o Bond van Nederlandse Margarinefabrikanten
Postbus 161
NL-2280 AD Rijswijk

tel : 0031 (70) 352 50 74
fax : 0031 (70) 358 46 79
margarine.bond@wxs.nl

3-8-2005