GR

ORIGINAL SUBMISSION

Palsgaard®

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Robert L. Martin, Ph.D.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835
United States of America

07.Nov.2008 -

Re: GRAS Notification for Polyglycerol Polyricinoleate (PGPR) Exemption Claim.

Dear Mr. Martin,

Attached you'll find the GRAS Notification for Polyglycerol Polyricinoleate in triplicate.

In case you need additional information, please feel free to contact either my colleague Mr Viggo Norn (vn@palsgaard.dk) or myself at hhw@palsgaard.dk

Best regards

PALSGAARD A/S

Hanns-Henrik Wikman.
Technical Sales Manager

Palsgaard®

GRAS Notification for Polyglycerol Polyricinoleate (PGPR) in Vegetable Fat Coatings.

1. Letter to Office Food Additive Safety, Food and Drug Administration.
2. Polyglycerol Polyricinoleate (PGPR). Chemistry, Properties, Manufacturing Process, Application in Food.
3. International Specifications on PGPR
4. List of National Permissions.
5. Summary of Toxicology Studies on PGPR
6. Toxicology Studies
7. Evaluation on the Safe Intake of PGPR in the United States of America
8. Analytical studies in Relation to PGPR
9. Analysis of PGPR in Chocolate-type products
10. Codex Standard for Chocolate, Codex Stan 87-1981

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Robert L. Martin, Ph.D.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

23.10.2008 -

Re: GRAS Notification for Polyglycerol Polyricinoleate. (PGPR).Exemption Claim.

Dear Mr. Martin,

Under the GRAS Notification Program, Palsgaard A/S hereby claims that Polyglycerol Polyricinoleate is Generally Recognized as Safe ("GRAS") for use as an emulsifier for vegetable fat coatings as defined in CFR 21 § 163.
Therefore the emulsifier is exempted from the statutory premarket approval requirements of the Federal Food Drug and Cosmetic Act.
Polyglycerol Polyricinoleate is authorized for use in the European Union under the E-number E 476, and is listed by the Joint FAO/WHO Expert Committee on Food Additives ("JECFA") in the Combined Compendium of Food Additive Specifications. (Codex specification INS number 476).

(i) The name and address of the notifier.

Palsgaard A/S
Palsgaardvej 10
7130 Juelsminde
Denmark

(ii) The common or usual name of the substance.

The common name of the emulsifier is Polyglycerol Polyricinoleate and/or PGPR

(iii) The applicable conditions of use.

Polyglycerol Polyricinoleate is to be used by the food industry as an emulsifier in vegetable fat coatings. This emulsifier has the ability to lower the Yield Value in both pure chocolate (semi-sweet chocolate, milk chocolate and white chocolate) and vegetable fat coatings when added at amounts up to 0.3 %. Hereby the candy manufacturer is able to control the flow properties of the liquid mass during production. The typical dosage of Polyglycerol Polyricinoleate is in the range 0.1 – 0.3 % to achieve the desired effect and in accordance with Good Manufacturing Practice.

Polyglycerol Polyricinoleate has previously been evaluated by the FDA Office of Premarket Approval – Agency Response Letter GRAS Notice No. GRN 000009, for use in chocolate only. However, due to the request by the food industry to be able to control the Yield Value also in vegetable fat based coatings, addition of Polyglycerol Polyricinoleate is in growing demand for this application as well.

(iv) Basis for the GRAS determination.

The GRAS determination is based on a scientific evaluation of the published toxicological studies on Polyglycerol Polyricinoleate combined with an evaluation of the consumption pattern of vegetable fat coatings in the US.
JECFA has for Polyglycerol Polyricinoleate established an accepted daily intake (ADI value) to 0-7.5mg per kg body weight per day.

The statistical data on consumption of vegetable fat coatings by the US population compared with the established ADI value on Polyglycerol Polyricinoleate clearly support the safety of the use of Polyglycerol Polyricinoleate at a maximum rate of 0.3 % in vegetable fat coatings.

(v) Available data and information.

Supporting documentation in triplicate is enclosed with this letter. Further data and information that are the basis for this GRAS determination and notification are available to the Food and Drug Administration for review and copying upon request.

Best regards

PALSGAARD A/S

Viggo Norn
R&D Director.

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Polyglycerol Polyricinoleate (PGPR).

Chemistry.
Polyglycerol Polyricinoleate (PGPR) also know under the trade names Palsgaard®4125 or Palsgaard®4150, is a food grade emulsifier consisting of poly-glycerol as the hydrophilic group and interesterified ricinoleic fatty acids as the hydrophobic group. (see fig.1)

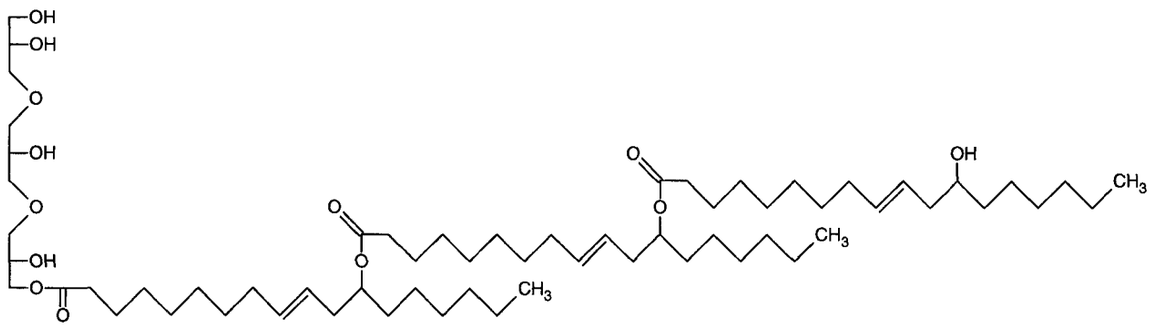

Fig.1. Chemical structure of PGPR. (Here the fraction consisting of Tri-Glycerol Tri-Ricinoleate is shown.)

The polyglycerol part of PGPR is mainly found as di- tri- or tetraglycerol (min 75%) and max 10% of the polyglycerol part will be found as heptaglycerol or higher.

Properties.
PGPR is a strong water-in-oil emulsifier used to manufacture stable pan release agents for the bakery industry and to stabilize low fat margarine systems with high water content.

PGPR also has the ability in improve the flow properties in chocolate and vegetable fat coatings by lowering the friction between the particles suspended in the liquid fat phase. Hereby the so-called Yield Value will be reduced and the liquid chocolate mass will flow easily even at a low total fat content.

Manufacturing process.
In step #1 glycerol is heated to temperatures above 200°C in a reactor. A small amount of alkali is added as catalyst. Two or more glycerol molecules will condensate and water will be released and removed over a vacuum pump.
Mainly straight-line polyglycerol units will be created, but a smaller amount of cyclic by-products will also be created.
In fig.2 the formation of di- and tri-glycerol is shown, but highly polymerized polyglycerols are also created.

In step #2 castor oil fatty acids will be heated in a reactor likewise to temperatures above 200°C. The fatty acids from castor oil are mainly found as ricinoleic fatty acids (approx 90%). The remaining fatty acids are found as oleic-, linoleic- stearic- fatty acids.

The ricinoleic fatty acids react in a simple linear esterification process to form interesterified ricinoleic fatty acid chains. Water is released during the process and removed over vacuum pumps.

In step #3 the interesterified ricinoleic fatty acids are mixed with the polyglycerol to form a complex mixture of polyglycerol-polyricinoleate molecules of different chain lengths.

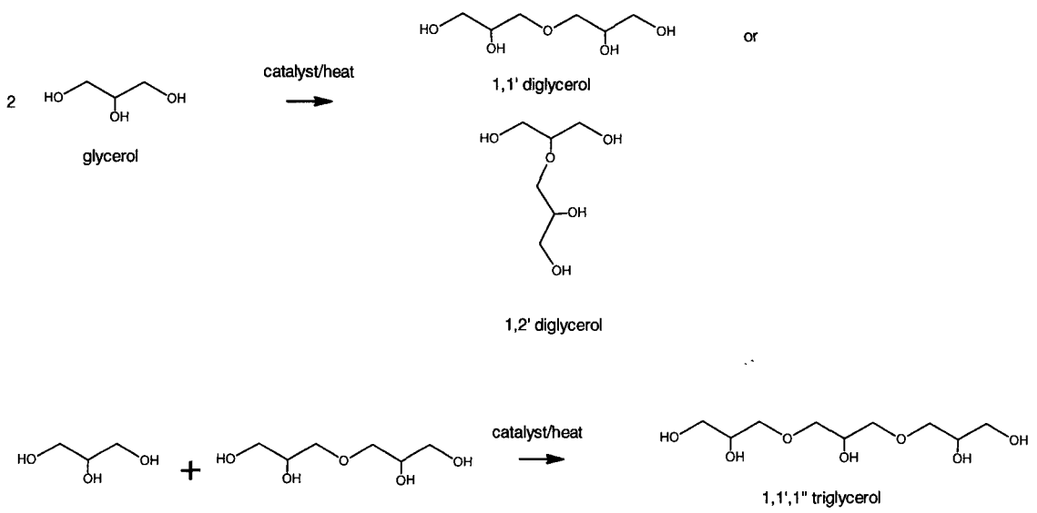

Fig.2. Polyglycerols are made from glycerol by alcaline condensation

Application in Foods.

PGPR has a dramatic impact on the flow properties of liquid chocolate and componds based on vegetable fats. In general it is understood that PGPR works by lowering the Yield Value of the chocolate system, whereas the Plastic Viscosity hardly is influenced.

This has the practical implication that PGPR as a general rule always is added as a co-emulsifier in combination with lecithin or ammonium phosphatide. These emulsifiers mainly reduce the plastic viscosity.

Cocoa butter and specialty vegetable fats are quite expensive raw materials, so the manufactures of chocolate and componds can benefit from the effect of PGPR and lower the total fat content in the ready to consume products. Also from a health point of view fat reduction in chocolate and componds is improving the quality in the eyes of the consumers.

Due to the strong effect on the yield value in chocolate it is possible to make the chocolate flow during production by use of much less fat. Therefore PGPR is an important tool in manufacturing of various types of chocolate-type products.

The effect in is further described by Steven T.Beckett. The Science of Chocolate. (Royal Society of Chemistry, 2000. p 81 ff) and by Schantz, b. and Rohm, H. (Lebensm.-Wiss.u.Technol. 38 (2005) p 41-45.

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International Specifications on Polyglycerol Polyricinoleate (PGPR)

1. **Combined Compendium of Food Additive Specifications.**
Joint FAO/WHO Expert Committee on Food Additives (JECFA). (2005)

2. **Food Chemical Codex 5th edition.**
Committee on Food Chemical Codex Food and Nutrition Board (2004)

3. **Commission Directive 98/86/EC.**
Amending Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners (1998)

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List of National Permissions. Polyglycerol Polyricinoleate (PGPR)

1. **USA. Agency Response Letter GRAS Notice No GRN 000009.**
   PGPR to be added to chocolate at a level up to 0.3 %.

2. **USA. Agency Response Letter GRAS Notice No GRN 000179.**
   PGPR to be added to margarines, low fat margarines, spreads, creamers and dairy analogs at levels no greater than 1 % by weight.

3. **EU Parliament and council Directive No 95/2/EC.**
   PGPR to be added to Cocoa-based confectionery, including chocolate up to 5g/kg
   PGPR to be added to Spreadable fats having a fat content below 41% up to 4g/kg
   PGPR to be added to Dressings up to 5g/kg

4. **Australia New Zealand Food Autrority P150 – A joint general standard for Food Additives.**
   PGPR to be added to Chocolate and Cocoa Products (included Compounded chocolate) up to 5000 mg/kg
   PGPR to be added to Margarine and similar products up to 5000 mg/kg

5. **Canada The Food and Drugs Act and Regulations.**
   PGPR to be added to Milk Chocolate ; Sweet Chocolate up to 0.5%
   PGPR to be added to Unstandardized chocolate flavoured confectionery coatings up to 0.25 %

U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

Agency Response Letter
GRAS Notice No. GRN 000009

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

April 2, 1999

Angel Diaz de Leon
Quest International
5115 Sedge Blvd.
Hoffman, IL 60192

Re: GRAS Notice No. GRN 000009

Dear Mr. Diaz de Leon:

In a letter dated March 2, 1999, the Food and Drug Administration (FDA) responded to your notice, dated October 10, 1998, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received your notice on October 22, 1998, and designated your notice as GRAS Notice No. GRN 000009. Your notice states that Quest International (Quest) has determined, through scientific procedures, that polyglycerol polyricinoleic acid (PGPR) is GRAS for use as an emulsifier for chocolate at a level up to 0.3 per cent.

In our March 2, 1999, letter, we mistakenly reported the maximum use level to be 3.0 per cent. To clarify that we evaluated a maximum use level of 0.3 per cent, we are issuing a second letter. This letter repeats the text of our letter dated March 2, 1999, with the exception of the maximum use level, which is corrected. We apologize for any inconvenience or confusion that may have resulted from our mistake.

Your notice describes (1) published information relating to the method of manufacture of PGPR, (2) published studies conducted with PGPR, (3) unpublished studies conducted with PGPR, and (4) published information on the functionality of PGPR in chocolate. In addition, your notice includes a report of a specially convened GRAS panel and a toxicological monograph on PGPR, which was published by the Joint Food and Agriculture Organization / World Health Organization's (FAO/WHO) Expert Committee on Food Additives (JECFA).

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Based on the information provided by Quest, as well as other information available to FDA, the agency has no questions at this time regarding Quest's conclusion that PGPR is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of PGPR. As always, it is your continuing responsibility to ensure that food ingredients that you market are safe, and are otherwise in compliance with all applicable

legal and regulatory requirements.

We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity. Standards of identity regarding chocolate products are described in 21 CFR Part 163 (Cacao Products). For your information, the standard of identity for chocolate liquor (§ 163.111) does not permit the addition of emulsifying agents as an optional ingredient in this standardized food.

We consulted with the Office of Food Labeling (OFL) regarding your view that PGPR is the common or usual name for polyglycerol polyricinoleic acid. OFL advised us that, in general, an ingredient should be declared using a common or usual term or term, i.e., terms that would be recognized by consumers. Because U.S. consumers have no prior experience with the use of PGPR, it is not clear that the consumer would recognize that PGPR stands for polyglycerol polyricinoleic acid. One mechanism to develop the requisite recognition is to declare PGPR using both the chemical term (polyglycerol polyricinoleic acid) and the abbreviation PGPR. After a period of time, PGPR would be recognized by consumers and the abbreviation could stand alone. If you have any questions about the appropriate name of this food ingredient, for labeling purposes, we recommend that you discuss those questions with OFL. An initial contact for such questions is Mr. John Foret, who can be reached at (202)205-4122.

In accordance with proposed § 170.36(f), a copy of this letter, as well as a copy of the information in your notice that conforms to the information in proposed § 170.36(c)(1), is available for public review and copying in the public reading room of the agency's Freedom of Information Staff. A copy of our letter dated March 2, 1999, which was placed in the public file during the week of March 22, 1999, has been removed from that file.

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

cc:

Mr. Gary Yingling
McKenna and Cuneo, L.L.P.
1900 K Street, N.W.
Washington, DC 20006-1108

Home	GRAS Notice Summary Table			

Content last updated by lsk on 1999-MAR-24
Hypertext last updated by rdb on 1999-JUN-04

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CFSAN/Office of Food Additive Safety
January 20, 2006

Agency Response Letter
GRAS Notice No. GRN 000179

Blaine Byers, Ph.D.
Stepan Company
22 West Frontage Rd.
North Field, IL 60093

Re: GRAS Notice No. GRN 000179

Dear Dr. Byers:

The Food and Drug Administration (FDA) is responding to the notice, dated July 19, 2005, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on July 20, 2005, filed it on July 25, 2005, and designated it as GRAS Notice No. GRN 000179.

The subject of the notice is polyglycerol polyricinoleic acid (PGPR). The notice informs FDA of the view of Stepan Company that PGPR is GRAS, through scientific procedures, for use as an emulsifier in margarines, low fat margarines, spreads, creamers, and dairy analogs, at levels no greater than 1.0 percent by weight.

Stepan Company defines PGPR as an interesterified polymer of polyricinoleic acid and polyglycerol and describes the manufacture of each of these components and PGPR. The first, polyricinoleic acid, is prepared by heating castor oil fatty acids, with or without a catalyst, to promote self-condensation of castor oil fatty acids (80 to 90 percent ricinoleic acid). Any catalysts used would include those currently used in the manufacture of food grade fats and oils. The second, polyglycerol, may be obtained either by polymerization of glycerin with a strong base catalyst[1] or by polymerization of epichlorohydrin. Stepan Company states that the polymerization of epichlorohydrin is the preferred method of manufacture; this method includes steam distillation at temperatures between 150 and 200 degrees Celsius, under vacuum conditions, to remove residual epichlorohydrin monomer. The resulting polymeric chlorohydrin is then hydrolyzed under basic conditions to produce polyglycerol. Stepan Company describes generally available information about the formation of PGPR from the interesterification of polyricinoleic acid and polyglycerol. Briefly, these two components, at specified levels, are heated to 200 degrees Celsius and allowed to react for a period of 12 hours. Stepan Company states that its PGPR product is consistent with the methods of manufacture and the specifications established for polyglycerol polyricinoleic acid in the Food Chemicals Codex (5th edition, 2004).

In an amendment dated January 9, 2006, Stepan Company addresses the issue of the potential for residual epichlorohydrin in PGPR obtained from the preferred method of manufacture of polyglycerol, stating that under the steam distillation conditions used, residual monomer is typically reduced to levels below 1 part per million (milligram per kilogram) in polyglycerol.

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Stepan Company notes that further reductions in concentration of epichlorohydrin are expected in the PGPR product, due in part to the limited level of polyglycerol (9 percent) used to produce PGPR, but also as a result of the 12 hour interesterification reaction. The final PGPR ingredient is used at a level of 1 percent or less in a formulated product, thus further diluting any residual epichlorohydrin. Stepan Company concludes that the residual epichlorohydrin levels in formulated products are expected to be negligible and far below detectable limits.

Stepan Company intends to use PGPR as an emulsifier in margarines, low fat margarines, spreads, creamers, and dairy analogs, at levels no greater than 1.0 percent by weight. Stepan Company states that the typical use levels of PGPR are 0.4 to 0.8 percent of the total weight of the food formulation, and describes the role of PGPR, often used in combination with lecithin and mono- and di-glycerides, in stabilizing emulsions with high ratios of water to fat. As the levels of fat decrease in the spread formulation, greater levels of emulsifiers are required to achieve a stable water-in-oil emulsion.

Stepan Company states that its determination that PGPR is GRAS for the intended conditions of use is based upon scientific procedures following its review of information on their method of manufacture, applications, exposure, animal toxicology and metabolism, and human consumption of PGPR from current use in chocolate. In its safety evaluation, Stepan Company references GRAS Notice No. GRN 000009 (PGPR for use as an emulsifier in chocolate) and a review by the Food and Agriculture Organization/World Health Organization Joint Expert Committee on Food Additives (JECFA). Stepan Company provides references to published studies and other relevant publications.

In the notice, Stepan Company states its intention to use PGPR in low fat margarine. FDA notes that margarine has a standard of identity specifying fat content (21 CFR 162.110) and that the term "low fat" is a nutrient content claim, the use of which is specified by regulation (21 CFR 101.62 (b)(2)). If you have any questions about the appropriate label for this food, we recommend that you contact the Office of Nutritional Products, Labeling, and Dietary Supplements in the Center for Food Safety and Applied Nutrition.

Based on the information provided by Stepan Company, as well as other information available to FDA, the agency has no questions at this time regarding Stepan Company's conclusion that PGPR is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of PGPR. As always, it is the continuing responsibility of Stepan Company to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,

Laura M. Tarantino, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

[1]FDA notes that Stepan Company cites a published reference providing greater detail regarding the method of manufacture of polyglycerol by polymerization of glycerin.

Food Ingredients and Packaging | Summary of all GRAS Notices

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FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by rxm February 23, 2006

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ANZFA
Australia New Zealand Food Authority

TE MANA WHAKARITE KAI
MO AHITEREIRIA ME AOTEAROA

INQUIRY REPORT

SUBJECT: P150 - A JOINT GENERAL STANDARD FOR FOOD ADDITIVES

EXECUTIVE SUMMARY

Executive Summary from the Full Assessment Report

The policy paper "The Regulation of Food Additives", published in March 1996, was used as the basis for the development of a proposed draft Australia New Zealand General Standard on Food Additives. The proposed draft standard - P150 - was released for public comment from March 1997 to September 1997. A total of 65 submissions were received. The overwhelming majority of submissions supported the proposed draft standard, and comments received were related to:

- omissions from the schedules of additive uses currently permitted in Australia and/or New Zealand;
- inconsistencies in the permitted use of various additives; and
- requests for extensions to recognise established additive uses permitted by Codex or allowed in the EU or Northern America.

A small number of submissions raised concerns related to the general policy for the regulation of food additives being applied.

At full assessment a draft general standard for food additives was prepared which reinforced the consistent policy previously established by ANZFA for the use of the additives. The standard was developed by applying risk analysis to ensure that the dietary exposure to food additives from the food supply did not present an unacceptable risk to public health and safety and that consumers would not be exposed unnecessarily to high levels of food additives. Thereafter, it facilitated both consumer choice and innovation in food technology by applying the minimum restriction on use consistent with Good Manufacturing Practice (GMP) for those additives where dietary exposure estimates indicated no public health and safety concerns.

The safety of food additives was been assessed in accordance with the ANZFA policy paper "Framework for the assessment and management of food-related health risks".

INS Number	Additive Name	Max level		Appl
2	**EDIBLE OILS AND OIL EMULSIONS**			
160b	Annatto extracts	20	mg/kg	
304	Ascorbyl palmitate	GMP		
306	Tocopherols concentrate mixed	GMP		
307	Tocopherol, d-alpha-, concentrate	GMP		
308	Synthetic gamma-tocopherol	GMP		
309	Synthetic delta-tocopherol	GMP		
310	Propyl gallate	100	mg/kg	
311	Octyl gallate	100	mg/kg	
312	Dodecyl gallate	100	mg/kg	
319	Tertiary butylhydroquinone	200	mg/kg	
320	Butylated hydroxyanisole	200	mg/kg	
321	Butylated hydroxytoluene	100	mg/kg	
2.1	**Edible oils essentially free of water***			
475	Polyglycerol esters of fatty acids	20000	mg/kg	shortening only
476	Polyglycerol esters of interesterified ricinoleic acids	20000	mg/kg	shortening only
900a	Polydimethylsiloxane	10	mg/kg	frying oils only
	olive oil			
	Additives in Schedules 3&4 must not be present in olive oil			
2.2	**Oil emulsions (water in oil)**			
2.2.1	**Oil emulsions (>80% oil)**			
2.2.1.1	**Butter**			
	Additives must not be present in foods in this category unless expressly permitted below			
160a	Carotenes	GMP		
160b	Annatto extracts	20	mg/kg	
508	Potassium chloride	GMP		
2.2.1.2	**Butter products***			
2.2.1.3	**Margarine and similar products***			
475	Polyglycerol esters of fatty acids	5000	mg/kg	
476	Polyglycerol esters of interesterified ricinoleic acids	5000	mg/kg	
2.2.2	**Oil emulsions (<80% oil)***			
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	2000	mg/kg	
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	1000	mg/kg	
234	Nisin	GMP		
281	Sodium propionate	GMP		
282	Calcium propionate	GMP		
475	Polyglycerol esters of fatty acids	10000	mg/kg	
476	Polyglycerol esters of interesterified ricinoleic acids	10000	mg/kg	

*** Additives in Schedules 2, 3, and 4 are permitted**

INS Number	Additive Name	Max level		Applications
5	**CONFECTIONERY**			
123	Amaranth	300	mg/kg	
173	Aluminium	GMP		
174	Silver	GMP		
175	Gold	GMP		
950	Acesulphame potassium	2000	mg/kg	Clause 4 limits do not apply to the use of permitted sweeteners in chewing gum and bubble gum
951	Aspartame	10000	mg/kg	
955	Sucralose	2500	mg/kg	
956	Alitame	300	mg/kg	
	fruit filling for confectionery containing not less than 200 g/kg of fruit			
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	500	mg/kg	
5.1	**Chocolate and cocoa products**			
	Additives in Schedules 3&4 must not be present in foods in this category unless expressly permitted below			Colours permitted on the surface of chocolate only
476	Polyglycerol esters of interesterified ricinoleic acids	5000	mg/kg	
477	Propylene glycol esters of fatty acids	4000	mg/kg	
5.2	**Sugar confectionery***			
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	1000	mg/kg	
	bubble gum and chewing gum			
304	Ascorbyl palmitate	GMP		
310	Propyl gallate	200	mg/kg	
320	Butylated hydroxyanisole	200	mg/kg	
321	Butylated hydroxytoluene	200	mg/kg	
	low joule chewing gum			
952	Cyclamates	20000	mg/kg	
954	Saccharin	1500	mg/kg	
5.3	**not assigned**			
.4	**Icings and frostings***			
160b	Annatto extracts	20	mg/kg	
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	1500	mg/kg	
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	1000	mg/kg	

*** Additives in Schedules 2, 3, and 4 are permitted**

Alphabetical Listing

INS number	Additive name
260	Acetic acid, glacial
472a	Acetic and fatty acid esters of glycerol
1422	Acetylated distarch adipate
1414	Acetylated distarch phosphate
1401	Acid treated starch
355	Adipic acid
406	Agar
400	Alginic acid
1402	Alkaline treated starch
1100	Alpha-amylase
559	Aluminium silicate
470	Aluminium, calcium, sodium magnesium potassium and ammonium salts of fatty acids
264	Ammonium acetate
403	Ammonium alginate
503	Ammonium carbonates
380	Ammonium citrates
368	Ammonium fumarate
328	Ammonium lactate
349	Ammonium malate
342	Ammonium phosphates
442	Ammonium salts of phosphatidic acid
409	Arabinogalactan (larch gum)
300	Ascorbic acid
951	Aspartame (technological use consistent with Clause 4 only)
901	Beeswax, white & yellow
558	Bentonite
1403	Bleached starch
263	Calcium acetate
404	Calcium alginate
556	Calcium aluminium silicate
302	Calcium ascorbate
170	Calcium carbonates
509	Calcium chloride
333	Calcium citrate
367	Calcium fumarate
578	Calcium gluconate
623	Calcium glutamate, Di-L-
526	Calcium hydroxide
327	Calcium lactate
352	Calcium malates
529	Calcium oxide

452	**Polyphosphates**	(additives are listed in Schedule 2)		
	9.1	Unprocessed fish and fish fillets (including frozen and thawed) *Subcategory: frozen fish* Application: fillets only	GMP	
460	**Cellulose, micro-crystalline and powdered**	(additives are listed in Schedule 2)		
	11.1	Sugar	GMP	
471	**Mono- and diglycerides of fatty acids**	(additives are listed in Schedule 2)		
	6.1	Cereals (whole and broken grains)	GMP	
		Application: precooked rice only		
473	**Sucrose esters of fatty acids**	(additives are listed in Schedule 2)		
	4.1.2	Surface treated fruits and vegetables	100	mg/kg
475	**Polyglycerol esters of fatty acids**			
	1.4.2	Cream products (flavoured, whipped, thickened, sour cream etc) *Subcategory: whipped thickened light cream*	5000	mg/kg
	2.1	Edible oils essentially free of water	20000	mg/kg
		Application: Shortening only		
	2.2.1.3	Margarine and similar products	5000	mg/kg
	2.2.2	Oil emulsions (<80 % oil)	10000	mg/kg
	7.2	Biscuits, cakes and pastries	15000	mg/kg
		Application: cake only		
	20	Mixed foods *Subcategory: dairy and fat based desserts, dips and snacks*	5000	mg/kg
	20	Mixed foods *Subcategory: sauces and toppings, including mayonnaises and salad dressings*	20000	mg/kg
476	**Polyglycerol esters of interesterified ricinoleic acids**			
	2.1	Edible oils essentially free of water	20000	mg/kg
	2.2.1.3	Margarine and similar products	5000	mg/kg
	2.2.2	Oil emulsions (<80 % oil)	10000	mg/kg
	5.1	Chocolate and cocoa products	5000	mg/kg
	20	Mixed foods *Subcategory: dairy and fat based desserts, dips and snacks*	5000	mg/kg
477	**Propylene glycol esters of fatty acids**	(additives are listed in Schedule 2)		
	5.1	Chocolate and cocoa products	4000	mg/kg

STANDARD Q3

COCOA AND COCOA PRODUCTS

(1) Cocoa bean is the fermented and dried whole seed of the cocoa tree, *Theobroma cacao* L.

(2) Cocoa nibs or cracked cocoa is the roasted cocoa bean freed from its shell or husk, with or without the germ.

(3) (a) For the purposes of this Code, the terms 'cocoa mass', 'cacao mass', 'cocoa slab', 'cocoa neat work' and 'cocoa liquor' are synonymous with the term 'cocoa paste' and any of those terms may be used in any label on or attached to a package containing or in any advertisement relating to those products in the stead of 'cocoa paste'.

(b) Cocoa paste is the product prepared by grinding cocoa nibs.

(c) Cocoa paste shall contain not less than 480 g/kg of cocoa butter.

(d) The water-free and fat-free residue of cocoa paste shall not contain more than -

(i) 190 g/kg of starch naturally present;
(ii) 70 g/kg of crude fibre when determined by the method prescribed by clause (13) of this Standard;
(iii) 80 g/kg of ash;
(iv) 55 g/kg of ash insoluble in water;
(v) 4 g/kg of ferric oxide.

(4) (a) Cocoa, cocoa powder or soluble cocoa is the powdered product prepared from cocoa paste, whether or not deprived of a portion of its fat and whether or not treated with alkali or alkaline salt.

(b) Cocoa, cocoa powder or soluble cocoa -

(i) may contain flavouring, lecithin or ammonium salts of phosphatidic acid;
(ii) shall comply in its water-free, fat-free and alkali-free content with clause (3)(d) of this Standard;
(iii) shall not contain in its water-free and fat-free content more than -

(A) 105 g/kg of total alkalinity, calculated as potassium carbonate;
(B) 125 g/kg of ash.

(5) (a) Prepared cocoa, compounded cocoa or sweetened cocoa is the product prepared by mixing cocoa, cocoa powder or soluble cocoa with other foods.

It shall contain not less than 200 g/kg of water-free, fat-free cocoa paste.

It shall comply in its water-free, fat-free and alkali-free content with clause (3)(d) of this Standard.

(b) There shall be written in the label on or attached to a package containing prepared cocoa, compounded cocoa or sweetened cocoa, in standard type, a statement in the form -

'CONTAINS NOT LESS THAN (here insert the proportion) OF DRY FAT-FREE COCOA PASTE'.

(6) (a) Chocolate, chocolate paste, drinking chocolate, confectioners' chocolate, chocolate coating or chocolate powder is the product prepared by mixing cocoa paste or soluble cocoa with sugar with or without the addition or subtraction of cocoa fat.

It -

(i) shall contain not less than 150 g/kg of water-free, fat-free cocoa paste;
(ii) may contain -

(A) spices and flavourings;
(B) lecithin and ammonium salts of phosphatidic acid;
(C) sorbitans and polysorbates specified in Group IV set out in Standard A10;
(D) not more than 2 g/kg of purified talc unavoidably included in the course of normal manufacture;
(E) not more than 4 g/kg of polyglycerol esters of interesterified ricinoleic acid;

(iii) shall comply in its water-free, fat-free and alkali-free content with clause (3)(d) of this Standard.

(7) (a) Milk chocolate is the product prepared by mixing cocoa paste or soluble cocoa with sugar, milk solids and cocoa fat.

(b) Milk chocolate -

(i) shall contain not less than -

(A) 45 g/kg of milk fat;
(B) 105 g/kg of milk solids non-fat;
(C) 30 g/kg of water-free, fat-free cocoa paste;

(ii) may contain -

(A) spices and flavourings;
(B) lecithin and ammonium salts of phosphatidic acid;
(C) sorbitans and polysorbates specified in Group IV set out in Standard A10;
(D) not more than 2 g/kg of purified talc unavoidably included in the course of normal manufacture;
(E) not more than 4 g/kg of polyglycerol esters of interesterified ricinoleic acid.

(c) Where milk chocolate is in the form of Easter eggs, seasonal novelties or other hollow moulded preparations, milk fat may be replaced, wholly or partly, by cocoa fat, provided that the proportion of total milk solids is not less than 150 g/kg.

(d) The words 'rich', 'full cream' or 'dairy' shall not appear in the label on or attached to a package containing milk chocolate unless the product complies with the standard specified in paragraph (b)(i) of this clause.

(8) (a) White chocolate is the product prepared by mixing cocoa butter, milk solids and sugar.

(b) White chocolate -

(i) shall contain, on a moisture-free basis, not less than -

(A) 200 g/kg of cocoa butter;
(B) 35 g/kg of milk fat;
(C) 105 g/kg of total milk solids non-fat;

(ii) may contain -

(A) spices;
(B) flavours;
(C) lecithin and the ammonium salts of phosphatidic acid;
(D) sorbitans and polysorbates specified in Group IV set out in Standard A10;
(E) not more than 4 g/kg of polyglycerol esters of interesterified ricinoleic acid;

(iii) shall not contain more than 550 g/kg of sugar on a moisture-free basis.

(c) Where white chocolate is in the form of Easter eggs, seasonal novelties or other hollow moulded preparations, milk fat may be replaced, wholly or partly, by cocoa butter, provided that the proportion of total milk solids is not less than 150 g/kg.

(d) The words 'rich', 'full cream' or 'dairy' shall not be written in the label on or attached to a package containing white chocolate unless the product contains not less than 45 g/kg of milk fat.

(e) *deleted*

(9) *deleted*

(10) (a) Compounded chocolate is the product prepared by mixing chocolate within the meaning of clause (6) of this Standard with other foods including edible fats.

The product -

(i) shall contain not less than 30 g/kg of water-free, fat-free cocoa paste;
(ii) may contain not more than 10 g/kg of sorbitan tristearate.

(b) *deleted*

(11) A product of cocoa beans shall not contain -

(a) foreign fat, save where otherwise expressly permitted by this Code;
(b) cocoa husks;
(c) paraffin.

(12) Chocolate confections may contain spirits, liqueurs, alcoholic cordials or alcoholic flavourings, as prescribed by Standard K3.

(13) **Methods of analysis.** The methods specified in this clause are the prescribed methods of analysis for the determination of crude fibre in cocoa paste, cocoa and chocolate, the determination of cocoa paste in chocolate and other cocoa products and the determination of starch in cocoa paste, cocoa and cocoa products.

(a) Determination of crude fibre in cocoa paste and cocoa.

Reagents

(i) Sulphuric acid solution - 0.125 molar (12.5 g of concentrated sulphuric acid per litre). The concentration of this solution must be checked by titration.

(ii) Sodium hydroxide solution - 0.31 molar (12.5 g of sodium hydroxide per litre free, or nearly so, from sodium carbonate). The concentration of this solution must be checked by titration.

(iii) Asbestos, Gooch grade, medium fibre, acid-washed, and ignited, is usually satisfactory but it should be tested for chemical stability and filtering speed before use. Digest on a steam bath, or at equivalent temperature, for at least 8 hours with 5% sodium hydroxide solution and wash thoroughly with hot water, then digest in similar manner for 8 hours with dilute hydrochloric acid (1+3) and again wash thoroughly with hot water. Dry and ignite at bright red heat.

Apparatus

(i) Condenser - use a condenser that maintains a constant volume of solution throughout digestion.

(ii) Digestion vessels - use digestion vessels of such size and shape as to ensure that the solution is not less than 26 mm nor greater than 38 mm in depth. A 700-750 mL Erlenmeyer flask is suitable.

(iii) Filtering cloth - use a filtering cloth of such character as to ensure that no solid matter passes through when filtering is rapid.

(iv) Gooch crucible.

Determination

(i) Dry a sufficient quantity of the sample and extract with ether.

(ii) Weigh 2 g of the residue and transfer, together with about 0.5 g of asbestos, to the digestion vessel; add 3 drops of a diluted (1+3) silicone anti-foaming agent. Add 200 mL of the boiling sulphuric acid solution; immediately connect the digestion vessel with the condenser, and heat under reflux. (Contents of vessel must come to boiling within 1 minute and brisk boiling must continue for exactly 30 minutes.)

Rotate vessel frequently until sample is thoroughly wet. Take care to prevent material remaining on sides of vessel out of contact with the solution. A blast of air conducted into the vessel serves to reduce frothing of the liquid. After 30 minutes remove the vessel, immediately filter through the filtering cloth and wash with boiling water until the washings are no longer acid. Wash the charge and asbestos back into the vessel with 200 mL of the boiling sodium hydroxide solution using a wash bottle marked to deliver 200 mL. Connect the vessel with reflux condenser and boil exactly 30 minutes.

After 30 minutes, remove the vessel and immediately filter as before. For materials difficult to filter in this procedure, use a vacuum and wash with hot 10% potassium sulphate solution. This solution may be added during filtering whenever filtration becomes difficult.

(iii) Transfer the residue to the Gooch crucible prepared with a thin but close layer of ignited asbestos, thoroughly washing all adhered material from cloth with hot

water. Thoroughly wash the contents of Gooch crucible with boiling water, then with 15 mL alcohol. Dry Gooch crucible and contents at 110°C to constant weight, cool in a desiccator, and weigh.

(iv) Ignite the contents of the crucible in an electric muffle furnace at dull red heat until carbonaceous matter is consumed (approximately 20 minutes). Cool in a desiccator and weigh, reporting loss in weight as crude fibre calculated as g/kg of water-free and fat-free residue.

(b) Determination of crude fibre in chocolate.

(i) Treat 50 g of the chocolate in a centrifuge bottle with 2 or 3 100 mL portions of ether, centrifuging and decanting the supernatant liquid after each addition.

(ii) Dry the residue in an oven at approximately 100°C and then pulverise it in the bottle with a flat-ended glass rod. If milk chocolate, shake with 100 mL of 1% sodium oxalate solution, let stand 30 minutes, centrifuge and decant supernatant liquid.

(iii) Wash the residue in the bottle with three 100 mL portions of water at room temperature, shaking well each time to remove particles adhering to the sides.

(iv) Centrifuge for 10-15 minutes after each washing, and decant the aqueous layer.

(v) Wash the residue in the same manner with two 100 mL portions of alcohol and one 100 mL portion of ether. Transfer the residue to a suitable dish, dry to constant weight, and grind in a mortar.

(vi) Weigh 2 g of the dried material and proceed as for crude fibre in cocoa paste commencing at subparagraph (ii) under the heading *Determination.*

(vii) Calculate the proportion of crude fibre in the water-free, fat-free, sugar-free chocolate by taking the proportion of crude fibre as determined and multiplying by 0.7 (as in *A.O.A.C.*, 14th Edition (1984), Section 13.013).

(c) Determination of cocoa paste in chocolate and other cocoa products.

Proceed according to the method set out in *A.O.A.C.*, 14th Edition (1984), Section 13.030.

(d) Determination of starch in cocoa paste, cocoa and cocoa products.

Proceed according to the method set out in *A.O.A.C.*, 14th Edition (1984), Section 13.062 which refers to the 10th Edition, Section 12.043.

COMMENTARY

Standard Q3 was published in the *Commonwealth of Australia Gazette* No. P 27 on 27 August 1987 and has been amended in subsequent gazettes as follows:

Amendment No. 1 (Gazette No. P 19, 15 July 1988)

Clause amended	**Reason**
(10)(a)	Permit the use of the emulsifier sorbitan tristearate in compounded chocolate.

(13)	Update the prescribed methods of analysis to the 14th edition (1984) of the *Official Methods of Analysis* of the Association of Official Analytical Chemists.

Amendment No. 7 (Gazette No. P 34, 14 November 1990)

Clause amended	**Reason**
(3)(a)	Include 'cacao mass' in the terms synonomous with 'cocoa paste'.
(9)	Delete the requirements for cocoa and milk products.

Amendment No. 9 (Gazette No. P 12, 17 May 1991)

Clause amended	**Reason**
(8)(e),(10)(b)	Review of print size recommendations by the Industries Assistance Commission (IAC).

CANADA

THE FOOD AND DRUGS ACT AND REGULATIONS

ROGER DUHAMEL, F.R.S.C.
QUEEN'S PRINTER AND CONTROLLER OF STATIONERY
OTTAWA

TABLE IV—(Continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
P.1A	Polyglycerol Esters of Fatty Acids	Unstandardized foods	Good Manufacturing Practice
P.1B	Polyglycerol Esters of Interesterified Castor Oil Fatty Acids	(1) Milk chocolate; Sweet chocolate	(1) A total of 0.5% of emulsifying agents in accordance with paragraph B.04.008(*b*) and paragraph B.04.009(*b*).
		(2) Unstandardized chocolate flavoured confectionery coatings	(2) 0.25%
P.2	Polyoxyethylene (20) Sorbitan Monooleate; Polysorbate 80	(1) Ice cream; Ice cream mix; Ice milk; Ice milk mix; Sherbet	(1) 0.1%. If Polyoxyethylene (20) Sorbitan Tristearate is also used, the total must not exceed 0.1%.
		(2) Unstandardized frozen desserts	(2) 0.1%
		(3) Pickles and relishes	(3) 0.05%
		(4) Beverage base or mix	(4) 0.05% of the beverage. If Sorbitan Monostearate is also used the total must not exceed 0.05% of the beverage.
		(5) Imitation dry cream mix	(5) 0.1%. If Polyoxyethylene (20) sorbitan monostearate, Polyoxyethylene (20) sorbitan tristearate or Sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.4%.
		(6) Whipped vegetable oil topping	(6) 0.05%. If Polyoxyethylene (20) sorbitan monostearate, Polyoxyethylene (20) sorbitan tristearate or Sorbitan monostearate, either single or in combination is also used, the total must not exceed 0.4%.
		(7) Cake icing; Cake icing mix	(7) 0.5% of the finished cake icing. If Polyoxyethylene (20) sorbitan monostearate, or Sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.5% of the finished cake icing.
		(8) Salt	(8) 10 parts per million.
		(9) Whipped cream	(9) 0.1%
		(10) Breath freshener products in candy, tablet or gum form	(10) 100 p.p.m.
		(11) Creamed cottage cheese	(11) 80 p.p.m.
		(12) Spice oils and spice oleoresins for use in pumping pickle employed in the curing of preserved meat or preserved meat by-product (Division 14)	(12) 0.2% of the pumping pickle
		(13) Sausage casings	(13) 0.15% of the casing

25-3-65 23-6-71 23-1-74 13-5-75 5-4-77 27-4-78 12-11-81

TABLE IV—(Continued)

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
A.9A	Ammonium Salt of Phosphorylated Glyceride	(1) Bread; Cream; (naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Smik milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids;	(1) Good Manufacturing Practice
		(2) Cocoa; Ice cream; Ice cream mix; Ice milk; Ice milk mix; Milk chocolate; Sweet chocolate	(2) A total of 0.5% of emulsifying agents in accordance with paragraph (*b*) of section B.04.008, paragraph (*b*) of section B.04.009 and paragraph (*b*) of section B.04.010
		(3) Sherbet	(3) 0.75%
		(4) Unstandardized foods	(4) Good Manufacturing Practice
A.10	Arabinogalactan	Essential oils; unstandardized dressing; pudding mixes; beverage bases and mixes; pie filling mixes	Good Manufacturing Practice
B.1	Baker's yeast Glycan	Unstandardized foods	Good Manufacturing Practice

5

Summary of Toxicology Studies on Polyglycerol Polyricinoleate (PGPR)

A status of safety assessments of food additives permitted in the EU was conducted in year 2000.

The toxicological studies published in the years 1973-1999 were evaluated with the following conclusion:
The toxicological data available to JECFA in 1973 and to SCF in 1977 did not include all the data, which are normally required for an ADI to be set for a food additive. However, later data confirm the safety of the substance within the ADI, and taken together with the limited exposure, there seems to be no need for an re-evalualion.
Polyglycerol Polyricinoleate as defined by the specifications seems to be covered by the toxicological evaluation.

POLYGLYCEROL POLYRICINOLEATE

E number: E 476

Recommendation: A re-evaluation of polyglycerol polyricinoleate is not necessary.

Chemical name/synonyms: Glycerol esters of condensed castor oil fatty acids, polyglycerol esters of polycondensed fatty acids from castor oil, polyglycerol esters of interesterified ricinoleic acid, PGPR.

Chemical formula: -

EINECS number: -

CAS number: -

Functional Class: Emulsifier.

Specification: The EU specification for these substances apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6% (expressed as sodium oleate).

Manufacture: Polyglycerol polyricinoleate is obtained by esterification of polyglycerol with condensed castor oil fatty acids.

Definition: Polyglycerol polyricinoleate consists of polyglycerol esters of interesterified fatty acids present in castor oil. It is insoluble in water and ethanol and soluble in ether.

EC specifications: E 476 Polyglycerol polyricinoleate [5].
Assay: -
Polyglycerols: The polyglycerol moiety shall be composed of not less than 75% of di-, tri- and tetraglycerol and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol.
In addition the specification includes purity criteria on Hydroxyl value, Acid value, Arsenic, Lead, Mercury, Cadmium and Heavy metals.

JECFA specifications: Polyglycerol esters of interesterified ricinoleic acid [4].
Assay: -
Polyglycerols: The polyglycerol moiety shall be composed of not less than 75% of di-, tri- and tetraglycerol and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol.
In addition the specification includes purity criteria on Arsenic and Heavy metals.

Exposure: Polyglycerol polyricinoleate is permitted only in cocoa-based confectionary, including chocolate up to 5 g/kg and in some fat-products up to 4 g/kg. I takes 90 chocolate with 5 g and 112,5 g fat product with 4 g additive to reach the ADI of 7.5 mg/ kg bw.

In the EU monitoring system polyglycerol polyricinoleate was examined at tier 2 level and the calculated intake by adults and the whole population is reported in the range of 4 - 33% of ADI, while the calculated intake by young children is reported by one member state as 49 - 53%. It was concluded that no further examination was needed at this stage.

SCF/JECFA evaluation:

SCF status: An ADI 0-7.5 mg/kg bw was established in 1978 [3]. The basis was not specified but it may be that the 1973 JECFA ADI was endorsed. The Committee noted that rats fed the substance at dietary levels of 18% developed a hepatomegaly, which was reversible and not associated with any significant abnormalities in the enlarged livers. Otherwise no toxicological data were specified.

JECFA status: An ADI 0-7.5 mg/kg bw was established in 1973 [1]. The basis was a study in rats with a level causing no toxicological effects on 15000 ppm (1.5%, highest dose) equivalent to 750 mg/kg bw in a long-term study in rats. The safety factor was 100.
In other long-term studies liver and kidney enlargement was noticed at higher doses, 5 and 10%.

Background data:

Subacute/subchronic toxicity: No obvious adverse effects. The liver hypertrophy can be regarded as a normal functional response to an increased hepatic work load.

Short-term studies are available in rat and chicken. Liver enlargement was noticed in two (same author) of eight studies in rats. Enlarged kidney and liver was reported in the only study conducted in chicken. These effects were not accompanied by effects as revealed by histopathology. In some special studies on the liver enlargement the effects were reversible in mice and not proportional to the feeding level. The hypertrophy was regarded as a normal functional response to an increased hepatic workload. No hyperplasia was observed. No other effects were demonstrated [2].

Genotoxicity: -

Chronic toxicity/Carcinogenicity: No evidence of carcinogenicity. The liver hypertrophy can be regarded as a normal functional response to an increased hepatic workload.

Long-term studies are available in mice and rats. The long-term studies in rats and mice did not show carcinogenic potential. The enlargement of liver and kidneys observed in long-term tests was not accompanied by any lesions detectable by histopathology. Only the rat study showed a no-effects level for liver enlargement, which was 1,5%, in the diet. The kidney lesions were not followed by histopathological findings [2].
The significance of the findings in kidneys is not possible to predict.

Carcinogenicity studies in rats and mice showed no carcinogenicity at 5% in the diet (highest dose). No kidney or liver effects were reported [8].

Reproduction toxicity: A three-generation study was carried out in rats. No adverse effect were noted even at the highest dose i.e. 1.5% [2].

One recent communication deals with teratology by suggesting that this additive may increase the sex ratio (proportion male). This may be caused by glycerol that may be involved in the process of sex selection [7]. However, this hypothesis is not supported by recent metabolism studies [6]. A

three-generation reproduction study in rats showed no effects on breeding performance at 1.5% in diet (highest dose) [9].

Effect in humans: A study is available in human volunteers eating up to 10 g/day for 2 weeks. This study showed no adverse effects [2].

A recent study in human volunteers showed no adverse effects at intake of 10g/day for 2 weeks (highest dose) [10].

Other: A study where rats were fed diet containing 18% of the substance (no dosing period specified) is available. It revealed the development of reversible hepatomegaly. No histopathological abnormalities of the enlarged livers were found. The hepatomegaly was not associated with hyperplasia [3].

Biochemical aspects: In vitro and *in vivo* studies are available. Radiolabel from orally administered substance was found in faeces, urine, and CO_2. It was suggested that the label in faeces was present as free polyglycerols, indicating hydrolysis in the gastrointestinal tract [2].

A thorough study on the metabolism in rats is published recently. Ingested polyglycerol polyricinoleate is extensively digested in the intestinal tract to its two major polymeric components: the polyglycerols, which are quantitatively excreted unchanged, and polyricinoleic acid that is degraded to ricinoleic acid that is absorbed and readily metabolised. Data show no evidence of tissue storage of its two major components [6].

Conclusion: The toxicological data available to JECFA in 1973 or to SCF in 1977 did not include all the data, which are normally required for an ADI to be set for a food additive. However, later data confirm the safety of the substance within the ADI, and taken together with the limited exposure, there seems to be no need for an re-evaluation.

Polyglycerol polyricinoleate as defined by the specifications seems to be covered by the toxicological evaluation.

References:

1. *[1973, NMRS 53/TRS 539-JECFA 17]*
Toxicological evaluation of certain food additives with a review of general principles and of specifications (Seventeenth report of the Joint FAO/WHO Expert Committee on Food Additives). *FAO Nutrition Meetings Series,* No. 53, 1974; *WHO Technical Report Series,* No. 539, 1974, and corrigendum.

2. *[1973, FAS 5/NMRS 53A-JECFA 17]*
Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers, and thickening agents. *FAO Nutrition Meetings Report Series,* No. 53A, 1974; *WHO Food Additives Series,* No. 5, 1974.

3. Reports from the Scientific Committee for Food (7th series). Opinion expressed 1978. *Food-science and techniques,* 1978.

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4. Compendium of Food Additive Specifications, *FAO Food and Nutrition Paper* no. 52, FAO, Rome, 1992. 17th session of JECFA held 1973, 1992.

5. Commission Directive 98/86/EC 1998 amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners, 1998.

6. Howes,D., Wilson,R., and James,C.T. (1998) The fate of ingested glyceran esters of condensed castor oil fatty acids [polyglycerol polyricinoleate (PGPR)] in the rat. *Food Chem.Toxicol.*, **36**, 719-738.

7. James,W.H. (1999) Does polyglycerol polyricinoleate alter offspring sex ratios? [letter]. *Food Chem.Toxicol.*, **37**, 919.

8. Smith,M.R., Wilson,R., and Hepburn,P.A. (1998) Assessment of the carcinogenic potential of polyglycerol polyricinoleate (PGPR) in rats and mice. *Food Chem.Toxicol.*, **36**, 747-754.

9. Wilson,R. and Smith,M. (1998) A three-generation reproduction study on polyglycerol polyricinoleate (PGPR) in Wistar rats. *Food Chem.Toxicol.*, **36**, 739-741.

10. Wilson,R. and Smith,M. (1998) Human studies on polyglycerol polyricinoleate (PGPR). *Food Chem.Toxicol.*, **36**, 743-745.

Food additives in Europe 2000

Status of safety assessments of food additives presently permitted in the EU

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7

EVALUATION ON SAFE INTAKE OF POLYGLYCEROL POLYRICINOLEATE (PGPR) IN THE UNITED STATES OF AMERICA.

Conclusion:
In order to establish an acceptable dosage level of PGPR in chocolate and vegetable fat coatings, the ADI value of this emulsifier has been compared with the typical intake of chocolate and chocolate-type confectionery by US consumers in 2005.
With a dosage of 0.30% PGPR in chocolate-type confectionery an average consumer will intake 46 mg per day. For a child with a body weight on 25kg it correlates to a daily intake on 1.8 mg/kg body weight/day. (ADI value for PGPR is set to 0-7.5mg/kg body weight/day). The same child can consume 4 times the average amount of chocolate-type confectionery without exceeding the ADI value.

Consumption of Chocolate and Chocolate-type confectionery in the U.S.:
(Source: U.S.Census Bureau July 2006 – attached).

In 2005 the US Manufacturers' shipments of chocolate-type confectionery was 3,529,387,000 lbs (1,602,341,698 kg).
The exports was in the same period was 119,773,000 kg and the imports 173,775,000 kg.
The total consumption was 1,656,344,000 kg.

The annual population estimate for 2005 is: 296,639,497 (U.S.Census Bureau, Population Division)

The average consumption of chocolate-type confectionery can be calculated to 5.58 kg per year (12.3 lbs).

ADI Value of Polyglycerol Polyricinoleate:

Established by JECFA (FAO/WHO): 0-7.5 mg/kg body weight/day

Calculation on typical intakes of Polyglycerol Polyricinoleate:

Dosage of Polyglycerol Polyricinoleate in the chocolate and chocolate: 0.30 % (3000 mg per kg)

Yearly consumption (kg)	Intake of Polyglycerol Polyricinoleate per day (mg)	Child (25 kg body weight) Daily intake/kg body weight/day (mg)	Adult (60 kg body weight) Daily intake/kg body weight/day (mg)
Average: 5.58kg	46	1.8	0.8
2 x Average: 11.16 kg	92	3.7	1.5
4 x Average: 22,32 kg	184	7.4	3.1

Confectionery: 2005

Issued July 2006

MA311D(05)-1

Current Industrial Reports

U S C E N S U S B U R E A U

Helping You Make Informed Decisions

U.S. Department of Commerce
Economics and Statistics Administration
U.S. CENSUS BUREAU

Table 1a. Summary of Manufacturers' Shipments of Confectionery Products: 1998 to 2005
[Quantity in millions of pounds. Value in millions of dollars]

Year	Quantity	Value	Per capita consumption 1/ (pounds)	Per capita consumption 1/ (dollars)
2005	6,493	16,880	25.7	61.5
2004	6,208	16,465	24.8	60.5
2003	6,247	15,615	24.6	57.6
2002	6,244	15,062	24.0	55.1
2001	6,313	15,143	23.6	54.7
2000	6,665	14,969	25.1	54.8
1999	6,614	14,447	26.0	55.0
1998	6,952	14,894	26.8	56.6

1/Source, Table 4, shipments plus imports minus exports divided by population, including armed forces abroad, as of July 1, 2005.

Source of population data: U.S. Census Bureau, Population Division, Table NA-EST2005-01 - Annual population estimates for the United States, including armed forces abroad, as of July 2005 and July 2004. July 2005 population was 296,639,497 and July 2004 population was 293,906,517.

Note: See Table 4 for information on U.S. imports and exports of confectionery products.

Table 1b. Summary of Manufacturers' Shipments of Confectionery Products (Excluding Chewing Gum, Bubble Gum, and Chewing Gum Base): 1998 to 2005
[Quantity in millions of pounds. Value in millions of dollars]

Year	Quantity	Value	Per capita consumption 1/ (pounds)	Per capita consumption 1/ (dollars)
2005	6,111	15,264	24.1	55.8
2004	5,780	14,636	23.0	53.9
2003	5,799	13,885	22.8	51.2
2002	5,810	13,355	22.2	48.9
2001	5,882	13,458	21.8	48.5
2000	6,258	13,503	23.4	49.3
1999	6,221	13,082	24.3	49.8
1998	6,546	13,569	25.3	51.6

1/Source, Table 4, shipments plus imports minus exports divided by population, including armed forces abroad, as of July 1, 2005.

Source of population data: U.S. Census Bureau, Population Division, Table NA-EST2005-01 - Annual population estimates for the United States, including armed forces abroad, as of July 2005 and July 2004. July 2005 population was 296,639,497 and July 2004 population was 293,906,517.

Note: See Table 4 for information on U.S. imports and exports of confectionery products.

Table 2a. Quantity and Value of Shipments of Confectionery Products: 2005 and 2004
[Quantity in thousands of pounds. Value in thousands of dollars]

Product description	2005		2004	
	Quantity	Value	Quantity	Value
Shipments	6,493,573	16,880,338	6,208,003	16,465,387
Chocolate and chocolate-type confectionery	3,529,387	9,982,793	3,321,509	9,637,758
Solid	557,171	1,380,880	515,558	1,324,781
Solid with inclusions	226,685	695,998	232,100	717,137
Enrobed or molded with candy, fruit, nut or granola center	1,373,626	3,780,645	1,314,552	3,748,341
Enrobed or molded with bakery product center	318,904	920,831	291,074	825,854
Panned	627,028	1,584,268	572,468	1,477,856
Assortments and other	425,973	1,620,171	395,757	1,543,789
Chocolate type, n.s.k.	-	-	-	-
Nonchocolate-type confectionery	2,375,779	4,782,775	2,260,636	4,508,332
Hard candy	581,815	1,341,513	568,283	1,247,816
Chewy candy, including granola bars	662,395	1,534,055	585,572	1,336,842
Soft candy	553,105	865,636	558,409	895,279
Iced/coated	6,898	34,495	(D)	(D)
Panned	392,094	764,620	370,594	746,049
Licorice and licorice type	179,472	242,456	(D)	(D)
Nonchocolate type, n.s.k.	-	-	-	-
Chewing gum, bubble gum, and chewing gum base	382,258	1,616,032	427,674	1,829,463
Confectionery, n.s.k. 1/	206,149	498,738	198,184	489,834

- Represents zero. D Withheld to avoid disclosing data for individual companies. N.s.k. Not specified by kind.

1/Represents estimated data for small companies, typically those with fewer than five employees, that were not included on the mailing panel.

Table 2b. Quantity and Value of Shipments of Nonconfectionery Products: 2005 and 2004
[Quantity in thousands of pounds. Value in thousands of dollars]

Product description	2005			2004		
	Quantity	Value		Quantity		Value
Shipments	1,908,364	2,154,035		1,790,441		2,114,798
Chocolate products other than confectionery:						
Baking chocolate (bars or blocks)	20,200	27,086	r/	20,157	r/	29,970
Chocolate coatings (blocks, wafers, liquid)	(S)	(S)		(S)		(S)
Chocolate liquor	(D)	(D)		(D)		(D)
Cocoa butter	(D)	(D)		(D)		(D)
Compound coatings (blocks, wafers, liquid)	261,258	215,849	r/	252,047	r/	217,539
Chocolate chips and baking pieces	696,396	982,012	r/	654,291	r/	892,954
Cocoa powder, syrup/toppings, and other	524,421	507,577		479,084		534,379
Nonconfectionery chocolate n.s.k.	-	-		-		-

- Represents zero. D Withheld to avoid disclosing data for individual companies. N.s.k. Not specified by kind. r/Revised by 5 or more percent from previously published data. S Does not meet publication standards.

Table 3. Consumption of Selected Ingredients by the U.S. Confectionery Industry: 2005 and 2004
[Quantity in thousands of pounds. Value in thousands of dollars]

Materials	2005		2004	
	Quantity	Value	Quantity	Value
Materials consumed	(X)	4,131,733	(X)	3,963,981
Sugar (cane-beet)	2,404,237	663,189	2,367,551	658,321
Cocoa beans	697,169	603,160	729,265	571,046
Corn syrup including HFCS and dextrose	1,402,857	172,264	1,363,482	162,671
Chocolate liquor, imported	(D)	(D)	(S)	(S)
Chocolate liquor, domestic	(D)	(D)	13,070	17,603
Cocoa powder composition coatings	(S)	(S)	(S)	(S)
Cocoa cake or powder	127,185	84,114	130,340	90,882
Cocoa butter	241,620	435,780	247,822	393,380
Chocolate coatings, milk	216,288	203,350	237,847	227,348
Chocolate coatings, other than milk	111,047	100,913	114,889	106,991
Fats and oils	228,785	112,547	221,772	102,107
Gum base	(D)	(D)	66,934	62,565
Milk and milk products	1,083,423	517,852	1,052,761	481,863
Peanuts, shelled basis	327,843	158,983	326,548	150,387
Almond kernels	53,731	105,141	50,675	81,024
Other nuts and nut meats (kernels)	35,104	100,366	38,421	97,970
Coconut meat	5,601	5,322	5,511	5,192
Other edible materials 1/	501,978	728,999	493,913	710,371
Materials, n.s.k.	(X)	2,133	(X)	2,048

D Withheld to avoid disclosing data for individual companies. N.s.k. Not specified by kind.
S Does not meet publication standards. X Not applicable.

1/Includes corn starch, essential oils, eggs and egg products, fruits, jams, and other materials on which specific data were not collected.

Note: Materials such as parts, containers, etc., consumed in the manufacturing process are not reported in this survey. This information is available in the 2002 Economic Census report for industries 311320, 311330, and 311340. Specifically excluded in this report are freight charges and other direct charges incurred by the establishment, fuels consumed, parts, containers, scrap, electric energy purchases, work done by others on materials or parts furnished by other establishments (contract work), and cost of products bought and resold in the same condition.

Table 4. Shipments, Exports, Imports, and Apparent Consumption of Confectionery Products: 2005 and 2004
[Quantity in thousands of kilograms. Value in thousands of dollars]

Product code 1/	Product description	Year	Manufacturers' shipments Quantity	Manufacturers' shipments Value	Exports of domestic merchandise 2/ Quantity	Exports of domestic merchandise 2/ Value	Percent exports to manufacturers' shipments Quantity	Percent exports to manufacturers' shipments Value
	Confectionery:							
3113301	Chocolate-type confectionery	2005	1,600,919	9,982,793	119,773	453,060	7.5	4.5
		2004	1,506,627	9,637,758	119,461	416,890	7.9	4.3
3113401	Nonchocolate-type confectionery	2005	1,077,646	4,782,775	86,832	222,977	8.1	4.7
		2004	1,025,418	4,508,332	85,138	220,567	8.3	4.9
3113404	Chewing gum, sugar and nonsugar	2005	173,391	1,616,032	18,354	56,633	10.6	3.5
		2004	193,992	1,829,463	14,844	49,886	7.7	2.7
	Nonconfectionery:							
3113201241	Cocoa butter	2005	(D)	(D)	14,860	64,688	(D)	(D)
		2004	(D)	(D)	13,728	57,443	(D)	(D)
31132014A1, 15C1	Chocolate coatings (blocks, wafers, liquid) and compound coatings (blocks, wafers, liquid)	2005	248,677	504,145	5,016	9,497	2.0	1.9
		2004	241,716	541,177	6,512	9,607	2.7	1.8
3113207471, 1231, 75G1, 76H1	Other chocolate and cocoa products	2005	(D)	(D)	82,042	187,037	(D)	(D)
		2004	(D)	(D)	84,509	203,851	(D)	(D)

Product code 1/	Product description	Year	Imports for consumption 3/ Quantity	Imports for consumption 3/ Value 4/	Apparent consumption 5/ Quantity	Apparent consumption 5/ Value	Percent imports to apparent consumption Quantity	Percent imports to apparent consumption Value
	Confectionery:							
3113301	Chocolate-type confectionery	2005	173,775	765,870	1,654,921	10,295,603	10.5	7.4
		2004	174,702	751,809	1,561,868	9,972,677	11.2	7.5
3113401	Nonchocolate-type confectionery	2005	507,219	1,198,754	1,498,033	5,758,552	33.9	20.8
		2004	477,697	1,093,974	1,417,977	5,381,739	33.7	20.3
3113404	Chewing gum, sugar and nonsugar	2005	55,652	138,972	210,689	1,698,371	26.4	8.2
		2004	55,262	159,172	234,410	1,938,749	23.6	8.2
	Nonconfectionery:							
3113201241	Cocoa butter	2005	96,876	402,427	(D)	(D)	(D)	(D)
		2004	94,890	306,883	(D)	(D)	(D)	(D)
31132014A1, 15C1	Chocolate coatings (blocks, wafers, liquid) and compound coatings (blocks, wafers, liquid)	2005	22,619	28,516	266,280	523,164	8.5	5.5
		2004	23,826	28,164	259,030	559,734	9.2	5.0
3113207471, 1231, 75G1, 76H1	Other chocolate and cocoa products	2005	436,554	757,077	(D)	(D)	(D)	(D)
		2004	421,348	784,932	(D)	(D)	(D)	(D)

D Withheld to avoid disclosing data for individual companies.

1/For comparison of North American Industry Classification System (NAICS)-based product codes (domestic output), Schedule B export codes, and HTSUSA import codes, see Table 5.
2/Source: Census Bureau report EM 545, U.S. Exports.
3/Source: Census Bureau report IM 146, U.S. Imports for Consumption.
4/This dollar value represents the c.i.f. (cost, insurance, and freight) value at first port of entry in the United States.
5/Apparent consumption is derived by subtracting exports from the total manufacturers' shipments plus imports.

Note: "Confectionery n.s.k." is excluded from this table.

Table 5. Comparison of North American Industry Classification System (NAICS)-Based Product Codes With Schedule B Export Codes, and HTSUSA Import Codes: 2005

Product code	Product description	Export code 1/	Import code 2/
3113301, 3000	Total, chocolate and chocolate-type confectionery products and nonconfectionery chocolate products	1806.31.0040 1806.31.0080 1806.32.1000 1806.32.3550 1806.90.0063 1806.90.0073 1806.90.0083 1806.90.0093	1806.31.0041 1806.31.0049 1806.31.0080 1806.32.0100 1806.32.0400 1806.32.0600 1806.32.0800 1806.32.1400 1806.32.1600 1806.32.1800 1806.32.3000 1806.32.5500 1806.32.6000 1806.32.7000 1806.32.8000 1806.32.9000 1806.90.0100 1806.90.0500 1806.90.0800 1806.90.1000 1806.90.1500 1806.90.1800 1806.90.2000 1806.90.2500 1806.90.2800 1806.90.3000 1806.90.3500 1806.90.3900 1806.90.4500 1806.90.4900 1806.90.5500 1806.90.5900 1806.90.9011 1806.90.9019 1806.90.9090
3113401	Total, nonchocolate confectionery products	1704.90.3000 1704.90.7000	1704.90.3520 1704.90.3550 1704.90.3590 2106.90.9985
3113404	Chewing gum, sugar and nonsugar	1704.10.0000	1704.10.0000
3113201241	Cocoa butter	1804.00.0000	1804.00.0000
31132014A1, 15C1	Chocolate coatings (blocks, wafers, liquid) and compound coatings (blocks, wafers, liquid)	1806.20.6000	1806.20.6000 1803.10.0000 1803.20.0000 1805.00.0000 1806.10.0500 1806.10.1000 1806.10.1500 1806.10.2200 1806.10.2400 1806.10.2800 1806.10.3400 1806.10.3800

Table 5. Comparison of North American Industry Classification System (NAICS)-Based Product Codes With Schedule B Export Codes, and HTSUSA Import Codes: 2005

Product code	Product description	Export code 1/	Import code 2/
31132014A1, 15C1	Chocolate coatings (blocks, wafers, liquid) and compound coatings (blocks, wafers, liquid) (continued).....		1806.10.4300
			1806.10.4500
			1806.10.5500
			1806.10.6500
			1806.10.7500
			1806.20.2010
			1806.20.2090
			1806.20.2200
			1806.20.2400
			1806.20.2600
3113201231, 3113207471, 31132075G1, 31132076H1	Chocolate liquor and Baking chocolate (bars and blocks) and Chocolate chips and baking pieces and Cocoa powder (sweetened and unsweetened), syrup, toppings, and other.....	1803.10.0000	1806.20.2800
		1803.20.0000	1806.20.3400
		1805.00.0000	1806.20.3600
		1806.10.0000	1806.20.3800
		1806.20.9000	1806.20.5000
			1806.20.6700
			1806.20.7100
			1806.20.7300
			1806.20.7500
			1806.20.7700
			1806.20.7800
			1806.20.7900
			1806.20.8100
			1806.20.8200
			1806.20.8700
			1806.20.8900
			1806.20.9100
			1806.20.9400
			1806.20.9500
			1806.20.9800
			1806.20.9900

1/Source: 2005 edition, Harmonized System-Based Schedule B, Statistical Classification of Domestic and Foreign Commodities Exported from the United States.

2/Source: Harmonized Tariff Schedule of the United States, Annotated (2005).

Appendix.
General CIR Survey Information, Explanation of General Terms and Historical Note

GENERAL

The CIR program has been providing monthly, quarterly, and annual measures of industrial activity for many years. Since 1904, with its cotton and fats and oils surveys, the CIR program has formed an essential part of an integrated statistical system involving the quinquennial economic census, manufacturing sector, and the annual survey of manufactures. The CIR surveys, however, provide current statistics at a more detailed product level than either of the other two statistical programs.

The primary objective of the CIR program is to produce timely, accurate data on production and shipments of selected products. The data are used to satisfy economic policy needs and for market analysis, forecasting, and decision making in the private sector. The product-level data generated by these surveys are used extensively by individual firms, trade associations, and market analysts in planning or recommending marketing and legislative strategies, particularly if their industry is significantly affected by foreign trade. Although production and shipments information are the two most common data items collected, the CIR program collects other measures also such as inventories, orders, and consumption. These surveys measure manufacturing activity in important commodity areas such as textiles and apparel, chemicals, primary metals, computer and electronic components, industrial equipment, aerospace equipment, and consumer goods.

The CIR program uses a unified data collection, processing, and publication system. The U.S. Census Bureau updates the survey panels for most reports annually and reconciles the estimates to the results of the broader-based annual survey of manufactures and the economic census, manufacturing sector. The manufacturing sector provides a complete list of all producers of the products covered by the CIR program and serves as the primary source for CIR sampling. Where a small number of producers exist, CIR surveys cover all known producers of a product. However, when the number of producers is too large, cutoff and random sampling techniques are used. Surveys are continually reviewed and modified to provide the most up-to-date information on products produced. The CIR program includes a group of mandatory and voluntary surveys. Typically the monthly and quarterly surveys are conducted on a voluntary basis. Those companies that choose not to respond to the voluntary surveys are required to submit a mandatory annual counterpart corresponding to the more frequent survey.

NORTH AMERICAN INDUSTRY CLASSIFICATION SYSTEM (NAICS), 1997

The adoption of the North American Industry Classification System (NAICS) in the 1997 Economic Census has had a major impact on the comparability of current and historic data. Approximately half of the industries in the manufacturing sector of NAICS do not have comparable industries in the Standard Industrial Classification (SIC) system that was used in the past.

While most of the change affecting the manufacturing sector was change within the sector, some industries left manufacturing and others came into manufacturing. Prominent among those that left manufacturing are logging and portions of publishing. Prominent among the industries that came into the manufacturing sector are bakeries, candy stores where candy is made on the premises, custom tailors, makers of custom draperies, and tire retreading. The net effect of the classification changes are such that if the 1997 value of shipments data for all manufacturers were tabulated on an SIC basis, it would be approximately 3 percent higher.

Listed below are the NAICS sectors:

21 Mining
22 Utilities
23 Construction
31-33 Manufacturing
42 Wholesale Trade
44-45 Retail Trade
48-49 Transportation and Warehousing
51 Information
52 Finance and Insurance
53 Real Estate and Rental and Leasing
54 Professional, Scientific, and Technical Services
55 Management of Companies and Enterprises
56 Administrative and Support and Waste Management and Remediation Services
61 Educational Services
62 Health Care and Social Assistance
71 Arts, Entertainment, and Recreation
72 Accommodation and Foodservices
81 Other Services (except Public Administration)

(Not listed above are the Agriculture, Forestry, Fishing, and Hunting sector (NAICS 11), partially covered by the census of agriculture conducted by the U.S. Department of Agriculture, and the Public Administration sector (NAICS 92), covered by the census of governments conducted by the Census Bureau.)

The 20 NAICS sectors are subdivided into 96 subsectors (three-digit codes), 313 industry groups (four-digit codes), and, as implemented in the United States, 1170 industries (five- and six-digit codes).

FUNDING

The Census Bureau funds most of the surveys. However, a number of surveys are paid for either fully or partially by other Federal Government agencies or private trade associations. A few surveys are mandated, but all are authorized by Title 13 of the United States Code.

RELIABILITY OF DATA

Survey error may result from several sources including the inability to obtain information about all cases in the survey, response errors, definitional difficulties, differences in the interpretation of questions, mistakes in recording or coding the reported data, and other errors of collection, response, coverage, and estimation. These nonsampling errors also occur in complete censuses. Although no direct measurement of the biases due to these nonsampling errors has been obtained, precautionary steps were taken in all phases of the collection, processing, and tabulation of the data in an effort to minimize their influence.

A major source of bias in the published estimates is the imputing of data for nonrespondents, for late reporters, and for data that fail logic edits. Missing figures are imputed based on period-to-period movements shown by reporting firms. A figure is considered to be an impute if the value was not directly reported on the questionnaire, directly derived from other reported items, directly available from supplemental sources, or obtained from the respondent during the analytical review phase. Imputation generally is limited to a maximum of 10 percent for any one data cell. Figures with imputation rates greater than 10 percent are suppressed or footnoted. The imputation rate is not an explicit indicator of the potential error in published figures due to nonresponse, because the actual yearly movements for nonrespondents may or may not closely agree with the imputed movements. The range of difference between the actual and imputed figures is assumed to be small. The degree of uncertainty regarding the accuracy of the published data increases as the percentage of imputation increases. Figures with imputation rates above 10 percent should be used with caution.

DATA REVISIONS

Statistics for previous years may be revised as the result of corrected figures from respondents, late reports for which imputations were originally made, or other corrections. Data that have been revised by more than 5percent from previously published data are indicated by footnotes.

DISCLOSURE

The Census Bureau collects the CIR data under the authority of Title 13, United States Code, which specifies that the information can only be used for statistical purposes and cannot be published or released in any manner that would identify a person, household, or establishment. "D" indicates that data in the cell have been suppressed to avoid disclosure of information pertaining to individual companies.

EXPLANATION OF GENERAL TERMS

Capacity. The maximum quantity of a product that can be produced in a plant in 1 day if operating for 24 hours. Includes the capacity of idle plants until the plant is reported to be destroyed, dismantled, or abandoned.

Consumption. Materials used in producing or processing a product or otherwise removing the product from the inventory.

Exports. Includes all types of products shipped to foreign countries, or to agents or exporters for reshipment to foreign countries.

Gross shipments. The quantity or value of physical shipments from domestic establishments of all products sold, transferred to other establishments of the same company, or shipped on consignment, whether for domestic or export sale or use. Shipments of products purchased for resale are omitted. Shipments of products made under toll arrangements are included.

Interplant transfers. Shipments to other domestic plants within a company for further assembly, fabrication, or manufacture.

Inventories. The quantity or value of finished goods, work in progress, and materials on hand.

Machinery in place. The number of machines of a particular type in place as of a particular date whether the machinery was used for production, prototype, or sampling, or was idle. Machinery in place includes all machinery set up in operating positions.

Net receipts. Derived by subtracting the materials held at the end of the previous month from the sum of materials used during the current month.

Production. The total volume of products produced, including: products sold; products transferred or added to inventory after adjustments for breakage, shrinkage, and obsolescence, plus any other inventory adjustment; and products that undergo further manufacture at the same establishment.

Quantities produced and consumed. Quantities of each type of product produced by a company for internal consumption within that same company.

Quantity and value of new orders. The sales value of orders received during the current reporting period for products and services to be delivered immediately or at some future date. Also represents the net sales value of contract change documents that increase or decrease the sales value of the orders to which they are related, when the parties concerned are in substantial agreement as to the amount involved. Included as orders are only those that are supported by binding legal documents such as signed contracts or letter contracts.

Quantity and value of shipments. The figures on quantity and value of shipments represent physical shipments of all products sold, transferred to other establishments of the same company, or shipped on consignment, whether for domestic or export sale. The value represents the net sales price, f.o.b. plant, to the customer or branch to which the products are shipped, net of discounts, allowances, freight charges, and returns. Shipments to a company's own branches are assigned the same value as comparable appropriate allocation of company overhead and profit. Products bought and resold without further manufacture are excluded.

Stocks. Total quantity of ending finished inventory.

Unfilled orders (backlog). Calculated by adding net new orders and subtracting net sales from the backlog at the end of the preceding year.

HISTORICAL NOTE

Data on confectionery products have been collected by the Census Bureau since1926. In 1989, data tables showing the quantity and value of shipments of chocolate and nonchocolate-type confectionery, by type of product and package, were discontinued. Also discontinued in 1989 were data showing the sales and resales of confectionery by type of customer.

Starting with the 1990 report, data showing the quantity and value of shipments by type of product of other chocolate products (nonconfectionery) were added. Starting with the 1993 report, data for chewing gum were added.

Historical data may be obtained from Current Industrial Reports (called Facts for Industry before 1959) available at your local Federal Depository Library.

Analytical Studies in relation to Polyglycerol Polyricinoleate (PGPR)

1. **Acid Value.**
   Combined Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives. (2006) Vol.4 Analytical methods p.161.

2. **Hydroxyl Value.**
   Combined Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives. (2006) Vol.4 Analytical methods p.168.

3. **Iodine Value.**
   Combined Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives. (2006) Vol.4 Analytical methods p.172.

4. **Polyglycerol Determination in Polyglycerol Esters.**
   Combined Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives. (2006) Vol.4 Analytical methods p.180-181.

5. **Saponification Value.**
   Combined Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives. (2006) Vol.4 Analytical methods p.184 - 185.

6. **Evaluation of PGPR in Chocolate**
   Palsgaard a/s Juelsminde – technical paper.

FATS, OILS AND HYDROCARBONS

Acid Value

Acid value is defined as the number of mg of potassium hydroxide required to neutralize the acids in 1 g of fatty material.

Unless otherwise directed, weigh accurately about 5 g of sample into a 500-ml Erlenmeyer flask, and add 75-100 ml of hot neutral ethanol. Agitation and further heating may be necessary to effect complete solution of the sample. For some samples, it may be necessary to use as the solvent a 1:1 mixture of neutralized diethyl ether/ethanol or petroleum spirit/ethanol. Add 0.5 ml of phenolphthalein TS and titrate immediately, while shaking, with 0.5 N KOH until the pink colour persists for at least 30 sec. (For acidity less than 2% by weight, 0.1 N KOH should be used for the titration; for acidity less than 0.2% by weight, it is necessary, in addition, to first neutralize the carbon dioxide in the reaction vessel.)

Acid value = (56.1 x T x N) / W

where

T is the titre (ml);
N is the normality of potassium hydroxide solution; and
W is the weight of sample (g).

Aromatic Hydrocarbons Determination

Determine by Gas Chromatography using the following conditions or equivalent that will elute n-decane before benzene:

Apparatus

Liquid phase:	Tetracyanoethylated Pentaerythritrol (TCEPE)
Length:	30 m
i.d.:	0.25 mm
Temperatures:	
Inlet:	275°
Detector:	250°
Column:	95°
Carrier gas:	N_2
Flow rate:	3 cm^3/min
Detector	Flame ionization
Split	100 – 1

Reagents

Isooctane: 99 mole percent minimum containing less than 0.05 mole percent aromatic material.

Benzene: 99.5 mole percent minimum.

Internal Standard: n-Decane and either n-undecane or n-dodecane according to the requirement of the System Suitability Test.

Reference Solution A: Prepare a standard solution containing 0.5% by weight each of the Internal Standard and of benzene in isooctane.

of the neutralized alcohol. The colour must persist for at least 30 sec. Calculate the percentage of free fatty acids (FFA) in the sample by the formula VN/W, in which V is the volume and N is the normality, respectively, of the sodium hydroxide used, W is the weight of the sample, in g, and e is the equivalence factor given in the monograph.

FFA Range (%)	g of sample	ml of alcohol	Strength of NaOH
0.00-0.2	56.4 ± 0.2	50	0.1
0.2-1.0	28.2 ± 0.2	50	0.1
1.0-30.0	7.05 ± 0.05	75	0.25
30.0-50.0	7.05 ± 0.05	100	0.25-1.0
50.0-100	3.525 ± 0.001	100	1.0

Hydroxyl Value

(Based on AOCS Method Cd 13-60)

Note: *This method involves use of pyridine which should be used with appropriate caution.*

Hydroxyl value is defined as the number of mg of potassium hydroxide required to neutralize the amount of acetic acid capable of combining by acetylation with 1 g of sample.

Weigh accurately the appropriate amount of sample according to the expected hydroxyl value and transfer it into a 250-ml glass-stoppered Erlenmeyer flask.

Hydroxyl value	Sample weight (g)
0 to 20	10
20 to 50	5
50 to 100	3
100 to 200	2

Pipet 5.0 ml of pyridine/acetic anhydride TS into the flask. (For samples having a 0-20 hydroxyl value, add an additional 5 ml of pyridine/acetic anhydride TS to the flask.) Thoroughly mix the contents by gently swirling. Pipet 5.0 ml of pyridine/acetic anhydride TS into an empty flask for the reagent blank. (If 10.0 ml of the reagent were used for the acetylation, use a 10.0-ml blank.) Place the flasks on a steam bath, under reflux condensers, and heat for 1 h. To hydrolyze excess acetic anhydride, add sufficient water (not exceeding about 10 ml) through the condensers to the flasks. If the solution separates into two layers, add sufficient pyridine to obtain a homogeneous solution. Heat on a steam bath for 10 min with reflux condensers attached. Add 25 ml of neutralized n-butanol, about half of it through the condensers and the remainder to wash down the sides of the flasks after removal of the condensers. Add 1 ml of phenolphthalein TS and titrate to a faint pink endpoint with 0.5 N ethanolic KOH solution. To correct for free acid, mix about 10 g of the sample, accurately weighed, with 10 ml of pyridine (neutralized to phenolphthalein), add 1 ml of

Test H: Glycerol

Transfer 5 ml of the aqueous layer resulting from the hydrolysis into a test tube. Add excess calcium hydroxide as a powder, place in boiling water for 5 min, shaking several times, cool and filter.

Transfer one drop of the filtrate into a tube and add about 50 mg of potassium hydrogen sulfate. Place a filter paper, moistened with Reagent for acrolein (a 5% solution of disodium pentacyanonitrosylferrate in water and a 20% piperidine solution in water; mix the solutions 1:1 immediately before use) on the top of the tube. Heat over a micro flame. A blue coloured filter paper indicates the presence of glycerol. The colour changes to light red after addition of sodium hydroxide TS.

The test cannot be employed in the presence of ethylene glycol or lactic acid, since they decompose under the prescribed conditions yielding acetaldehyde which reacts with the reagents in the same manner as acrolein.

Iodine Value (Modified Wijs Method)

(Based on AOCS Method Cd 1d-92)

The iodine value (IV) is a measure of unsaturation and is expressed as the number of g of iodine absorbed, under the prescribed conditions, by 100 g of the test substance. For fats and oils, the Iodine Value may be calculated from the results of gas chromatographic quantification of methyl ester (see Methyl Esters of Fatty Acids, above)

Reagents

Cyclohexane
Glacial acetic acid
Wijs Solution: this reagent should be purchased commercially.
Potassium iodide TS
N sodium thiosulfate

Procedure

The appropriate weight of the sample, in g, is calculated by dividing the number 25 by the expected iodine value. Melt the sample, if necessary, and filter it through a dry filter paper. Transfer the accurately weighed quantity of sample into a clean, dry, 500-ml glass-stoppered bottle or flask containing 20 ml of glacial acetic acid/cyclohexane, 1:1, v/v, and pipet 25.0 ml of Wijs Solution into the flask. The excess of iodine should be between 50% and 60% of the quantity added, that is, between 100% and 150% of the quantity absorbed. Swirl, and let stand in the dark for 1.0 h where the iodine value is <150 and for 2.0 h where the iodine value is ≥150. Add 20 ml of potassium iodide TS and 100 ml of recently boiled and cooled water, and titrate the excess iodine with 0.1 N sodium thiosulfate, adding the titrant gradually and shaking constantly until the yellow colour of the solution almost disappears. Add starch TS, and continue the titration until the blue colour disappears entirely. Toward the end of the titration, stopper the container and shake it violently so that any iodine remaining in solution in the glacial acetic acid/cyclohexane layer may be taken up by the potassium iodide solution. Concomitantly, conduct two determinations on blanks in the same manner and at the same temperature.

Calculation

Calculate the iodine value by the formula

$$(B - S) \times 12.69N/W$$

ml portions of isooctane, swirling the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5 ml wash reaches the top of the adsorbent, add 100 ml of isooctane to the reservoir and continue the percolation at the 2-3 ml per min rate. Just before the last of the isooctane reaches the adsorbent level, add 100 ml of 10% benzene in isooctane to the reservoir and continue the percolation at the aforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 ml of 20% benzene in isooctane to the reservoir and continue the percolation at 2-3 ml per min until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point.

Add 300 ml of the acetone-benzene-water mixture to the reservoir and percolate through the column to elute the polynuclear compounds. Collect the eluate in a clean 1-l separatory funnel. Allow the column to drain until most of the solvent mixture is removed. Wash the eluate three times with 300 ml portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation). Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate prewashed with benzene (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-ml Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20 ml portions of benzene which are also filtered through the sodium sulfate. Add 1 ml of n-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under Organic Solvents. Quantitatively transfer the residue with isooctane to a 25 ml volumetric flask and adjust the volume. Determine the absorbance of the solution in the 5 cm path length cells compared to isooctane as reference between 250 and 400 nm. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without a wash sample. If either spectrum shows the characteristic benzene peaks in the 250 - 260 nm region, evaporate the solution to remove benzene by the procedure under Organic Solvents. Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 25 ml volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits prescribed in the Characteristics the sample meets the ultraviolet absorbance specifications.

Polyglycerol Determination in Polyglycerol Esters

Principle

Polyglycerol esters are saponified with alcoholic potassium hydroxide solution and the fatty acids removed by extraction. The polyols are converted to trimethylsilyl (TMS) derivatives and analyzed by gas liquid chromatography.

Procedure

Preparation of the polyol sample

Weigh about 0.5 g of sample and reflux with 20 ml of ethanolic potassium hydroxide solution (1 N) for 2 h. Reduce the volume of ethanol by evaporation at 45-50° in a stream of nitrogen. Add 10 ml of water and convert the soaps to free fatty acids by acidifying with concentrated hydrochloric acid. Extract the fatty acids from the aqueous phase with successive 20 ml portions of light petroleum (boiling range 40-60°). Wash the combined petroleum extracts with water (20 ml) and combine the wash with the aqueous phase.

Adjust the aqueous polyol solution to pH 7.0 with aqueous potassium hydroxide solution with the aid of a pH-meter. Evaporate to a small volume (2-3 ml) under reduced pressure and extract three times with 30 ml of boiling ethanol. Filter off any residue and evaporate the ethanol under reduced pressure to yield a viscous liquid sample of polyols.

Dissolve a 0.1 g sample of polyol in 0.5 ml of warm pyridine (previously dried over potassium hydroxide) in a 10-ml capped vial. Add 0.2 ml hexamethyl disilazane, shake, add 0.2 ml trimethylchlorosilane and shake again. Place on a warm plate (about 80°) for 3-5 min. Check that white fumes are present indicating an excess of reagent.

Gas-liquid chromatography

Any suitable gas chromatograph equipped as follows:

Stationary phase: 3% OV-1
Carrier gas: Nitrogen
Temperature of injection port: 275°
Column temperature: 90° to 330° at 4-6°/min
Detector type: FID, temperature: 350°

Inject a 2.0 µl sample of TMS derivatives of polyols. The following sequence of peaks are recorded on the resultant chromatogram :

Elution sequence of peaks	Identity	Description
1	Solvent	Out of scale
2	Glycerol	Single peak
3	Cyclic diglycerols	Single peak
4	Diglycerols	Single peak
5	Cyclic triglycerols	Single peak
6	Triglycerols	Single peak
7	Cyclic tetraglycerols	Single peak
8	Tetraglycerols	Multiple peaks
9	Pentaglycerols	Single peak
10	Hexaglycerols	Single peak
11	Heptaglycerols	Single peak
12	Octaglycerols	Single peak
13	Nonaglycerols	Barely discernible in the tail of peak 12

Calculation

Measure each peak area by a suitable method.

% di-, tri- and tetraglycerols =
(Sum of corrected areas of peaks 3 to 8 x 100) / (Sum of corrected areas of peaks 3 to 13)

% polyglycerols equal to or greater than heptaglycerol =
(Sum of corrected areas of peaks 11 to 13 x 100) / (Sum of corrected areas of peaks 3 to 13)

Polyols

Principle

The sample is hydrolysed. Fatty acids are removed by ion exchange in combination with hexane extraction. The components of the filtrate are separated by thin layer chromatography.

A_{IR} is the peak area of triethylene glycol (reference solution);
W is the weight (g) of sample of propylene glycol esters of fatty acids;
W_{DR} is the [1]weight (g) of dipropylene glycol in the reference solution;
W_{TR} is the [1]weight (g) of tripropylene glycol in the reference solution;
W_{IS} is the [1]weight (g) of triethylene glycol added to the sample solution; and
W_{IR} is the [1]weight (g) of triethylene glycol in the reference solution.

[1] Corrected for the actual content of polyol (e.g. W_{DR} is the weight of dipropylene glycol taken x % of assay).

Saponification

(AOCS Methods Tl 1a-64 and Cd 3-25)

Weigh accurately about 20 g of the sample and subject to alkaline hydrolysis by refluxing for 2 h with ethanolic potassium hydroxide TS containing a quantity of potassium hydroxide 100% in excess of the calculated amount required to saponify the sample completely. After hydrolysis, convert the ethanolic soap solution to an aqueous solution by the addition of water and evaporation of the alcohol on a steam bath. Acidify the hot aqueous soap solution with sulfuric acid to liberate the fatty acid. Extract the acid solution with 3 portions of petroleum ether to remove the fatty acid. Evaporate the petroleum ether extracts on a steam bath and dry the residue to constant weight under vacuum at 75° to recover the fatty acid. Multiply the weight of recovered fatty acid by 100/W to obtain the yield of fatty acid from a 100-g sample (where W is the exact weight of sample taken). The fatty acid can be identified by determination of the physical and chemical constants, e.g. the solidification temperature, or by gas-liquid chromatography.

Neutralize the aqueous polyol solution to pH 7 with potassium hydroxide. Evaporate the polyol solution to a moist residue on a steam bath and extract the polyol from the salts with 3 portions of hot absolute ethanol. Evaporate off the alcohol on a steam bath and dry the residue to constant weight under vacuum at 75° to yield the polyol moiety of the sample. Multiply the weight of recovered polyol by 100/W to obtain the yield of polyols from a 100-g sample (where W is the exact weight of sample taken).

Saponification Value

Definition

Saponification value is defined as the number of mg of potassium hydroxide required to neutralize the free acids and saponify the esters in 1 g of test substance.

Procedure

Melt the sample, if necessary, and filter it through a dry filter paper to remove any traces of moisture. Unless otherwise directed, weigh accurately into a 250-ml flask a sample of such size (usually about 4-5 g) that the titration of the sample solution after saponification will require between 45 and 55% of the volume of 0.5 N hydrochloric acid required for the blank. Add 50.0 ml of ethanolic potassium hydroxide TS from a pipet and allow the pipet to drain for a definite period of time. Prepare and conduct blank determinations simultaneously with the sample and similar in all respects. Connect an air condenser to each flask and boil gently but steadily, with occasional mixing, until the sample is completely saponified. (This usually requires about 1 h for normal samples). After the flasks and condensers have cooled somewhat but not sufficiently for the contents to gel, wash down the inside of the condensers with a few ml of distilled water. Disconnect the condensers, add about 1 ml of

phenolphthalein TS to reach flask, and titrate with 0.5 N hydrochloric acid until the pink colour has just disappeared.

Saponification value = [56.1 x N (A - B)] / W

Where

A is ml of HCl required for the titration of the blank;
B is ml of HCl required for the titration of the sample;
W is the weight of sample in g; and
N is normality of the HCl.

Sorbitan Ester Content

Principle

Sorbitan esters may be assayed by alkaline saponification followed by recovery of the polyol and determination of the isosorbide content by gas-liquid chromatography.

Procedure

Saponification and recovery of the polyol

Weigh accurately about 25 g of the sample into a 500-ml round-bottomed boiling flask. Add 250 ml of ethanol and a quantity of potassium hydroxide 100% in excess of the calculated amount required for saponification (approximately 7.5 g). Boil the mixture for 2 h under reflux. Transfer the saponification mixture to an 800-ml beaker. Rinse the flask with about 100 ml of water and add to the mixture. Place the beaker on a steam bath to evaporate the alcohol. Add water occasionally to replace the ethanol. When the odour of ethanol can no longer be detected, adjust the volume of the soap solution to approximately 250 ml with hot water.

Acidify the hot soap solution with stirring using sufficient 1:1 sulfuric acid to provide a 10% excess. Heat and stir the mixture until the fatty acid layer separates. Transfer the hot mixture to a 500-ml separating funnel using hot water to rinse the beaker. Cool the contents of the funnel and extract three times with 100-ml portions of petroleum ether. Combine the petroleum ether extracts in a second funnel and wash once with 100 ml of water. Combine the water wash with the aqueous phase in an 800-ml beaker.

Neutralize the polyol solution with 10% aqueous potassium hydroxide solution to pH 7 using a pH meter. Place the beaker in a steam bath and evaporate the solvent to incipient dryness. Extract the residue four times with 150-ml portions of boiling absolute ethanol. Filter the combined extracts into a 1-l suction flask through a 10-cm Buchner funnel containing a 1-3 cm bed of silicagel. Wash the funnel with absolute ethanol. Transfer the filtrate and washings to a 1,000-ml volumetric flask. Cool to room temperature and dilute to volume with ethanol. Use this as the sample solution for gas-liquid chromatography.

Gas-liquid chromatography

The experimental operating conditions for the isosorbide analyses are not critical, suitable conditions are listed below . Minor fluctuations in temperature and gas flow rate do not affect resolution or analytical results.

Stationary phase: 15% Carbowax 20 M
Carrier gas: Argon
Temperature of injection port: 295°
Column temperature: 195°

Evaluation of PGPR in Chocolate

Palsgaard®

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Evaluation of PGPR in Chocolate

INTRODUCTION

The purpose of this leaflet is to describe a precise and practical way to evaluate PGPR in chocolate

Palsgaard has for the last 15 years been market leader of PGPR for the confectionary industry, and in this period many of our customers have been visiting our chocolate application department in order to gain from our knowledge in this field.
However, we have not been able to reach all people interested in this matter, so we believe there is a need for a good detailed procedure to help our customers, wherever they are, to perform a correct evaluation of PGPR.
In this way, communication to our customers will be easier and they will be able to compare apples to apples, or rather PGPR to PGPR.

Palsgaard®

Contents

1. Standard reference chocolate

In order to perform a good evaluation of PGPR it is imperative to use a standard reference chocolate,where lecithin or ammonium phosphatide is added.
The chocolate should be manufactured and stored according to the following procedures to obtain a correct result.

2. Composition of the reference chocolate

Palsgaard standard chocolate for evaluation of PGPR is a 30% milk chocolate with the following composition:

	%
Cocoa liquor	15.00
Cocoa butter	14.20
Icing sugar	46.20
Whole milk powder	24.00
Palsgaard®4448	0.60
	100.00

* Palsgaard®4448 is Ammonium Phosphatide (E 442)

3. Procedure for making the reference chocolate

Melt cocoa liquor and cocoa butter and heat to approx. 60°C.
Add icing sugar and whole milk powder.
Mix all by means of a beater/mixer with heated jacket.
Temperature 48°C, low gear (1st at Hobart).

Pass the blend/paste through a 3 roll refiner and reduce the particle size to approx. 25 micron and below.

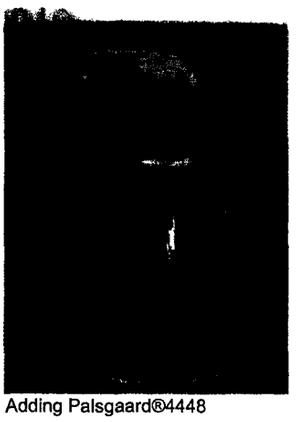
Mixing the ingredients (minus Palsgaard®4448) Hobart beater/mixer with heated jacket

3 Roll refiner

Measuring the particle size

Conch at 60°C in the Hobart.
After 2 - 3 hours' conching, add Palsgaard®4448 or lecithin.
We use Palsgaard®4448 due to its consistent quality.

Conching is terminated when a viscosity between 90.000 to 120.000 mPas measured at 0.50[1/S] has been achieved.
Expect a conching time of 8 to 10 hours or more depending on the equipment being used.
After conching, the moisture should be below 1%.


Adding Palsgaard®4448

4. Packaging and storage

Cool the chocolate mass and fill it into a plastic cup (approx 1200-1300 g) or what will be convenient for your test programme. Leave the cup open in a dry room for minimum 24 hours for crystallization of the chocolate.


Filling chocolate into the plastic cup

Close the cup with a lid and seal the sample with a moisture proof aluminium foil.
Store the samples at 5°C.
Shelf life 1 year.

NB: If you are unable to manufacture the above test chocolate, Palsgaard application department may be of asistance with a sample.


Plastic cup sealed in aluminium foil

5. Pre-treatment of chocolate

A sample of the chocolate is taken from the cold storage and put into a heating cabinet at 50°C. Leave the sample to melt until next day.

Unwrap the sample and pour the chocolate into a small mixer equipped with a heating jacket (Hobart or similar).

Adjust the temperature of the heating jacket to 50°C.

Mix for approx. 15 minutes, low gear (1st at Hobart)

The sample of 1200 ml will be sufficient for 10 measurements, where one will be reference chocolate without PGPR.

Re-melting the chocolate at 50°C

6. Reference chocolate

Pour 100.00 gram chocolate into a 150 ml beaker glass and put it into a heating cabinet at a temperature of 48°C.

Weighing out 100 g chocolate into glass beaker

7. Reference chocolate with PGPR

Pour 99.80 gram chocolate into a 150 ml beaker glass.
Add 0.200 gram PGPR to be tested.
Use a good scale in order to weigh the amount of PGPR (0.200 gram +/- 0.002 gram)
Please be accurate here.

Adding Palsgaard PGPR to the chocolate

8. Reference chocolate with another PGPR

Same procedure as above.

Stir the samples clockwise as well as anticlockwise with a metal rod for 2 minutes.

Put the samples into the heating cabinet at 48°C, and leave them until you are ready for measuring.

Agitation to ensure a homogenious chocolate

9. Measure viscosity at a low shear rate

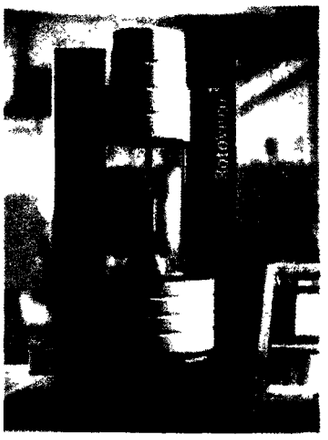
Several methods may be used to evaluate the function of PGPR.
Methods can be Casson yield values or comparing viscosity curves at different shear rates.
Palsgaard has chosen to measure viscosity at a low shear rate, because we find it relevant to conditions in the chocolate plant.

Low shear rate: = 0.50 [1/S]

Other emulsifiers such as Palsgaard®4448/lecithin are evaluated using the same measuring method. If more information is required, please contact Palsgaard A/S (chocolate department).

10. Equipment

The viscometer used could be any standard type available that are capable of measuring viscosity at different shear rates
At Palsgaard we are using a Haake Rotovisco-1 or a Brookfield DV-3 viscometers.



Haake viscometer

Brookfield viscometer

11. Measurements

Switch on the viscometer, the computer and the water bath.
Open the software part "job manager" and select the measuring programme from the list of available programmes.

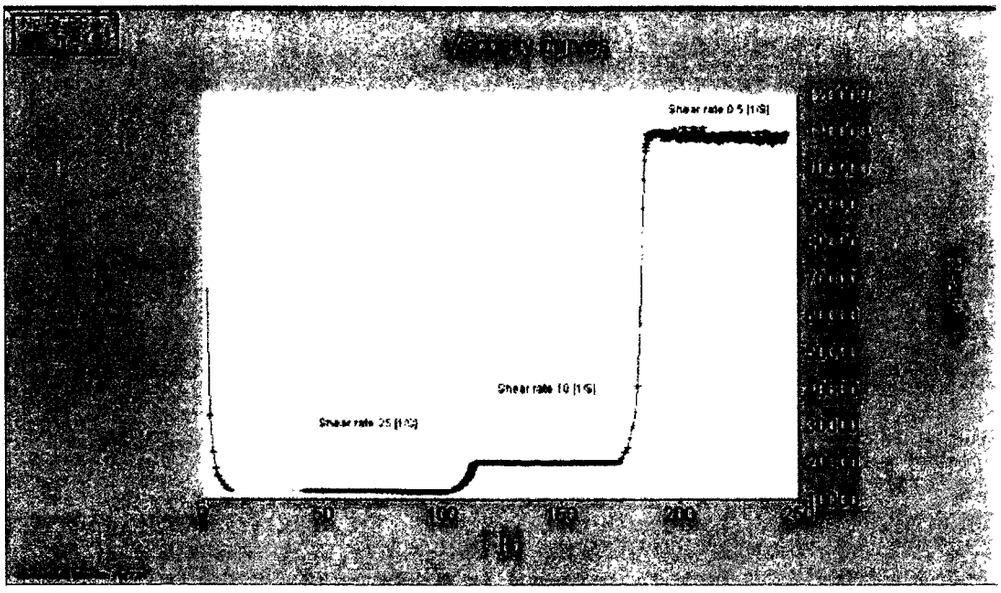
Palsgaard programme:

1. Check the temperature of the viscometer (40°C ± 0.5°C)
2. Go from shear rate 0 to shear rate 30[1/S] in 30 sec. (2 data points)
3. Stay at shear rate 30[1/S] within 90 sec. (2 data points)
4. Go to shear rate 25.0[1/S], within 10 sec. (10 data points)
5. Stay at shear rate 25.0[1/S], for 60 sec. (200 data points)
6. Go to shear rate 10.0[1/S], within 10 sec. (2 data points)
7. Stay at shear rate 10.0[1/S] for 60 sec. (200 data points)
8. Go to shear rate 0.50[1/S] within 10 sec.(2 data points)
9. Stay at shear rate 0.50[1/S] for 60 sec. (200 data points).

Measuring the reference chocolate

Below viscosity curve shows the reference milk chocolate (paragraph 6) measured according to above described Palsgaard programme.
According to (paragraph 9) we are mainly interested in viscosity measured at shear rate 0.50[1/S], here equal to 110000 mPas (red curve).

Viscosity curve showing the 3 selected viscosities of 25.0; 10.0; 0.50[1/S]

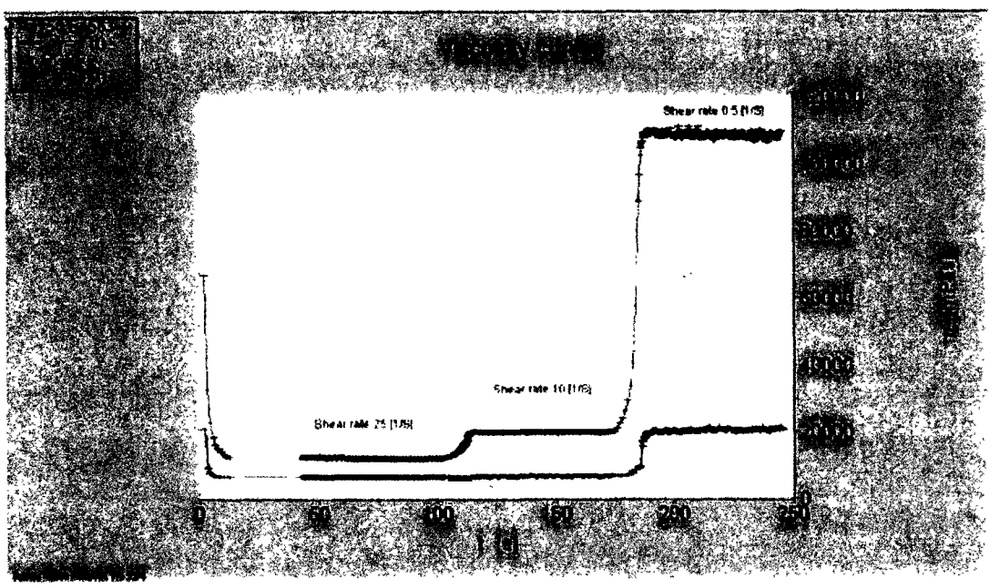


NB: The milk chocolate contains 0.60% Palsgaard®4448 (Ammonium Phospatide)

Measuring the reference chocolate with PGPR

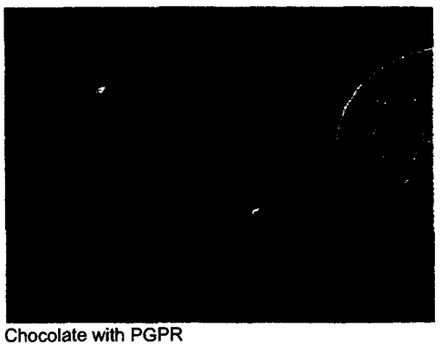
Below viscosity curve shows the reference milk chocolate (part 7) now added 0.20% Palsgaard®4150, measured according to above described Palsgaard programme.

Reference milk chocolate = red curve
Reference milk chocolate added 0.20% Palsgaard®4150 = blue curve



NB: The milk chocolate contains 0.60% Palsgaard®4448 + 0.20% Palsgaard®4150.

The viscosity at 0.50[1/S] is 20000 mPas (blue curve).
Addition of 0.20% Palsgaard®4150 has thus been able to reduce the viscosity from 110000 down to 20000 mPas.
This means that the viscosity of the milk chocolate been reduced by 90000mPas as a result of the 0.20% Palsgaard®4150 addition.


Chocolate with PGPR


Chocolate without PGPR

12. Viscosity reduction power %, (VRP%) of PGPR

Definition: The achieved viscosity reduction in the reference chocolate by adding PGPR in percentage of the reference sample (without PGPR).

A. Measure viscosity of the reference chocolate using shear rate 0.50 sec [1/S].
B. Measure viscosity of the reference chocolate with 0.2% PGPR added, using shear rate 0.50 sec [1/S].

The difference between the results is showing the VRP. (A – B)
We normally express this in % of the reference chocolate. $\frac{(A - B) \times 100}{A}$

Example:

Reference chocolate	110.000 mPas	(A)
Reference chocolate, added 0.2% PGPR	- 20.000 mPas	(B)
Viscosity reduction power, (VRP)	90.000 mPas	(A – B)

Expressed as % : $\frac{(A - B) \times 100}{A} = \frac{(110.00 - 20.000) \times 100}{110.000} = 82\%$

A low percentage shows little effect of the added PGPR.
A high percentage shows good effect of the added PGPR.

13. Control of consistent PGPR functionality

Palsgaard A/S is using the VRP method to control every batch of PGPR.
This ensures constant functionality for every delivery of Palsgaard PGPR.

In order to reduce the effect of other variable factors on the VRP%, we always include a known PGPR as standard.

This reference PGPR is tested parallel with the new batch PGPR:

$$\text{VPR Index} = \frac{\text{VRP new Batch PGPR} \times 100}{\text{VRP reference PGPR}}$$

A higher VRP Index shows that the new batch PGPR is more functional than the reference PGPR.

The reference PGPR must be kept cool and dry, protected from direct sunlight, and we recommend a new reference PGPR is selected every 12 months.

14. Legal issues regarding PGPR (E 476)

Palsgaard PGPR is in conformity with the below mentioned specifications on Identity and Purity:

- Commission Directive 96/77/EC
- FAO Food & Nutrition Paper no. 52/2
- Food Chemicals Codex ed. IV

Addition of PGPR to food products is regulated in the local food law and should always be checked before use.

9

Analysis of Polyglycerol Polyricinoleate (PGPR) in Chocolate type products.

In the literature only one work reports the determination of PGPR in chocolate. (Dick R, Miserez A., Gas chromatographic detection and determination of foodstuffs emulsifiers. Mitt Gebiete Lebensm. Hyg. &/, 472-487(1976))
The method uses the presence of ricinoleic fatty acid as a marker for PGPR.

For analysing PGPR in chocolate and vegetable fat compounds, we recommend to separate the lipid material from the solid matters i.e. cocoa, sugar and other non-fat compounds, using the AOAC Official Methods 963.15 ; Fat in cocoa products, chapter 31 p 10 based on a solvent extraction.

Pages 000163 - 000172 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

10

CODEX STANDARD FOR CHOCOLATE AND CHOCOLATE PRODUCTS

(CODEX STAN 87-1981, Rev. 1 - 2003)

1 SCOPE

The standard applies to chocolate and chocolate products intended for human consumption and listed in Section 2. Chocolate and chocolate products shall be prepared from cocoa and cocoa materials with sugars and may contain sweeteners, milk products, flavouring substances and other food ingredients.

2 DESCRIPTION AND ESSENTIAL COMPOSITION FACTORS

Chocolate is the generic name for the homogenous products complying with the descriptions below and summarized in Table 1. It is obtained by an adequate manufacturing process from cocoa materials which may be combined with milk products, sugars and/or sweeteners, and other additives listed in section 3 of the present standard. Other edible foodstuffs, excluding added flour and starch (except for products in sections 2.1.1.1 and 2.1.2.1 of this Standard) and animal fats other than milk fat, may be added to form various chocolate products. These combined additions shall be limited to 40 % of the total weight of the finished product, subject to the labelling provisions under Section 5.

The addition of vegetable fats other than cocoa butter shall not exceed 5% of the finished product, after deduction of the total weight of any other added edible foodstuffs, without reducing the minimum contents of cocoa materials. Where required by the authorities having jurisdiction, the nature of the vegetable fats permitted for this purpose may be prescribed in applicable legislation.

2.1 CHOCOLATE TYPES (COMPOSITION)

2.1.1 Chocolate

Chocolate (in some regions also named *bittersweet chocolate, semi-sweet chocolate, dark chocolate* or *"chocolat fondant"*) shall contain, on a dry matter basis, not less than 35% total cocoa solids, of which not less than 18% shall be cocoa butter and not less than 14% fat-free cocoa solids.

2.1.1.1 *Chocolate a la taza* is the product described under Section 2.1.1 of this Standard and containing a maximum of 8% m/m flour and/or starch from wheat, maize or rice.

2.1.2 Sweet Chocolate

Sweet Chocolate shall contain, on a dry matter basis, not less than 30% total cocoa solids, of which at least 18% shall be cocoa butter and at least 12% fat-free cocoa solids.

2.1.2.1 *Chocolate familiar a la taza* is the product described under Section 2.1.2 of this Standard and containing a maximum of 18% m/m flour and/or starch from wheat, maize or rice.

2.1.3 Couverture Chocolate

Couverture Chocolate shall contain, on a dry matter basis, not less than 35% total cocoa solids of which not less than 31% shall be cocoa butter and not less than 2.5% of fat-free cocoa solids.

2.1.4 Milk Chocolate

Milk Chocolate shall contain, on a dry matter basis, not less than 25% cocoa solids (including a minimum of 2.5% fat-free cocoa solids) and a specified minimum of milk solids between 12% and 14% (including a minimum of milk fat between 2.5% and 3.5%). The minimum content for milk solids and milk fat shall be applied by the authority having jurisdiction in accordance with applicable legislation. "Milk solids" refers to the addition of milk ingredients in their natural proportions, except that milk fat may be added, or removed.

Where required by the competent authority, a minimum content of cocoa butter plus milk fat may also be set.

2.1.5 Family Milk Chocolate

Family Milk Chocolate shall contain, on a dry matter basis, not less than 20% cocoa solids (including a minimum of 2.5% fat-free cocoa solids) and not less than 20% milk solids (including a minimum of 5% milk fat). "Milk solids" refers to the addition of milk ingredients in their natural proportions, except that milk fat may be added, or removed.

Where required by the competent authority, a minimum content of cocoa butter plus milk fat may also be set.

2.1.6 Milk Chocolate Couverture

Milk Chocolate Couverture shall contain, on a dry matter basis, not less than 25% cocoa solids (including a minimum of 2.5% non-fat cocoa solids) and not less than 14% milk solids (including a minimum of 3.5% milk fat) and a total fat of not less than 31%. "Milk solids" refers to the addition of milk ingredients in their natural proportions, except that milk fat may be added, or removed.

2.1.7 Other chocolate products

2.1.7.1 White Chocolate

White Chocolate shall contain, on a dry matter basis, not less than 20% cocoa butter and not less than 14% milk solids (including a minimum milk fat in a range of 2.5% to 3.5% as applied by the authority having jurisdiction in accordance with applicable legislation). "Milk solids" refers to the addition of milk ingredients in their natural proportions, except that milk fat may be added, or removed.

Where required by the competent authority, a minimum content of cocoa butter plus milk fat may also be set.

2.1.7.2 Gianduja Chocolate

"*Gianduja*" (or one of the derivatives of the word "*Gianduja*") *Chocolate* is the product obtained, firstly, from chocolate having a minimum total dry cocoa solids content of 32%, including a minimum dry non-fat cocoa solids content of 8%, and, secondly, from finely ground hazelnuts such that the product contains not less than 20 % and not more than 40% of hazelnuts.

The following may be added:

- (a) milk and/or dry milk solids obtained by evaporation, in such proportion that the finished product does not contain more than 5% dry milk solids ;
- (b) almonds, hazelnuts and other nut varieties, either whole or broken, in such quantities that, together with the ground hazelnuts, they do not exceed 60% of the total weight of the product.

2.1.7.3 Gianduja Milk Chocolate

"*Gianduja*" (or one of the derivatives of the word "*Gianduja*") *Milk Chocolate* is the product obtained, firstly, from milk chocolate having a minimum dry milk solids content of 10% and, secondly, from finely ground hazelnuts such that the product contains not less than 15 % and not more than 40% of hazelnuts. "Milk solids" refers to the addition of milk ingredients in their natural proportions, except that milk fat may be added or removed.

The following may be added: Almonds, hazelnuts and other nut varieties, either whole or broken, in such quantities that, together with the ground hazelnuts, they do not exceed 60% of the total weight of the product.

Where required by the competent authority, a minimum content of cocoa butter plus milk fat may also be set.

2.1.7.4 Chocolate para mesa

Chocolate para mesa is unrefined chocolate in which the grain size of sugars is larger than 70 microns.

2.1.7.4.1 Chocolate para mesa

Chocolate para mesa shall contain, on a dry matter basis, not less than 20% total cocoa solids (including a minimum of 11% cocoa butter and a minimum of 9% fat-free cocoa solids).

2.1.7.4.2 Semi-bitter chocolate para mesa

Semi-bitter Chocolate para mesa shall contain, on a dry matter basis, not less than 30% total cocoa solids (including a minimum of 15% cocoa butter and a minimum of 14% fat-free cocoa solids).

2.1.7.4.3 Bitter chocolate para mesa

Bitter Chocolate para mesa shall contain, on a dry matter basis, not less than 40% total cocoa solids (including a minimum of 22% cocoa butter and a minimum of 18% fat-free cocoa solids).

2.2 CHOCOLAT TYPES (FORMS)

2.2.1 Chocolate Vermicelli and Chocolate Flakes

Chocolate Vermicelli and Chocolate Flakes are cocoa products obtained by a mixing, extrusion and hardening technique which gives unique, crisp textural properties to the products. Vermicelli are presented in the form of short, cylindrical grains and flakes in the form of small flat pieces.

2.2.1.1 Chocolate Vermicelli / Chocolate Flakes

Chocolate Vermicelli / Chocolate Flakes shall contain, on a dry matter basis, not less than 32% total cocoa solids, of which at least 12% shall be cocoa butter and 14% fat-free cocoa solids.

2.2.1.2 Milk Chocolate Vermicelli / Milk Chocolate Flakes

Milk Chocolate Vermicelli / Milk Chocolate Flakes shall contain, on a dry matter basis, not less than 20% cocoa solids (including a minimum of 2.5% fat-free cocoa solids) and not less than 12% milk solids (including a minimum of 3% milk fat). "Milk solids" refers to the addition of milk ingredients in their natural proportions, except that milk fat may be added, or removed.

Where required by the competent authority, a minimum content of cocoa butter plus milk fat may also be set.

2.2.2 Filled Chocolate

Filled Chocolate is a product covered by a coating of one or more of the Chocolates defined in Section 2.1, with exception of *chocolate a la taza, chocolate familiar a la taza* and products defined in section 2.1.7.4 (*chocolate para mesa)*, the centre of which is clearly distinct, through its composition, from the external coating. Filled Chocolate does not include Flour Confectionery, Pastry, Biscuit or Ice Cream products. The chocolate part of the coating must make up at least 25% of the total weight of the product concerned.

If the centre part of the product is made up of a component or components for which a separate Codex Standard exists, the component(s) must comply with the applicable standard.

2.2.3 A Chocolate or Praline

A Chocolate or *Praline* designates the product in a single mouthful size, where the amount of the chocolate component shall not be less than 25% of the total weight of the product. The product shall consist of either filled chocolate or a single or combination of the chocolates as defined under Section 2.1, with exception of *chocolate a la taza, chocolate familiar a la taza* and products defined in section 2.1.7.4 (*chocolate para mesa*).

TABLE 1. SUMMARY TABLE OF COMPOSITIONAL REQUIREMENTS OF SECTION 2[1]

(% calculated on the dry matter in the product and after deduction of the weight of the other edible foodstuffs authorized under Section 2)

PRODUCTS	CONSTITUENTS (%)						
2. Chocolate Types	**Cocoa Butter**	**Fat-free Cocoa Solids**	**Total Cocoa Solids**	**Milk Fat**	**Total Milk Solids**	**Starch / Flour**	**Ground Hazelnuts**
2.1 CHOCOLATE TYPES (COMPOSITION)							
2.1.1 Chocolate	≥18	≥14	≥35				
2.1.1.1 Chocolate a la taza	≥18	≥14	≥35			< 8	
2.1.2 Sweet Chocolate	≥18	≥12	≥30				
2.1.2.1 Chocolate familiar a la taza	≥18	≥12	≥30			< 18	
2.1.3 Couverture Chocolate	≥31	≥2.5	≥35				
2.1.4 Milk Chocolate		≥2.5	≥25	≥2.5-3.5	≥12-14		
2.1.5 Family Milk Chocolate		≥2.5	≥20	≥5	≥20		
2.1.6 Milk Chocolate Couverture		≥2.5	≥25	≥3.5	≥14		
2.1.7 Other chocolate products							
2.1.7.1. White Chocolate	≥20			≥2.5-3.5	≥14		
2.1.7.2 Gianduja Chocolate		≥8	≥32				≥20 and ≤40
2.1.7.3 Gianduja Milk Chocolate		≥2.5	≥25	≥2.5-3.5	≥10		≥15 and ≤40
2.1.7.4 Chocolate para mesa							
2.1.7.4.1 Chocolate para mesa	≥ 11	≥ 9	≥ 20				
2.1.7.4.2 Semi-bitter chocolate para mesa	≥15	≥14	≥ 30				
2.1.7.4.3 Bitter chocolate para mesa	≥ 22	≥18	≥ 40				
2.2 CHOCOLATE TYPES (forms)							
2.2.1 Chocolate Vermicelli / Chocolate Flakes							
2.2.1.1 Chocolate Vermicelli / Chocolate Flakes	≥12	≥14	≥32				
2.2.1.2 Milk Chocolate Vermicelli / Milk Chocolate Flakes		≥2.5	≥ 20	≥3	≥12		
2.2.2 Filled Chocolate (see section 2.2.2)							
2.2.3 A Chocolate or Praline (see section 2.2.3)							

[1] "***Milk solids***" refers to the addition of milk ingredients in their natural proportions except that milk fat may be added or removed.

3 FOOD ADDITIVES

The food additives listed below may be used and only within the limits specified.

Other additives from the General Standard for Food Additives (GSFA) approved list may be used, subject to the authority having jurisdiction in accordance with applicable legislation.

3.1 Alkalizing and neutralizing agents carried over as a result of processing cocoa materials in proportion to the maximum quantity as provided for.

3.2 ACIDITY REGULATORS		**Maximum Level**
503(i)	Ammonium carbonate	Limited by GMP
527	Ammonium hydroxide	
503(ii)	Ammonium hydrogen carbonate	
170(i)	Calcium carbonate	
330	Citric acid	
504(i)	Magnesium carbonate	
528	Magnesium hydroxide	
530	Magnesium oxide	
501(i)	Potassium carbonate	
525	Potassium hydroxide	
501(ii)	Potassium hydrogen carbonate	
500(i)	Sodium carbonate	
524	Sodium hydroxide	
500(ii)	Sodium hydrogen carbonate	
526	Calcium hydroxide	
338	Orthophosphoric acid	2.5 g/kg expressed as P_2O_5 in finished cocoa and chocolate products
334	L-Tartaric acid	5 g/kg in finished cocoa and chocolate products

3.3 EMULSIFIERS		**Maximum Level**	**Products**
471	Mono- and di-glycerides of fatty acids	GMP	Products described under 2.1 and 2.2
322	Lecithins		" "

422	Glycerol			"	"
442	Ammonium salts of phosphatidic acids	10 g/kg		"	"
476	Polyglycerol esters interesterified recinoleic acid	5 g/kg	15 g/kg	"	"
491	Sorbitan monostearate	10 g/kg	in combination	"	"
492	Sorbitan tristearate	10 g/kg		"	"
435	Polyoxyethylene (20) sorbitan monostearate	10 g/kg			

3.4 FLAVOURING AGENTS

3.4.1	Natural flavours as defined in the Codex Alimentarius, and their synthetic equivalents, except those which would imitate natural chocolate or milk flavours[2]	GMP		Products described under 2.1 and 2.2
3.4.2	Vanillin		1 g/kg in combination	Products described under 2.1 and 2.2
3.4.3	Ethyl vanillin			Products described under 2.1 and 2.2

3.5 SWEETENERS

950	Acesulfame K	500 mg/kg		Products described under 2.1 and 2.2
951	Aspartame	2 000 mg/kg		" "
952	Cyclamic acid and its Na and Ca salts	500 mg/kg		" "
954	Saccharin and its Na and Ca salts	500 mg/kg		" "
957	Thaumatin			" "

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[2] Temporarily endorsed

420	Sorbitol			" "
421	Mannitol			" "
953	Isomalt		GMP	" "
965	Maltitol			" "
966	Lactitol			" "
967	Xylitol			" "
3.6	**GLAZING AGENTS**			
414	Gum Arabic (Acacia gum)			Products described under 2.1 and 2.2
440	Pectin			" "
901	Beeswax, white and yellow		GMP	" "
902	Candelilla wax			" "
904	Shellac			" "
3.7	**ANTIOXIDANTS**			
304	Ascorbyl palmitate		200 mg/kg	Products described under 2.1.7.1 calculated on a fat content basis
319	Tertiary butylhydroquine		200 mg/kg singly or in combination	"
320	Butylated hydroxyanisole			"
321	Butylated hydroxytoluene			"
310	Propylgallate			"
307	α-Tocopherol		750 mg/kg	"
3.8	**COLOURS (FOR DECORATION PURPOSE ONLY)**			
175	Gold		GMP	Products described
174	Silver		GMP	under 2.1 and 2.2

3.9 BULKING AGENTS

1200	Polydextrose A and N	GMP	Products described under 2.1 and 2.2

3.10 PROCESSING AID

	Maximum Level	
Hexane (62°C - 82°C)	1 mg/kg	calculated on a fat content basis

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4 HYGIENE

4.1 It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 3-1997), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

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

5 LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 Rev. 1-1991), the following declarations shall be made:

5.1 NAME OF THE FOOD

5.1.1 Products described under Sections 2.1 and 2.2 of this Standard and complying with the appropriate requirements of the relevant section shall be designated according to the name listed in Section 2 under subsequent section and subject to the provisions under Section 5 of this Standard. The products defined in section 2.1.1 may be described as "*Bittersweet chocolate*", "*Semi-sweet chocolate*", "*Dark chocolate*" or "*Chocolat fondant*".

5.1.1.1 When sugars are fully or partly replaced by sweeteners, an appropriate declaration should be included in proximity of the sales designation of the chocolate, mentioning the presence of sweeteners. *Example*: "X Chocolate with sweeteners".

5.1.1.2 The use of vegetable fats in addition to Cocoa butter in accordance with the provisions of Section 2 shall be indicated on the label in association with the name and/or the representation of the product.

The authorities having jurisdiction may prescribe the specific manner in which this declaration shall be made.

5.1.2 Filled Chocolate

5.1.2.1 Products described under Section 2.2.2. shall be designated "Filled Chocolate", "X Filled Chocolate", "Chocolate with X Filling" or "Chocolate with X Centre", where "X" is descriptive of the nature of the filling.

5.1.2.2 The type of chocolate used in the external coating may be specified, whereby the designations used shall be the same as stated under Section 5.1.1 of this Standard.

5.1.2.3 An appropriate statement shall inform the consumer about the nature of the centre.

5.1.3 A Chocolate or Praline

Products in a single mouthful size described under Section 2.2.3 of this Standard shall be designated "*A Chocolate*" or "*Praline*".

5.1.4 Assorted Chocolates

Where the products described under Section 2.1 or 2.2 with exception of *chocolate a la taza*, *chocolate familiar a la taza* and *chocolate para mesa* are sold in assortments, the product name may be replaced by the words "*Assorted Chocolates*" or "*Assorted filled Chocolates*", "*Assorted Chocolate Vermicelli*", etc. In that case, there shall be a single list of ingredients for all the products in the assortment or alternatively lists of ingredients by products.

5.1.5 Other Information Required

5.1.5.1 Any characterizing flavour, other than chocolate flavour shall be in the designation of the product.

5.1.5.2 Ingredients, which are especially aromatic and characterize the product shall form part of the name of the product (e.g. Mocca Chocolate).

5.1.6 Use of the Term Chocolate

Products not defined under this Standard, and where the chocolate taste is solely derived from non-fat cocoa solids, can carry the term "chocolate" in their designations in accordance with the provisions or customs applicable in the country in which the product is sold to the final consumer and this to designate other products which cannot be confused with those defined in this Standard.

5.2 DECLARATION OF MINIMUM COCOA CONTENT

When required by the authority having jurisdiction, products described under Section 2.1 of this Standard, except for *white chocolat*, shall carry a declaration of cocoa solids. For the purpose of this declaration, the percentages declared shall be made on the chocolate part of the product after the deduction of the other permitted edible foodstuffs.

5.3 LABELLING OF NON-RETAIL CONTAINERS

5.3.1 Information required in Section 5.1 and 5.2 of this Standard and Section 4 of the *Codex General Standard for the Labelling of Prepackaged Foods* shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer, packer, distributor and/or importer shall appear on the container.

5.3.2 However, lot identification, and the name and address of the manufacturer, packer, distributor and/or importer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents.

6 METHODS OF ANALYSIS AND SAMPLING

6.1 DETERMINATION OF CENTRE AND COATING OF FILLED CHOCOLATE

All methods approved for the chocolate type used for the coating and those approved for the type of centre concerned.

6.2 DETERMINATION OF COCOA BUTTER

According to AOAC 963.15 or IOCCC 14-1972.

6.3 DETERMINATION OF FAT-FREE COCOA SOLID

According to AOAC 931.05.

6.4 DETERMINATION OF FAT-FREE MILK SOLIDS

According to IOCCC 17-1973 or AOAC 939.02.

6.5 DETERMINATION OF MILK FAT

According to IOCCC 5-1962 or AOAC 945.34, 925.41B, 920.80.

6.6 DETERMINATION OF MOISTURE

According to IOCCC 26-1988 or AOAC 977.10 (Karl Fischer method); or AOAC 931.04 or IOCCC 1-1952 (gravimetry).

6.7 DETERMINATION OF TOTAL FAT

According to AOAC 963.15.

6.8 DETERMINATION OF NON-COCOA BUTTER VEGETABLE FAT IN CHOCOLATE AND CHOCOLATE PRODUCTS

The following methods of analysis are the best available at the present time. Further systematic improvement is required. Documentation identifying the type of commercial blends of non-cocoa butter vegetable fats used must be made available upon request by competent authorities.

6.8.1 Detection of Non-Cocoa Butter Vegetable Fats in Chocolate

Detecting sterol breakdown products in refined vegetable fats added to chocolate by method AOCS Ce 10/02 (02).

6.8.2 Quantitative Determination of Non-Cocoa Butter Vegetable Fats[*]

Determination of the triacyglycerols (C50, C52, C54) present in cocoa butters and non-cocoa butter vegetable fats by GC-FID in *J. Amer. Oil Chem. Soc.* (1980), **57**, 286-293. In milk chocolate, there is a need to correct for the milk fat

- **Interpretation:**

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[*] This method is intended to measure vegetable fats which are cocoa butter equivalents (CBE) i.e. SOS type triglycerides. Other vegetable fats can only be added in very limited amounts before they affect the physical properties of chocolate in a detrimental way. These can be determined by conventional methods i.e. fatty acid and triacyglycerol analyses.

When type of non-cocoa butter vegetable fat is known, the amount of non-cocoa butter vegetable fat is calculated according to *J. Amer. Oil Chem. Soc.* (1980), **57**, 286-293.

When type of non-cocoa butter vegetable fat is not known, the calculation is made according to *J. Amer. Oil Chem. Soc.* (1982), **61 (3)**, 576-581.

SUBMISSION END

Reference List for Industry Submission, GRN 000266

Pages	*Author*	*Title*	*Publish Date*	*Publisher*	*BIB_Info*
000011 - 000029	Beckett, Stephen T.	Controlling the Flow Properties of Liquid Chocolate	NA	The Science of Chocolate	Chapter 5, pgs 66-84
000030 - 000034	Schantz, Birgit; Rohm, Harald	Influence of lecithin-PGPR blends on the rheological properties of chocolate	2005	Lebensm - Wiss. u. - Technol	Volume 38, pgs 41-45
000037 - 000039	Joint FAO/WHO Expert Committee on Food Additives	Combined Compendium of Food Additive Specifications	2005	FAO JECFA Monographs	NA
000040 - 000043	Committee on Food Chemicals Codex: Food and Nutrition Board	Polyglycerol Esters of fatty Acids	2004	Food Chemicals Codex, Fifth Edition	pgs 343-345
000044 - 000046	NA	Commission Directive 98/86/EC of 11 November 1998 amending Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners	12.9.98	Official Journal of the European Communities	pgs L334/1-2, pg L334/53
000054 - 000064	NA	Directive No 95/2 EC on Food Additives Other Than Colours And Sweeteners	1995	European Parliament and Council Directive	OJ No L 61, 18. 3., pg 1
000086 - 000088	Wilson, R.; Smith, M.	Human Studies on Polyglycerol Polyricinoleate (PGPR)	1998	Food and Chemical Toxicology	Volume 36, pgs 743-745
000089 - 000096	Wilson, R.; Van Schie, B.J.; Howes, D.	Overview of the Preparation, Use and Biological Studies on Polyglycerol Polyricinoleate (PGPR)	1998	Food and Chemical Tocicology	Volume 36, pgs 711-718
000097 - 0000104	Smith, M.R.; Wilson, R.; Hepburn, P.A.	Assessment of the Carciniogenic Potential of Polyglycerol Polyricinoleate (PGPR) in Rats and Mice	1998	Food and Chemical Toxicology	Volume 36, pgs 747-754

NA- Not applicable

Pages	Author	Title	Publish Date	Publisher	BIB_Info
000105 - 000123	Howes, D.; Wilson, R.; James, C.T.	The Fate of Ingested Glyceran Esters of Condensed Castor Oil Fatty Acids [Polygycerol Polyricinoleate (PGPR)] in the Rat	1998	Food and Chemical Toxicology	Volume 36, pgs 719-738
000124 - 000126	Wilson, R.; Smith, M.	A Three-generation Reproduction Study on Polyglycerol Polyricinoleate (PGPR) in Wistar Rats	1998	Food and Chemical Toxicology	Volume 36, pgs 739-741
000150	Joint FAO/WHO Expert Committee on Food Additives	Combined Compendium of Food Additive Specifications	2006	FAO JECFA Monographs	NA
000163 - 000172	Dick, R.; Miserez, A.	Gas chromatographic detection and determination of foodstuffs emulsifiers	1976	Mitt. Gebiete Lebensm.Hyg.	Volume 67, pgs 472-487
000173	AOAC International	31.4.02 AOAC Official Method 963.15 Fat in Cacao Products: Soxhlet Extraction Method; 31.4.03 AOAC Official Method 920.75: Separation of Fat in Cacao Products	2000	AOAC Official Methods of Analysis (2: Cacao Beans and its Products	Chapter 31, pg 10

NA- Not applicable

AM

Mcmahon, Carrie

From: Mcmahon, Carrie
Sent: Monday, April 13, 2009 2:57 PM
To: 'hhw@palsgaard.dk'
Cc: 'Viggo Norn'
Subject: RE: GRAS notice, GRN 000266

Mr. Wikman -

RE: GRN 266 (PGPR); February 11th request for clarifications

This email confirms receipt of Palsgaard's response to FDA's request for clarifications. We will review your response and contact Mr. Norn, as directed, if we need additional information.

If you have any questions, please do not hesitate to contact me.

Regards,

Carrie H. McMahon, Ph.D.
Consumer Safety Officer
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Biotechnology and GRAS Notice Review

tel: (301) 436-1202
email: Carrie.McMahon@fda.hhs.gov

From: hhw@palsgaard.dk [mailto:hhw@palsgaard.dk]
Sent: Sunday, April 12, 2009 7:13 PM
To: Mcmahon, Carrie
Cc: vn@palsgaard.dk
Subject: GRAS notice, GRN 000266
Importance: High

Dear Ms McMahon,

Further to your e-mail dated 11th of Feb. 2009 and the reminder sent on the 6th of April, requesting additional clarification on a number of points, we hereby send our comments. Please see the attached PDF document.

We are sorry for the late reply and look forward to hearing from you soon.
If you need additional information, please contact Mr Viggo Norn directly.

Kind regards

Hans-Henrik Wikman
Technical sales manager
Bakery and Confectionery Group

000195

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mobile: +45 2092 0120

Attachment to email dated 4-12-

GRN 266 (polyglycerol polyricinoleate) April 8 , 2009

Ms. Carrie H. McMahon,

Further to your request dated Feb. 11th 2009, we hereby send the following points of clarification to the GRAS notice (GRN No. 000266) for use of polyglycerol polyricinoleate as an emulsifier in vegetable fat coatings.

Specifications.

The food grade Polyglycerol Polyricinoleate (Palsgaard®PGPR) will meet all the three listed specifications: FAO/WHO , FCC 5th edition and EU Commission Directive.

Intended Use and Estimate of Daily Intake.

1) The intended use of PGPR covered in the GRAS notice – GRN 266, is for chocolate-type products only, but limited to products based on vegetable fats other than cocoa butter.

The GRN 009 filed back in 1999 restricted the application to "chocolate" only, and the US chocolate industry need clarification if products based on vegetable fats may also contain PGPR.

Well known products in the market are: BabyRuth and 5th Avenue (The chocolate-type coating based on vegetable fat sometimes referred to as "Chocolatey").

2) The method we have used in estimating the safe intake of PGPR in the US is based on the reported consumption of chocolate and chocolate-type confectionery only. Under this category we have included the following types of products:

- Solid moulded products like plain "Hershey Kisses" or "Dove" chocolate tablets
- Solid moulded with inclusions – chocolate tablets with Almonds, Peanuts of Fruit pieces.
- Enrobed with Candy, Fruit, Nut or Granola center like the "Sneakers" or "Baby Ruth"
- Enrobed with Bakery centre like "Kit-Kat"
- Panned products like "M&M's"

We have evaluated that PGPR is unlikely to be used in most on the Non-confectionery types of products like Cocoa Powder, Syrup/Toppings, Cocoa liquor, Cocoa Butter etc.

Compound Coatings and Chocolate Chips baking pieces as listed under the Non-confectionery part by U.S.Census Bureau, are likely to be used in production of chocolate-type confectionery products. It could be as coating of candy bars, or as inclusions in Granola-bars.

Summary of Toxicological Studies.

Studies report that the PGPR had no adverse effects on the growth, food intake and utilisation. The metabolism of the PGPR emulsifier in rat indicates that the PGPR is digested in the intestinal tract resulting in free glycerol, polyglycerols, polyricinoleic acid as well as

ricinoleic acid. The polyglycerol are excreted as the di- and triglycerols are absorbed and excreted unchanged in the urine while the more polymerized glycerol are excreted in faeces. The fatty acids are degraded followed of absorption and metabolised up to a 90% level. Data show no evidence of accumulation in tissues.
A number of older studies done on PGPR qualities defined within the specifications of FAO/WHO are published and some of the short term studies have reported enlarged liver and kidney: In the case of liver enlargement special studies have reported the enlargements were reversible and not proportional to the feeding level. Histology of the organs showed to be normal. The hypotrophy was regarded as a normal response to the increased hepatic workload. No other acute or sub acute effects were reported.
Chronic toxicity has been studied in a number of long-term feeding studies on mice and rats with feeding over 2 years. No carcinogenic effects of the emulsifier in a 5% feeding level were observed. The enlargement of liver and kidneys observed was not accompanied by any lesions detectable by histopathology. Only the rat study showed a no-effect level for liver enlargement at a feeding level of 1.5% PGPR in the diet.
A carcinogenicity study in rats and mice showed no carcinogenicity at a 5% PGPR level in the feed. In addition no kidney or liver effects were reported.
Reproduction study reports that no adverse affect were observed over three generations of rats using a 1.5% PGPR diet.
Two studies on application of 10 gram per day in two weeks to did showed any adverse effect humans.
PGPR as defined by the specifications of FAO/WHO which also cover the specifications of the PGPR marketed by Palsgaard seem to be covered by a number of studies according to the list below an thus confirming the safety of the emulsifier within the suggested applications and level of use.

Toxicological evaluation of certain food additives with a review of general principles and af the specifications *FAO Nutrition Meetings Series* No 53, 1974; *WHO Tech. Report* Ser No 539 1974, and corrigendum.

Toxicological evaluation of some food additives including anti-caking, antimicrobials, antioxidants, emulsifiers and thickening agents, *FAO Nutrition Meeting Report* Ser No 53A, 1974

Howes D, et al (1998) The fate of ingested glyceran esters of condensed castor oil fatty acids (PGPR) in the rat. *Food Chem. Toxicol.*, **36**, 719-738

James W.H. (1999) Does polyglycerol polyricinoleate alter offspring sex ratios? *Food Chem. Toxicol 37*, 919

Smith M. R. et al, (1998), Assessment of the carcinogenic potential of polyglycerol polyricinoleate (PGPR) in rats and mice *Food Chem. Toxicol* **36** 747-754

Wilson R et al, (1998), A three-generation reproduction study on polyglycerol polyricinoleate (PGPR) in Wistar rats *Food Chem. Toxicol* **36** 739-74

WilsonR et al (1998), Human studies on polyglycerol polyricinoleate (PGPR) *Food Chem. Toxicol* **36** 743-745

If you need additional clarification to the GRAS notice (GRN 000266), please do not hesitate contacting me again.

Kind regards

Viggo Norn
R&D Director

vn@palsgaard.dk

AM

Mcmahon, Carrie

Subject: FW: GRAS notice, GRN 000266

From: Viggo Norn [mailto:vn@palsgaard.dk]
Sent: Monday, May 04, 2009 10:45 PM
To: Mcmahon, Carrie
Subject: RE: GRAS notice, GRN 000266

Dear Carrie McMahon,

I can confirm that the calculation of the PGPR intake include contribution from chocolate based on cocoa as well as contribution from chocolate product based on vegetable fats.
Concerning the intakeof PGPR from other sources of food, we have estimated this to be very small and without any significance as to our best knowledge the contribution only will come from specialities as extreme low fat spreads.
I hope the above can be a help in yuor evaluation of our Gras notice

Kind regards

Viggo Norn

Palsgaard A/S
7130 Juelsminde
Denmark

+45 7682 7682
vn@palsgaard.dk

"Mcmahon, Carrie" <Carrie.McMahon@fda.hhs.gov>

29-04-2009 21:40

To "Mcmahon, Carrie" <Carrie.McMahon@fda.hhs.gov>, <hhw@palsgaard dk>

cc "Viggo Norn" <vn@palsgaard.dk>

Subject RE. GRAS notice, GRN 000266

Mr. Norn –

000203

5/11/2009

We have two additional requests for clarification based on Palsgaard's response (email dated April 12, 2009) to FDA's original request for clarification (email dated February 11, 2009).

It is our understanding, based on your April 12th response, that the intended use of PGPR covered in your notice is "as an emulsifier in chocolate-type products only, and is limited to products based on vegetable fats other than cocoa butter" (i.e., chocolate and vegetable fat coatings, per US regulation 21 CFR 163).

You calculate the estimated per capita intake of PGPR based on total US product manufactures' shipments and trade data for "chocolate-type confectionary." It is therefore our understanding that your calculations of PGPR intake (shown in the table in Section 7 of your notice) include both chocolate products based on cocoa butter and chocolate products based on vegetable fat. Please confirm.

You calculate that the EDI for PGPR from consumption of chocolate and vegetable fat coatings (intended use) is 1.8 mg/kg bw/day for children and 0.8 mg/kg bw/day for adults. You use your intake calculations in support of your safety assessment, noting that the estimated intakes for the intended use are several-fold below the ADI for PGPR established by JECFA (0 – 7.5 mg/kg bw/day). However, as you note in Section 4 of your GRAS notice, PGPR may currently be used in a variety of food products in the United States (current uses), including chocolate products (GRAS Notice No. GRN 000009) and margarines, low fat margarines, spreads, creamers and dairy analogs (GRAS Notice No. GRN 000179).

Please confirm that your evaluation on the safe use of PGPR in chocolate and vegetable fat coatings included consideration of the safety of the cumulative intake of PGPR (i.e., the intended use and current uses combined) in the United States.

Carrie H. McMahon, Ph.D.
Consumer Safety Officer
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Biotechnology and GRAS Notice Review

tel: (301) 436-1202
email: Carrie.McMahon@fda.hhs.gov

From: Mcmahon, Carrie
Sent: Monday, April 13, 2009 2:57 PM
To: 'hhw@palsgaard.dk'
Cc: 'Viggo Norn'
Subject: RE: GRAS notice, GRN 000266

Mr. Wikman -

RE: GRN 266 (PGPR); February 11th request for clarifications

This email confirms receipt of Palsgaard's response to FDA's request for clarifications. We will review your response and contact Mr. Norn, as directed, if we need additional information.

If you have any questions, please do not hesitate to contact me.

Regards,

Carrie H. McMahon, Ph.D.
Consumer Safety Officer
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Biotechnology and GRAS Notice Review

tel: (301) 436-1202
email: Carrie.McMahon@fda.hhs.gov

AM

Mcmahon, Carrie

Subject: FW: FW: GRAS notice, GRN 000266

From: Viggo Norn [mailto:vn@palsgaard.dk]
Sent: Monday, May 11, 2009 8:13 AM
To: Mcmahon, Carrie
Subject: Re: FW: GRAS notice, GRN 000266

Dear Dr. Carrie McMahon,

I am sorry for the incorrect points in our notice and can submit following corrections:

One study on PGPR fed to human with a diet containing 5 g PGPR per day for one week and 10 g PGPR per week the following week did not showed any adverse effects according to Wilson and Smith (1998) Food and Chemical Toxicology **36**, 743-745. No other studies on human are reported and the reference to two studies is to be corrected to one study.

The word "hypotrophy" in the responce of the 8th of April 2009 has to be corrected to "hypertrophy".

Kind regards

Viggo Norn

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"Mcmahon, Carrie" <Carrie.McMahon@fda.hhs.gov>

04-05-2009 22:31

To "Viggo Norn" <vn@palsgaard.dk>
cc
Subject FW: GRAS notice, GRN 000266

000206

Mr. Norn -

Another point of clarification: in your April 8th response, Summary of Toxicological Studies, you wrote:

"Two studies on application of 10 gram per day in two weeks to did showed any adverse effect humans."

First, your notice provides the citation to one study on humans (Wilson, R., et al (1998) Food and Chemical Toxicology 36: 743-745.) We could not find the second study to which your April 8th response refers. Please provide this citation or otherwise correct your statement.

Second, did you mean "did not show any adverse effect on humans" ?

Regards,

Carrie H. McMahon, Ph.D.
Consumer Safety Officer
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Biotechnology and GRAS Notice Review

tel: (301) 436-1202
email: Carrie.McMahon@fda.hhs.gov

From: Mcmahon, Carrie
Sent: Monday, May 04, 2009 2:55 PM
To: 'Viggo Norn'
Subject: RE: FW: GRAS notice, GRN 000266

Mr. Norn -

Thank you for the confirmation. I will wait for your answer. One other small correction is needed: In your April 8th response, Summary of Toxicological Studies, you wrote:

"The hypotrophy was regarded as a normal response to the increased hepatic workload."

We presume that you meant to say hypertrophy as you described reports of liver enlargement. Please confirm.

Regards,

Carrie H. McMahon, Ph.D.
Consumer Safety Officer
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Biotechnology and GRAS Notice Review

tel: (301) 436-1202
email: Carrie.McMahon@fda.hhs.gov

From: Viggo Norn [mailto:vn@palsgaard.dk]
Sent: Sunday, May 03, 2009 11:43 PM
To: Mcmahon, Carrie
Subject: Re: FW: GRAS notice, GRN 000266

Dear Carrie McMahon,

I have earlier today asked my college, who just have started in a new position in another company to inform me about the calculation, and I expect to answer your question within a few day.

Best regards
Viggo Norn

Palsgaard
7130 Juelsminde
Denmark

+45 7682 7682
vn@palsgaard.dk

"Mcmahon, Carrie" <Carrie.McMahon@fda.hhs.gov>

01-05-2009 17 11

To "Viggo Norn" <vn@palsgaard dk>
cc
Subject FW· GRAS notice, GRN 000266

AM

Mcmahon, Carrie

From: Viggo Norn [vn@palsgaard.dk]
Sent: Wednesday, May 13, 2009 4:57 PM
To: Mcmahon, Carrie
Subject: Re: GRN 266- your GRAS notice
Attachments: PGPR_FCC-6edition.pdf

Dear Dr. Carrie McMahon,

All qualities of Palsgaard PGPR manufactured and marketed in the USA are within the legal specification of the lastest edition of Food Chemical Codex i.e. the 6th ed.. Also our PGPR will fullfil the EU as well as the FAO/WHO specifications. In addition I can inform you that we have within our group a "documentation dept" of people which currently monitor the food emulsifier legislation and changes of the same.

Kind regards
Viggo Norn

Palsgaard A/S
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vn@palsgaard.dk

"Mcmahon, Carrie" <Carrie.McMahon@fda.hhs.gov>

12-05-2009 21 47

To "Viggo Norn" <vn@palsgaard.dk>
cc
Subject GRN 266- your GRAS notice

Mr. Norn -

Regarding GRN 266 - Polyglycerol polyricinoleic acid (PGPR) for use in chocolate and vegetable fat coatings

Thank you for your most recent email (dated May 11, 2009) responding to our questions. I apologize for the

continued requests for clarification, however:

In your specifications, you reference the monograph for PGPR in the fifth edition of the Food Chemicals Codex (2004). FDA notes that fifth edition contained an oversight in the specification of the temperature at which the refractive index is determined (i.e., the temperature wasn't specified in the monograph itself, and so defaulted to the temperature of 25 degrees as specified in Appendix II: Physical Tests and Determination). This oversight was corrected in the sixth edition of the Food Chemicals Codex (2008) where the temperature is specified at 65 degrees and which is consistent with the European Commission Directive 98/86/EC.

I have highlighted the refractive index specification in the attached monograph for your convenience.

Please confirm that your food-grade PGPR meets the specifications per the monograph in the 6th edition (the most current) of the Food Chemicals Codex.

Regards,

Carrie H. McMahon, Ph.D.
Consumer Safety Officer
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Biotechnology and GRAS Notice Review

tel: (301) 436-1202
email: Carrie.McMahon@fda.hhs.gov