



Canadian International  
Trade Tribunal

Tribunal canadien du  
commerce extérieur

CANADIAN  
INTERNATIONAL  
TRADE TRIBUNAL

# Appeals

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## DECISION AND REASONS

Appeal No. AP-2009-017

Nutricia North America

v.

President of the Canada Border  
Services Agency

*Decision and reasons issued  
Wednesday, May 18, 2011*

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IN THE MATTER OF an appeal heard on February 10, 2011, pursuant to subsection 67(1) of the *Customs Act*, R.S.C. 1985 (2d Supp.), c. 1;

AND IN THE MATTER OF decisions of the President of the Canada Border Services Agency, dated March 31 and April 9, 2009, with respect to requests for re-determination, pursuant to subsection 60(4) of the *Customs Act*.

**BETWEEN**

**NUTRICIA NORTH AMERICA**

**Appellant**

**AND**

**THE PRESIDENT OF THE CANADA BORDER SERVICES  
AGENCY**

**Respondent**

**DECISION**

The appeal is dismissed.

Pasquale Michael Saroli  
Pasquale Michael Saroli  
Presiding Member

Dominique Laporte  
Dominique Laporte  
Secretary

Place of Hearing: Ottawa, Ontario  
Date of Hearing: February 10, 2011

Tribunal Member: Pasquale Michael Saroli, Presiding Member

Counsel for the Tribunal: Courtney Fitzpatrick

Research Director: Randolph W. Heggart

Research Officer: Jan Wojcik

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**PARTICIPANTS:****Appellant**

Nutricia North America

**Counsel/Representative**

Wendy J. Wagner

**Respondent**

President of the Canada Border Services Agency

**Counsel/Representatives**

Andrew Gibbs

**WITNESSES:**

Ulrike Reichert  
Manager, Medical and Scientific Affairs  
Nutricia North America

Bernard Fortier  
Business Director—Canada  
Nutricia North America

David Mack  
Head  
Division of Gastroenterology,  
Hepatology & Nutrition  
Department of Pediatrics  
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## STATEMENT OF REASONS

### BACKGROUND

1. This is an appeal filed by Nutricia North America (Nutricia) with the Canadian International Trade Tribunal (the Tribunal) pursuant to subsection 67(1) of the *Customs Act*<sup>1</sup> from decisions made by the President of the Canada Border Services Agency (CBSA) pursuant to subsection 60(4).

2. There are two issues in this appeal. The first issue is whether Neocate<sup>®</sup> formulas (the goods in issue) are properly classified under tariff item No. 2106.90.99 of the schedule to the *Customs Tariff*<sup>2</sup> as other food preparations, as determined by the CBSA, or should be classified under tariff item No. 3004.50.00 as medicaments consisting of mixed products for therapeutic or prophylactic uses, put up in measured doses, containing vitamins, as claimed by Nutricia. The second issue is whether the goods in issue may also be classified under tariff item No. 9979.00.00 as goods specifically designed to assist persons with disabilities in alleviating the effects of those disabilities, thereby benefitting from duty-free treatment.

### PROCEDURAL HISTORY

3. The goods in issue were imported between March 16 and September 17, 2007, by Nutricia under five import transactions, under tariff item No. 3004.50.00.

4. On February 4, 2008, pursuant to subsection 59(1) of the *Act*, the CBSA re-determined the tariff classification of the goods in issue and classified them under tariff item No. 2106.90.99 as other food preparations.

5. On or about April 17, 2008, Nutricia requested a re-determination, pursuant to subsection 60(1) of the *Act*. On April 9, 2009, the CBSA issued a further re-determination pursuant to subsection 60(4) that confirmed the classification of the goods in issue under tariff item No. 2106.90.99.

6. On March 5, 2008, Nutricia requested advance rulings pursuant to subsection 43.1(1) of the *Act*. On May 13, 2008, the CBSA issued advance rulings pursuant to paragraph 43.1(1)(c), which classified the goods in issue under tariff item No. 2106.90.99.

7. On June 11, 2008, Nutricia requested a review of the advance rulings pursuant to subsection 60(2) of the *Act*. On March 31, 2009, the CBSA affirmed the advance rulings pursuant to subsection 60(4).

8. On June 26, 2009, Nutricia filed the present appeal with the Tribunal pursuant to subsection 67(1) of the *Act*.

9. The Tribunal held a public hearing in Ottawa, Ontario, on February 10, 2011.

10. Nutricia called three witnesses at the hearing: Ms. Ulrike Reichert, Manager, Medical and Scientific Affairs, Nutricia; Mr. Bernard Fortier, Business Director—Canada, Nutricia; and Dr. David Mack, Head, Division of Gastroenterology, Hepatology & Nutrition, Department of Pediatrics, Children's Hospital of Eastern Ontario (CHEO). The Tribunal qualified Dr. Mack as an expert in pediatric gastroenterology. The CBSA submitted an expert report by Dr. Margaret Patricia Boland, Associate Professor, Department of Pediatrics, University of Ottawa, and Pediatrician, a specialist in gastroenterology and nutrition at CHEO, but did not call her to testify.

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1. R.S.C.1985 (2d Supp.), c. 1 [*Act*].

2. S.C. 1997, c. 36.

## GOODS IN ISSUE

11. The goods in issue are the following four types of Neocate<sup>®</sup> formulas for infants and children: infant Neocate<sup>®</sup> (hypoallergenic); junior Neocate<sup>®</sup> (unflavoured); junior Neocate<sup>®</sup> (tropical fruit flavour); and junior Neocate<sup>®</sup> (chocolate flavour).

12. The goods in issue are amino acid-based powdered formulas, which contain single amino acids rather than complex proteins.<sup>3</sup> The goods in issue facilitate digestion by infants (0 to 12 months) and children (1 to 10 years) who are unable to metabolize the long chains of amino acids that comprise the standard food proteins found in breast milk, infant formulas, soy or extensively hydrolyzed protein formulas, as well as ordinary foods and beverages.<sup>4</sup>

13. Nutricia filed physical exhibits of each of the goods in issue.<sup>5</sup>

## ANALYSIS

### Statutory Framework

14. In appeals pursuant to section 67 of the *Act* concerning tariff classification matters, the Tribunal determines the proper tariff classification of the goods in issue in accordance with prescribed interpretative rules.

15. The tariff nomenclature is set out in detail in the schedule to the *Customs Tariff*, which is designed to conform to the Harmonized Commodity Description and Coding System (the Harmonized System) developed by the World Customs Organization (WCO).<sup>6</sup> The schedule is divided into sections and chapters, with each chapter containing a list of goods categorized in a number of headings and subheadings and under tariff items. Sections and chapters may include notes concerning their interpretation. Sections 10 and 11 of the *Customs Tariff* prescribe the approach that the Tribunal must follow when interpreting the schedule in order to arrive at the proper tariff classification of goods.

16. Subsection 10(1) of the *Customs Tariff* provides as follows: "... the classification of imported goods under a tariff item shall, unless otherwise provided, be determined in accordance with the General Rules for the Interpretation of the Harmonized System<sup>7</sup> and the Canadian Rules<sup>8</sup> set out in the schedule."

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3. *Canadian Oxford Dictionary*, 2<sup>nd</sup> edition, 2004, s.v. "formula": "an infant's liquid food preparation, given as a substitute for breast milk"; s.v. "protein": "any of a group of organic compounds composed of one or more chains of amino acids and forming an essential part of all living organisms"; s.v. "amino acid": "any of a group of organic compounds containing both the carboxyl (COOH) and amino (NH<sub>2</sub>) group, occurring naturally in plant and animal tissues and forming the basic constituents of proteins."

4. Tribunal Exhibit AP-2009-017-08A at para.17.

5. Tribunal Exhibit A-01, Neocate junior Chocolate; Tribunal Exhibit A-02, Neocate junior Unflavoured; Tribunal Exhibit A-03, Neocate Infant; Tribunal Exhibit A-04, Neocate junior Tropical Fruit flavour. Each exhibit is a 400g container containing the goods in issue.

6. Canada is a signatory to the *International Convention on the Harmonized Commodity Description and Coding System*, which governs the Harmonized System.

7. S.C. 1997, c. 36, schedule [*General Rules*].

8. S.C. 1997, c. 36, schedule.

17. The *General Rules* comprise six rules structured in sequence so that, if the classification of the goods cannot be determined in accordance with Rule 1, then regard must be had to Rule 2, and so on, until classification is completed.<sup>9</sup> Classification therefore begins with Rule 1, which provides as follows: “. . . for legal purposes, classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes and, provided such headings or Notes do not otherwise require, according to the following provisions.”

18. Section 11 of the *Customs Tariff* provides as follows: “In interpreting the headings and subheadings, regard shall be had to the Compendium of Classification Opinions to the Harmonized Commodity Description and Coding System<sup>[10]</sup> and the Explanatory Notes to the Harmonized Commodity Description and Coding System<sup>[11]</sup> published by the Customs Co-operation Council (also known as the World Customs Organization [WCO]), as amended from time to time.” Accordingly, unlike chapter and section notes, the *Explanatory Notes* are not binding on the Tribunal in its classification of imported goods. However, the Federal Court of Appeal has stated that these notes should be applied, unless there is a sound reason to do otherwise, as they serve as an interpretative guide to tariff classification in Canada.

19. Thus, the Tribunal must first determine in which heading the goods in issue can be classified according to the terms of the headings and any relevant section or chapter notes in the *Customs Tariff*, having regard to any relevant *Explanatory Notes* and *Classification Opinions*.

20. Once the Tribunal has determined the proper heading, the next step is to determine the proper subheading (six-digit level), pursuant to Rule 6 of the *General Rules*, according to the terms of the subheading, any related section, chapter and subheading notes, and according to Rules 1 to 5 with the necessary changes (i.e. by replacing the word “heading” with “subheading”).

21. Once the Tribunal has determined the proper subheading, the next step is to determine the proper tariff item (eight-digit level), pursuant to Rule 1 of the *Canadian Rules*, according to the terms of the tariff item and by applying Rules 1 to 5 of the *General Rules* with the necessary changes (i.e. by replacing the word “heading” with “tariff item”).

22. The Tribunal notes that Section 13 of the *Official Languages Act*<sup>12</sup> provides that the English and French versions of any act of Parliament are equally authoritative. Thus, the Tribunal may examine both the English and French versions of the schedule to the *Customs Tariff*, the *Explanatory Notes* and the *Compendium* in interpreting the tariff nomenclature.

23. Chapter 99 of the *Customs Tariff* provides special classification provisions that allow certain goods to be imported into Canada with tariff relief. As none of the headings of Chapter 99 are divided at the subheading or tariff item level, the Tribunal need only consider, as the circumstances may require, Rules 1 through 5 of the *General Rules* in determining whether goods may be classified in that chapter.<sup>13</sup> Moreover, since the Harmonized System reserves Chapter 99 for special classifications (i.e. for the exclusive use of individual countries), there are no *Classification Opinions* or *Explanatory Notes* to consider.

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9. Rules 1 through 5 of the *General Rules* apply to classification at the heading level (i.e. to four digits). Pursuant to Rule 6 of the *General Rules*, Rules 1 through 5 apply to classification at the subheading level (i.e. to six digits). Similarly, the *Canadian Rules* make Rules 1 through 5 of the *General Rules* applicable to classification at the tariff item level (i.e. to eight digits).

10. World Customs Organization, 2d ed., Brussels, 2003 [*Classification Opinions*].

11. World Customs Organization, 4th ed., Brussels, 2007 [*Explanatory Notes*].

12. R.S.C. 1985 (4th Supp.), c. 31.

13. However, Note 1 to Chapter 99 provides that the rule of specificity in Rule 3 (a) of the *General Rules* does not apply to the provisions of Chapter 99. This reflects the fact that classification in Chapters 1 to 97 and Chapter 99 is not mutually exclusive.

24. There are no section notes to Section XXI, which includes Chapter 99. Note 3 to Chapter 99 is, however, relevant to the present appeal. It provides as follows:

Goods may be classified under a tariff item in this Chapter and be entitled to the Most-Favoured-Nation Tariff or a preferential tariff rate of customs duty under this Chapter that applies to those goods according to the tariff treatment applicable to their country of origin only after classification under a tariff item in Chapters 1 to 97 has been determined and the conditions of any Chapter 99 provision and any applicable regulations or orders in relation thereto have been met.

25. In accordance with the preceding note, goods may only be classified in Chapter 99 after a determination has been made that the goods in issue are properly classified under a tariff item in Chapters 1 to 97. Accordingly, the Tribunal will first determine whether the goods in issue are classifiable under tariff item No. 2106.90.99 or tariff item No. 3004.50.00, which the Tribunal has determined, on a *prima facie* basis, to be the only tariff provisions of relevance in this case. If the Tribunal determines that the goods in issue are indeed classifiable under one of those tariff items, it will proceed to a determination of whether the goods in issue are eligible for the benefit of duty-free treatment under tariff item No. 9979.00.00.

### Relevant Provisions of the Customs Tariff and Explanatory Notes

26. The relevant provisions of the *Customs Tariff*, which Nutricia considers applicable to the goods in issue, provide as follows:

#### Section VI

#### PRODUCTS OF THE CHEMICAL OR ALLIED INDUSTRIES

...

#### Chapter 30

#### PHARMACEUTICAL PRODUCTS

...

**30.04** Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.

...

**3004.50.00** -Other medicaments containing vitamins or other products of heading 29.36.

...

27. There are no relevant section notes to Section VI.

28. The relevant chapter notes to Chapter 30 provide as follows:

1. This Chapter does not cover:

- (a) Foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (Section IV);

...

29. There are no relevant *Explanatory Notes* to Section VI or Chapter 30.



30. The relevant *Explanatory Notes* to heading No. 30.04 provide as follows:

This heading covers medicaments consisting of mixed or unmixed products, **provided they are:**

...

- (b) **In packings for retail sale for therapeutic or prophylactic use.** This refers to products (for example, sodium bicarbonate and tamarind powder) which, because of their packing and, in particular, the presence of appropriate indications (statement of disease or condition for which they are to be used, method of use or application, statement of dose, etc.) are clearly intended for sale directly to users (private persons, hospitals, etc.) without repacking, for the above purposes.

These indications (in any language) may be given by label, literature or otherwise. However, the mere indication of pharmaceutical or other degree of purity is not alone sufficient to justify classification in this heading.

...

Medicaments consisting of mixed products for therapeutic or prophylactic uses and not put up in measured doses or in forms or packings for retail sale are classified in **heading 30.03** (see the corresponding Explanatory Note).

31. The *Explanatory Notes* to heading No. 30.03 provide as follows:

This heading covers medicinal preparations for use in the internal or external treatment or prevention of human or animal ailments. These preparations are obtained by mixing together two or more substances. However, if put up in measured doses or in forms or packings for retail sale, they fall in **heading 30.04**.

...

The provisions of the heading text do not apply to foodstuffs or beverages such as dietetic, diabetic or fortified foods, tonic beverages or mineral waters (natural or artificial), which fall to be **classified under their own appropriate headings**. This is essentially the case as regards food preparations containing only nutritional substances. The major nutritional substances in food are proteins, carbohydrates and fats. Vitamins and mineral salts also play a part in nutrition.

Similarly foodstuffs and beverages containing medicinal substances are **excluded** from the heading if those substances are added solely to ensure a better dietetic balance, to increase the energy-giving or nutritional value of the product or to improve its flavour, always provided that the product retains its character of a foodstuff or a beverage.

...

Further, this heading **excludes** food supplements containing vitamins or mineral salts which are put up for the purpose of maintaining health or well-being but have no indication as to use for the prevention or treatment of any disease or ailment. These products which are usually in liquid form but may also be put up in powder or tablet form, are generally classified in **heading 21.06** or **Chapter 22**.

On the other hand, the heading covers preparations in which the foodstuff or the beverage merely serves as a support, vehicle or sweetening agent for the medicinal substances (e.g., in order to facilitate ingestion).

32. Chapter 99, which includes tariff item No. 9979.00.00, provides as follows:

**Chapter 99**

**SPECIAL CLASSIFICATION PROVISIONS – COMMERCIAL**

...

**9979.00.00 Goods specifically designed to assist persons with disabilities in alleviating the effects of those disabilities, and articles and materials for use in such goods.**

33. The relevant chapter notes to Chapter 99 provide as follows:

1. The provisions of this Chapter are not subject to the rule of specificity in General Interpretative Rule 3 (a).

...

3. *Goods may be classified under a tariff item* in this Chapter and be entitled to the Most-Favoured-Nation Tariff or a preferential tariff rate of customs duty under this Chapter that applies to those goods according to the tariff treatment applicable to their country of origin *only after classification under a tariff item in Chapters 1 to 97 has been determined* and the conditions of any Chapter 99 provision and any applicable regulations or orders in relation thereto have been met.

4. The words and expressions used in this Chapter have the same meaning as in Chapters 1 to 97.

[Emphasis added]

34. The relevant provisions of the *Customs Tariff*, which the CBSA considers applicable to the goods in issue, provide as follows:

**Section IV**

**PREPARED FOODSTUFFS; BEVERAGES, SPIRITS AND VINEGAR;  
TOBACCO AND MANUFACTURED TOBACCO SUBSTITUTES**

...

**Chapter 21**

**MISCELLANEOUS EDIBLE PREPARATIONS**

...

**21.06 Food preparations not elsewhere specified or included.**

...

**2106.90 -Other**

...

---Other:

2106.90.99 ----Other

...

35. There are no relevant section notes to Section IV.

36. The relevant chapter notes to Chapter 21 provide as follows:
1. This Chapter does not cover:  
...  
(f) Yeast put up as a medicament or other products of heading 30.03 or 30.04; or  
...
37. There are no relevant *Explanatory Notes* to Section XI or Chapter 21.
38. The relevant *Explanatory Notes* to heading No. 21.06 provide as follows:
- Provided that they are not covered by any other heading of the Nomenclature**, this heading covers:
- (A) Preparations for use, either directly or after processing (such as cooking, dissolving or boiling in water, milk, etc.), for human consumption.
  - (B) Preparations consisting wholly or partly of foodstuffs, used in the making of beverages or food preparations for human consumption. The heading includes preparations consisting of mixtures of chemicals (organic acids, calcium salts, etc.) with foodstuffs (flour, sugar, milk powder, etc.), for incorporation in food preparations either as ingredients or to improve some of their characteristics (appearance, keeping qualities, etc.) . . . .  
...  
This heading includes, *inter alia*:  
...
- (16) Preparations, often referred to as *food supplements*, based on extracts from plants, fruit concentrates, honey, fructose, etc. and containing added vitamins and sometimes minute quantities of iron compounds. These preparations are often put up in packagings with indications that they maintain general health or well-being. Similar preparations, however, intended for the prevention or treatment of diseases or ailments are **excluded (heading 30.03 or 30.04)**

### Tariff Classifications at Issue—Heading Nos. 30.04 and 21.06

#### Positions of Parties

##### – Nutricia

39. Nutricia submitted that the goods in issue are medicaments of heading No. 30.04. In support of this position, Nutricia referred to the Tribunal's decision in *Hilary's Distribution Ltd. v. Deputy M.N.R.*,<sup>14</sup> in which the Tribunal interpreted the term "medicament" as referring to substances used to treat or prevent human diseases, ailments or disorders. In this regard, Nutricia submitted that the goods in issue are fed to infants and children to prevent or reverse the signs and symptoms associated with various gastrointestinal diseases, ailments and disorders, including eosinophilic esophagitis, gastroesophageal reflux, multiple food protein allergies and protein intolerance.

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14. (25 September 1998), AP-97-010 (CITT) [*Hilary's Distribution*].

40. Nutricia submitted that the Tribunal's finding in *Hilary's Distribution* demonstrates that proof of efficacy is not required in order for the goods in issue to be classified as medicaments, although the existence of clinical studies and trials in support of their medicinal qualities may be relevant.<sup>15</sup> It argued that the numerous clinical studies, and the evidence of its expert witness, demonstrate the use and effectiveness of the goods in issue as therapy to treat the symptoms of gastrointestinal disorders caused by food-protein allergies and that they are therefore medicaments. It further submitted that these conditions cannot be treated by simply avoiding the allergen, as the allergen often cannot be identified, leaving no standard protein which can be tolerated.

41. Nutricia contended that there is no requirement for the goods in issue to contain an active ingredient in order for them to be considered medicaments. It submitted that the key component of the goods in issue is a specially synthesized amino acid, which is a pharmaceutical ingredient not found in nature. The witness for Nutricia, Ms. Reichert, testified that the goods in issue are manufactured to strict specifications, similar to those of a drug, in order to ensure the complete absence of cow's milk protein or other allergens in the final product. Nutricia submitted that the goods in issue are necessary for the growth and survival of infants and children for whom protein triggers an allergic reaction and noted that simple avoidance of the protein allergen, similar to the removal of peanut butter from a person with a nut allergy, would deprive infants and children of the essential nutrition provided by protein.

42. Nutricia also referred to *Pfizer Canada Inc. v. Commissioner of the Canada Customs and Revenue Agency*<sup>16</sup> in support of its view that the marketing, packaging and actual use of a product is relevant in determining whether it is a medicament. In this regard, Nutricia submitted that the goods in issue are labelled for use by a unique and limited sub-group of the population, are used under the supervision of a medical healthcare professional and are marketed primarily to physicians and other healthcare professionals. It further argued that the sales of the goods in issue are restricted, in that they can only be purchased from hospitals, "behind the counter" from pharmacies, from specialty stores or through direct order. It contended that the goods in issue are not intended for general use to promote the health and well-being of infants and children, as the goods in issue are significantly more expensive than traditional formulas and provide no additional nutritional benefit to healthy infants and children. Finally, Nutricia also noted that the goods in issue are covered by some governmental and private health care insurance plans.

43. Nutricia argued that there are no section or chapter notes which preclude the goods in issue from being classified in heading No. 30.04. While acknowledging that Note 1(a) to Chapter 30 provides that "[t]his Chapter does not cover: (a) Foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (Section IV)", it submitted that the goods in issue are not a "food" or "beverage" in the ordinary sense of those words. In particular, Nutricia submitted that the goods in issue are not appropriate food for children who do not suffer from the medical and dietary conditions that they are designed to treat. It further noted that the goods in issue are prescribed for use in specific dosages and are neither palatable in the same way as an ordinary food or beverage nor intended for life-long consumption.

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15. *Hilary's Distribution* at 9: "The Tribunal believes, for its part, that there must be reasonable indications that the goods are medicaments, but does not consider it reasonable or necessary to apply the exacting standards as urged by counsel for the respondent. . . . Having said this, the Tribunal believes that it is equally clear that simply declaring that a product is a medicament does not make it so. In fact, in the present case, the appellant submitted a considerable body of evidence to demonstrate that the goods were medicaments. . . ."

16. (9 October 2003), AP-2002-038 to AP-2002-090 (CITT) [*Pfizer*] at 7: ". . . Dr. Wright [the witness for Pfizer] indicated that the goods in issue meet the criteria of the Health Canada monograph and have a DIN number and, hence, can be sold as a drug. He further indicated that they are marketed as a drug and that their packaging clearly indicates that they should be taken according to directions, for the relief of certain specified medical symptoms. . . ." [Footnotes omitted]

44. Nutricia also claimed that the goods in issue are not comparable to dietetic or diabetic foods, as those foods do not have prophylactic or curative properties, nor are they comparable to a “fortified food”, “food supplement”, “tonic beverage” or “mineral water”, which are all optional additions to a diet and not intended for the management or treatment of a specific disease.

45. Nutricia relied upon the Tribunal’s decision in *Baxter Corporation v. Deputy M.N.R.*,<sup>17</sup> in which the Tribunal determined that Peptamen (a mixture of amino acids, protein hydrolysates and vitamins) provided treatment for patients with amino acid disorders and was more than a nutritional supplement or dietetic food. The Tribunal classified Peptamen in heading No. 30.04 as a medicament, despite the existence of Note 1(a) to Chapter 30. In this regard, Nutricia submitted that, in *Baxter*, the Tribunal adopted a narrow interpretation of the term “dietetic food”.

46. In response to arguments made by the CBSA, Nutricia submitted that the change in 1999 to Note 1(a) to Chapter 30, which resulted in the addition of the phrase “other than nutritional preparations for intravenous administration”, did not invalidate the Tribunal’s analysis in *Baxter*, as it applies to the goods in issue. Nutricia, referring to the minutes of the WCO Harmonized System Committee that led to the change in Note 1(a) to Chapter 30, submitted that the change simply clarified that nutritional products that are administered intravenously are considered medicaments.

47. Nutricia also referred to Memorandum D10-14-30,<sup>18</sup> which explains the CBSA’s policy in respect of the classification of medicaments. The memorandum provides as follows:

(c) Medicaments are generally not included in the common understanding of the term food. However, certain nutritional dietary supplements, sometimes considered food preparations, can be classified in heading 30.04 as a medicament. This is the case when the supplement is expressly for use in the prevention or treatment of a disease, illness or ailment and put up in a form specified in that heading.<sup>19</sup>

48. In addition to the claim that the memorandum supports its position, Nutricia submitted that it clearly demonstrates that the CBSA’s policy is such that gastrointestinal disorders constitute a form of disorder or ailment.<sup>20</sup>

49. In response to the CBSA’s classification of the goods in issue as “other food preparations not elsewhere specified or included”, Nutricia noted Note 1(f) to Chapter 21, which excludes from heading No. 21.06 “[y]east put up as a medicament or other products of heading 30.03 or 30.04”. In this regard, it argued that, because the goods in issue are specifically indicated for use in the prevention and treatment of certain gastrointestinal diseases, they are “elsewhere specified or included” as a medicament of heading No. 30.04.

50. Finally, Nutricia argued that the goods in issue, not being a “food supplement” or used to “maintain general health or well-being”, are not described by Note 16 of the *Explanatory Notes* to heading No. 21.06.

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17. (26 July 1994), AP-93-092 (CITT) [*Baxter*] at 4: “... ‘dietetic food’ refers to ordinary food that has been specially formulated for persons with a special dietetic need, such as a low-sodium, low-calorie or low-fat diet. . . .”

18. “Tariff Classification of Medicaments Including Natural Health Products” (20 August 2004).

19. *Ibid.* at para. 4.

20. *Ibid.* at para. 13.

– CBSA

51. The CBSA countered that the goods in issue are dietetic foods or nutritional preparations other than for intravenous administration, which are properly classified in heading No. 21.06.

52. The CBSA contended that Note 1(a) to Chapter 30 excludes all foods “. . . other than nutritional preparations for intravenous administration” from classification in Chapter 30. It noted that “dietetic foods” are expressly excluded from classification in that chapter and argued that the goods in issue, being dietetic foods, are therefore excluded from classification in Chapter 30.

53. In this regard, the CBSA submitted that the term “dietetic food” is not limited to food for weight loss and includes food for people with special medical conditions, such as the gastrointestinal conditions that the goods in issue are used to treat. To support its position, the CBSA referred to the WCO’s discussions regarding the classification of dietetic foods, wherein the WCO Secretariat stated that, whether interpreted broadly or narrowly, dietetic food, unless considered to be a medicament, is excluded from Chapter 30.

54. The CBSA noted that the goods in issue provide complete nutrition and contain only nutritional substances (i.e. proteins broken down into amino acids, carbohydrates, fats, vitamins and minerals). The CBSA argued that the goods in issue are food preparations as defined in the *Explanatory Notes* to heading No. 30.04 and are therefore excluded from classification as a medicament.

55. The CBSA argued that the goods in issue contain no medicinal substances or active ingredients, are available without a prescription and are ingested by mouth or through a tube rather than being administered intravenously.

56. Having regard to these considerations, the CBSA submitted that the goods in issue should not be considered a medicament and, therefore, should be classified in heading No. 21.06 as “food preparations not elsewhere specified or included”.

#### Tribunal’s Analysis

57. The parties agree that the correct approach to classifying the goods in issue is through the application of Rule 1 of the *General Rules*. The parties, however, disagree as to the appropriate chapter, heading, subheading and tariff item for the classification of the goods. Rule 1 provides as follows:

. . . for legal purposes, classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes . . . .

58. Heading No. 21.06 covers “[f]ood preparations not elsewhere specified or included”,<sup>21</sup> while heading No. 30.04 covers “[m]edicaments . . . consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.”

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21. As has been previously noted by the Tribunal, heading No. 21.06 is a residual heading for goods not covered by any other heading of the nomenclature. See *Hilary’s Distribution* at 10.

59. Note 1(f) to Chapter 21, which excludes “medicaments” from the scope of that chapter and, by extension, from the ambit of heading No. 21.06, provides as follows:

1. This Chapter does not cover:

...

(f) Yeast put up as a medicament or other products of heading 30.03 or 30.04; or

...

60. Note 1(a) to Chapter 30, which, in turn, excludes food preparations from the scope of that chapter and, by extension, from the ambit of heading No. 30.04, provides as follows:

1. This Chapter does not cover:

(a) Foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (Section IV);

61. ... Accordingly, heading Nos. 21.06 and 30.04 must be considered mutually exclusive.

62. Note 2 to Section VI of the *Customs Tariff* provides as follows:

2. ... *goods classifiable in heading 30.04 ... by reason of being put up in measured doses or for retail sale are to be classified in [that heading] and in no other heading of the Nomenclature.*

[Emphasis added]

63. Therefore, having regard to the exclusivity of classification provided for in Note 2 to Section VI and the residual nature of heading No. 21.06, the Tribunal will take, as its point of departure, an analysis of whether the goods in issue are classifiable in heading No. 30.04 and, specifically, under tariff item No. 3004.50.00. If it is found that the goods in issue are not classifiable in that heading, the Tribunal will then determine whether the goods fall to be classified in heading No. 21.06 and, in particular, under tariff item No. 2106.90.99. The Tribunal will then proceed to a consideration of whether the goods in issue are also classifiable under tariff item No. 9979.00.00 and thereby entitled to duty-free treatment.<sup>22</sup>

#### Classification in Heading No. 30.04

– Are the goods in issue in the nature of medicaments?

64. As was noted by the Tribunal, “. . . the intent of heading No. 30.04 is essentially to cover goods that are in the nature of medicaments.”<sup>23</sup>

65. The *Canadian Oxford Dictionary*<sup>24</sup> defines “medicament” as “a substance used for medical treatment”, while *The Oxford English Dictionary*<sup>25</sup> defines the same term as a “substance used in curative treatment”.

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22. By virtue of Note 1 to Chapter 99, the provisions of the chapter are not subject to the rule of specificity in Rule 3 (a) of the *General Rules*.

23. *Pfizer* at 9.

24. Second ed., s.v. “medicament”.

25. 1989, s.v. “medicament”.

66. In this regard, it is uncontested, and the Tribunal finds, that the use of amino acid-based nutritional formulations, such as the goods in issue, is widely recognized in medical circles as an effective treatment for certain gastrointestinal diseases and ailments in infants and children.<sup>26</sup>

67. It is also uncontested, and the Tribunal finds, that the goods in issue:

- are intended for use under the supervision of a medical healthcare professional;<sup>27</sup>
- are not available from grocery stores and can only be purchased by direct order, from behind the counter at pharmacies and from hospital specialty stores;<sup>28</sup>
- are not suitable for the general infant and child population;<sup>29</sup> and
- are covered under certain public and private health care plans.<sup>30</sup>

68. The Tribunal therefore finds that, with regard to their marketing and intended use, the goods in issue possess characteristics consistent with those of goods in the nature of medicaments.<sup>31</sup>

– Do the goods in issue fall in an excluded heading?

69. It is uncontested, and the Tribunal is satisfied, that the goods in issue do not fall in heading No. 30.02, 30.05 or 30.06, the goods of which are expressly excluded from the ambit of heading No. 30.04.

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26. Tribunal Exhibit AP-2009-017-08B, tabs 14-22; *Transcript of Public Hearing*, 10 February 2011, at 49-55.

27. *Transcript of Public Hearing*, 10 February 2011, at 21-22. Although the Tribunal accepts that the goods in issue are intended for use under the supervision of a medical healthcare professional, it notes the testimony of Ms. Reichert who stated that the goods in issue are intended to be used under medical supervision not because of their nature but rather because, by the time amino acid-based nutritional therapy becomes necessary, the stage of the gastrointestinal disease or ailment and the associated symptoms are often so severe that the infant or child requires medical attention.

28. *Transcript of Public Hearing*, 10 February 2011, at 28-30; Tribunal Exhibit AP-2009-017-08B, tab 13. The Tribunal notes Mr. Fortier's testimony that the goods in issue are marketed primarily to health care and medical professionals and distributed through wholesalers, pharmacies, hospitals and directly to consumers via telephone orders. Mr. Fortier also testified that the goods in issue are not distributed through grocery stores or found on the shelves at pharmacies. They are "behind the counter" products.

29. *Transcript of Public Hearing*, 10 February 2011, at 20-21. The Tribunal notes that, although the goods in issue may not be suitable for the general population, Ms. Reichert testified that children with non-compromised gastrointestinal systems would derive full nutritional benefit from the goods in issue without experiencing any counter-indications or ill effects from their consumption. The Tribunal finds that the non-suitability of the goods in issue for the general infant and child population stems not from health-related concerns, but from economic considerations (i.e. the high cost of the goods in issue relative to standard formulas).

30. *Transcript of Public Hearing*, 10 February 2011, at 30-31; Tribunal Exhibit AP-2009-017-08B, tab 23. Nutricia submitted that various public and private health care plans cover the goods in issue. It notes as an example that the goods in issue are covered under the Ontario Drug Benefit program (as a nutritional product) when prescribed by a doctor and dispensed by a pharmacist. The Tribunal also notes the testimony of Mr. Fortier, who stated that the cost of the goods in issue is reimbursed in almost all provinces when they are purchased through a pharmacy and, in particular, that the cost of the goods in issue is covered in Quebec as an exception drug.

31. The Tribunal finds that, while Neocate<sup>®</sup> has not been assigned a drug identification number, this, in and of itself, is not dispositive of whether or not Neocate<sup>®</sup> could be categorized as a medicament. This is consistent with the Federal Court of Appeal's decision in *Flora Manufacturing & Distributing Ltd. v. Deputy Canada (Minister of National Revenue)*, 2000 CanLII 15919 (F.C.A.) [*Flora Manufacturing*], in which it determined that the Tribunal did not err by not considering the presence of a drug identification number to be conclusive evidence of a medicament.



- Are the goods in issue mixed products?

70. It is also uncontested, and the Tribunal finds, that the goods in issue are mixtures that include amino acids, carbohydrates, fats, vitamins and minerals.<sup>32</sup>

- Are the goods in issue intended for therapeutic or prophylactic use?

71. The Tribunal finds that the goods in issue are specifically indicated for use with, and are effective in the treatment of, various gastrointestinal diseases and ailments, including eosinophilic esophagitis (EE), gastroesophageal reflux disease (GERD) and multiple food protein intolerance.

72. Indeed, while not a *sine qua non* to the classification of goods as medicaments,<sup>33</sup> there is a significant body of scientific evidence attesting to the therapeutic and prophylactic efficacy of the goods in issue in the management of such disorders.

73. Eosinophilic esophagitis is a disease of the upper gastrointestinal tract whose symptoms include regurgitation, vomiting, epigastric pain, difficulty swallowing and food impaction.<sup>34</sup> In this regard, clinical evidence indicates that the goods in issue are effective in decreasing the number of eosinophils (i.e. white blood cells) in the oesophagus, thereby resulting in a significant decrease in both EE symptoms and histological evidence of the disease. The Tribunal notes, for example, that a 2007 study, which was sponsored by the American Gastroenterological Association Institute and the North American Society of Pediatric Gastroenterology, Hepatology and Nutrition, found that an amino acid-based formula was effective not only in relieving the symptoms of EE but also in resolving its underlying histopathology, as indicated by the following:

**Studies: amino acid-based formula.** . . . In children, the use of an elemental formula has been shown to be extremely effective in 92%-98% of patients. Patients' symptoms resolved within 7 to 10 days followed by almost complete histologic resolution of the esophageal eosinophilia within 4 to 5 weeks.<sup>35</sup>

[Footnotes omitted]

74. The following similar results were reported in a sister study:

Elemental diet resulted in striking improvement in both symptoms and histologic evidence of disease in children and adolescents with [EE], as identified by strict diagnostic criteria.<sup>36</sup>

75. Gastroesophageal Reflux Disease is a pathological condition that involves the involuntary passage of gastric contents into the oesophagus. Symptoms include regurgitation, vomiting, esophagitis, respiratory infections, weight loss and distressed behaviour. The goods in issue have been shown to induce the disappearance of GERD symptoms in the majority of cases within a relatively short period of time and are often preferred to alternative therapies, for example, where the patient is unresponsive to extensively hydrolyzed formula (eHF).<sup>37</sup>

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32. Tribunal Exhibit AP-2009-017-08B, tabs 11, 12; Tribunal Exhibit AP-2009-017-17A, tabs B, D; *Transcript of Public Hearing*, 10 February 2011, at 57-58.

33. *Hilary's Distribution* at 9.

34. Tribunal Exhibit AP-2009-017-08A at paras. 24-27; Tribunal Exhibit AP-2009-017-08B, tabs 14, 15.

35. Tribunal Exhibit AP-2009-017-21A at 136.

36. Tribunal Exhibit AP-2009-017-08B, tab 16 at 1.

37. Tribunal Exhibit AP-2009-017-08A at paras. 28-30; Tribunal Exhibit AP-2009-017-08B, tabs 17, 18.

76. Multiple Food Protein Intolerance is a disorder that involves intolerance to cow's milk, soy, eHF and a range of other products and whose symptoms include irritability, vomiting, diarrhea, atopic dermatitis and growth failure. Again, clinical evidence indicates that the administration of the goods in issue causes a remission of symptoms within a short period of time, with one study reporting that symptoms in the test group of infants "...remitted within 2 weeks of commencement of feeding with an elemental amino acid-based complete infant formula . . . ."<sup>38</sup>

77. The Tribunal finds the following evidence of the expert witness, Dr. Mack, particularly compelling:

*Amino acid formulas such as Neocate® [the goods in issue] provide an important therapeutic approach of using nutrition as a therapy . . . .*

*[F]or those individuals with this non-IgE-mediated immune based reaction, there are some patients that require an amino acid formula in the treatment of their disease to provide both adequate nutrition and a form of therapy for their underlying medical disease.*

*In summary, medical therapies using amino acid formulas is an important advance in the treatment of immune-based disorders as they provide a therapeutic strategy that is not nutritionally limiting.*<sup>39</sup>

[Emphasis added]

78. Indeed, the CBSA acknowledged that "... **THE GOODS AT ISSUE CAN ARGUABLY HAVE A THERAPEUTIC OR PROPHYLACTIC USE,**"<sup>40</sup> but goes on to argue that they are not medicaments by virtue of a specific exclusion contained in Note 1(a) to Chapter 30, which is examined in greater detail below.

- Are the goods in issue put up in measured doses or in forms or packings for retail sale?

79. It is uncontested, and the Tribunal is satisfied, that the goods in issue are put up in packings for retail sale. On the basis of the physical exhibits filed by Nutricia, it is evident that the goods in issue are sold directly to the consumer in 400-g containers and are not sold in bulk. Moreover, the information on the labels of the goods in issue about the conditions for which they are to be used, directions for preparation and use and a statement of dosage is an indication that the goods in issue are clearly intended for sale directly to the consumer without repacking.<sup>41</sup>

- Are the goods in issue excluded from heading No. 30.04?

80. While the goods in issue appear to satisfy the constituent elements of heading No. 30.04, there remains the issue of whether they are explicitly excluded by virtue of any relevant section or chapter notes.

81. In this regard, Note 1(a) to Chapter 30 provides as follows:

1. This Chapter does not cover:

- (a) Foods or beverages (*such as dietetic*, diabetic or fortified foods, food supplements, tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (*Section IV*).

[Emphasis added]

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38. Tribunal Exhibit AP-2009-017-08B, tab 21 at 1.

39. Tribunal Exhibit AP-2009-017-20A at 5, 7.

40. Tribunal Exhibit AP-2009-017-17A at 12.

41. Tribunal Exhibit AP-2009-017-08B, tabs 11, 12; Tribunal Exhibit AP-2009-017-17A, tabs B, D; Exhibits A-01, A-02, A-03 and A-04.

82. The Tribunal notes the parties' disagreement with respect to the correct interpretation of the term "dietetic food". The CBSA submitted that "dietetic food" should be interpreted broadly as a category of food aimed at meeting the nutritional needs of people with special medical conditions and that it is not restricted to food for weight loss or weight management. Nutricia countered that the term "dietetic food" should be ascribed a narrower meaning and referred to the decision in *Baxter*, in which the Tribunal defined "dietetic food" as ordinary food that has been specially formulated for persons with a special dietary need, such as a low-sodium, low-calorie or low-fat diet. In this regard, Nutricia sought to distinguish dietetic and diabetic foods from the goods in issue on the basis that the former do not have prophylactic or curative properties.

83. The Tribunal notes that *A Dictionary of Food and Nutrition* offers the following expansive definition of "dietetic foods", which would capture the goods in issue:

Foods prepared to meet the particular nutritional needs of people whose assimilation and metabolism of foods are modified, or for whom a particular effect is obtained by a controlled intake of foods or individual nutrients. They may be formulated for people suffering from physiological disorders or for healthy people with additional needs.<sup>42</sup>

84. However, insofar as "diabetic foods", "fortified foods" and "food supplements" would presumably have been subsumed in a wider definition of "dietetic foods", the fact that these are broken out and referred to separately from "dietetic foods" in Note 1(a) to Chapter 30 suggests that the phrase "dietetic foods" was intended to have a narrower connotation.

85. Indeed, as noted above, in *Baxter*, the Tribunal ascribed a narrower meaning to "dietetic foods" in Note 1(a) to Chapter 30, indicating that the phrase referred to ordinary food specially formulated for persons with special (e.g. low-sodium, low-calorie or low-fat) dietary needs.

86. In the Tribunal's view, the amendment in 1999 to Note 1(a) to Chapter 30, which added the phrase "nutritional preparations for intravenous administration", did not affect the continuing relevancy of *Baxter* to the meaning of "dietetic foods", and the Tribunal agrees with Nutricia's position that "[t]here has . . . been no change to the definition of dietetic that was adopted by the Tribunal in the *Baxter* decision, and . . . no basis for the assertion that it now means something broader than was considered in that decision."<sup>43</sup>

87. The Tribunal, in delineating the scope of Note 1(a) to Chapter 30, accords particular importance to the fact that the bracketed list referring to ". . . dietetic, diabetic or fortified foods, food supplements . . ." is rendered illustrative by the words "such as" that immediately precede it. This implies that other unspecified products can also be read into the list as constituting "food".

88. Given that they are all intended for use in the attainment of particular health-related outcomes, the Tribunal is of the view that the goods in issue are goods of the same class or kind as dietetic foods, diabetic foods and fortified foods and, as such, can properly be read into the illustrative list of foods contained in Note 1(a) to Chapter 30.

89. That being said, the Tribunal is of the view that resolution of this issue does not turn solely upon an *ejusdem generis*<sup>44</sup> reading of the illustrative list in Note 1(a) to Chapter 30.

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42. Tribunal Exhibit AP-2009-017-17A, tab I.

43. *Transcript of Public Hearing*, 10 February 2011, at 84.

44. *Black's Law Dictionary*, 9th ed., s.v. "*ejusdem generis*": ". . . [Latin 'of the same kind or class'] . . . **1.** A canon of construction holding that when a general word or phrase follows a list of specifics, the general word or phrase will be interpreted to include only items of the same class as those listed. • For example, in the phrase *horses, cattle, sheep, pigs, goats, or any other farm animals*, the general language *or any other farm animals* – despite its seeming breadth – would probably be held to include only four-legged, hooved mammals typically found on farms, and thus would exclude chickens." [Emphasis in original]

90. In this regard, the *Explanatory Notes* to heading No. 30.04 provide useful guidance in interpreting the meaning of the term “foodstuffs” and, by logical extension, the scope of Note 1(a) to Chapter 30. They provide as follows:

*The provisions of the heading text do not apply to foodstuffs or beverages such as dietetic, diabetic or fortified foods, tonic beverages or mineral waters (natural or artificial), which fall to be **classified under their own appropriate headings**. This is essentially the case as regards food preparations containing only nutritional substances. The major nutritional substances in food are proteins, carbohydrates and fats. Vitamins and mineral salts also play a part in nutrition.*<sup>45</sup>

[Italics added for emphasis]

91. A reading of Note 1(a) to Chapter 30 in the light of the *Explanatory Notes* to heading No. 30.04 leads the Tribunal to conclude that Note 1(a) is intended to exclude all preparations containing only nutritional substances, of which dietetic, diabetic and fortified foods are but illustrative examples.

92. Indeed, this view coincides with the following past comments of the WCO Secretariat to the WCO Harmonized System Committee:

*... the objective of present Note 1 is to exclude all foods or beverages from Chapter 30. Dietetic food is indicated in that Note as just one example of such foods.*

...

It appears that, provided medicaments are clearly distinguished from foodstuffs, it does not matter for the practical application of the Nomenclature where a particular administration draws the distinction between “dietetic” foods and other foods.<sup>46</sup>

[Emphasis added]

93. In this case, it is uncontested that the formulations of the goods in issue consist only of nutritional substances, i.e. amino acids (which are described as the precursors of proteins<sup>47</sup> or protein equivalents), carbohydrates, fats, vitamins and minerals.<sup>48</sup> In this regard, the Tribunal finds the following exchange particularly compelling:

MR. GIBBS: *In your opinion, is Neocate [the goods in issue] a drug?*

DR. MACK: *Neocate is a food. It's a sole source nutrition, but it's food as therapy.*<sup>49</sup>

[Emphasis added]

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45. The separate reference to vitamins and mineral salts, as playing a part in nutrition, implicitly recognizes that these substances may also serve other purposes, with vitamins, for example, having prophylactic and/or therapeutic applications in preventing or reversing deficiencies linked to particular diseases or ailments. See, for example, the Tribunal's decisions in *DSM Nutritional Products Canada Inc. v. President of the Canada Border Services Agency* (2 December 2008), AP-2007-012 (CITT) and *Roche Vitamins Canada Inc. v. Commissioner of the Canada Customs and Revenue Agency* (26 January 2006), AP-2003-036, as well as the Federal Court of Appeal's decision in *Flora Manufacturing*.

46. Tribunal Exhibit AP-2009-017-17A at 97, paras. 18, 21. The Tribunal is of the view that these comments by the WTO Secretariat remain relevant and were not affected by the 1999 amendment to Note 1(a) to Chapter 30, as these comments were made after the WTO Harmonized System Committee's decision to adopt the 1999 amendment. Moreover, the WTO Secretariat's comments are unrelated to the form of administration of the food or medicament. They were made in response to a proposal by a member administration that the definition of the term “dietetic” found in Note 1(a) to Chapter 30 should be clarified and given a broad interpretation.

47. Tribunal Exhibit AP-2009-017-21A at 2, para. 11c.

48. Tribunal Exhibit AP-2009-017-08B, tabs 11, 12; Tribunal Exhibit AP-2009-017-17A, tabs B, D. The Tribunal notes that, according to the list of ingredients, each of the goods in issue contains (in descending order of weight) corn syrup, solids, vegetable oils, a mixture of amino acids, vitamins, minerals and other ingredients.

49. *Transcript of Public Hearing*, 10 February 2011, at 74. The Tribunal notes that Dr. Mack's conclusion on this issue was consistent with that of Dr. Boland's, who stated in her report that “. . . Neocate Infant or Neocate Junior [the goods in issue] despite its therapeutic effect is food”, Tribunal Exhibit AP-2009-017-21A at 3, para. 11h.

94. Furthermore, that the goods in issue are passive, containing no active ingredients, was not disputed in these proceedings and, indeed, was confirmed by Dr. Mack in the following exchange:

PRESIDING MEMBER: . . . Does Neocate [the goods in issue] contain any particular ingredient that actively challenges the underlying histopathological manifestations of these [gastrointestinal] disorders in infants and children . . . .

DR. MACK: I would say it's the opposite. It does not contain things that propagate the problem. It's kind of the reverse way of looking at it.

PRESIDING MEMBER: . . . [I]t contributes to the resolution of the problem . . . strictly through antigen avoidance. Is that correct?

DR. MACK: Correct.<sup>50</sup>

95. Finally, it is undisputed that the goods in issue are not nutritional preparations designed for intravenous administration, which, otherwise, would have brought them within the ambit of Chapter 30 as "medicaments".<sup>51</sup> The precautions listed in the product literature explicitly state that the goods in issue are not for intravenous (parenteral) use.<sup>52</sup> Intravenous administration differs from feeding by mouth or by tube. Dr. Mack testified that, should a patient refuse to eat by mouth, the goods in issue may be administered by means of a tube inserted directly into the intestines. He confirmed that the goods in issue would absolutely not be administered intravenously.<sup>53</sup>

96. The Tribunal therefore agrees with the CBSA that, despite their acknowledged therapeutic effect, the goods in issue are not medicaments but, rather, are in the nature of food preparations, which, as such, fall outside the scope of Chapter 30 by virtue of Note 1(a) to that chapter.

97. The Tribunal is aware of the need for the uniform interpretation and application of the Harmonized System among the members of the WCO. Although not binding on the Tribunal, it does consider, as appropriate, the classification rulings issued by other customs administrations in an effort to determine how Canada's trading partners classify similar goods.<sup>54</sup>

98. In this regard, the CBSA submitted a number of rulings issued by United States Customs and Border Protection (USCBP). The Tribunal, in its review of these rulings, notes that they deal with the classification of food preparations that consist of only nutritional substances, which provide complete, balanced nutrition to patients who suffer from Crohn's disease,<sup>55</sup> pancreatic insufficiency or lactose intolerance.<sup>56</sup> While recognizing that these decisions deal with products that are not identical to the goods in issue, the Tribunal notes that, in each decision, USCBP classified the goods in heading No. 21.06 as food preparations not elsewhere specified or included.

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50. *Transcript of Public Hearing*, 10 February 2011, at 74, 75.

51. *Ibid.* at 83.

52. Tribunal Exhibit AP-2009-017-17A, tab B.

53. *Transcript of Public Hearing*, 10 February 2011, at 59-61.

54. *Fisher Scientific Limited v. Deputy M.N.R.C.E.* (3 May 1994), AP-89-181 and AP-89-244 (CITT).

55. Tribunal Exhibit AP-2009-017-38A at 13.

56. *Ibid.* at 20.

Classification in Heading No. 21.06

99. Having regard to their nature as food preparations and to the fact that they are not for parenteral use, the goods in issue fall squarely within the following exclusion in Note 1(a) to Chapter 30 and, therefore, fall to be classified in Section IV in their own appropriate headings:

1. This Chapter does not cover:
  - (a) Foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (*Section IV*).

[Emphasis added]

100. Upon review of the terms of the various headings in Section IV, the Tribunal, in its application of Rule 1 of the *General Rules*, determines that the goods in issue are properly classified in heading No. 21.06 as food preparations not elsewhere specified or included.

101. In reaching this conclusion, the Tribunal considered Nutricia's point that the goods in issue are not specifically included in the list of covered goods set out in the *Explanatory Notes* to heading No. 21.06. However, the Tribunal is of the view that the term "*inter alia*" at the beginning of the list renders the list illustrative, not exhaustive. Moreover, and as noted above, heading No. 21.06 is a residual heading that captures goods not covered by the terms of any other heading of the nomenclature. The Tribunal is therefore satisfied that the goods in issue are properly classified in heading No. 21.06, notwithstanding the fact that they are not explicitly named in the *Explanatory Notes* thereto.<sup>57</sup>

102. As foods that are not specifically covered by the preceding subheadings or tariff items, the Tribunal finds that, pursuant to Rule 6 of the *General Rules* and Rule 1 of the *Canadian Rules*, the goods in issue are properly classified under tariff item No. 2106.90.99 as other food preparations not elsewhere specified or included.

**Tariff Classification at Issue—Tariff Item No. 9979.00.00**

Positions of Parties

– Nutricia

103. Nutricia submitted that the goods in issue meet the two requirements specified in tariff item No. 9979.00.00, namely, (1) they are specifically designed to assist infants and children with disabilities, in particular, the various gastrointestinal disorders that prevent the metabolism of food proteins, and (2) they are specifically designed to allow infants and children with gastrointestinal disorders (such as protein allergies) to alleviate the effects of those disorders by allowing the symptoms to subside. In support of this position, Nutricia referred to the Tribunal's decision in *Sigvaris Corporation v. President of the Canada Border Services Agency*.<sup>58</sup>

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57 The Tribunal notes that the *Explanatory Notes* to heading No. 21.06 indicate that the heading includes preparations for use, either directly or after processing (such as cooking, dissolving or boiling in water, milk, etc.), for human consumption, provided they are not covered by any other heading of the nomenclature.

58. (23 February 2009), AP-2007-009 (CITT) [*Sigvaris*].

104. With respect to the first requirement, Nutricia noted that there appears to be no disagreement between the parties that the goods in issue are specifically designed to assist infants and children who suffer from various gastrointestinal disorders. Nutricia further submitted that these gastrointestinal disorders meet the definition of disability set out by the Tribunal in *Sigvaris*, in that they affect the ability of infants and children to perform normal physiological activities, such as digestion. Nutricia argued that the result of this disability is that the infants and children are often not able to grow and thrive, or to perform normal activities. It also argued that these infants and children have certain functional limitations as a result of their disorders and the treatments that they must undergo.<sup>59</sup>

105. In further support of its position that these gastrointestinal disorders constitute a disability, Nutricia referred to decisions by certain other agencies, tribunals and courts, involving legislation other than the *Customs Tariff*, which found that various allergies were disabilities.<sup>60</sup>

106. With respect to the second requirement, Nutricia contended that the goods in issue are designed to alleviate the effects of food protein allergies and related gastrointestinal disorders. In support of its position, it referred to scientific literature, clinical studies and the expert evidence of Dr. Mack, all of which indicated that the goods in issue are effective in treating the symptoms of such disorders. Nutricia further submitted that the CBSA is essentially in agreement that the symptoms of food protein allergies subside when the goods in issue are ingested.

107. Nutricia also rejected the CBSA's contention that the scope of tariff item No. 9979.00.00 was confined by its legislative history, arguing that the existence of a formerly closed list of goods for people with disabilities, which qualified for duty-relief, did not limit the scope of current tariff item No. 9979.00.00, which replaced the previous list. Nutricia also noted that there is no qualifying language in tariff item No. 9979.0.00 itself and that, had Parliament intended to limit the scope of that tariff item, it could have done so, for example, by maintaining a closed list of products.

108. Nutricia argued that the CBSA's position with respect to the intended revenue neutrality of the 1998 amendments to the *Customs Tariff* does not support the argument that tariff item No. 9979.00.00 should be interpreted only to include items on the former list and submitted that statements made by the Government with respect to the intended revenue neutrality of the tariff amendments referred to their overall impact and not to specific tariff items.

– CBSA

109. The CBSA submitted that the intent of Parliament was for tariff item No. 9979.00.00 to apply to a specific list of goods, which did not include foodstuffs. In this regard, it argued that classification of the goods in issue under tariff item No. 9979.00.00 would extend the benefits of the tariff item to a range of products beyond the intent of Parliament. Citing the Supreme Court of Canada's decision in *Bogoch Seed Company v. C.P.R. and C.N.R.*,<sup>61</sup> the CBSA argued that, as the inclusion of foodstuff under tariff item No. 9979.00.00 was not contemplated by Parliament when the provision was originally enacted, it ought not to be read into the provision now in the absence of a clear indication to the contrary.

59. Tribunal Exhibit AP-2009-017-08B, tab 8.

60. *APPLICATIONS by Sophia Huyer and Rhonda Nugent, on behalf of her daughter Melanie Nugent, against Air Canada* (6 January 2010), 4-AT-A-2010 (Canadian Transportation Agency); *APPLICATIONS by Katherine Covell and Sarah Daviau against Air Canada and an application by Dr. J. David Spence against Air Canada, Air Canada Jazz and WestJet* (25 February 2010), 66-AT-A-2010 (Canadian Transportation Agency); *Canada v. Hamilton*, 2002 FCA 118 (CanLII); *Jasper v. The Queen*, 2003 CanLII 818 (T.C.C.); *Nantel v. The Queen*, 2000 CanLII 383 (T.C.C.); *Wachal v. Manitoba Pool Elevators*, 2000 CanLII 5489 (C.H.R.T.); *Dewdney v. Bluebird Cabs Ltd.*, 2003 BCHRT 7 (B.C. Human Rights Tribunal).

61. [1963] S.C.R. 247.

110. In this regard, the CBSA submitted extensive legislative history, including regulatory impact analysis statements and designation orders, which described the tariff items and tariff codes that preceded tariff item No. 9979.00.00, in support of its position that Parliament never intended for the tariff item to cover goods such as those in issue. Moreover, the CBSA claimed that the Government's 1998 tariff simplification exercise, which resulted in a number of amendments to the *Customs Tariff*, was not intended to have a substantive impact on existing policy or new financial implications, which would be the case if duty relief were to be extended to the goods in issue.

111. Finally, the CBSA submitted that the Tribunal's interpretation of the term "disability" in *Sigvaris* was overly broad and suggestive of a subjective approach to the determination of whether a disability exists. In this regard, the CBSA argued that an objective approach to the interpretation of that term was more appropriate and that *Sigvaris* should be confined to its own facts.<sup>62</sup>

#### Tribunal's Analysis

112. Tariff item No. 9979.00.00 provides as follows:

Goods specifically designed to assist persons with *disabilities* in *alleviating the effects of those disabilities*, and articles and materials for use in such goods.

[Emphasis added]

113. There are no notes to Section XXI. However, the Tribunal considers Notes 3 and 4 to Chapter 99 to be relevant to the issue of whether the goods in issue are classifiable under tariff item No. 9979.00.00. These notes provide as follows:

3. Goods may be classified under a tariff item in this Chapter and be entitled to the Most-Favoured-Nation Tariff or a preferential tariff rate of customs duty under this Chapter that applies to those goods according to the tariff treatment applicable to their country of origin *only after classification under a tariff item in Chapters 1 to 97 has been determined and the conditions of any Chapter 99 provision and any applicable regulations or orders in relation thereto have been met.*

4. *The words and expressions used in this Chapter have the same meaning as in Chapters 1 to 97.*

[Emphasis added]

114. According to the first requirement of Note 3 to Chapter 99, the goods in issue may only be classified in Chapter 99 after classification under a tariff item in Chapters 1 to 97 has been determined. With the Tribunal having found that the goods in issue are properly classified under tariff item No. 2106.90.99, it considers this condition to have been satisfied for the purposes of this appeal.

115. According to the second requirement of Note 3 to Chapter 99, the classification of the goods in issue under tariff item No. 9979.00.00 is contingent on the "conditions" of that provision having been met.

116. The conditions for classification under tariff item No. 9979.00.00 were identified by the Tribunal in *Sigvaris* to be as follows: (1) the goods in issue must be "... specifically designed to assist persons with disabilities ..."; and (2) the goods in issue must be specifically designed to assist such persons in "... alleviating the effects of those disabilities ...".<sup>63</sup>

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62. *Transcript of Public Hearing*, 10 February 2011, at 172-76, 180.

63. *Sigvaris* at para. 26.



117. The rule of modern statutory interpretation holds that the words of an act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the act, the object of the act and the intent of Parliament.<sup>64</sup> In this regard, the Tribunal reaffirms its conclusion in *Sigvaris* that, unlike the provisions of certain social policy legislation which may have been read by the courts in a broad and generous manner, “. . . there is nothing particular about tariff item No. 9979.00.00, or the law concerning tariff classification in general, that would require such a liberal interpretation. Like most other tariff-related provisions, tariff item No. 9979.00.00 is such that . . . emphasis should be placed on the grammatical and ordinary sense of the provision and that neither an overly liberal nor an overly strict interpretation is warranted.”<sup>65</sup>

118. In the Tribunal’s view, Note 4 to Chapter 99 is of particular relevance to the contextual reading of key words and phrases in tariff item No. 9979.00.00. In this regard, in reaffirming the well-established principle of consistent expression by providing that the words and expressions used in Chapter 99 have the same meaning as in Chapters 1 to 97, Note 4 allows one to infer, by logical implication and in accordance with well-established canons of construction, that, where words or expressions that are different from those in Chapters 1 to 97 are used in Chapter 99, those words or expressions are intended to have a different meaning.<sup>66</sup>

119. With these considerations in mind, the Tribunal will now turn to the issue of whether the goods in issue are “. . . specifically designed to assist persons with disabilities in alleviating the effects of those disabilities . . . .”

120. In accordance with Note 4 to Chapter 99 and the related presumption of consistent expression, the Tribunal is of the view that a distinction must be drawn between “diseases and ailments”<sup>67</sup> on the one hand, and “disabilities” on the other. In addition, tariff item No. 9979.00.00, by its own terms, clearly requires that the “effects” of disabilities be distinguished from the disabilities themselves. The Tribunal, guided by the Supreme Court of Canada’s decision in *Granovsky v. Canada (Minister of Employment and Immigration)*<sup>68</sup> and relevant pronouncements of the World Health Organization,<sup>69</sup> is of the view that “disabilities” refer to the functional limitations resulting from a disease, ailment or other impairment, with the “effects of those disabilities” being the inability to perform activities in a manner, or within the range, considered normal.

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64. *Bell ExpressVu Limited Partnership v. Rex*, [2002] 2 S.C.R. 559 at para. 26.

65. *Sigvaris* at para. 29.

66. R. Sullivan, *Sullivan on the Construction of Statutes*, 5th ed. (Toronto: Butterworths, 2008) at 216, states the following:

***Different words, different meaning.*** Given the presumption of consistent expression, it is possible to infer from the use of different words or a different form of expression that a different meaning was intended. . . .

67. For example, Note 16 of the *Explanatory Notes* to heading No. 21.06 refers to “diseases or ailments”.

68. [2000] 1 S.C.R. 703. The Supreme Court of Canada considered the definition of “disability”, albeit in a different context. In doing so, it equated the concept of disability with that of functional limitations and suggested that “[n]ot all physical or mental impairments (first aspect) give rise to functional limitations (second aspect).”

69. The World Health Organization in its *International Classification of Impairments, Disabilities and Handicaps: A Manual of Classification Relating to the Consequence of Disease*, defines “disability” as follows: “. . . any restriction or lack of ability to perform an activity in a manner or within the range considered normal for a human being. The term disability reflects the consequences of impairment in terms of functional performance and activity by the individual . . . .” See *Sigvaris* at para. 41.

121. Goods that “. . . assist persons with disabilities in alleviating the effects of those disabilities . . .” are therefore those goods that assist such persons in improving their ability to perform normal activities by mitigating the functional limitations resulting from disease, ailment or other impairment.

122. The Tribunal also notes that tariff item No. 9979.00.00 requires that the goods in issue be “specifically” designed to achieve this purpose. The adverb “specifically” (the definition of which in the *Shorter Oxford English Dictionary* includes “precisely”<sup>70</sup>) implies a direct, purposeful connection between the design of the goods in issue and the alleviation of the effects of disabilities (such as exists, for example, between the design of a wheelchair or automatic stairlift and alleviation of the effects of a disability on a person’s mobility or ability to climb stairs).

123. As noted by Nutricia, the goods in issue are “. . . specifically indicated to treat the serious gastrointestinal disorders . . . associated with severe food protein allergy. . . . [They are] clinically proven as effective to treat the symptoms of [these] disorders . . . .”<sup>71</sup>

124. The Tribunal also notes Dr. Mack’s testimony that the goods in issue work to settle the underlying disorder and his confirmation that the goods in issue contribute to the resolution of these disorders strictly through antigen avoidance.<sup>72</sup>

125. In addition, Ms. Reichert testified that the goods in issue were originally developed in the 1980s in order to treat a child with severe gastrointestinal problems who was unresponsive to alternative formulas and could not be fed intravenously. She further testified that the goods in issue are intended for the treatment, dietary management and diagnosis of cow’s milk allergy.<sup>73</sup>

126. On the basis of the evidence, the Tribunal is of the view that the goods in issue were not specifically designed to alleviate the effects of the disabilities resulting from these gastrointestinal disorders but, rather, as a form of nutritional therapy indicated for use in the treatment of the underlying gastrointestinal disorders themselves. As explained by Dr. Mack, “. . . [the goods in issue provide] appropriate infant nutrition with [their] protein source being amino acids, and [address] the symptoms caused by the offending antigens which are not present in the amino acid formula.”<sup>74</sup>

127. Alleviation of the effects of disabilities resulting from these gastrointestinal diseases and ailments is, in the Tribunal’s view, a consequence of the antigen-avoiding nutritional treatment of the underlying diseases and ailments themselves, which, in the Tribunal’s view, is the precise purpose for which the goods in issue were in fact specifically designed.

128. Accordingly, the Tribunal finds that the goods in issue were not “. . . specifically designed to assist persons with disabilities in alleviating the effects of those disabilities . . .”, within the meaning of that phrase in tariff item No. 9979.00.00. Indeed, to suggest that this tariff item captures food preparations such as the goods in issue would, in the Tribunal’s view, expand the scope of that provision well beyond what was intended.<sup>75</sup>

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70. Fifth ed., s.v. “specifically”.

71. *Transcript of Public Hearing*, 10 February 2011, at 85.

72. *Ibid.* at 75.

73. *Ibid.* at 7.

74. Tribunal Exhibit AP-2009-017-20A at 5-6.

75. That the scope of tariff item No. 9979.00.00 explicitly extends to the “articles and materials” used in the goods falling under that tariff item lends further support to the Tribunal’s finding insofar as one would not likely associate these terms with food preparations. Note, by way of contrast, the use of the term “ingredients” in Note 3 to Chapter 21.

129. Therefore, the Tribunal finds that the goods in issue are not classifiable under tariff item No. 9979.00.00.

### **DECISION**

130. For all the above reasons, the Tribunal determines that the goods in issue are properly classified under tariff item No. 2106.90.99 as other food preparations not elsewhere specified or included and that the goods in issue are not classifiable under tariff item No. 9979.00.00 and, thus, not entitled to the benefits of that tariff item.

131. The appeal is therefore dismissed.

Pasquale Michael Saroli  
Pasquale Michael Saroli  
Presiding Member