[2012] UKFTT 134 (TC)

TC01829

Appeal number: TC/2009/14700

CUSTOMS DUTIES *– tariff classification – post-clearance demand note in sum of £427,903.36 and VAT of £70,028.26 - amino acid premixes imported from USA – whether to be classified as medicaments (Chapter 30) or food preparations (Chapter 21) – product to be classified under Chapter 30 as medicaments.*

FIRST-TIER TRIBUNAL

TAX

SHS INTERNATIONAL LIMITED **Appellant**

- and -

THE COMMISSIONERS FOR HER MAJESTY'S REVENUE AND CUSTOMS **Respondents**

TRIBUNAL: DAVID S PORTER (JUDGE)
ANNE CHRISTIAN (MEMBER)

Sitting in public at Alexandra House, Manchester on 6,7 and 8 December 2011

Timothy Brown, of counsel, for the Appellant

Vinesh L Mandalia, of counsel, instructed by the General Counsel and Solicitor to HM Revenue and Customs, for the Respondents

DECISION

1. Rogerio Pacheco (Mr Pacheco), operations Director for SHS International Limited (SHS), appeals on behalf of SHS against the decision contained in a letter dated 18 June 2009 from the Commissioners (HMRC) (reviewed and confirmed on 28 August 2009) imposing a post-clearance demand for duty of £427,903.36 and VAT of £70,028.26 arising from the classification of amino acids RM510, used in its 'Maxamums' range of products, and RM630, used in the production of its 'Neocate' range of products, as dietary supplements under Chapter 21.06. SHS consider that the products should be classified under Chapter 30.04 as medicaments.

2. Timothy Brown, of counsel, appeared for SHS and called the following all of whom gave evidence under oath:

Mr Pacheo, operations director for SHS

Paul Cowley (Mr Cowley), formerly innovation and process manager at SHS in Liverpool but now quality and cost manager.

Dr Anita MacDonald (Dr MacDonald) a consultant dietician in inherited metabolic disorders at Birmingham Children's hospital NHS Foundation.

Dr Rosan Meyer (Dr Meyer) a paediatric teaching fellow at Imperial College, London.

Emma Strebe (Mrs Strebe) a global medical manager at Danone, the Netherlands.

Josephine Garvey (Mrs Garvey) a senior medical affairs manager for Allergy & Paediatric Nutrition at Danone, the Netherlands.

3, Vinesh L Mandalia (Mr Mandalia), of counsel, appeared for the Respondent (HMRC) and called Michael John Desmond Gamlin (Dr Gamlin) an independent consultant working for Pharmaceutical Development Services, who gave his evidence under oath. Mr Brown and Mr Mandalia produced 3 agreed bundles with skeleton arguments and Mr Mandalia provided a written summation.

4. We were referred to the following cases:

Bioforce GmbH v Oberfinanzdirection Munchen (No1) (Case C – 177/91)[1993] ECR 1 -45

Glob-Sped AG v Hauptzollamt Lorrach Case C -328/97) ECR [1998] 1-8357

Unigreg Ltd v Customs and Excise Commissioners (1998, unreported)

Nutri (Imports & Exports) Ltd C00166

Laboratories de Therapeutique Moderne (LTM) v Fonds d'Intervention et de Regularisation du Marche du Sucre (FIRS) Case C-201/96

The Law and cases

5. We think it would be helpful if we set out the law as we understand it. This has been succinctly set out by Judge Colin Bishopp in *Nutri (Imports & Exports) Ltd*, in which he states:- " the system of levying duty on goods imported into the European Union is uniform in each member state. The procedure is regulated by Council Regulation 2658/87, which contains the rules for applying and interpreting the Combined Nomenclature (CN), which is set out as annex 1 to the regulations. The CN consists of Chapters, identified by a two digit number, the first four digits of the code, composed of the Chapter number followed by a two digit sub-Chapter code, together form the heading number. Further refinement is provided by adding additional pairs of digits, to a maximum of 10.The appeals are heard pursuant to section 16 of the Finance Act 1994, since they are appeals against decisions reached by the Commissioners on undertaking a review in accordance with section 15 of the same Act"

6. The Commissioners review letter refusing to withdraw the post-clearance demands was dated 28 August 2009. There are no ancillary matters falling within Schedule 5 to the 1994 Act, and our jurisdiction is therefore not limited by section 16(4). Accordingly we can, if we so decide, substitute our own decision for that of the Commissioners, though we have also the power granted by subsection 16 (4) to require the Commissioners to conduct a further review.

7. "Classification can be difficult and these difficulties are addressed by the General Rules for the Interpretation of the Harmonized System (GIRs) of which there are six. Those of particular relevance to this appeal are Rules 1, 2(b), 3 and 6.

- Rule 1. "The title to the sections, chapters and sub-Chapters are provided for ease of reference only; 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."
- Rule 2 (b). Any reference in a heading to a material or substance shall be taken to include a reference to mixtures or combinations of that material or substance with other materials or substances. Any reference to goods of a given material or substance shall be taken to include a reference to goods consisting wholly or partly of such material or substance. The classification of goods consisting of more than one material or substance shall be according to the principles of Rule 3."
- Rule 3 is provided in order to resolve conflicts where more than one classification might be possible. " When by application of Rule 2 (b) or for any other reason, goods are *prima facie* classifiable under two or more headings, classification shall be effected as follows:

  (a) The heading which provides the most specific description shall be preferred to headings providing a more general description. However, when two or more headings each refer to a part only of the materials or

substances contained in mixed or composite goods or to part only of the items in a set put up for retail sale, those headings are to be regarded as equally specific in relation to those goods, even if one of them gives a more complete or precise description of the goods;

(b) Mixtures, composite goods consisting of different materials or made up of different components, and goods put up in sets for retail sale, which cannot be classified by reference to Rule 3 (a), shall be classified as if they consisted of the material or component which gives them their essential character, in so far as this criterion is applicable;

(c) When goods cannot be classified by reference to 3 (a) or 3(b), they shall be classified under the heading which occurs last in numerical order among those which equally merit consideration,"

- [Rule 4 allows the goods to be classified with those to which they are most akin
- Rule 5 Refers to specific goods and their packing not the subject of this appeal].
- Rule 6. " For legal purposes, the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings and any related subheading notes and *mutatis mutandis* to the above rules, on the understanding that only subheadings at the same level are comparable. For the purposes of this rule the relative section and chapter notes also apply, unless the context otherwise requires."

8. The Harmonised System Explanatory Notes (HSEN) - are not binding, but are regarded as important aids to interpretation. The HSEN for Rule 2 (b) states;

2 (b) "Rule 2 (b) concerns mixtures and combinations of materials or substances, and goods consisting of two or more materials or substances. The headings to which it refers are the headings in which there is a reference to a material or substance…., and headings in which there is a reference to goods of a given material or substance….It will be noted that the rule only applies if the headings or the Section or Chapter Notes do not otherwise require…"

9. We have been referred to the following cases and set out the decsions as they affect this case. In *Bioforce GmbH v Oberfinanzdirection Munchen* the Court of Justice was required to consider a product whose importer claimed it came within heading 30.04, which applies to certain types of "medicaments… for therapeutic or prophylactic uses". The court said at paragraphs 8 and 9 :

(a) "8… the decisive criterion for the classification of goods for Customs purposes is to be sought, regard being had to the requirements of legal certainty, in their objective characteristics and properties, as defined in the wording of the headings of the Common Customs tariff.

(b) 9. It should therefore be considered whether the product in question has the objective characteristics and properties defined in heading 30.04

of the Common Customs Tariff, which must be interpreted in the light of medical developments.

It went on to find that the product in question had "clearly defined therapeutic and, above all, prophylactic characteristics, the effect of which is concentrated on precise functions of the human organism" and that its ability to satisfy that test brought it within heading 30.04. (The product was for the treatment of the heart and to aid cardiac irrigation).

10. In *Glob-Sped AG v Hauptzollamt Lorrach* the Court was required to consider the correct tariff classification of two vitamin preparations and said:

> "26. It is settled case law that, in the interests of legal certainty and for ease of verification, the decisive criterion for the classification of goods for customs purposes is in general sought in their objective characteristics and properties as defined in the wording of the relevant heading of the CN. There are also explanatory notes drawn up, as regards the CN, by the Commission and, as regard the harmonised Commodity Description and Coding System, by the Customs Cooperation Council, which may be an important aid to the interpretation of the scope of the various tariff headings, but do not have legally binding force (see, in particular, Case C- 201/96 *LTM V FIRS* [1997]ECR 1- 6147, paragraph 17)
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> 27. It is therefore necessary to examine whether the products at issue in the main proceedings exhibit the objective characteristics and properties defined under CN heading 30.04, which, as the Court held in paragraph 13 of the judgment in *Bioforce*, cited above, must be interpreted in the light of medical developments.
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> 28. In that regard, as the documents before the Court show, it is undisputed that the vitamin C content of the products in question is much greater than what is necessary or recommended for general dietary purposes. Furthermore, besides assisting the immune system in the human organism to resist infection in cases of, *inter alia*, asthenia or severe strain, such doses of vitamin C, which the human body is incapable of making for itself, are also recommended as treatment for allergic reactions and severe traumatisms, of the kind which might result from an injury or a surgical operation, or to combat deficiency-related illnesses, such as scurvy or Moeller-Barlow disease."

11. In *Unigreg Ltd v Customs and Excise Commissioners* (1998, unreported), a decision of Moses J, the importer sought to have its products classified under heading 30.04 while the Commissioners advanced heading 21.06. The product was licensed to be sold only through registered pharmacies. It was held out as being effective in the correction of vitamin and mineral deficiencies, particularly for those suffering from dietary insufficiency and its Medicine Act licence permitted it to be sold for the treatment of such conditions. The Tribunal found that the product had the capacity to alleviate such conditions, but it nevertheless found that it was a food supplement, and not a pharmaceutical product within heading 30.04. In the course of his judgment on the appeal, Moses J said

i. "2… The fact that a product has broad spectrum of prophylactic or preventative functions does not disqualify it from being classified under heading 30.04. That proposition is not in dispute, but it is a

proposition which must be based on a finding that the product does have specific effects, even though they may be a number of specific effects. The difficulty in this case is that on the findings of the Tribunal this product had no specific effect at all. It has not been shown to have an effect or even effects concentrated on precise functions of the human organism.

ii. … I accept that the mere fact that vitamins play a part in providing nutrition does not prevent vitamins and minerals from classification as a medicament. The HSEN to 30.04, which I have cited, demonstrates that a product may be a food supplement containing or even consisting of minerals and vitamins, which promote general health and well-being and within 30.04, provided always that they have an indication as to the use for the prevention of any disease or aliment. The difficulty which Unigreg faces is that on the evidence before the Tribunal there was, in the words of the HSEN, no indication as to the use for the prevention or treatment of any specific disease or ailment at all.

iii. …this product is not classified as a medicament because on the facts found, it made good deficiencies in nourishment. Such a product has not been shown to have a clearly defined therapeutic and prophylactic active effect on precise functions of the human organism"

As a result it is not enough that any effect the product might have is incidental; its medicinal effect, if it is to come within heading 30.04, must be central.

12. In *Nutri (Imports & Exports) Ltd* C00166 HMRC proposed that the vitamin tablets packaged for sale should be classified under heading 21.06 "Food preparations not elsewhere specified or included" - subheadings "90- other" – "92 –other, containing no milk fats, sucrose, isoglucose, glucose or starch containing, by weight less than 1.5% milk fat, 5% sucrose or isoglucose, 5% glucose or starch" CN 21069092. The Appellant proposed that the products should be classified under Chapter 29.36 "pro-vitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent"- subheading 90 other, including natural concentrates"- 90 "Inter-mixtures, whether or not in any solvent". CN21069090. The Appellant did no claim that the products had any medicinal value. Judge Bishopp in finding for the classification proposed by HMRC said at paragraph 57.

> "We derive from these cases the principle that the first consideration must always be the objective characteristics of the product, and the examination must be rigorous. Not only must it contain material which meets the description of the relevant heading but, where the heading refers to a use, or purpose, it must be demonstrable that the product has the capacity to be put to that use, or achieve its prescribed purpose. The importer's claimed use or purpose must be judged against the product's objectively ascertained characteristics: if it cannot be demonstrated that the product is capable of the

claimed use or of achieving the claimed purposes, a tribunal must put the importer's assertion to one side. And, taking pharmaceutical products as an example, it is not enough that any effect the product might have is incidental; its medicinal effect, if it is to come within heading 30.04, must be central".

13. The Oxford dictionary defines;

"Medicament as - thing used as medicine"

"Therapeutic as – of or for or tending to the cure of disease, curative branch of medicine; medical treatment"

"Prophylactic as – done or used as preventative against disease".

"Disease as – a serious derangement of health, disordered state of an organism or organ, any particular form of this with special symptoms and name".

The Facts

14. Mr Pacheco provided us with a background to SHS and the products involved. SHS is now owned by the Danone Group of France and forms part of the medical Nutrition Division. Its main expertise is in the development of medical nutritional supplements. In broad terms SHS specialises in the following areas of medical nutrition:

a. Metabolic disorders – patients who have an impaired metabolism and cannot break down certain amino acids in protein. Failure to manage this properly can result in a wide range of medical conditions from brain damage, severe learning difficulties or even death.

b. Allergy relief – some babies are allergic to cow's milk which allergy can result in vomiting, diarrhoea, breathing problems and skin problems such as inflammation, rashes and itching.

15. SHS owns and operates a factory in Wavertree Technology Park, Liverpool designed and built to ensure its products are blended and packaged in a clinical protein free environment, the only protein–free facility in the world for the production of theses types of specialist products. SHS has created the formulas for the two amino acid pre-mixes, the subjects of this appeal. RM0510 is used as a basis for the 'Maxamums' range of products and is prescribed by registered health professionals to children and adults' who suffer from a metabolic disorder called Phenylketonuria (PKU). RM630 has a slightly different composition making it suitable for babies who are intolerant to cow's milk. It is the basis for its product 'Neocate' also only available on prescription. We were told that the NHS pays £270 for the tin of 'Maxamums' and £88.08 for the tin of 'Neocate' which were produced to the Tribunal. We also tasted both products, mixed with water as required on the tin, which we found both products to be unpalatable..

16. Due to demand for its products SHS had out-sourced the production of its amino acids RM0510 and RM630 to Ajinomoto in Belgium, which manufactured the amino acids to SHS' specification. Prior to June 2008, the amino acids were supplied from Ajinomoto's premises in Belgium, but after that date the manufacturing was transferred to their company in the USA.

17. Both 'Maxamums' and 'Neocate' are listed in the United Kingdom Tariff as Borderline Substances. In certain conditions some foods and toilet preparations have characteristics of drugs and the Advisory Committee on Borderline Substances advises as to the circumstances in which such substances may be regarded as drugs. Both products are shown in List A and as a result can only be obtained by a patient with a prescription that has been issued by a doctor. It is not possible for an individual to merely purchase these products 'over the counter' from a pharmacy, because the sale of medical nutritional products is a controlled activity.

18. In cross-examination, Mr Pacheco conceded that SHS was not licensed for the production of medicine as the products were not classified as medicine. Mr Mandalia submitted that the products supported a dietary regime to help patients with allergies but Mr Pacheco did not feel qualified to answer that question.

19. Mrs Strebe explained that metabolism refers to the chemical reactions in living organisms, usually:-

b. Catabolism, the breakdown of organic matter (for example, to gain energy in cellular respiration); and

c. Anabolism, the use of energy to construct components of cells such as proteins and nucleic acids.

Inherited metabolic disorders (IMD) are genetic alterations in biochemical pathways that disturb and prevent the metabolism of nutrients, in particular, proteins, carbohydrates and fats. Metabolic disorders are most commonly hereditary, although they can occur as a result of organ failure or disease. Many IMDs present with severe symptoms in the neonatal period

- Non-specifically 'unwell' baby
- Lethargy
- Feeding problems
- Vomiting
- Abnormal breathing
- Hypotonia or low muscle tone
- Seizures

20. If left undiagnosed and untreated IMDs can result in:

- Impaired development resulting in conditions such as microcephaly

- Severe learning disability and/or physical handicap including:

    (a) Mental retardation

    (b) Delayed development of speech

    (c) Behavioural abnormalities

    (d) Seizures

    (e) Eczema

    (f) Death

As a result, patients must be provided with medical foods that omit the offending metabolite but contain certain other essential nutrients and substrates. In cross-examination, Mrs Strebe conceded that there was no cure for PKU, however all the product managed the patient's diet. The information for 'XPMaxamums' reveals that only 47% of the ingredients are the amino acids the remaining 57% were food supplements.

21. Dr MacDonald explained in considerable detail the workings of 'Maxamums' and RM510. She advised that PKU is a rare, and inherited metabolic condition, there is a deficiency of the enzyme, phenylalanine hydroxylase, which results in an inability to metabolise the amino acid, phenylalanine. 'Maxamums' assists the release of phenylalanine into body tissues rather than the blood stream, thereby improving the patient's concentration and executive functions. In PKU, phenylalanine is a known neurotoxin and untreated individuals, with high blood phenylalanine concentrations, almost always develop sever intellectual disability. Other neurological symptoms such as epilepsy, behavioural problems, depression and anxiety disorders may occur.

22. In contrast, individuals who are treated with PKU, neonatally with a low phenylalanine diet, have a general cognitive ability within normal range and function as the average population. The treatment involves reducing dietary phenylalanine intake by severely restricting natural protein intake and supplementing with L-amino acids free of phenylalanine. Protein substitutes are an integral essential component in the successful treatment of PKU. They are made up of 19 L-amino acids except phenylalanine. They provide the primary source of non-phenylalanine nitrogen, tyrosine and large neutral amino acids. Protein substitutes supply 75% of protein requirements. They also have a pharmacological effect and suppress blood phenylalanine concentrations as revealed by Mrs MacDonald's study in 2006. It is impossible to control patients with PKU by a low phenylalanine diet, without the use of a protein substitute.

23. The two case studies she referred to revealed a substantial increase in concentration, short term memory and attention span in an 8 year old child and concentration and executive functions in a 56 year old, who had not originally been so treated. It appears that as a result of treatment at age 51, he has, in the last 5 years, studied computers, French and basic mathematics and English skills at college,

24. Dr MacDonald conceded that the pre- mix RM510 was not taken on its own but she confirmed that given on its own it would have a metabolic effect and would help the condition. She suggested that if 'Maxamums' was not available in India (being the example of a country which might not have a manufacturing facility near to where the patient lived) and there was no other product she would use the amino acids RM510. She also understood that in rare cases the protein substitute has had to be administered by a nascogastric tube. Under cross-examination she insisted that 'Maxamums' was a treatment and could not be considered a food preparation. We found her evidence succinct and convincing.

25. We heard evidence from Dr Meyer who, as a paediatric dietician at Imperial College London, is regularly asked to trial specialist products for dietary management of food allergy in his clinic practice for SHS and other competitors. She indicted that food allergy has been associated with significant growth retardation and vitamin and mineral deficiencies. There is a significant body of evidence indicating that the use of an amino acid formula as a treatment of food allergies leads to improved nutritional status. The prevention of faltering growth and the early intervention/correction of this condition has been shown to have a significant long term effect on growth development as well as intelligence quotient.

26. She produced an example of a baby ,exclusively breast fed, who, at one month old, developed severe eczema. Both parents suffered from hay fever and the mother was advised to omit cow's milk, egg, soy, wheat and nuts from the baby's diet. She followed the diet for 2 months and the eczema became worse and the child's weight dropped. The baby was prescribed ''Neocate'' and within 5 days there was a marked improvement in his eczema and after 3 weeks his eczema had totally cleared. Amino acids feeds (ie ''Neocate'' range) form the mainstay of treatment for children with cow's milk protein allergy because they do not contain whole proteins. As a result, they should not be considered a food preparation.

27. Mrs Garvey concurred with the other experts and said that the most basic treatment for any adverse food protein, including cow's milk protein, is the complete avoidance of the implicating food/protein. While the mainstay of clinical management remains the prescription of hypoallergenic formulae, particularly when breast-milk is not an option. When cow's milk allergy is diagnosed in an only-breast fed infant, the practitioner recommends the most appropriate milk substitute to ensure the nutritional needs of the infant are met whilst treating the underlying allergy symptoms. There is no cure for food allergy. Allergy relief products include ''Neocate' range' which has been designed for infants and children with food allergic diseases or conditions. These products fall into the category of dietary Foods for Special Medical Purposes (FSMPs), which are prescribed under the auspices of the Advisory Committee on Borderline Substances.

28. The European Commission has issued a specific directive 1999/21/EC to regulate the vitamin and natural composition, labelling and marketing of FSMPs including those for infants. Through its implementation, this directive ensures harmonised European legislation and more particularly the healthcare professional and patients

can have confidence that a product, which complies with the directive, is suitable for its intended purpose.

29. Patients with specific medical conditions have different physiological or nutritional requirements to normal healthy individuals. FSMPs are formulated for adults, children and infants who are, or may be at risk of becoming nutritionally compromised. Any patient, who is malnourished, should receive appropriate nutritional support as part of the disease management. FSMPs are an essential component of the healthcare strategy to prevent malnutrition and to manage disease related malnutrition. ''Neocate'' has been extensively studied in many different clinical settings and has been validated in the management of food allergic disease. Under cross-examination Mrs Garvey insisted that the products provide nutrients. She conceded that ''Neocate'' was not produced under a medical license, but insisted that it was a food for medical purposes.

30. Mr Cowley gave evidence as to the development and manufacture of the products and of the outsourcing of SHS' 'pre-mixes', the subject of this appeal. The amino acid profile in the 'pre-mix' is part of the nutritional product, the balance of which will depend upon the profile of the end user-whether it is infant or an adult- and the medical condition that the product is designed to treat. The flavour of the 'pre-mix' shows acute bitterness with astringent, sour and sulphurous notes. He added that the taste of the finished product is not particularly palatable and, as we have discovered, it is not something that you would want to take voluntarily if you did not have to. Under cross-examination Mr Cowley confirmed that there is no reference to a medical application on the tin and the amino acids form 15.5% of the formula. We note that the instructions attached to the tin for XP 'Maxamums' carry an important notice which reads in part:-

> "Use under medical supervision. Suitable for children 8 years and over. Not suitable as a sole source of nutrition. **Only intended for use by patients with phenylketonuria.** Not for parenteral use…."

He also indicated that SHS did not provide the products to the patients as this was done through the prescription.

31. Dr Gamlen gave expert evidence on behalf of HMRC. He advised that he had appeared as an expert witness on a number of patent and commercial cases. He concurred with the general description and functions of amino acids and indicated that the boundaries between medicines and foods frequently give rise to confusion in both professional and lay people. He specifically addressed the issue as to whether the products were a food supplement or a medicine. The absence of specific nutrients, or the inability of the body to properly digest certain dietary elements, leads to diseases of deficiency which are well known (e.g. scurvy caused by the absence of vitamin C). In the cases of disease caused by dietary deficiency of errors of metabolism, administration of the deficient component, or rectification of the incapacity by the provisions of supplements, does not make the product administered to treat the condition a medicine. If the administration of any material that prevented deficiency of metabolic disease is to be accepted as medical treatment, then all foods, vitamins

and water would be classified and controlled as medicines – because their absence results, ultimately in death.

32. Medicines are materials licensed for the treatment of disease under medicine controlled legislation. Food supplements are not so controlled. SHS' food supplements are essential for life and, as their incorrect manufacture could result in patient harm or death, supplies in the USA are covered by statutory manufacturing standards under the Infant Formula Program and Compliance Program 7321.006. They are not controlled as medicines by the US food and drugs administration and the SHS' facility used for their manufacture would not comply with the requirements for medical products. The United Kingdom 'Drug Tariff' includes a number of products, which are either specialist foods or food supplements and which are reimbursed **as if** they were medicines, the purpose of which is to allow pharmacies to supply them by subscription under the NHS.

33. SHS's own literature confirms that the sole purpose of ''Neocate'' is to treat the inability of some children to tolerate or metabolise certain foodstuffs, or absorb certain dietary components. This does not make the product a medicine. Having examined the relevant sections of the customs tariff classifications, he was of the opinion that the most appropriate classification was 2106909260, which refers to, amongst other items, protein concentrates for infant use. In his second witness statement, Dr Gamlen indicated that foods intended for particular nutritional uses are regulated by framework directive 89/398/EEC and by specific Directives adopted under the framework. A 'food for a particular nutritional use' (a 'parnuts' food) which is a food, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption and is sold in such a way as to indicate its suitability for its claimed nutritional purpose. A particular nutritional use means the fulfilment of the particular nutritional requirements of certain categories of persons:

i. Whose digestive processes or metabolism are disturbed or

ii. Whose physiological condition renders them able to obtain special benefit from controlled consumption of certain substances in foodstuffs, or

iii. Of infants or children in good health.

These directives include specific directives relating to FSMPs and provide strict guidelines on composition, labelling and advertising of 'parnuts'.

34. Directive 1999/2w1/EC lists substances for specific nutritional purposes intended for additions to FSMPs together with the purity criteria applicable to the substances. This list includes the 22 amino acids from which SHS amino acids are prepared. 'Parnuts' food include infant formulas, processed cereal based foods and baby foods for infants and young children, certain weight reduction products, 'sports foods'; and foods for special medical purposes. Under the 'parnuts' directive, additional nutritional substances e.g. vitamins, minerals, amino acids may be added to foods for particular nutritional uses in order to ensure that the particular nutritional requirements of the person for whom those foods are intended are fulfilled.

35. It is clear from the 'parnuts' legislation that the intention of the European directive is that FSMPs should be treated as foods and not as medicines. The purpose of prescribing ''Neocate'' and ''Maxamums' is to ensure the health and well being of the patient through providing them with food which meets their particular nutritional requirements. Mr Brown suggested that Dr Gamlin's expertise related to foods not medicines and that it appeared that Dr Gamlin had not given evidence with regard to classifications before. Dr Gamlin also indicated that he had difficulty describing what a 'medicament' was but he was satisfied that the amino acids the subject of the appeal were not medicine and they therefore had to be classified as a food supplement.

Submissions

36. Mr Mandalia provided a written submission. He referred to his skeleton argument but did not intend to repeat it. RM510 was used by SHS in the production of products to assist in the treatment of PKU: The ''Maxamums'' range of products. RM0630 forms part of the ''Neocate'' range of products for dietary management of 'Cow's Milk Allergy'. When the amino acids were imported SHS classified them under Chapter 30.03:-

> "Medicaments [excluding goods of heading 30.02 (which relates to blood), 30 05 (being bandages etc) and 30.06 (pharmaceutical goods)] consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale".

The correct classification concerns the two amino acids pre-mixes and not the finished product. HMRC take the view that the pre-mix are more properly classified under Chapter 21.06:-

> "Food preparations not elsewhere specified or included: Protein concentrates and textured protein substances:- containing no milk fats, sucrose, isoglucose or starch or contained by weight, less than 1.5% milk fat, 5% sucrose or isoglucose, 5% glucose or starch - other"

37. In deciding the classification he submits that the starting point is Rule 1 and consideration of the objective characteristics of the products. Not only must the products contain material, which meets the description of the general heading, but where the heading refers to a use or purpose, it must be demonstrable that the product has the capacity to be put to that use, or to achieve its prescribed purpose. Taking pharmaceutical products as an example, it is not enough that any effect the product might have is incidental; It's medicinal effect, if it is to come within heading 30.04, must be central. As Moses J indicated in *Unigreg Ltd v Customs and Excise Commissioner* (Mr Mandalia paraphrased):-

> " .. although the fact that the product is not a medicine under the Medicine Act 1968 is not of itself relevant, given the width of the concept of medical products, if a product is not capable of coming within that legislation it is in practice unlikely to be a medicament under the tariff".

38. Chapter 30 clearly states ".. This chapter does not cover…foods or beverages.. such as fortified foods, food supplements, other than nutritional preparations for intravenous administration". The evidence of the SHS has concentrated entirely upon the two product ranges that form the finished product, and of which the amino acid pre-mix form a component of the ingredients, but these are not the product which is imported into the United Kingdom. The amino acids represent less than half the ingredients in the two tins produced to the Tribunal. In the ''Maxamums'' product range only 16 of the L-amino acids are imported in the pre-mix. The three remaining amino acids are manufactured internally by SHS. There has been no evidence that the amino acids pre-mix has any benefit other than as a food supplement or substitute nutritional value. All the witnesses for SHS have indicated that the amino acid pre-mix could not be given to a patient or client group on its own. Dr MacDonald has only indicated that only if there was no alternative the pre-mix could be used for medicinal purposes. Mr Cowley did not claim that the products were medicinal.

39. The nutritional benefits of the final products ('Maxamums'' and ''Neocate'') for patients diagnosed with PKU or Cow's Milk Allergy are not in issue. However, it is plain that there is no evidence that the amino acid pre-mix has any known therapeutic or prophylactic purpose as it does not cure or heal an underlying condition. The evidence of the experts is that there is no cure. Nor does the pre-mix prevent or defend against the occurrence of PKU or Cow's milk allergy. As a result, the pre-mixes do not meet the description in the general heading. It has not been demonstrated that the product has the capacity to be put to that use, or to achieve the purpose set out in 30 03.

40. The nutritional value of the product can only lead to the conclusion that the amino acid pre-mix (and even the finished product) is properly to be regarded as a food supplement and or substitute under chapter 21 06 as a food product not elsewhere specified or included. Mr Pacheo and Mr Cowley have indicated that SHS specialises in 'nutritional supplements'. The human body needs amino acids which can be ingested as part of dietary management of an underlying condition such as PKU or allergy. The products are for dietary management as indicated on the tins.

41. SHS' employees describe the products (not the amino acid pre-mixes) as 'medical nutritional supplements', but it is plain that that is on the basis that the finished product (not the pre-mixes) are described as 'Foods for Special Medical Purpose' in the United Kingdom Drug Tariff. That does not make either the pre-mixes or the final products medicaments or pharmaceutical products in any proper sense of the words. It is clear from the cost of the products that unless available on prescription, a majority of people would be unable to afford the nutritional supplements needed to maintain their health. It is not therefore surprising that those suffering from PKU and infants with Cow's Milk Allergy have access to the products by prescription. HMRC therefore submit that the correct classification is under chapter 21 06.

42. Mr Brown confirmed that he had no difficulty in agreeing the basis on which classification is to be determined. He submitted that Dr Gamlen's evidence was of little assistance to HMRC. DR Gamlen had no experience in these matters. Dr

Gamlen had not seen the general rules nor referred to the case law. He had been unable to define what a medicament might be. The word medicine does not appear in the wording to Chapter 30. Pharmaceutical products do not include food supplements. In *Bioforce GmbH v Oberfinanzdirection Munchen (No1)* at paragraph 12 the Court said:

> " It follows from those considerations that the product at issue may not be regarded as a food supplement within the meaning of Note 1(a) of the introductory notes to Chapter 30 of the Common Customs Tariff as a spirituous beverage designed to maintain general health or well-being within the meaning of Note 14 of the Explanatory Notes to the Harmonised System for designation and codification of goods relating to heading 22.08, but as a product having defined therapeutic and, above all, prophylactic characteristics, the effects of which is concentrated on precise functions of the human organism, namely, the cardiac, circulatory and neuro-vegetative functions".

43. The notes to Chapter 21 06 are unhelpful to HMRC's suggested classification as they refer to "preparations for infant use containing milk and products from milk". ''Neocate'' is prepared without milk to alleviate the difficulties arising from a Cow's Milk Allergy. Note 16 provides:-

> "Preparations, often referred to as *food supplements*, based on extracts from plants, fruit concentrates, honey, fructose, etc, and containing added vitamins and sometime 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**".

44. The note to 30 03 indicates:-

> "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 final products of ''Maxamums'' and ''Neocate'' have therapeutic and prophylactic properties as they are used as part of a medical treatment for the patients - " the effect of which is concentrated on precise functions of the human organism" (See *Laboratories de Therapeutique Moderne (LTM) v Fonds d'Intervention et de Regularisation du Marche du Sucre (FIRS)* paragraph 29).

45. Dr MacDonald has indicated that patients, who are left untreated with PKU, are at risk of a substantial deterioration in their health. She accepted that there was no cure for the condition, but its effect can be contained and alleviated by the ''Maxamums'' products. The products are used to manage the conditions that the patients are suffering from. Dr Meyer has provided evidence to the effect that ''Neocate'' taken by a baby almost completely eradicated that child's eczema.

Josephine Garvey has shown that ‘‘Neocate’’ is efficacious in bringing immediate and sustained improvement in symptoms of gastroesophageal reflux in infants. In *Glob-Sped AG v Hauptzollamt Lorrach* at paragraphs 26 and 28:-

> “26. It is settled law that, in the interests of legal certainty and for the ease of verification, the decisive criterion for the classification of goods for customs purposes is in general sought in their objective characteristics and properties defined in the wording of the relevant heading of the CN…..
>
> 11. In that regard, as the documents before the Court show, it is undisputed that the vitamin C content of the products in question is much greater than what is necessary or recommended for general dietary purposes….”

46. The evidence from Dr MacDonald not only indicated that ‘‘Maxamums’’ and ‘‘Neocate’’ were to be used for the treatment of patients, but that even the pre-mix, could, if necessary, be used for the same purpose. There is no doubt from the evidence that the products ‘object characteristics’ are as medicaments with both therapeutic and prophylactic properties. Further, the pre-mix at the point of entry into the United Kingdom has similar properties and is correctly classified under 30.03 and the Tribunal should so decide.

The decision

47. We have considered the law and the evidence and have decided that the pre-mix should be classified under Chapter 30 03. *Bioforce GmbH v Oberfinanzdirection Munchen (No1)* requires that we should decide what the objective characteristic of the pre-mix is. Substantial evidence has been given on behalf of SHS as to the medicinal effects of the end products ‘Maxamums’ and ‘Neocate’. We have no doubt that both products have therapeutic and prophylactic properties. The Oxford dictionary defines therapeutic as – “of or for or tending to the cure of disease, curative branch of medicine”; medical treatment and prophylactic as – “done or used as preventative against disease”. It defines disease as –“ a serious derangement of health, disordered state of an organism or organ, any particular form of this with special symptoms and name”. We are satisfied that the case studies and the evidence clearly show that the ‘Maxamums’ and ‘Neocate’ range of products have medicinal properties. Dr MacDonald is an eminent consultant dietician in inherited metabolic disorders. She has made it abundantly clear that she considers that both the ‘Maxamums’ and ‘Neocate’ range of products are medicinal and not food supplements. In fact, she went further in advising that the pre-mixes, the subject of this appeal, have the same qualities. Nor was she deterred in her view by robust cross-examination by Mr Mandalia.

48. We have found Dr Gamlen’s evidence to be unsatisfactory in that he appeared unfamiliar with the classification procedure and he was unable to provide a satisfactory definition for ‘medicament’. In any event we take the view that a ‘food preparation’ under 21 06 relates more properly to food taken as a supplement to an ordinary diet. On any definition, it needs to be reasonable pleasant to eat as food and to be priced at a level that is generally affordable. Mr Cowley has indicated that the

pre-mix "shows acute bitterness with astringent, sour and sulphurous notes'. We consider that to be a reasonable description of the tastes of both 'Maxamums' and 'Neocate' never mind the pre-mix. We are satisfied that because of:

- the fact that they are registered as Borderline Substances; that they can only be obtained by prescription; and
- the instructions on the 'XP Maxamums' tin reveal that the products are to be used under medical supervision… and it is not suitable as a sole source of nutrition (which a food; would have to be) and
- the cost of the products;

that the products are a 'medicament'.

49. We accept that it is the pre-mix that has been imported into the United Kingdom. We have decided that the pre-mix is also a medicament, because the 'objective characteristics' are shared by those of the products. They have been specifically prepared to the formulae required by SHS and have been manufactured away from the Liverpool factory because SHS cannot handle the production in view of the quantities required. The pre-mix is a substantial and essential part of the products. We have therefore decided that the pre-mix should be classified under 30 03. Dr Gamlen referred to Directive 1999/2W1/EC being the lists of substances for specific nutritional purposes. We have not been addressed by either counsel on that directive. We have, however, decided that the pre-mix is produced for specific medical nutritional problems and not merely for nutritional purposes and we have not therefore considered the directive further. We have not been addressed as to costs and we therefore award none.

49. This document contains full findings of fact and reasons for the decision. Any party dissatisfied with this decision has a right to apply for permission to appeal against it pursuant to Rule 39 of the Tribunal Procedure (First-tier Tribunal) (Tax Chamber) Rules 2009. The application must be received by this Tribunal not later than 56 days after this decision is sent to that party. The parties are referred to "Guidance to accompany a Decision from the First-tier Tribunal (Tax Chamber)" which accompanies and forms part of this decision notice.

TRIBUNAL JUDGE
RELEASE DATE: 16 February 2012