OPINION OF ADVOCATE GENERAL KOKOTT

delivered on 19 January 2006 [1]

I — Introduction

1. Are flakes made out of a silicone elastomer to be classified as a plastic, an artificial body part or a medicament under the Combined Nomenclature where they are imported into the Community in sterile packages of 1 kilogram in weight, are placed with a hydrogel into syringes here, and are thereafter implanted into the human body to treat incontinence?

2. This is the essence of the question referred by the Gerechtshof (Regional Court of Appeal) Amsterdam ('the national court') to the Court for a preliminary ruling in order to enable it to give a decision in a dispute between Uroplasty BV ('Uroplasty') and the Inspecteur van de Belastingdienst/Douane district Rotterdam ('the Inspector') in relation to a binding tariff information.

3. Whereas the Inspector classified the flakes as a plastic, Uroplasty and the national court consider they should be classified as an artificial body part. The Commission suggests classification as a medicament.

II — Legal framework

4. The legal framework for the case is provided by the Harmonised System ('HS') and the Combined Nomenclature ('CN').

A — *The Harmonised System*

5. The HS was set out by an international convention under the auspices of the World Customs Organisation. It is a multi-purpose nomenclature which is intended to encom-

1 — Original language: German.

pass all commodities traded internationally. The Community is a Contracting Party to the convention, [2] which is binding in English and French.

1. Medicaments

6. The authoritative language versions of heading 30.04 HS provide as follows:

'Medicaments ... consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses ... or in forms or packings for retail sale.'

'Médicaments ... constitués par des produits mélangés ou non mélangés, préparés à des fins thérapeutiques ou prophylactiques, présentés sous forme de doses ... ou conditionnés pour la vente au détail.'

7. The World Customs Organisation issues explanatory notes to the HS. They state the following as regards heading 30.04 HS:

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

(a) Put up in measured doses in forms such as tablets, ampoules ... capsules, cachets, drops or pastilles, medicaments in the form of transdermal administration systems, or small quantities of powder, ready for taking as single doses for therapeutic or prophylactic use.

...

The heading applies to such single doses whether in bulk, in packing for retail sale, etc.; or ...

(b) In packings for retail sale for therapeutic or prophylactic use. This refers to products ... 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.

2 — International Convention on the Harmonised Commodity Description and Coding System, OJ 1987 L 198, p. 3.

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.

Il n'est pas tenu compte du mode d'emballage de ses doses (vrac, emballages de vente au détail, etc.) pour le classement sous la présente rubrique.

On the other hand, even if no indications are given, unmixed products are to be regarded as being put up for retail sale for therapeutic or prophylactic use if they are put up in a form clearly specialised for such use.'

(b) Soit sous un conditionnement de vente au détail en vue d'usages thérapeutiques ou prophylactiques. Sont à considérér comme tels, les produits ... qui, en raison de leur conditionnement et notamment de la présence sous une forme quelconque d'indications appropriées (nature des affections contre lesquelles ils doivent être employés, mode d'emploi, posologie, etc.) sont identifiables comme destinées à la vente directe et sans autre conditionnement aux utilisateurs (particuliers, hôpitaux, etc.), pour être employé aux fins indiqués ci-dessus.

'La présente position comprend les médicaments constitués par des produits mélangés ou non mélangés, à condition qu'ils soient présentés:

(a) Soit sous forme de doses, c'est-à-dire, répartis uniformément sur les quantités dans lesquelles ils doivent être employés à des fins thérapeutiques ou prophylactiques. Ils se présentent généralement en ampoules ... cachets, comprimés, pastilles ou tablettes, médicaments sous forme de doses destinées à être administré par voie percutanée, ou même en poudre s'ils sont présentés sous forme de doses dans des sachets.

Ces indications (en toutes langues) peuvent être portées sur le récipient ou l'emballage, sur des notices jointes au produit ou de tout autre manière, la seule mention du degré de pureté (pharmaceutique ou autre) d'un produit ne suffisant pas toutefois à le faire classer ici.

En revanche, même en l'absence de toute indication, sont également à considérér comme conditionnés pour la vente au détail en vue d'usages thérapeutiques ou prophylactiques, les pro-

...

duits non mélangés, lorsqu'ils sont présentés sous des formes caractéristiques ne laissant aucun doute sur cette utilisation.'

2. Plastics

8. According to the World Customs Organisation's Explanatory Notes, the chapter relating to plastics and articles thereof is structured as follows:

'The Chapter is divided into two sub-chapters. sub-chapter I covers polymers in primary forms and sub-chapter II covers waste, parings and scrap, and semi-manufactures and articles.

In sub-chapter I, relating to primary forms, the products of headings 39.01 to 39.11 are obtained by chemical synthesis ...

In sub-Chapter II, ... [h]eadings 39.16 to 39.25 cover semi-manufactures or specified articles of plastics. Heading 39.26 is a residual heading which covers articles, not elsewhere specified or included, of plastics or of other materials of headings 39.01 to 39.14.'

'Le chapitre est divisé en deux sous-chapitres. Le sous-chapitre I couvre les polymères sous forme primaire et le sous-chapitre II les déchets, rognures et débris ainsi que les demi-produits et les ouvrages.

Dans le sous-chapitre I, relatif aux formes primaires, les produits de n^{os} 39.01 à 39.11 sont obtenus par synthèse chimique ...

Dans le sous-chapitre II ... [l]es n^{os} 39.16 à 39.25 couvrent les demi-produits ou certains ouvrages particuliers en matière plastique. Le n^{o} 39.26 est une position résiduelle qui couvre les ouvrages non dénommés ni compris ailleurs en matière plastique ou en autres matières des numéros 39.01 à 39.14.'

9. Heading 39.10 HS is:

'39.10 — Silicones in primary forms.'

'39.10 — Silicones sous formes primaires.'

10. The World Customs Organisation's Explanatory Notes describe the primary forms in more detail:

'Headings 39.01 to 39.14 cover goods in primary forms only. The expression "primary forms" is defined in Note 6 to this chapter. It applies only to the following forms:

...

(2) Powder, granules and flakes. In these forms they are employed for moulding, for the manufacture of varnishes, glues, etc. ...'

'Les n^{os} 39.01 à 39.14 couvrent uniquement les produits sous forme primaire. Le terme *formes primaires* est défini dans la note 6 du présent Chapitre et ne s'applique qu'aux matières présentées sous les formes ci-après:

...

(2) Sous forme de granulés, de flocons, de grumeaux ou de poudre. Sous ces divers aspects, ces produits peuvent être utilisés pour le moulage, pour la fabrication de vernis, de colles, etc. ...'

3. Artificial parts of the body

11. Heading 90.21 HS is:

'Orthopaedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability.'

'Articles et appareils d'orthopédie, y compris les ceintures et bandages médico-chirurgicaux et les béquilles; attelles, gouttières et autres articles et appareils pour fractures; articles et appareils de prothèse; appareils pour faciliter l'audition aux sourds et autres appareils à tenir à la main, à porter sur la personne ou à implanter dans l'organisme, afin de compenser une déficience ou une infirmité.'

B — *The Combined Nomenclature*

12. The CN is based on the HS and is likewise intended to enable classification of all commodities traded internationally. It adopted the structure of the HS, but includes another subdivision which serves tariff and

statistical purposes. The headings (the first four numbers) and the first level of subheadings (to the sixth number of the customs classification) are based on the HS. The further subdivisions are based solely on secondary Community law.

13. In the relevant period the CN provided inter alia as follows.

1. General rules for the interpretation of the Combined Nomenclature

14. The general rules for the interpretation of the Combined Nomenclature provide inter alia:

'1. The titles of sections, chapters and subchapters 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.

...

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 requires otherwise.'

2. Medicaments

15. Chapter 30 CN includes the following entries under heading 3004 CN:

'3004	Medicaments (excluding goods of heading No 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale.
3004 10	— ...

...		3926	Other articles of plastics and articles of other materials of heading Nos 3901 to 3914:
3004 90	— Other:		
	— — Put up in forms or in packings of a kind sold by retail:	3926 10 00	— ...
		3926 90	— Other:
...			
	— — Other:	3926 90 10	— — ...
3004 90 91	— — — Containing iodine or iodine compounds		— —Other:
3004 90 99	— — — Other'	3926 90 50	— — — ...
			— — — Other:
		3926 90 91	— — — — ...
		3926 90 99	— — — — Other'
'3910 00 00	Silicones in primary forms		
...			

16. The import of medicaments falling within these headings was duty free.

3. Plastics and articles thereof

17. Chapter 39 CN included the following entries inter alia:

18. The rate of duty on plastics within headings 3190 00 00 CN and 3926 90 99 CN was 6.5% in each case.

19. The explanatory notes to Chapter 39 CN include the following classification guidance:

'2. This chapter does not cover:

...

(r) Articles of Chapter 90 (for example, optical elements, spectacle frames, drawing instruments);

...

3. Heading Nos 3901 to 3911 apply only to goods of a kind produced by chemical synthesis, falling in the following categories:

...

(d) silicones (heading 3910);

...

6. In heading Nos 3901 to 3914, the expression "primary forms" applies only to the following forms:

...

(b) blocks of irregular shape, lumps, powders (including moulding powders), granules, flakes and similar bulk forms.'

4. Artificial parts of the body

20. Chapter 90 CN included the following entries under heading 9021 CN:

'9021 Orthopaedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or

	carried, or implanted in the body, to compensate for a defect or disability:	21. The explanatory notes to Chapter 90 CN included the following classification guidance:
	— Artificial joints and other orthopaedic or fracture appliances:	'1. This chapter does not cover:
	...	...
9021 19	— — Other:	
9021 19 10	— — — Orthopaedic appliances	(f) parts of general use, as defined in note 2 to section XV, of base metal (Section XV) or similar goods of plastics (Chapter 39);
...		...
9021 30	— Other artificial parts of the body:	
	...	2. Subject to note 1 above, parts and accessories for machines, apparatus, instruments or articles of this chapter are to be classified according to the following rules:
9021 30 90	— — Other	
...		...
9021 90	— Other:	
...		(b) Other parts and accessories, if suitable for use solely or principally with a particular kind of machine, instrument or apparatus, or with a number of machines, instruments or apparatus of the same heading
9021 90 90	— — Other'	

(including a machine, instrument or apparatus of heading No 9010, 9013 or 9031) are to be classified with the machines, instruments or apparatus of that kind'.

22. With effect from 1 January 2002 Note 6 to Chapter 90 CN states:

'6. For the purposes of heading 9021, the expression "orthopaedic appliances" means appliances for:

— Preventing or correcting bodily deformities; or

— Supporting or holding parts of the body following an illness, operation or injury.'

23. At the material time the import of items falling within this heading and its subheadings was duty free.

III — Facts and main proceedings

24. Uroplasty manufactures the product Macroplastique-implantaat ('Macroplastique'). The essential components of Macroplastique are sterile flakes of polydimethylsiloxane — a silicone in the form of an elastomer — which vary in structure and dimension, ranging from 0.01 mm to about 5.0 mm.

25. To treat stress incontinence and vesicoureteral reflux, Macroplastique flakes are inserted into the muscular tissue of the neck of the bladder or the mouth of the urethra. The body encapsulates the flakes by connective tissue so that they remain permanently in that place in the body. As a result of the accumulation of the encapsulated flakes the neck of the bladder or the mouth of the urethra is narrowed and the problems caused by certain forms of incontinence can be reduced or remedied.

26. In order to make it possible to insert the flakes into the body, they are dissolved in a sterile hydrogel which renders them soft and flexible, distributes them evenly throughout the liquid, and ensures that they pass easily through a hypodermic needle. Whereas the flakes remain behind after the injection, the hydrogel is removed from the body.

27. Uroplasty obtains the polydimethylsiloxane flakes it uses in Macroplastique from the United States of America, where they are manufactured. There they are sealed under sterile conditions in bags of around 1 kilogram and are sent to the Netherlands. The bags are opened under sterile conditions at one of Uroplasty's establishments, the flakes are inserted into the hydrogel, and the solution is placed in hypodermic syringes of either 1.5 ml or 2.5 ml volume, which are intended for single use. In this state Macroplastique is supplied to doctors and hospitals, ready for use.

28. On 22 February 2001 Uroplasty made an application to the Inspector for the issue of a binding tariff information in respect of 'polydimethylsiloxane in the form of white flakes' and proposed classification under subheading 9021 90 00 CN. A sample of the product, a brochure and a pre-filled hypodermic syringe as supplied to doctors and hospitals were submitted with the application.

29. The Inspector sent the sample to the laboratory of the Inland Revenue Department for more detailed examination. The result of the examination of the sample of 20 March 2001 is worded — in so far as it is relevant — as follows:

'... Polydimethylsiloxane in the form of white flakes. Recommended commodity code: 3910.0000 ...'

30. On 26 April 2001 the Inspector issued his binding tariff information and classified the product under subheading 3910 00 00 CN. He gave his reasons by referring to the wording of CN headings 3910, 3910 00 and 3910 00 00 and to General Rules 1 and 6 CN. In the binding tariff information the product is described as follows:

'Polydimethylsiloxane in the form of white flakes, a semi-finished product which after being dissolved in a biodegradable gel of polyvinylpyrrolidone (PVP) is inserted as a medical implant into the muscular tissue of the bladder or urinary passages.'

31. In another binding tariff information the hypodermic syringes filled with Macroplastique were classified under subheading 9021 90 90 CN. The classification was justified again by reference to the application of General Rules 1 and 6 CN, and this time by the wording of CN codes 9021, 9021 90 and 9021 90 90. The finished product was described as:

'An implant in the form of a gel, consisting of polydimethylsiloxane dissolved in polyvinyl-

pyrrolidone and water, sterile packed in bags made of a metal foil and with a content of 3 cc. The product is injected into the muscular tissue of the bladder or urinary passages and serves to make them elastic, thereby reducing and relieving incontinence. The product, put up for retail sale, is intended for medical and/or surgical use.'

32. Uroplasty remained of the view that Macroplastique flakes should be classified under heading 9021 CN and not under heading 3910 CN, and accordingly raised an action challenging the binding tariff information before the Gerechtshof Amsterdam.

33. The national court was unsure as to the correct classification for Macroplastique flakes. The flakes were manufactured with precision and under sterile conditions. They were accordingly a high value product intended solely to remedy a physical defect or disability. In addition, the mixing of the flakes with the hydrogel was strictly temporary, and was intended solely to enable them to be injected into the human body. The flakes were therefore to be regarded as an end product and not as a raw material or a semi-finished product. On that basis the national court thought that heading 9021 CN was more appropriate than heading 3910 CN. However, it was uncertain whether heading 9021 CN was broad enough to cover a product such as Macroplastique flakes. If it did not, the national court was of the view that the product should be classified under heading 3926 CN.

34. The national court also queried which General Rule was to be applied in classifying the product and which subheading was applicable if Macroplastique flakes were to be classified under heading 9021 CN.

IV — Reference for a preliminary ruling

35. For those reasons by order dated 30 November 2004 lodged at the Registry of the Court on 15 December 2004 the Gerechtshof Amsterdam referred the following questions to the Court for preliminary ruling:

'(1) (a) Must heading 9021 of the CCT be interpreted as meaning that a product consisting of sterile, white flakes of polydimethylsiloxane, specially developed and intended solely for use as a medical/surgical implant, can be classified under that heading?

(b) If so, under which subheading of heading 9021 of the CCT must the product be classified?

(2) If heading 9021 is not possible in this case, is the product eligible for classification under heading 3926 of the CCT?

(3) If not, classification under which other heading results from the interpretation of the CCT?'

36. The Netherlands Government, Uroplasty and the Commission made written observations in the proceedings before the Court.

V — Legal analysis

37. Although it has posed its question in stages, the Gerechtshof Amsterdam is ultimately seeking guidance as to the classification of Macroplastique flakes.

A — *Submissions of the parties*

38. The Inspector and the Netherlands submitted that Macroplastique flakes were to be classified under heading 3910 CN. The flakes were a silicone in one of the primary forms mentioned in that heading. It was not an end product, because the flakes had to be mixed with a hydrogel before they could be used. Accordingly, the flakes were not to be regarded as an orthopaedic appliance within the meaning of heading 9021 CN either.

39. Uroplasty emphasised that Macroplastique flakes were an end product which was not changed by being mixed with hydrogel. The sole purpose of the mixing was to ensure that the flakes were injected effectively, but this could also be achieved by other means without affecting the product's effects. Both the flakes and the hypodermic syringes prefilled with Macroplastique were to be classified under heading 9021 CN. The correct subheading was 9021 90 90 CN, the product being an implant which was an alien object inserted into the body, and not a prosthetic replacing a part of the body which had ceased to perform its function, within the meaning of subheading 9021 30 90 CN. Heading 3926 CN was not appropriate, because the only end products it encompassed were consumables not requiring medical intervention.

40. The Commission was of the view that the wording of heading 9021 CN did not cover implants such as Macroplastique flakes and that accordingly it was only by analogy that they could be classified under that heading. However, this classification was precluded by the fact that the wording of other headings covered the product. This

was in particular the case as regards heading 3004 CN, a more specific provision which had to be applied in precedence to headings 3910 CN and 3926 CN. The way they functioned meant that Macroplastique flakes satisfied the Community definition of medicaments. The fact that heading 3004 CN covered medicaments only if imported in measured doses did not preclude classification under it, as was clear from the World Customs Organisation's Explanatory Notes to heading 30.04 HS, under letter (b).

B — *Legal criteria*

41. As I explained in my Opinions in *Ikegami* and *Algemene Scheeps Agentuur Dordrecht*, [3] the correct approach to classifying commodities in the Combined Nomenclature is as follows.

42. First, the intended use and material composition of the article must be precisely determined. Next, in the light of the wording of the headings of the relevant sections and chapters a provisional classification must be undertaken according to the article's intended use and material composition. There must then be considered whether on a combined examination of the wording of the headings and the explanatory notes to the relevant sections and chapters a definitive classification may be reached. If not, then in order to resolve the conflict between the competing provisions recourse must be had to Rules 2 to 5 of the general rules. Lastly, classification must be made under the subheadings.

43. Classification must proceed on a strictly hierarchical basis taking each level of the CN in turn. The wording of one heading can be compared only with the wording of another heading; the wording of a first subheading can be compared only with the wording of other first subheadings of the same heading; and the wording of a second subheading can be compared only with the wording of other second subheadings of the same first subheading. [4]

44. In this exercise the wording of the headings and the explanatory notes of the CN are to be interpreted so as to be consistent with the Harmonised System. The Court has consistently held that the explanatory notes drawn up, as regards the Harmonised System, by the World Customs Organisation, may be an important aid to the interpretation of the individual tariff headings, although they do not have legally binding force. [5]

3 — See my Opinions in Case C-467/03 *Ikegami Electronics (Europe)* v *Oberfinanzdirektion Nürnberg* [2005] ECR I-2389, points 31 to 36, and in Case C-311/04 *Algemene Scheeps Agentuur Dordrecht* v *Inspecteur der Belastingdienst — Douanedistrict Rotterdam* [2006] ECR I-609, points 27, 28 and 35.

4 — See my Opinion in *Ikegami Electronics (Europe)* (cited above, footnote 3), point 34.

5 — See Case C-328/97 *Glob-Sped* v *Hauptzollamt Lörrach* [1998] ECR I-8357, paragraph 26, and Case C-201/96 *LTM* [1997] ECR I-6147, paragraph 17.

C — *Guidance on classification*

45. Although it is for the national courts to apply the Community law criteria to the particular case,[6] the Court is able to give indications and guidance by reference to the facts of the individual case.[7]

1. Classification of the commodity

46. According to the information provided by the national court, Macroplastique flakes are a silicone elastomer in the form of flakes varying in dimension from approximately 0.01 mm to 5.0 mm. They are manufactured under sterile conditions, and imported into the Community in sterile bags of approximately 1 kilogram in weight.

47. It is not disputed that given these essential characteristics Macroplastique flakes are intended for the sole purpose of being injected as an implant into the human body and of remaining there to treat incontinence. For that purpose, once within the Community they are mixed with a hydrogel which makes them soft and flexible and are placed into syringes of 1.5 ml and 2.5 ml. The syringes are delivered to doctors and hospitals in that condition, ready to use. Subsequently the hydrogel is removed from the human body.

2. Classification according to the wording of the headings

48. On the wording of the headings, the essential characteristics of Macroplastique flakes suggest they should be classified under headings 3910 CN or 3926 CN, whereas their objective purpose suggests classification under heading 3004 CN or 9021 CN.

49. As regards *heading 3910 CN*, under which the Inspector classified the flakes, it is first to be recalled that Macroplastique flakes consist in a silicone within the meaning of that heading,[8] and in a form identified in note 6 to Chapter 39 CN[9] as one of the primary forms.

6 — See Case C-424/97 *Salomone Haim* v *Kassenzahnärztliche Vereinigung Nordrhein* [2000] ECR I-5123, paragraph 44, and Joined Cases C-46/93 and C-48/93 *Brasserie du Pêcheur and Factortame* [1996] ECR I-1029, paragraph 58.

7 — See Case C-150/99 *Stockholm Lindöpark* v *Sweden* [2001] ECR I-493, paragraph 38; Case C-392/93 *The Queen* v *HM Treasury*, ex parte *British Telecommunications* [1996] ECR I-1631, paragraphs 41 ff.; Joined Cases C-283/94, C-291/94 and C-292/94 *Denkavit International and Others* [1996] ECR I-5063, paragraphs 49 ff.; and Case C-224/01 *Köbler* v *Austria* [2003] ECR I-10239, paragraphs 101 ff.

8 — See note 3 to Chapter 39 CN (cited above, point 19).

9 — See above, point 19.

50. However, it follows from the very concept of a primary form, the structure of Chapter 39 HS and CN,[10] and note 1(f) to Chapter 90 CN[11] that heading 3910 CN is intended to encompass only silicones which are to be subjected to a further process. Ultimately, the primary forms specified there are raw materials which are particularly suited to further processing and which are intended for that. This heading, which is for primary products, is not intended to cover end products.

51. The national court is correct in its view that Macroplastique flakes are not a raw material to be subjected to further processing but are an end product which cannot be classified under heading 3910 CN. First, the flakes are manufactured with precision so as to be between 0.01 mm and 5 mm in size, and second, they are manufactured and packaged under sterile conditions. Both are sophisticated, cost-intensive, and unusual in the preparation of raw materials.

52. In addition, the ultimate purpose for which Macroplastique flakes are used, and which is not disputed, suggests that they are an end product and should not be classified under heading 3910 CN. After being injected into the human body, the flakes, and nothing else, remain there, whereas the hydrogel injected with them is removed. The mixing with the hydrogel is therefore temporary and has the sole purpose of improving the placing of the flakes into the human body which, according to the manufacturer, could be achieved in other ways, without mixing them with a hydrogel. It therefore cannot be held that Macroplastique flakes are a semi-finished product which becomes an end product only once mixed with a hydrogel.

53. Thus, the national court was correct to hold that this is a high-value end product manufactured with precision and packaged under sterile conditions which cannot be classified under heading 3910 CN as a silicone in primary form.

54. As regards *heading 3004 CN*, which the Commission considers to be the correct one, it is unnecessary to decide whether Macroplastique flakes come within the relevant definition of medicaments. This is because they are not imported into the Community 'in measured doses or in forms or packings for retail sale', as they would have to be in order to be classified under heading 3004 CN.

55. Contrary to the Commission's submission, this follows also from the World Customs Organisation's Explanatory Notes to the HS. They state that a 'dose' is a measured unit of a medicament the amount

10 — See above, point 10.
11 — See above, point 21.

of which has been determined for use as a single dose. The only circumstance in which the fact that a delivery is *wholesale* does not preclude classification under heading 30.04 HS is where the wholesale delivery consists in such single doses. [12]

56. A medicament is put up in a 'form or packing for retail sale' if its packaging, form, and labelling make it clear that it is intended for direct sale to final consumers without being re-packaged. If there are no directions for use, the labelling must make it clear beyond doubt that it is intended for direct delivery to final consumers. [13]

57. Macroplastique flakes are imported into the Community in packages of approximately 1 kilogram. By contrast, retail sale is of 1.5 ml to 2.5 ml of a hydrogel solution which contains flakes. The mixing and filling into ready-to-use hypodermic syringes are not done until the goods are inside the Community. It follows that what is imported is neither a single dose nor a form or packing for retail sale.

58. By contrast, the wording of *heading 9021 CN* offers at least a possibility that it covers Macroplastique flakes. Specifically, they may be classified as,'other appliances which are ... implanted in the body, to compensate for a defect'. It is unnecessary to decide whether they could also be classified as 'other orthopaedic appliances'.

59. Although one would normally regard the term 'appliance' as referring to some sort of technical apparatus, an approach based on the wording of the HS requires a broad interpretation. The English word 'appliance' [14] means not only 'apparatus', 'instrument', or 'device' but also 'medical support' or 'support'. That the English word 'appliance' is in fact intended to include the German 'Hilfsmittel' ('medical support') is demonstrated for example by the first item specifically mentioned, indicating that crutches are 'orthopaedic appliances', which in Germany are regarded as medical supports ('Hilfsmittel').

60. The French version uses the phrase 'articles et appareils' [15] almost throughout as the equivalent to the English 'appliance', even where the English version uses the phrase 'artificial parts of the body'. Whereas 'appareil' could be rendered in German as

12 — See above, point 7.
13 — See above, point 7.
14 — See above, point 11.
15 — See above, point 11.

'Apparat' ('apparatus') or 'Gerät' ('instrument'), 'article' corresponds best to the German 'Ware' ('product') or 'Gegenstand' ('object'). This too is intended to encompass medical supports and other objects having a medical purpose. This confirms that a broad interpretation is to be given to the German word 'Vorrichtung' where it appears in the CN.

61. Thus, read as a whole heading 9021 CN assumes a broad interpretation and is intended to cover all medical objects by means of which the medical purposes identified in the heading are pursued. [16] Accordingly, the term 'appliance' does not restrict the technical structure of a product but is intended to encompass also 'medical supports', 'supports', 'products' and 'objects' which are intended to compensate for defects by being implanted into the body.

62. Macroplastique flakes satisfy these requirements. The fact that they are manufactured precisely, under sterile conditions and at high cost, together with the way in which they function, which requires a number of differently sized flakes to combine, mean that they may well satisfy the strict meaning of the term 'appliance'. However, they are covered in any event as 'medical supports', 'supports', 'products' or 'objects' intended to assist in compensating for defective sphincter muscles by being implanted in the body. This is because this is the purpose which, objectively, their essential characteristics are designed to achieve. It follows that it is possible to classify them under heading 9021 CN.

63. According to Explanatory Notes 2(r) to Chapter 39 CN [17] and 1(f) to Chapter 90 CN, [18] heading 9021 CN takes precedence over the headings in Chapter 39 CN. According to Explanatory Note 2(b) to Chapter 90 CN, [19] this applies even if only the ready-to-use, pre-filled hypodermic syringes are regarded as end products, because it is clear that the flakes in question are intended solely for use in them. [20]

64. Thus, heading 9021 CN takes precedence over heading 3926 CN, which might also be applicable in the case of products made from plastics. It is accordingly unnecessary to consider the latter heading in any more detail.

16 — The fact that in the last possibility considered in the present case, the French text uses only the word 'appareil' for the English word 'appliance' and not the phrase 'articles et appareils' is not to be regarded as disclosing a restrictive intention. Instead, a single, broad interpretation covering all the possibilities is to be adopted.

17 — See above, point 19.

18 — See above, point 21.

19 — See above, point 21.

20 — See the above discussion as to whether Macroplastique flakes are an end product, points 51 to 53.

3. Classification according to the wording of the subheadings

65. Uroplasty suggested classification under subheading 9021 90 90 CN, whereas the national court held classification under subheading 9021 30 90 CN to be correct.

66. Macroplastique flakes can be classified under subheading 9021 30 CN only if they are 'artificial parts of the body' or 'other artificial parts of the body'. The essence of an artificial body part is that it is a substitute performing the function of a defective part of the human body — generally of a part providing movement or support. This is made particularly clear by the English version of the HS, which uses the term 'artificial parts of the body' for the German 'Prothese' ('prosthetic'). It follows that an orthopaedic appliance must equally be intended to substitute for at least part of some bodily function.

67. However, the information provided by the national court does not indicate that Macroplastique flakes have any such function of substitution. According to it, the flakes do not themselves perform the function of the defective muscles, but instead promote the growth of connective tissue. The growth of collagen around the flakes is intended to result in a narrowing which improves the efficiency of the muscle fibres which still function so that they make up for the failure of the muscle fibres which do not function. In other words, the flakes do not substitute for muscle fibres, because they cannot perform their function or provide their strength, but they compensate for their failure by means of a different mechanism, namely by indirectly filling the gap left by those muscles.

68. This modus operandi is more similar to that of a medicament (as the Commission argued) than to that of an artificial body part and suggests classification as an 'other appliance ... implanted in the body, to compensate for a defect': in other words, under subheading 9021 90 CN.

69. Classification under subheading 9021 19 CN as an 'other orthopaedic appliance' might also be thought appropriate. However, the use of Macroplastique flakes is more closely connected to urology, which is concerned with urinary organs, than to orthopaedics, which is concerned with defects in body parts which support movement, such as bones, joints, muscles and tendons. This is not affected by the new Explanatory Note 6 to Chapter 90 CN,[21] since 'supporting or holding parts of the body following an illness' is performing the function of muscles and tissue which provide support.[22]

21 — See above, point 22.

22 — This observation cannot be applicable in the present Case, having been adopted into the CN after the facts of the present Case occurred.

70. On the basis of the available information, classification under subheading 9021 90 CN as an 'other appliance ... implanted in the body, to compensate for a defect' is to be recommended to the national court. The only other possible subheading is subheading 9021 90 90 CN.

4. Conclusions

71. Accordingly, the national court's first question can be answered to the effect that a product such as that described in the request for a preliminary ruling may be classified under subheading 9021 90 90 CN. It is unnecessary to answer the second and third questions.

VI — Conclusion

72. On the basis of the foregoing considerations, I suggest to the Court that it should answer the Gerechtshof Amsterdam as follows:

'Subheading 9021 90 90 CN is to be interpreted as meaning that a product such as that described in the request for a preliminary ruling — a silicone elastomer in the form of flakes which vary in dimension from 0.01 mm to around 5.0 mm, which are manufactured under sterile conditions, which are imported into the Community in sterile bags of about 1 kilogram in weight to be placed with a hydrogel into 1.5 ml and 2.5 ml hypodermic syringes, and which are to be implanted into the human body for the purpose of treating incontinence — may be classified under that subheading.'