# IN THE CUSTOMS, EXCISE AND SERVICE TAX APPELLATE TRIBUNAL
# CHENNAI

REGIONAL BENCH – COURT NO. III

## Customs Appeal No.204 of 2012

(Arising out of Order-in-Appeal No.C.Cus No.480/2012 dated 15.06.2012 passed by Commissioner of Customs (Appeals), Chennai)

**Dr. Reddy's Laboratories Ltd.**
7-1-27 Ameerpet,
Hyderabad 500 016 **...Appellant**

**VERSUS**

**Commissioner of Customs (AIR),**
Airport & Air Cargo Complex,
New Custom House,
Meenambakkam,
Chennai 600 027 **...Respondent**

**APPEARANCE:**

Mr. P.R. Renganath, Advocate for the Appellant
Ms. Anandalakshmi Ganeshram, Superintendent (A.R) for the Respondent

**CORAM:**

**HON'BLE MS. SULEKHA BEEVI C.S., MEMBER (JUDICIAL)**
**HON'BLE MR. VASA SESHAGIRI RAO, MEMBER (TECHNICAL)**

**DATE OF HEARING : 01.03.2023**
**DATE OF PRONOUNCEMENT:17.03.2023**

**FINAL ORDER NO. 40176 / 2023**

**Order : [Per Ms. Sulekha Beevi C.S.]**

1. Brief facts are that the appellant imported a consignment of 270 Kg 'Saccharomyces Boulardii' in bulk, valued at Euro 80190 (CIF) *vide* Bill

of Entry dated 21.03.2009 under DEPB Scheme. The Bill of Entry was facilitated through RMS without assessment and examination. The appellant had declared the classification as CTH 29183090 and duty was debited by the system accordingly. During post clearance audit, it was noticed from the analytical certificate dated 26.02.2009 issued by the supplier, that the goods imported are mentioned as 'Lyophilized Saccharomyces Boulardii'. The description was noted as 'light brown powder with characteristic odour' and identified as 'ovoid yeasts to the exclusion of all other micro organism'. The report did not mention the presence of any other ingredient. The Department was of the view that the goods are rightly classifiable as yeast under chapter 21 and not under CTH 29183090 as 'Carboxylic acid'. Yeast, active or inactive is specifically mentioned under CTH 2102. The 'Saccharomyces Boulardii' being yeast falls under CTH 21021090. Show Cause Notice was issued proposing to re-determine the classification of the goods and for demand of differential duty along with interest. After due process of law the original authority confirmed the classification under 21021090 and also confirmed the demand of the differential duty of Rs.13,57,549/- along with interest. On appeal, the Commissioner (Appeals) *vide* order impugned herein upheld the same. Hence this appeal.

*2.* On behalf of the appellant the learned counsel Shri. P.R. Renganath appeared and argued. It is submitted that the goods imported are 'Lyophilized Saccharomyces Boulardii' which is Saccharomyces Boulardii cells and 13% of lactose. The authorities below erred in observing that the test report issued by supplier did not mention the presence of any other ingredient. A mere perusal of the certificate

issued by Biocodex (the manufacturers) clearly indicates the imported material to be "bulk of lyophilized Saccharomyces Boulardii, composed of Saccharomyces Boulardii cells and 13% of lactose". It is to be noted that lactose is a necessary component or in pharmaceutical terms is an "active ingredient" without which the drug substance "lyophilized Saccharomyces Boulardii" would be unviable, that is, it will not perform the pharmacological function that is meant to be performed. The process of lyophilisation with the adjunct of lactose is absolutely essential to render the probiotic characteristics to the drug substance, which is the ability of the drug substance, lyophilized Saccharomyces Boulardii to pass through the gastric system without being broken down as part of the digestive process and to be delivered in the gut where its therapeutic process commences. Without the lyophilisation with the adjunct of lactose, Saccharomyces Boulardii by itself would be unviable. Also lactose the SECOND CONSTITUENT is not present in trace quantities but at a SIGNIFICANT 13% (THIRTEEN PERCENT) weight by weight. This clearly goes on to establish that the said product as in the form in which it is imported falls under Chapter 3003 of CTA, 1975 satisfying the criteria, *"consists 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."*

3. The learned counsel submitted that the imported goods being a medicament would be outside the scope of Chapter 21 of CTA, 1975. These are drugs within the meaning of Section 3(b) of the Drugs and Cosmetics Act, 1940. The learned counsel adverted to Chapter Note 1(f) of Chapter 21 and pointed out that this chapter note categorically states that

'yeast put up as a medicament or other products of heading 3003 or 3004" are excluded from Chapter 21. Lyophilized Saccharomyces Boulardii contains 13% lactose and was imported in bulk. Therefore being a medicament cannot be classified under Chapter 21.

4. There is abundant medical literature that Saccharomyces Boulardii is a medicine used for treatment of antibiotic-associated diarrhoea, acute diarrhoea in children and in adults, traveller's diarrhoea, AID's related diarrhoea, clostridium difficile disease, relapses of Crohn's disease etc. The product is sold as a medicine in pharmacies. The product is to be consumed as per the dosage prescribed by a Physician. Further, that the imported goods are drug within the meaning of Section 3(b) of the Drugs and Cosmetics Act, 1940. The appellant holds necessary permission under the Drugs and Cosmetics Act & Rules to import Saccharomyces Boulardii. In the Analysis Certificate issued by the supplier it is stated that it has expiry period which is 3 years. This itself would indicate that it is a medicine, rather than an edible preparation under chapter 21 which products have usually shorter shelf-life.

5. To support the argument that the goods are medicaments, the learned counsel relied on various literature which are as under:

(i) (Textbook) Gut Microflora-Digestive Physiology and Pathology-John Libbey Eurotext, Paris.

> *"Lyophilised Saccharomyces boulardii is produced by freeze-drying in the presence of lactose, a method which preserves the yeast's viability and stability. Analysis of the pharmacodynamis properties of*

*Saccharomyces boulardii has shown that its activities are largely dependent upon its ability to survive. As with all yeasts, Saccharomyces boulardii is naturally resistant to antibacterial antibiotics: its MIC for almost all antibiotics investigated is very high (over 128) mg/L) [7].*

*Saccharomyces boulardii is resistant to gastric acidity and to proteolysis, so that it can reach very rapidly high concentrations in the gastrointestinal tract and then persist there at a constant level in viable form [6]"*

(ii) (Journal) Gastroenterology Clinics of North America,

*"Saccharmyces boulardii is a nonpathogenic yeast widely prescribed in a lyophilized form in many countries of the world and used in adults and children as a biotherapeutic agent [1,2]. Controlled clinical trials have demonstrated the efficacy of S boulardii for preventing or treating several intestinal disorders including antibiotic associated diarrhoea [3,4], recurrent Clostridium difficile discase [5,6], C difficile associated enterocolopathies in infants and children [7], acute diarrhoea in children [8] and in adults [9], traveler's diarrhoea [10,11], diarrhoea I tube-fed patients [12], AIDS related diarrhoea [13], and relapses of Crohn's disease [14] or ulcerative colitis [15].*

*S boulardii differs from S cerevisiae by several taxonomic, metabolic, and genetic properties [16,17]. Lyophilized S boulardii is obtained by cryodessication, a technique that allows it to preserve viability and stability. The pharmacodynamic properties of S boulardii are linked mostly to the revitalization capacity of the yeast after oral administration to the host.*

*According to these pharmacological and clinical data, S boulardii is a biotherapeutic medication clearly distinct from nutrient probiotic foods containing various species of micro organisms or of substances able to modify the microflora and given in fermented milks or in yogurts to improve host physiology [11]."*

(iii) [Article Review]-Therapeutic Effects of Saccharomyces Boulardii in Crohn's Disease (adapted from Z Gastroenterol 1993; 31:129-134)

*" The effects of the well-known yeast preparation Saccharomyces boulardii (S.b.), which has been used so far mainly in the treatment of acute diarrhoea and in the prevention of antibiotic-associated diarrhoea, are attributed partly to its inhibitory effect on the growth of interstinal germs and to the neutralization of toxins." Furthermore S.b. has been shown to increase the activity of brush border disaccharidases in human*

*volunteers and patients with congenital sucrose isomatase deficiency, an effect, which can be used in the prevention of diarrhoea in this syndrome. In addition, the immune system is probably supported by an enganced release of secretoy lgA into the intestinal lumen. Due to these specific effects of S.b. on the intestinal flora and in view of the mentioned immunopathogenic concepts concerning the etiology of Crohn's disease, there was good reason to investigate also the effects of S.b. in patients suffering from Crohn's disease."*

(iv) Journal Correspondence-Clinical infectious Diseases-February 1996-

*" However, S. boulardii is a completely different species of yeast from baker's, brewer's, or wine yeast, and thus the results of S. boulardii therapy in the cited clinical studies are not applicable to S. cerevisiae therapy or to the four case descriptions. S. boulardii has been shown to be a separate species of Saccharomyces on the basis of several taxonomic, metabolic, and molecular parameters. S. boullardi is a wild Saccharomyces strain that does not produce ascospores or use galactose as a carbon source (as do wild S. cerevisiae strains). This strain is also given a separate designation by the American Type Culture Collection (ATTC #74012). S. boulardii has different oxidative utilization and fermentation patterns that can distinguish it from S. cerevisiae (Professor Jean-Marie Bastide, personal communication)."*

6. The learned counsel pointed out that the authorities below had erroneously relied on the decision passed in the case of *Kasturi Foods & Chemicals Vs CCE 1995 (77) ELT 584 (Tribunal)* which is distinguishable on facts. Though similar issue came up for consideration, there was no medical literature furnished by the assessee therein to prove that the imported goods are medicaments. Further in that case the goods imported are "Saccharomyces Cerevisiae" which is different from the goods imported by the appellant herein. The goods were imported by assessee therein as raw materials for preparation of medicament. The appellant has imported the goods in bulk and is clearing them as such by packing them into

sachets. The learned counsel therefore urged that the decision laid in Kasthuri Foods (*supra)* is not applicable as the facts are entirely different.

7. The learned counsel drew support on the judgment of the Hon'ble Apex Court in the case of *Commissioner of Central Excise Vs. Wockhardt Life Sciences Ltd. 2012 (227) ELT 299 (S.C.)* to argue that one major factor that has to be looked into is whether the goods are understood as pharmaceutical product in common parlance. Saccharomyces Boullardii is used as medicaments for gut related disease.

8. The decision in the case of *CCE Hyderabad Vs. Sarvotham Care Ltd. 2015 (322) ELT 575 (SC)* was relied to argue that when the product is used as per prescription of Physician, it would be a medicament. The learned counsel submitted that "Saccharomyces Boulardii" has to be taken in measured doses as per direction of physician, which would establish that it is a medicament.

> *" 16. The use is suggested only on the advice of a Doctor and there is a suggestion that literature/material showing that dandruff is a disorder which affects the hairy scalp. It is generally triggered by a single celled organism which is kind of fungus, with scientific name 'Pityrosporum Ovale'. For treatment of this disease, 'Nizral Shampoo' is to be used like a medicine, unlike other normal Shampoos."*

9. The decision in the case of *CCE Chennai Vs. Hindustan Lever Ltd. 2015 (323) ELT 209 (SC)* was relied to contend that the onus lies on the Revenue to establish that the product is not a medicament. The learned counsel prayed that the appeal may be allowed.

10. The learned AR G. Anandalakshmi Ganeshram supported the findings in the impugned order. The chapter heading in Chapter 21 was referred by the learned AR to explain that *"Yeast (active or inactive); other single cell micro-organisms, dead (but not including Vaccines of heading 30.02); prepared baking powders"* come under this heading. In ordinary parlance the impugned goods are known as yeasts'. The goods are not medicaments so as to merit classification under 3003 or 3004. The main argument of the appellant is that the imported goods contain one other ingredient viz; lactose which is added for its pharmacological function. The said argument is incorrect. As per the Analysis report issued by the supplier the goods are described as "Ovoid Yeasts to the exclusion of all other micro-organisms". The presence of lactose in small quantity is only for the purpose of stabilization i.e; lyophilization. This not take away the essential nature of the goods which is nothing but active micro organism-yeast. The learned AR referred to Part (B) of Chapter 21 and argued that even if stabilizing agents and antioxidants are added, yeast has to be classified under Chapter 21. The relevant Part (B) of Chapter 21 reads as under:

> ***"(B) OTHER SINGLE CELL MICRO-ORGANISMS, DEAD***
> *This category covers single-cell micro-organisms such as bacteria and unicellular algae, which are not alive. Inter alia, covered here are those which have been obtained by cultivation on substrates containing hydrocarbons or carbon dioxide. These products are particularly rich in protein and are generally used in animal feeding.*
>
> *Certain products of this group may be put up as food supplements for human consumption or animal feeding (e.g., in powder or tablet form) and may contain small quantities of excipients, e.g., stabilizing agents and anti-oxidants. Such products remain classified here provided that the addition of such ingredients does not alter their character as micro-organisms."*

11. It is submitted that the very same issue came up for consideration in the case of *Kasthuri Foods and Products (supra)* and the Tribunal held that the goods are classifiable under Chapter 21. The said decision was followed in the case of *M/s. Zymonutrients Ltd*. Final Order No.41574-41580/2019 dated 26.11.2019. Learned AR prayed that the appeal may be dismissed.

12. Heard both sides.

13. The moot point to be decided is whether the imported goods merit classification under 29183090 as adopted by appellant or under 21021090 as determined by the Department. It is to be mentioned that at the time of import, though appellant classified the goods under CTH 29, the argument now advanced is that being a medicament which falls under CTH 30, the goods cannot be classified under Chapter 21. For better appreciation the relevant tariff headings are noticed as under:

| **Tariff Item** | **Description of goods** | **Unit** | **Rate of duty€#** | |
|---|---|---|---|---|
| | | | *Standard* | *Preferential Areas* |
| (1) | (2) | (3) | (4) | (5) |
| **2102** | **Yeasts (active or inactive); other single cell micro-organisms, dead (but not including vaccines if heading 3002); prepared baking powders** | | | |
| 2102 10 | - *Active yeasts*: | kg. | 30% | - |
| 2102 10 10 | --- Culture yeast . . . . . | kg. | 30% | - |
| 2102 10 20 | . . . | kg. | 30% | - |
| 2102 10 90 | --- Baker's yeast . . . . . | kg. | 30% | - |
| 2102 20 00 | . . . | kg. | 30% | - |
| 2102 30 00 | --- Other . . . . . | kg. | 30% | - |
| | . . . . | | | |
| | --- Inactive yeasts, other single-cell micro-Organisms, dead . . . . . | | | |
| | . . . . . | | | |
| | - Prepared baking powders . . . . . | | | |

*"Chapter 21 Miscellaneous edible preparations:*

*1. This Chapter does not cover:*

*(a) mixed vegetables of heading 0712;*

*(b) roasted coffee substitutes containing coffee in any proportion (heading 0901);*

*(c) flavoured tea (heading 0902)*

*(d) spices or other products of headings 0904 to 0910;*

*(e) food preparations, other than the products described in heading 2103 or 2104, containing more than 20% by weight of sausage, meat, meat offal, fish or crustaceans, mollusks or other aquatic invertebrates, or any combination thereof (Chapter 16);*

*(f) Yeast put up as a medicament or other products of heading 30.3 or 30.04; or*

*(g) prepared enzymes of heading 3507."*

" ***(A)Yeasts***

*The yeasts of this heading may be in the active or inactive state.*

*Active yeasts generally provoke fermentation. They consist essentially of certain micro-organisms (almost exclusively of the genus Saccharomyces), which multiply during alcoholic fermentation, according to the aeration process.*

*The active yeasts include:*

*(1)* ***Brewery yeast,*** *This forms in beer fermentation vats. It is presented as a yellowish-brown paste or solid generally with the bitter flavor of hops and the odour of beer.*

*(2)* ***Distiller yeasts,*** *This is produced during the fermentation, o, e.g., grain, potatoes or fruit, in distilleries. It is a firm cream-coloured paste varying in odour according to the product used in the distillation.*

*(3)* ***Baker's yeast,*** *produced by the propagation under special conditions of specially cultured strains of yeast in a carbohydrate medium such as molasses. It is generally marketed in the form of pressed yellowish-grey cakes (pressed yeasts) which sometimes have an alcoholic odour. It is, however, also marketed in the dried form (usually in grains) or as liquid yeast.*

*(4)* ***Culture yeast,*** *a pure strain of yeast prepared under laboratory conditions. It may be suspended in distilled water or in gelatin or agar-agar. It is usually marketed in measured quantities put up in sealed containers to protect in from contamination.*

*(5)* ***Seed yeast,*** *produced from culture yeast by successive fermentation processes, is used to "seed" commercial yeast. It is usually marketed in the form of the moist pressed and plastic mass or in the form of a liquid suspension.*

***Inactive yeast,*** *obtained by drying, are generally brewery, distillery or bakers yeasts which have become insufficiently active for further use in those industries. They are used for human consumption (source of vitamin B) or for feeding animals. It should, however, be noted that, owing to their growing importance, these dried yeasts are to an increasing extent being produced directly from specially prepared active yeasts."*

14. The appellant has classified the goods as carboxylic acid under Chapter 29 which is as under:

| Tariff Item | Description of goods | Unit | Rate of duty | |
|---|---|---|---|---|
| | | | *Standard* | *Preferential Areas* |
| (1) | (2) | (3) | (4) | (5) |
| **2918** | **CARBOXYLIC ACIDS WITH ADDITIONAL OXYGEN FUNCTION AND THEIR ANHYDRIDES, HALDES, PEROXIDES AND PEROXYACIDS; THEIR HALOGENATED, SULPHONATED, NITRATED OR NITROSATED DERIVATICES**<br><br>-Carboxylic acids with alcohol function, but without other oxygen function, their anhydrides, halides, peroxides, peroxyacids and their derivatives: | | | |
| 2918 30 | Carboxylic acids with aldehyde or ketone function but without other oxygen function, their anhydrides, halides, peroxides | | | |
| 2918 30 90 | Other | Kg. | 10% | - |

> *"12. Chapter 29*
> *Notes.1.- Except where the context otherwise requires, the headings of this Chapter apply only to:*
> *(a) Separate chemically defined organic compounds, whether or not containing impurities;*
> *(b) Mixtures of two or more isomers of the same organic compound (whether or ot containing impurities), except mixtures of acyclic hydrocarbon isomers (other than stereo isomers), whether or not saturated (Chapter 27);"*

15. From the above, it is very much clear that the goods do not merit classification under Chapter 29. The appellant though classified the goods under Chapter 29, now contends that the classification determined by department is incorrect for the reason that Chapter 21 excludes yeast put up as medicament or other products of heading 3003 or 3004. At the

cost of repetition it has to be stated that though the appellant contends that the imported goods are in the nature of medicine for diarrhoea, they have not adopted the classification under chapter heading 3003 or 3004 in the Bill of Entry but has classified the goods under chapter heading CTH 29.

| **Tariff Item** | **Description of goods** | **Unit** | **Rate of duty** | |
|---|---|---|---|---|
| | | | *Standard* | *Preferential Areas* |
| (1) | (2) | (3) | (4) | (5) |
| **3002** | **HUMAN BLOOD; ANIMAL BLOOD PREPARED FOR THERAPEUTIC, PROPHYLACTIC OR DIAGNOSTIC USES; ANTISERA AND OTHER BLOOD FRACTIONS AND MODIFIED IMMUNOLOGICAL PRODUCTS, WHETHER OR NOT OBTAINED BY MEANS OF BIOTECHNOLOGICAL PROCESSES; VACCINES, TOXINS CULTURE OR MICRO-ORGANISMS (EXCLUDING YEASTS) AND SIMILAR PRODUCTS** | | | |
| **3003** | **MEDICAMENTS (EXCLUDING GOODS OF HEADING 3002, 3005 OR 3006) 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** | | | |
| **3004** | **MEDICAMENTS (EXCLUDING GOODS OF HEADING 3002, 2005 OR 3006) CONSISING OF MIXED OR UNMIXED PRODUCTS FOR THERAPEUTIC OR PROPHYLACTIC USES, PUT UP IN MEASURED DOSES (INCLUDING THOSE IN THE FORM OF TRANDERMAL ADMINISTRATION SYSTEMS) OR IN FORMS OR PACKINGS FOR RETAIL SALE** | | | |

***"14.1 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 utritional preparations for intravenour administration (Secton IV);*

*3.- For the purposes of headings 30.03 and 30.04 and of Note 4 (d) to this Chapter, the following are to be treated:*

*(a) As unmixed products:*
*(1) Unmixed products dissolved in water;*
*(2) All goods of Chapter 28 or 29; and*
*(3) Simple vegetable extracts of heading 13.02, merely standardized or dissolved in any solvent;*
*(b) As products which have been mixed:*
*(1)Colloidla solutions and suspensions (other than colloidal sulphur);*
*(2) vegetable extracts obtained by the treatment of mixtures of vegetable materials; and*
*(3) Salts and concentrates obtained by evaporating natural mineral water."*

16. The foreign supplier has furnished an Analysis Certificate along with the goods. As rightly pointed out by the learned AR the goods are described in the said certificate as below:-

*"Ovoid yeasts to the exclusion of all other micro organisms"*

The learned counsel has been at pains to contend that along with yeast there is another ingredient which is lactose and therefore the goods cannot be considered as yeasts.

17. The 'safety data sheet' issued by the supplier describes the goods as under:

*"Lyophilized Saccharromyces boulardii is manufactured from yeast cells to which is added a small quantity of lactose as auxiliary of lyophilization."*

18. From the Safety Data Sheet itself it is clear that lactose is added as auxiliary for lyophilization. It is not an ingredient added to make it a medicine. Lyophilization is nothing but freeze drying. It is just a stabilizing process to preserve a perishable product for the convenience of transport.

On the samples placed before us it is mentioned as "Saccharromyces Boulardii" and does not mention the ingredient of lactose, so as to consider it as an ingredient added to make it a medicament.

19. The appellant has furnished medical literature to argue that Saccharromyces Boulardii is used as medicine for diarrohea. However, there is no evidence to show that this product is known in the market in ordinary parlance as a medicament for gut related problems. Thus in fact though much medical literature has been placed before us to contend that Saccharromyces Boulardii can be used in the treatment of gut related problems there is no evidence to establish that it is known as a medicament. The appellant has failed to show that it is sold as a medicine for diarrhoea. Merely because the appellant has been issued a License by the Drugs & Cosmetics Act, it cannot be said that the imported goods are known and understood as medicine.

20. The adjudicating authority after perusing the brochure and catalogs pertaining to the overseas supplier, BIOCODEX, has noted in Para 2.2 of the Order-in-Original as under:

> *"2.2 The supplier is Bio-Codex, France. On verification of the literature and catalogs pertaining to Bio-Codex the following are noted:*
>
> *(a)Bio-Codex is the manufacturer/producer of "Saccharomyces Boulardii". It supplies the "Saccharomyces Boulardi" to various other manufacturers in different countries, who in turn manufacture dietary supplements under different brand names. Bio-Codex also manufactures "Florastor" (USA), UltraLevure (France) etc. Bio-Codex, USA markets its Florastor® as a probiotic made of live freeze dried yeast cells of the species Saccharomyces boulardii. Dr.Reddy's Laboratories, authorized agent in India manufactures "Econorm" capsules/sachets by using the "Saccharomyces Boulardii" supplied by the Bio-Codec.*

*(b) Bio-Codex, USA submitted a letter no 5677 dated July 2000 to the Food and Drug Administration (FDA), USA regarding new dietary supplement "Florastor" which states the facts about dietary supplement containing "Saccharomyces Boulardii"*

*"Item No.IV) Health Claim states "The label on Florastr states that it maintains balance of intestinal flora and it promotes intestinal health. No claims to diagnosis, treat, cure or prevent any disease in made".*

*Item No.V) Active Ingredient states "The active ingredient of Florastor is Saccharomyces Boulardii, a non-pathogenic fungus. No other dietary ingredient is contained in the supplement."*

*(c) Also, the Bio-Codex markets its "Florastor" as dietary supplement only and not as a drug. Food and Drug Administration (FDA), USA classifies the "Econorm" manufactured by DrReddy's as "Dietary Supplement" only along with "Florastor" and other products based on "Saccharomyces Boulardii"*

(d) Department of Health and Human Services, FDA "decided to regulate S. boulardii as a biological product, S. boulardii is not eligible for consideration to be included in an OTC (Over The Counter) drug monograph."

21. The conclusions arrived by the adjudicating authority after appreciation of the facts and evidence are worth reproducing and reads as under:

*"16.5. From the above, the following conclusion may be drawn:*

*(i) The imported "Saccharomyces Boulardii" is found to be "Yeast" a "living microorganism".*

*(ii) It does not fall under chapter 29 as it is not an "organic compound" like carboxylic acid in view of its character and the sense of the chapter.*

*(iii) It is also not a "culture media" to be classified under 3821.*

*(iv) It did not attain the form required to be classified under 3003 or 3004.*

*(v) It is specifically covered as "Yeast" whether active or inactive under Chapter 21021090."*

22. We are in full agreement with the findings of the adjudicating authority and do not find any material to accept the contention of appellant that the imported goods are medicaments. We are supported by the

proposition laid in the case of Kasturi Foods & Chemicals (*supra)* wherein similar issue came up for consideration before the Tribunal. The assessee therein had imported dried yeasts (BPC 73) or pharma yeast. The contention of the assessee in the said case was that they have imported pharma yeast and wanted to classify it under Chapter 30. The Tribunal in the case of Kasturi Foods and Products Ltd. observed as under:

> *"9. From the impugned Order-in-Appeal, we find that the said contentions were also raised by the appellants before the Collector (Appeals) which he had disposed of as below :-*
>
> *"Coming to the other submissions of the respondents, I find that it is true that in Chapter 21, the Chapter Note 1 states, "this Chapter does not cover yeast as a medicament or other products of Chapter 30". Obviously, therefore, yeast tablets which are manufactured by manufacturers of medicines, by using the respondents' dry yeast and after compression of the same with binding material are clearly outside the purview of Chapter 21. But that is not the product of the respondents. The products of the respondents are not put up as medicament, but are sold as a raw material for manufacture of such medicaments, as clearly stated by the respondents in their objections filed in the present application.*
>
> *Coming to the question of coverage of Chapter 21 and whether it will cover dry inactive yeast manufactured by the respondents, I find that Tariff Heading 21.02 reads as follows "Yeasts (active or inactive) other single cell micro-organisms, dead (but not including vaccines of Chapter 30); prepared baking powders". Sub-heading 2102.10 states, put up in unit containers and ordinarily intended for sale; sub-heading 2102.90 is for `other'. Yeast both active or inactive are covered under Tariff Heading 21.02 falling under Chapter 21. Active yeasts have been classified under Brewery yeast, Distillery yeast, Baker's yeast, Culture yeast and Seed yeast. These are all squarely covered under Tariff Heading 21.02 as per page 156-157 of Explanatory Notes to Harmonised Commodity Description and Coding System.*
>
> *Coming to inactive yeast, it is stated, "Inactive yeasts obtained by drying, are generally brewery, distillery or bakers' yeasts which have become insufficiently active for further use in those industries. They are used for human consumption (source of vitamin B) or for feeding animals. It should, however, be noted that, owing to their growing importance, these dried yeasts are to an increasing extent being produced directly from specially prepared active yeasts. The heading also covers other types of dried yeasts e.g.Candidalipolytica or tropicalia, candida maltosa) developed from the yeast not belonging to Saccharomyces. They are obtained by drying the yeasts which have been cultivated on substrates containing hydrocarbons (such as gas-oils or n-paraffins) or carbohydrates. These dried yeasts are particularly rich in protein and are used in animal*

*feeding. They are commonly known as petroproteins or yeast bioproteins".*

*It will be apparent from the above Explanatory Note that what the respondents manufacture are inactive yeasts in dried form, basing on carbohydrates. The same are not used as medicine and there is no evidence that they are used as medicines though respondents may have obtained a licence under Drugs and Cosmetics Act. What are used as medicines are prepared from inactive dry yeasts, by several manufacturers of medicines who buy the respondents' products and after compression and addition of binding material, such compressed yeast tablets are sold as medicines. Further the definition of Medicaments, given in Chapter Note 2 of Chapter 30 of Central Excise Tariff Act also does not cover appellants' product which is unmixed product and not put up in measured doses or in packings for retail sale or for use in hospitals. Therefore, the claim of the respondents that their products squarely fall under 3003, is not correct. For the products manufactured out of their inactive dry yeasts by manufacturers of medicines, the classification under Chapter 30, will be relevant and not for the respondents' products which squarely fall, for the reasons stated by me above, under Chapter 21."*

*10. After giving our serious thoughts to the contentions raised in the present case in the light of the facts and circumstances of the case, we agree with the Collector (Appeals) that the products of the appellants are not put up as medicaments, but are sold as a raw material for manufacture of such medicaments. We agree with the findings of the Collector (Appeals), as extracted above. Consequently, the appeal is dismissed."*

22 (a). The learned counsel for the appellant has made a frail effort to distinguish on facts. It is submitted that the product imported in the said case is Saccharomyces Cerevisiae whereas the appellant has imported Saccharomyces Boulardii. It is also argued by the learned counsel for the appellant that in the said case the assessee has failed to impress upon the Tribunal as to the function of the yeast in treating ailments and therefore can be used as a medicament. Another argument put forward to differentiate the facts is that the assessee therein has imported it as raw-materials for manufacture of medicaments whereas in the present case the appellant has imported it for being sold as such by packing into sachets. The learned AR has pointed out before us that analysis report issued by

the foreign supplier shows that imported goods are raw-material. On perusal of the report heading mentions as 'analytical test report raw-material'. There is no evidence to controvert the analytical report which states that the imported goods are raw-material.

23. In the case of M*/s. Zymonutrients Pvt. Ltd. Vs. Commissioner of Customs vide* Final Order No.41574/41580/2019 dated 26.11.2019, the Tribunal followed the decision in the case of Kasturi Foods and Chemicals to hold that the goods imported are to be classified under Chapter 21 as determined by the Department. The discussion of the Tribunal reads as under:

> *"10. Going by the test reports of CRCL, impugned goods are inactive yeast; in view of the explanatory notes to chapter 21 dried yeast is also known as inactive yeast and for that reason inactive yeast is to be considered as dried yeast. We find that appellants have tried to argue that the impugned goods are not fit for human consumption on the basis of CFTRI report and hence do not fall under 2102. However, we find that under chapter sub heading 2102, there is no condition stating that it should be fit for human consumption. Either under 2102 or 21022000, one single dash covers yeasts; other single micro-organisms, dead; prepared baking powders; inactive yeast, other single cell micro organisms, dead. We find that there is no exclusion for yeast which are declared not to fit for human consumption. On the contrary, we find that heading 23.09 has got only two single dashes. One single dash contains dog or cat food, put up for retail sale and the second single dash contains "others" and 9 the various foods and concentrates for animals are listed subsequently. It is clear that the entire heading 2309 talks of preparations of a kind used in animal feeding. By no stretch of imagination the impugned products imported by the appellants are preparations of a kind animal feeding. At the best, they may be used for preparation of animal feeds that is to say that they are raw material used for preparation of animal feed. Therefore, they cannot be classified along with animal feed merely by virtue of the inclusive definition given in the explanatory notes for the heading 2309 CETA.*

*11. The appellants have greatly relied upon the decision of the Larger Bench in the case of Tetrogone Chemie (supra) wherein the vitamins used for mixing in the animal feed was held to be classified under chapter 23 of CETA. However, we find that this judgment is in respect of Central Excise Tariff Act, 1985; the issue before the Bench was the assessments of Vitamins manufactured by the manufacturers of Animal feed/ supplements; it was rendered in the context of Tariff existing at that time. The present case is about the imports which are to be classified under Customs Tariff Act. Therefore no inference can be drawn from the case cited above. Moreover, we find that note to chapter 23 specifically says that "heading 2309 includes products of a kind used in animal feed, not elsewhere specified or included, obtained by processing vegetable or animal materials to such extent that they have lost the essential characteristics of the original material, other than vegetable waste, vegetable residues and byproducts of such processing". Therefore, it is clear that the chapter 23 shall include products of a kind used in animal feed. However, the 10 emphasis that they are not elsewhere included. As submitted by the Ld. A.R and as held by the Commissioner (Appeals) heading 21022000 specifically mentions yeast active or inactive. Therefore, when yeast has a specific mention under heading 2102, that cannot be classified under any other heading under chapter 23 in view of the chapter note mentioned above. Therefore, we find that the classification arrived by the department and upheld by the Ld. Commissioner (Appeals) is consistent with the relevant chapter heading and notes and also general interpretative rules for classification wherein it is specified under rule 3 (a) of Interpretative Rules that the heading which provides most specific description shall be preferred to heading providing a more general description. We find that issue of import of Vitamin "E" 40% to 50% and claimed to be animal feed came before the Tribunal for discussion and that Tribunal in the case of CC Vs Sonam International - 2012 (275) ELT 326 (All.) has come to the conclusion that vitamins imported by the appellants therein are to be classified under 293600 and not under 2302 as „animal feed supplement" as claimed by the appellants. We further find that in the above case of Sonam International Tribunal has discussed and distinguished the case of Tetragon Chemie (supra) and moreover, it is the later judgment on the issue and directly on the subject of import of similar items. In view of the above, we uphold the classification of impugned goods under CTH 21022000 as assessed by the department and as upheld by the Commissioner (Appeals).*

*12. In view of the above, we find that to extent of classification of the impugned goods is concerned; the order of the Ld. Commissioner (Appeals) does not*

> *require to be interfered with. In the result, we uphold the impugned order in so far as the classification of the impugned goods is concerned. We hold that classification of impugned goods i.e. yeast is correctly arrived by the Revenue under CTH 21022000. Under such circumstances, the appellant's submissions on the issue of time bar loose relevance in the instant case."*

24. After appreciating the facts and the evidence placed before us, we are of the considered opinion that the decisions passed by the Tribunal as to the classification in the case of Kasturi Foods and Products Ltd. as well as in the case of M/s. Zymonutrients Pvt. Ltd. would apply and the impugned goods are to be classified under Chapter 21 as determined by the Department. The issue is answered in favor of revenue and against the appellant.

25. In the result, the impugned order is sustained. The appeal is dismissed.

(Pronounced in the open court on 17.3.2023)

Sd/-
**(SULEKHA BEEVI C.S.)**
MEMBER (JUDICIAL)

Sd/-
**(VASA SESHAGIRI RAO)**
MEMBER (TECHNICAL)

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