

Food Drug Cosmetic Law JOURNAL

Latin-American Food Code: Chapter XI—
Fruits and Vegetables

Building Tomorrow's System

. James L. Goddard



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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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REPORTS

TO THE READER

Latin-American Food Code.—In August 1964, the Latin-American Food Code Council published the Second Edition of the Latin-American Food Code. Chapter XI of this code, which begins on page 396 is a system of regulations governing both the sale of fresh fruits and vegetables in the market and the preservation of these foods, either by drying or canning; the kind and degree of chemical additive permissible in the canning process is stated for each product. The value of the Code is enhanced by this chapter which, if detached from the whole, could serve as a valuable handbook containing a comprehensive classification of fruits, vegetables and legumes with a percentage statement of the nutritive composition of each genus.

Chapters I-V were published in the September 1965 issue of this JOURNAL; Chapters XII and XIII in the October 1965 issue; Chapter XVII in the November 1965 issue; Chapter X in the December 1965 issue; Chapter VII in the June 1966 issue; Chapter XVIII in the August 1966 issue; Chapter XVI in the May 1967 issue; Chapter VI in the August 1967 issue and Chapter XV in the October 1967 issue. All

translations have been by *Ann M. Wolf* of New York City.

Building Tomorrow's System.—In the article which begins on page 432, *James L. Goddard* points out the disparity between new knowledge of drugs and the efficacy with which such knowledge is spread. Dr. Goddard is hopeful that a new system of coding as developed in the National Drug Code Directory will be the means of a "transition toward a more rational, more manageable, and more understandable delivery system." In the proposed United States Drug Compendium and its envisioned quarterly updating, the author expects a wholeness in the organization and channeling of vital information. The article, sympathetic toward the problems of the pharmacist, was originally presented as a speech before the Association of Retail Drug-gists, Bal Harbour, Florida.

Dr. Goddard, whose resignation as Commissioner of the Food and Drug Administration became effective July 1, 1968, is now the director of a regional office of EDP Technology, Inc. and specializes in the use of data processing and information systems in the area of medicine.



Food·Drug·Cosmetic Law

Journal

Latin-American Food Code 1964 Edition

In August, 1964, the Latin-American Food Code Council Published the Second Edition of the Latin-American Food Code. Information Concerning the Code and the Table of Contents of the New Edition Appeared in the April 1965 Issue of the Food Drug Cosmetic Law Journal (Vol. 20, page 238). The First Five Chapters Were Published in the September 1965 Issue; Chapters XII and XIII in the October 1965 Issue; Chapter XVII in the November 1965 Issue; Chapter X in the December 1965 Issue; Chapter VII in the June 1966 Issue; Chapter XVIII in the August 1966 Issue; Chapter XVI in the May 1967 Issue; Chapter VI in the August 1967 Issue; and Chapter XV in the October 1967 Issue. Chapter XI appears below. The Translation Is by Ann M. Wolf of New York City.

Chapter XI: Fruits and Vegetables

Fruits

Article 376.—The term “Fruit” means the product intended for human consumption which results from the fructification of a healthy plant, or a plant affected by a disease not considered a national blight. “Fresh Fruit” is fruit harvested recently for immediate consumption. “Dry Fruit” is fruit whose natural moisture content is low and whose pericarp is more or less lignified, the seed being the food substance (walnuts, peanuts, chestnuts, etc.) “Dried Fruit” is fruit obtained by natural desiccation (exposure to air and sun), or artificial desiccation, of sound, clean, whole or sectioned fresh fruits. When desiccation has taken place in special devices known as “dehydrators” (tunnel dehydrators) fruits are named “dehydrated.”

Article 377.—Ripeness or maturity is divided into two types: “physiological” ripeness, reached by the fruit when its sugar and protein content are highest and it has reached full maturity, after which decay begins to set in; and “commercial” ripeness, attained by fruit harvested before it has reached full maturity

to be preserved in freezers or to be prepared for long-distance transportation.

Article 378.—Fruit is considered *sound* when it is virtually free from insects, parasites, cryptogamic diseases or other physical or mechanical flaws that affect its appearance: it is considered *clean* when it is suitable for human consumption and its skin is free from foreign matter which, while not actually causing damage, may disfigure the fruit in whole or in part.

All fresh, dry, dried or dehydrated fruits offered for sale and consumption or used in canning must be clean.

Article 379.—All fruits exhibited for sale for direct human consumption must have reached physiological ripeness. Retail outlets shall display signs warning the public: "For reasons of hygiene, please do not touch the fruit."

Dealers who sell immature fruit as table fruit shall be liable to summary seizure of the product.

Immature fruit shall be stored separately from ripe fruit intended for sale to the public. Retail outlets may keep only limited quantities of immature fruit to be sold for the preparation of jams. Both storage racks for and containers of immature fruit shall have a sign clearly showing the use for which such fruit is intended: "Immature fruit for use in jams," etc.

Fruits exhibited or sold in boxes whose labeling indicates a specific quality shall meet the claims made in the labeling, the re-use of such boxes for products of a different origin or quality being prohibited.

Article 380.—Citrus fruits may be packed in paper which contains fungicides authorized by the health authority. Diphenyl (5 to 9 mg. per 100 cm²) may be added to such paper only if it is used for citrus fruits intended for export to countries permitting said chemical.

Article 381.—The fruits usually sold fresh include the following varieties:

1. Barbadoes Cherry: *Malpighia glabra* L. Average percentage composition: Water 82; proteins 1.5; fats 0.2; assimilable carbohydrates 14; crude fiber 1; ash 0.8; ascorbic acid 20 mg.

2. Avocado. Alligator Pear: *Persea americana* Mill. Average percentage composition: Water 60 to 85; proteins 1 to 3; fats 5 to 30; assimilable carbohydrates (sugars 2.3) 5 to 8; crude fiber 1.2 to 7; ash 0.9 to 2; ascorbic acid 12 mg.

3. "Aguaje"*: *Mauritia flexuosa*. Average percentage composition: Water 52; proteins 4; fats 21; assimilable carbohydrates 12; crude fiber 10; ash 0.8.

4. Pineapple: *Ananas sativus* L., *Ananas comosus* L., etc. Average percentage composition: Pulp: Water 84.5; proteins 0.4; fats 0.2; assimilable carbohydrates (sugars 11) 14; crude fiber 0.2; ash 0.4. Juice: Water 87; proteins 0.2; fats 0.1; assimilable carbohydrates (sugars 9) 12; ash 0.4; ascorbic acid 54 mg.

5. Banana, Plantain: *Musa paradisiaca* L. and varieties thereof. Average percentage composition: Water 65; proteins 0.8; fats 0.3; assimilable carbohydrates (sugars 28) 32; crude fiber 0.6; ash 8; ascorbic acid 18 mg.

6. Star Apple: *Chrysophyllum cainito* L. Average percentage composition: Water 80; proteins 1; fats 1.9; assimilable carbohydrates 15; crude fiber 1; ash 0.4; ascorbic acid 11 mg.

7. "Camu-Camu"*: *Myrtus* sp. Average percentage composition: Water 94; proteins 0.5; assimilable carbohydrates 4; crude fiber 0.5; ash 0.2.

8. Sweet Cherry: *Prunus capuli* Ca. Average percentage composition: Water 83; proteins 1; fats 0.5; assimilable carbohydrates 14; crude fiber 0.5; ash 0.6; ascorbic acid 15 mg.

9. Citron: *Citrus medica* L. Average percentage composition: Water 87; proteins 0.6; fats 1.8; assimilable carbohydrates 1; crude fiber 0.1; ash 0.4; ascorbic acid 30 mg.

10. Plum: *Prunus domestica* L. Average percentage composition: Water 86; proteins 0.6; fats 0.1; assimilable carbohydrates 12; crude fiber 0.4; ash 0.6; ascorbic acid 15 mg.

11. Sponge Tree† Fruit: *Inga* spp. Average percentage composition: Water 81; proteins 8.1; fats 0.1; assimilable carbohydrates 9; crude fiber 1; ash 0.4; ascorbic acid 10 mg.

12. "Cuchamper":**Vincetoxicum salvanii* Standl. Average percentage composition: Water 92; proteins 1.1; fats 0.2; assimilable carbohydrates 5; crude fiber 0.8; ash 0.4; ascorbic acid 5 mg.

13. "Chambiro":* *Petiveria aliaceae*. Average percentage composition: Water 72; proteins 1.5; fats 6.3; assimilable carbohydrates 12.5; crude fiber 6.4; ash 0.8; ascorbic acid 5 mg.

14. Black Avocado: *Persea schiedeana* Nees. Average percentage composition: Water 67; proteins 1.8; fats 13; assimilable carbohydrates 16; crude fiber 1; ash 0.8; ascorbic acid 10 mg.

*Note of the Translator: Local fruit whose name has no English equivalent.

†Note of the Translator: A tree native of the Caribbean Islands.

15. Apricot: *Prunus armeniaca* L. Average percentage composition: Water 83; proteins 0.9; fats 0.1; assimilable carbohydrates 14; crude fiber 0.8; ash 0.5; ascorbic acid 12 mg.

16. Date: *Phoenix dactylifera* L. Average percentage composition: Water 34; proteins 1.4; fats 0.4; assimilable carbohydrates 60; crude fiber 2.5; ash 1.5; ascorbic acid 4 mg.

17. Peach ("Durazo"): *Prunus persica* L. Peaches with yellow or green pulp are also called "Melocotones," and peaches in which the stone can be removed easily are called "Freestone Peaches." Average percentage composition: Water 86; proteins 0.6; fats 0.8; assimilable carbohydrates 11; crude fiber 0.8; ash 0.7; ascorbic acid 23 mg.

18. Raspberry: *Rubus idaeus* L. Average percentage composition: Water 85; proteins 1; fats 0.5; assimilable carbohydrates (sugars 5) 7; crude fiber 5; ash 0.7.

19. Strawberry: *Fragaria* L. Average percentage composition: Water 89; proteins 0.9; fats 0.6; assimilable carbohydrates (sugars 6) 7; crude fiber 1.2; ash 0.7; ascorbic acid 65 mg.

20. Pomegranate: *Punica granatum* L. Average percentage composition: Water 85; proteins 0.5; fats 0.3; assimilable carbohydrates 13; crude fiber 0.8; ash 0.3; ascorbic acid 5 mg.

21. Sweet Granadilla: *Passiflora ligularis* Juss; Giant Granadilla: *Passiflora quadrangularis* L. Average percentage composition: Water 74; proteins 2.5; fats 2.7; assimilable carbohydrates 16; crude fiber 3.5; ash 1.2; ascorbic acid 18 mg.

22. Red Currant: *Ribes* L. Average percentage composition: Water 87; proteins 1.2; fats 0.4; assimilable carbohydrates (sugars 7.5) 9; crude fiber 1.2; ash 0.6; ascorbic acid 4 mg.

23. Soursop: *Annona muricata* L. Average percentage composition: Water 83; proteins 0.9; fats 0.2; assimilable carbohydrates 14; crude fiber 1; ash 0.6; ascorbic acid 20 mg.

24. Guava: *Psidium guajava* L. Average percentage composition: Water 83; proteins 0.8; fats 0.6; assimilable carbohydrates (sugars 8) 9.5; crude fiber 5; ash 0.7; ascorbic acid 180 mg.

25. Sour Cherry: *Prunus cerasus* L. Average percentage composition: Water 84; proteins 1; fats 0.5; assimilable carbohydrates (sugars 9) 13; crude fiber 0.4; ash 0.5; ascorbic acid 12 mg.

26. Fig ("Higo"): *Ficus carica* L. First-crop figs are usually called "Brevas," while the word "Higo" is used only for second-crop figs. Average percentage composition: Water 80; proteins 1.3; fats

0.2; assimilable carbohydrates (sugars 14) 16; crude fiber 1.4; ash 0.6; ascorbic acid 8 mg.

27. Prickly Pear: *Opuntia spp.* Average percentage composition: Water 82; proteins 0.9; fats 0.2; assimilable carbohydrates 13; crude fiber 2.8; ash 0.6; ascorbic acid 18 mg.

28. Spiny Clu^o Palm: *Bactris minor Jacq.* and *Bactris sublobosa Wendl.* Average percentage composition: Water 82; proteins 1.5; fats 0.1; assimilable carbohydrates 13; crude fiber 1.5; ash 1.4; ascorbic acid 5 mg.

29. "Huito"*: *Genipa americana.* Average percentage composition: Water 83; proteins 1.2; fats 0.1; assimilable carbohydrates 13; crude fiber 1.6; ash 0.8; ascorbic acid 5 mg.

30. Cocoa Plum: *Chrysobalanus icaco L.* Average percentage composition: Water 86; proteins 0.4; fats 0.1; assimilable carbohydrates 12; crude fiber 0.5; ash 0.8; ascorbic acid 5 mg.

31. Spanish Plum: *Spondias mombin L.*; Red Mombin: *Spondias purpurea L.* Average percentage composition: Water 71; proteins 1; fats 0.2; assimilable carbohydrates 26; crude fiber 0.5; ash 1; ascorbic acid 35 mg.

32. Japanese Fersimmon: *Diospyrus kaki L.* Average percentage composition: Water 80; proteins 0.6; fats 0.3; assimilable carbohydrates 18; crude fiber 0.5; ash 0.5; ascorbic acid 10 mg.

33. Kumquat: *Fortunella japonica Swingle.* Average percentage composition: Water 85; proteins 0.6; fats 0.4; assimilable carbohydrates 13; crude fiber 0.5; ash 0.4; ascorbic acid 38 mg. The oval or Nagami kumquat is *Fortunella margarita Swingle.*

34. Sweet Lime: *Citrus limetta Risso*; Lime: *Citrus aurantifolia Swingle.* Average percentage composition: Water 89; proteins 0.7; fats 0.1; assimilable carbohydrates 9; crude fiber 0.3; ash 0.4; ascorbic acid 40 mg.

35. Lemon: *Citrus limonia Osbeck.* Average percentage composition: Water 90; proteins 0.5; fats 1; assimilable carbohydrates (sugars 5) 7; crude fiber 0.5; ash 0.4; ascorbic acid 48 mg.

36. "Lucuma": *Lucuma abovate.* Average percentage composition: Water 70; proteins 1.6; fats 0.5; assimilable carbohydrates 27; crude fiber 0.3; ash 0.5; ascorbic acid 6 mg.

37. Mammee or Mamey: *Mammea americana L.* Average percentage composition: Water 88; proteins 0.5; fats 0.1; assimilable car-

*Note of the Translator: A fruit found in Chile and Peru whose name has no English equivalent.

bohydrates 9; crude fiber 1.2; ash 0.8; ascorbic acid 12 mg.

38. Genipap: *Melicocca bijuga* L. Average percentage composition: Water 76; proteins 1.2; fats 0.1; assimilable carbohydrates 21; crude fiber 1; ash 0.6; ascorbic acid 4 mg.

39. Mandarin: *Citrus deliciosa* Ten., Tangerine: *Citrus bergamina* Risso. Average percentage composition: Water 87; proteins 0.8; fats 0.2; assimilable carbohydrates 11; crude fiber 0.4; ash 0.5; ascorbic acid 30 mg.

40. Mango: *Mangifera indica* L. Average percentage composition: Water 84; proteins 0.7; fats 0.2; assimilable carbohydrates 14; crude fiber 0.6; ash 0.4; ascorbic acid 55 mg.

41. Apple: *Pyrus malus* L. Average percentage composition: Water 85; proteins 0.3; fats 0.2; assimilable carbohydrates 13; crude fiber 0.8; ash 0.3; ascorbic acid 5 mg.

42. Hawthorn Berry: *Crataegus pubescens* Stued. Average percentage composition: Water 75; proteins 0.7; fats 0.3; assimilable carbohydrates 21; crude fiber 1.7; ash 0.8; ascorbic acid 65 mg.

43. Cashew Apple: *Anacardium occidentale* L.; Japanese Cashew Apple: *Syzygium malaccense* L. Average percentage composition: Water 87; proteins 0.8; fats 0.2; assimilable carbohydrates 11; crude fiber 0.5; ash 0.3; ascorbic acid 210 mg.

44. White Sapota*: *Casimiroa edulis* Llav. & Lex. Average percentage composition: Water 78; proteins 0.9; fats 0; assimilable carbohydrates 19; crude fiber 1; ash 0.5; ascorbic acid 30 mg.

45. Muskmelon: *Cucumis melo* L. Average percentage composition: Water 94; proteins 0.6; fats 0.1; assimilable carbohydrates 4; crude fiber 0.5; ash 0.6; ascorbic acid 25 mg.

46. Quince: *Cydonia vulgaris* Pers. Average percentage composition: Water 83; proteins 0.4; fats 0.4; assimilable carbohydrates 14; crude fiber 1.5; ash 0.4; ascorbic acid 15 mg.

47. Jujube: *Zizyphus mistol* Griseb. Average percentage composition: Water 33; proteins 6; fats 6.5; assimilable carbohydrates (starch 3) 49; crude fiber 1.3; ash 8.0.

48. Blackberry: *Rubus glaucus* Benth. Average percentage composition: Water 85; proteins 1; fats 0.2; assimilable carbohydrates 10; crude fiber 3; ash 0.5; ascorbic acid 10 mg.

49. "Nance" "Nancito"**: *Byrsonima crassifolia* L. Average percentage composition: Water 83; proteins 0.7; fats 1; assimilable carbohydrates 12; crude fiber 2.5; ascorbic acid 96 mg.

* Note of the Translator: A fruit that grows in Honduras and Salvador.

** Note of the Translator: A small tasty fruit that grows in Honduras.

50. Orange: *Citrus sinensis* L. Average percentage composition: Water 87; proteins 0.9; fats 0.1; assimilable carbohydrates (sugars 8) 11; crude fiber 0.4; ash 0.4; ascorbic acid 45 mg.

Bitter Orange: *Citrus aurantium* L. Average percentage composition: Water 80; proteins 1; fats 0.1; assimilable carbohydrates 16; crude fiber 1.6; ash 0.4; ascorbic acid 40 mg.

51. Medlar: *Mespilus agarolus* L.; *Achras zapota* L., *Manilkara spectabilis* Standl. Average percentage composition: Water 76; proteins 0.6; fats 0.4; assimilable carbohydrates 21; crude fiber 1.2; ash 0.6; ascorbic acid 10 mg.

Japanese Medlar: *Eriobotrya japonica* Lindl. Average percentage composition: Water 89; proteins 0.3; fats 0.6; assimilable carbohydrates 9; crude fiber 0.4; ash 0.4; ascorbic acid 8 mg.

52. Papaya: *Carica papaya* L. Average percentage composition: Water 90; proteins 0.5; fats 0.2; assimilable carbohydrates (sugars 5) 8; crude fiber 0.6; ash 0.5; ascorbic acid 55 mg.

53. "Pejibay"*: *Guilielma utilis* Oerts. or *Guilielma gasipaes*. Average percentage composition: Water 55; proteins 2; fats 2.8; assimilable carbohydrates 37; crude fiber 2.4; ash 0.8; ascorbic acid 15 mg.

54. Guava: *Inglá Leptoloba* Schlecht. Average percentage composition: Water 81; proteins 0.8; fats 0.1; assimilable carbohydrates 16.5; crude fiber 1; ash 0.3; ascorbic acid 5 mg.

55. Sweet Cucumber: *Solanum muricatum* Ait. Average percentage composition: Water 91; proteins 0.5; fats 0.1; assimilable carbohydrates 7; crude fiber 0.5; ash 0.3; ascorbic acid 40 mg.

56. Pear: *Pyrus communis* L. Average percentage composition: Water 85; proteins 0.4; fats 0.3; assimilable carbohydrates (sugars 9) 12; crude fiber 1.5; ash 0.3; ascorbic acid 5 mg.

57. Cypress nut: *Bromelia pinguin* L. Average percentage composition: Water 87; proteins 1.2; fats 0.2; assimilable carbohydrates 10; crude fiber 0.4; ash 0.8; ascorbic acid 40 mg.

58. "Pitahaya"**: *Hylocereus undatus* Britt and Rose. Average percentage composition: Water 83; proteins 1; fats 0.4; assimilable carbohydrates 14; crude fiber 0.8; ash 0.6; ascorbic acid 8 mg.

59. Grape Fruit, Pomelo: *Citrus maxima* Osbeck. Average percentage composition: Water 88; proteins 0.6; fats 0.3; assimilable carbohydrates 10; crude fiber 0.2; ash 0.4; ascorbic acid 45 mg.

* Note of the Translator: A palm nut variety that grows in Costa Rica and Honduras.

** Note of the Translator: Fruit of a Peruvian cactus plant.

60. "Quinoto" or "Kinoto": *Citrus arantium*, variety of *Myrtifolia* Ker-Gawl.

61. Watermelon: *Citrullus vulgaris* Schrad. Average percentage composition: Water 94; proteins 0.3; fats 0.2; assimilable carbohydrates 5; crude fiber 0.2; ash 0.2; ascorbic acid 5 mg.

62. Sweetsop: *Annona Squamosa* L., *Annona cherimolia* Lamb., *Annona diversifolia* Safford, Bullock's Heart: *Annona reticulata* L. Average percentage composition: Water 80; proteins 0.7; fats 0.1; assimilable carbohydrates 15; crude fiber 0.6; ash 0.4; ascorbic acid 22 mg.

63. Sapota: *Licania platyphus* Fritsch. Average percentage composition: Water 68; proteins 1.4; fats 0.5; assimilable carbohydrates 28; crude fiber 0.8; ash 1; ascorbic acid 10 mg.

64. Tamarind: *Tamarindus indica* L. Average percentage composition: Water 22; proteins 1.4; fats 0.9; assimilable carbohydrates 71; crude fiber 2.5; ash 1.8; ascorbic acid 6 mg.

65. Grape: *Vitis vinifera* L. and other species and varieties of the genus *Vitis*. Average percentage composition: Water 83; proteins 0.5; fats 0.3; assimilable carbohydrates 15; crude fiber 0.6; ash 0.3; ascorbic acid 3 mg.

66. Indian Jujube: *Zyziphus mauritiana* Lam. Average percentage composition: Water 84; proteins 1.5; fats 0.1; assimilable carbohydrates 13; crude fiber 0.5; ash 0.5; ascorbic acid 60 mg.

67. Sapota: *Calocarpum mammosum* Pierre; Green Sapota: *Calocarpum viride* Pitt. Average percentage composition: Water 70; proteins 0.9; fats 0.4; assimilable carbohydrates 26; crude fiber 1.5; ash 0.8; ascorbic acid 35 mg.

Article 382.—The term "Almond" means the lignified endocarp (core) of the sweet variety of *Prunus amygdalus* Stokes. Average percentage composition: Water 5 to 10; proteins 16 to 25; fats 42 to 58; assimilable carbohydrates 11 to 14; crude fiber 2.5 to 3.5; ash 1.5 to 2.5.

Article 383.—The term "Hazelnut" means the clean dry fruit of several species of *Corylus* (*Corylus avellana*, *Corylus maxima*, *Corylus colurna*, etc.). Average percentage composition: Water 8; proteins 14; fats 64; assimilable carbohydrates (sucrose 5) 9; crude fiber 2.5; ash 2.5.

Article 384.—The term "Chestnut" ("castaña") means the clean dry fruit of *Castanea vesca* Gaertn. Large chestnuts are called "Marrons" and the peeled dried fruit (without the pericarp) is called "Castaña pilonga" or "Castaña apilada."

Article 385.—The terms “Para Nut” and “Brazil Nut” mean the clean dry seed of *Bertholletia nobilis* Miers. Average percentage composition: Water 3; proteins 13; fats 60; assimilable carbohydrates 20; crude fiber 1; ash 3.

Article 386.—The term “Cashew Nut” means the clean dry seed of *Anacardium occidentale* L. Average percentage composition: Water 5 to 9; proteins 9 to 18; fats 46 to 52; assimilable carbohydrates 4.3 to 9; crude fiber 1 to 1.5; ash 1 to 2.5. (See Article 381, numeral 43.)

Article 387.—The name “Coconut” is used in the trade to designate the nuts or fruits (endocarp) of the coconut palm (*Cocos nucifera* L.) from which the outer skin (epicarp) and the fibrous tissue (mesocarp) have been removed.

The milky juice found in immature coconuts is called “Coconut water.” Average percentage composition: Water 94; proteins 0.2; fats 0.1; assimilable carbohydrates 4; crude fiber 0.5; ash 0.7.

The term “Coconut Milk” means the emulsion prepared from the albumen of the fruit. It must contain not less than 20 per cent of the natural coconut fat, and sucrose may be added to it in a proportion of not more than 40 per cent with a declaration to that effect in the labeling.

Canned products which consist of mixtures of coconut meat and coconut milk or concentrated coconut milk circulate on the market under the name “Coconut milk.” To these products sucrose may be added in a proportion of not more than 40 per cent, and such addition must be declared in the labeling. Average percentage composition: Water 13; proteins 2.8; fats 38; assimilable carbohydrates 45; crude fiber 1.

The kernel or endosperm of the coconut is called “Coconut meat.” Average percentage composition of fresh meat: Water 45; proteins 3; fats 36; assimilable carbohydrates 12; crude fiber 3; ash 1; ascorbic acid 4 mg. When dried and shredded, this meat is named “Shredded coconut,” “Grated coconut” or “Coconut powder,” to which sucrose may be added in a proportion of up to 40 per cent with a declaration to that effect in the labeling. Average percentage composition of dried meat, without sugar: Water 5; proteins 6; fats 64; assimilable carbohydrates 19; crude fiber 3.5; ash 1.5.

Article 388.—The term “Guaraná” means the seeds of *Paulinia cupana* Kunth. Guaraná rolls may not contain cacao, tapioca, rice flour, or other foreign matter. Grated guaraná rolls form what is called “Guaraná Powder.”

Article 389.—The term “Peanut” means the seeded pod of *Arachis hypogaea* L. as well as the, raw or roasted, sound seeds of the same plant, peeled or still in their reddish tegument.

Average percentage composition: Water 5 to 15; proteins 23 to 33; fats 35 to 48; assimilable carbohydrates 8 to 14; crude fiber 1.4 to 4; ash 1 to 2.5.

Article 390.—The term “Walnut” means the endocarp of the sound dry fruits of the walnut tree: *Juglans regia* L., etc. Average percentage composition: Water 5 to 7; proteins 13 to 16; fats 50 to 62; assimilable carbohydrates 11 to 13; crude fiber 1 to 3; ash 1 to 2.5; ascorbic acid — none.

Article 391.—The terms “Piñón” and “Pine Nut” mean the clean peeled seeds of the ripe fruit or cone of the domestic pine tree (*Pinus pinea* L.) and other species, such as the araucaria (*Pinus araucanus* Mol.). Immature Pine Nuts are poor in fats and rich in starch. Average percentage composition: Water 6 to 10; proteins 26 to 34; fats 42 to 50; assimilable carbohydrates 8 to 17; crude fiber 0.5 to 1.5; ash 1 to 2.

Article 392.—The term “Pistachio Nut” means the sound seed of the fruits of *Pistacia Vera* L. Average percentage composition: Water 4 to 8; proteins 18 to 23; fats 45 to 55; assimilable carbohydrates 12 to 18; crude fiber 1.8 to 3; ash 2.5 to 3.5.

Article 393.—Fruits intended for drying must be harvested as soon as they reach the peak of their growth and sugar content and the flavor and color typical of the variety are fully developed. Discarded fruits and fruits which are undersized, diseased, injured, otherwise damaged or not sufficiently ripe are prohibited from being dried.

Fruits intended for drying shall be free from arsenic salt or other products used as insecticides or fungicides. Hot lye treatment and sulfur fumigation are permitted.

Sweetened or unsweetened dried fruits may not contain water in a proportion of more than 25 per cent.

Dried or dehydrated fruits may, prior to packing, be fumigated with propylene oxide (Article 57); residue in the treated product may not exceed 700 p.p.m., however.

Article 394.—In packing dried fruit mixtures containing walnuts, hazelnuts or other fruits with earthy impurities, together with products which are consumed without prior washing

(raisins, shelled nuts, sugar almonds, etc.) the latter must be separated from the former.

Article 395.—The name “whole cored peaches” (fruit of *Prunus persica*, L.) means dried peaches without their skin (epicarp), core, or stone which, during drying, have been pressed and flattened so as to close the cavity left by the stone and form a large disk called “Medallion.” The name “cored peach halves” means cored dried peaches split into halves, with or without the skin, in which case the presence or absence of the skin must be stated in the labeling. Dried peaches from which the skin, but not the core or stone has been removed are called “peaches with cores.” The name “Peach strips” means peeled and cored peaches cut into long strips and dried. Average percentage composition: Water 25; proteins 4; fats 0.5; assimilable carbohydrates (sugars 51) 67; crude fiber 3; ash 2.5.

The name “Huesillo” means the stone or seed of the peach dried with the small amount of pulp clinging to it.

Article 396.—Dried prunes (fruit of *Prunus domestica* L.), with or without the stone, must before packing be subjected to a hot water or steam bath which destroys any eggs, larvae or insects they may contain and makes them glossy. They may also be immersed shortly in a hot sugar solution or a plum syrup which enhances their gloss. Average percentage composition: Water 24; proteins 2.3; fats 0.6; assimilable carbohydrates 69; crude fiber 1.6; ash 2.

Article 397.—The term “Raisin” means the naturally or artificially dried fruit of *Vitis vinifera* L. and varieties thereof. Raisins named after special grape varieties must have been obtained from the variety named, such as: corinth, sultanine, sultana, muscat, etc. They may be packed in two ways: in layers, or loose. Average percentage composition: Water 20; proteins 2.5; fats 0.3; assimilable carbohydrates 74; crude fiber 0.8; ash 1.5.

Article 393.—Dried figs (fruit of *Ficus carica* L.) are, according to their color, classified into white and black figs. They are dried round or coin-shaped and flat, and are usually packed like medallions, the same as peaches, pressed into compact loaves, with or without the addition of nuts or almonds, or ground to a paste with sugar and citric acid. Average percentage composition: Water 25; proteins 3.8; fats 1; assimilable carbohydrates 62; crude fiber 5.8; ash 2.

Article 399.—Dried pears (fruit of *Pyrus communis L.*) may be sold with or without the skin (epicarp), whole, halved, or sliced. Before drying they are sprayed with, or immersed in, a 3-5% brine to prevent them from turning black when in contact with air. Average percentage composition: Water 25; proteins 2; fats 0.4; assimilable carbohydrates 64; crude fiber 6; ash 1.5.

Article 400.—Dried apples (fruit of *Pyrus malus L.*) may be sold with or without the skin (epicarp), whole, halved, or sliced. Before drying they are sprayed with, or immersed in, a 2% brine or a 2% sodium sulfate solution. Average percentage composition: Water 24; proteins 1.7; fats 0.5; assimilable carbohydrates 68; crude fiber 3.6; ash 2.

“Apple flour” is prepared by grinding dried sectioned apples. Average percentage composition: Water 6.5; proteins 2; fats 0.6; assimilable carbohydrates 84; crude fiber 4.4; ash 2.4.

“Apple Powder” is the product obtained by the dehydration of the clean, slightly fumigated fruit. The dry product is crushed, and 2% of tricalcium phosphate, or another permitted substance, is added to it as a preservative.

Article 401.—Dried apricots (fruit of *prunus armeniaca L.*) may be sold whole, with or without the stone, and the stones may be halved or not. Average percentage composition: Water 24; proteins 4.9; fats 0.8; assimilable carbohydrates 64; crude fiber 3; ash 2.4.

Article 402.—The term “Date” means the fruit of the date palm *Phoenix dactylifera L.* There are two types of dates: juicy or soft and dried or hard dates.

In the dates found in commerce, which are sun-dried or oven-dried, 75-85% is meat and 15-25% stone. Average percentage composition: Water 9 to 22; proteins 1.8 to 2.3; fats 0.3 to 0.6; assimilable carbohydrates 43 to 73; crude fiber 2 to 3.5; ash 1 to 2.

Article 403.—The term “Olives” means the sound fruits of various varieties of olive trees (*Olearia europea L.*), picked green or ripe, which may have been treated with alkaline lye to remove their tartness and were pickled in brine, to which aromatics may have been added. They are usually preserved in brine, but may also be preserved in oil. They may also be dehydrated to the consistency of prunes (raisin olive).

Naturally green olives are olives which, to preserve their original

color, were picked when they had almost reached physiological ripeness. The pH of the brine used for their preservation shall not exceed 5.8 and its salt content must not be less than 3 per cent. The containers shall have a hermetic closure and be sterilized in an autoclave at above 100° C.

Fermented green olives are olives which have undergone lactic fermentation. The brine used for their preservation shall have a pH of between 3.5 and 4.5 and its salt content may fluctuate between 5 and 10 per cent. Its lactic acidity may fluctuate between 0.5 and 1.2 per cent, expressed as lactic acid.

Naturally black olives are picked when they have reached full physiological ripeness and acquired a naturally dark—black, brown or purple—color, and are preserved in a brine containing salt in a proportion not exceeding 10 per cent, which turns dark with time.

The color of California-type black olives is due to an oxidation process of the skin and the mesocarp, and the brine in which they are packed shall contain salt in a proportion of between 3 and 10 per cent and have a pH not exceeding 7. They must be sold in hermetically sealed containers sterilized in the autoclave at above 100° C. Greek-type black olives have undergone partial dehydration in an oil or salt medium, with or without condiments.

Both green and black olives must have firm flesh. They shall have no tendency to decompose, have the aroma and flavor characteristic of their type, and be free from spoilage or decomposition. With the exception of Greek-type black olives, they shall be sold classified into the following grades:

1. Select: olives of uniform size and color which have no defects of any kind, except those normally caused by processing. 10% may have small defects.

2. Common: olives of reasonably uniform size and color. They may have defects caused by hail, harvesting operations and other marks which do not essentially affect their appearance and do not cover more than 5% of their surface.

For commercial purposes, olives are classified by size into:

Giant olives, or No. 0: from 80 to 140 olives per Kg.

Large olives, or No. 1: from 141 to 180 olives per Kg.

Medium olives, or No. 2: from 181 to 210 olives per Kg.

Small olives, or No. 3: from 211 to 250 olives per Kg.

Tiny olives, or No. 4: from 251 to 300 olives per Kg.

Dwarf olives, or No. 5: more than 300 olives per Kg.

Average percentage composition: green olive pulp: Water 65;

proteins 1.2; fats 27; assimilable carbohydrates 2.5; crude fiber 1; ash 2; Pulp of processed ripe (black) olives: Water 43; proteins 2; fats 35; assimilable carbohydrates 12; crude fiber 3.5; ash 4.

Stuffed olives are olives which after pickling are machine-pitted and stuffed with capers, anchovies or sardines, sweet peppers, truffles, etc.

Minced olives used in sandwich-making and cooking must be prepared from sound fruits, not waste.

Vegetables (Green Vegetables and Legumes)

Article 404.—The terms “Fruit Store” and “Vegetable Store” mean outlets at which fresh fruits and vegetables are sold. Such stores are not permitted to keep fowl or live birds.

Article 405.—The generic name “Vegetable” means any herbaceous plant grown in a vegetable garden, one or several parts of which may be used as food in their natural state. The designation “green vegetable” distinguishes the edible green parts of plants, and the term “legume” the seeds and fruits of leguminous plants.

The term “fresh vegetables” means freshly harvested vegetables intended for immediate consumption. “Dried vegetables” are vegetables from which part of the water content has been removed by exposure to air, sun or artificial heat in ovens.

Vegetables dried in special devices called “dehydrators” are distinguished by the name “dehydrated vegetables.” Dehydrated vegetables are different from sun-dried ones in that they generally contain a larger proportion of vitamins and water and can be reconstituted or re-hydrated more quickly. Dehydrated vegetables are usually of better quality than sun-dried ones.

A vegetable is considered sound when it is virtually free from insects, mites, cryptogamic diseases or other physical or mechanical defects that affect its appearance, and a sound vegetable is considered clean when no foreign bodies cling to its surface.

All fresh, dry or dried, and dehydrated vegetables offered for sale and consumption or intended for canning must be clean.

Vegetables intended for drying must be fresh, in a perfect state of development, mature and clean. They shall be dried immediately after picking and before they begin to wither. Discarded, diseased, withered or otherwise damaged vegetables are prohibited from being dried.

Dry, dried or dehydrated vegetables may not contain water in a proportion of more than 12 per cent and ash insoluble in 10 per cent

hydrochloric acid in a proportion of more than 1.5 per cent. Cooking them in potable water must not take more than 3 hours.

Vehicles and storage rooms used for fruits and vegetables may not be used for purposes that constitute a health hazard (manure transportation, etc.).

Tubers and Roots

Article 406.—All tubers and roots must be cleaned from the earth clinging to them before they are sold:

1. The name "Angelica" means *Angelica Archangelica* L. Its stems, leaf stalks and seeds are used in jams; the rhizomes in liqueur making and its raw or cooked stems and rhizomes in cooking.

2. The name "Arracacia" means the root of *Arracacha xanthoryhiza* Pancroft. Average percentage composition: Water 93; proteins 0.8; fats 0.2; assimilable carbohydrates 24; crude fiber 0.4; ash 1; ascorbic acid 25 mg.

3. The name "Sweet potato" means the tuber of *Ipomoea batatas* L. Average percentage composition: Water 78; proteins 0.9; fats, traces; assimilable carbohydrates 19; crude fiber 0.7; ash 0.9; ascorbic acid 42 mg.

4. The name "Cyperus" means the tuber of *Cyperus esculentus* L. Percentage composition: Oil 18 to 27; sucrose 15 to 30; starch 25 to 30.

5. The name "Chayote root" means the root of *Sechium edule* Swartz. Average percentage composition: Water 79; proteins 2; fats 0.2; assimilable carbohydrates 17; crude fiber 0.5; ash 1; ascorbic acid 18 mg. The names "Puntas de Chayote," "Puntas de güiquil," "Puntas de pataste" mean the stems of *Sechium edule* Swartz. Average percentage composition: Water 90; proteins 1; fats 0.2; assimilable carbohydrates 7; crude fiber 0.6; ash 0.4; ascorbic acid 15 mg.

6. The names "Manioc" and "Cassava" mean the root of bitter cassava (*Manihot utilissima* Pohl and its varieties) and sweet cassava (*Manihot palmata* Müll.). Average percentage composition: Water 63; proteins 1; fats, traces; assimilable carbohydrates 34; crude fiber 1.2; ash 0.7; ascorbic acid 25 mg.

Cassava leaves have the following average percentage composition: Water 78; proteins 6.8; fats 1.3; assimilable carbohydrates 10; crude fiber 2.5; ash 1.3; ascorbic acid 250 mg.

7. The name "Turnip" means the root of *Brassica rapa* L. Average percentage composition: Water 92; proteins 0.8; fats 0.2; assimilable carbohydrates 5.5; crude fiber 0.8; ash 0.7; ascorbic acid 25 mg. Turnip leaves have the following average percentage composition:

Water 91; proteins 3; fats 0.6; assimilable carbohydrates 3; crude fiber 1; ash 1.3; ascorbic acid 110 mg.

8. The name "Yam" means the root of *Dioscorea alata* L. and its varieties. Average percentage composition: Water 70; proteins 1.2; fats 0.2; assimilable carbohydrates 27; crude fiber 0.5; ash 0.8; ascorbic acid 5 mg.

9. The name "Taro" means the root of *Colocasia esculenta* L. Average percentage composition: Water 71; proteins 1.8; fats 0.3; assimilable carbohydrates 25; crude fiber 0.6; ash 0.8; ascorbic acid 5 mg.

10. The name "Potato" means the tuber of *Solanum tuberosum* L. and its varieties. Potatoes must be protected from daylight which favors sprouting; nor should they be kept in complete darkness or at a temperature of below 6° C. The pulp of potatoes intended for human consumption may not contain solanine in a proportion of more than 0.18 grams per kilo. Percentage composition (when fresh): Water 66 to 85; proteins 0.7 to 3.7; fats 0.2 to 0.5; assimilable carbohydrates (starch 11 to 28) 14 to 29; crude fiber 0.3 to 3; ash 0.3 to 1.8; ascorbic acid 20 mg. (when dehydrated): Water 12; proteins 9; fats 0.6; assimilable carbohydrates 72; crude fiber 1.8; ash 4.

11. The name "Parsnip" means the root of *Pastinaca sativa* L. Average percentage composition: Water 79; proteins 1.5; fats 0.5; assimilable carbohydrates 16; crude fiber 2; ash 0.8.

12. The name "Radish" means the roots of different species and varieties of *Raphanus sativus* L. Average percentage composition: Water 92; proteins 1; fats 0.1; assimilable carbohydrates (sugars 0.8) 5; crude fiber 0.8; ash 0.7; ascorbic acid 25 mg. Radish leaves have the following average percentage composition: Water 85; proteins 2.5; fats 0.5; assimilable carbohydrates 10; crude fiber 1; ash 1; ascorbic acid 120 mg.

13. The name "Beet" means the root of *Beta vulgaris* L. v. *hortensis*. Average percentage composition: Water 85; proteins 2; fats 0.1; assimilable carbohydrates 11; crude fiber 0.8; ash 0.7; ascorbic acid 5 mg. Beet leaves have the following average percentage composition: Water 83; proteins 3; fats 0.4; assimilable carbohydrates 8; crude fiber 3.6; ash 2; ascorbic acid 50 mg.

14. The name "Salsify" means the root of *Tragopogon porrifolius* L. Average percentage composition: Water 81; proteins 2.5; fats 0.5; assimilable carbohydrates (sugars 2.5) 13; crude fiber 2; ash 0.9; ascorbic acid 10 mg.

15. The name "Jerusalem artichoke" is the tuber of *Helianthus tuberosus* L. Average percentage composition: Water 83; proteins 1.5; fats 0.1; assimilable carbohydrates 13; crude fiber 0.7; ash 1.

16. The name "Carrot" means the root of *Daucus carota* L. Average percentage composition: Water 88; proteins 1; fats 0.5; assimilable carbohydrates (sugars 2) 8; crude fiber 0.8; ash 1; ascorbic acid 5 mg.

17. The name "Yantia" means the root of *Xanthosoma violaceum* Schott. Average percentage composition: Water 62; proteins 1.8; fats 0.2; assimilable carbohydrates 34; crude fiber 0.8; ash 1; ascorbic acid 8 mg.

Bulbs and Stems

Article 407.—The name "Garlic" means the bulb of *Allium sativum* L. These bulbs consist of egg-shaped cloves. The bulbs are usually strung to form tresses. Average percentage composition: Water 76; proteins 3.5; fats 0.3; assimilable carbohydrates 18; crude fiber 0.9; ash 1; ascorbic acid 6 mg.

Garlic Powder: see Article 618.

Garlic Salt: see Article 618.

Article 408.—The term "Celery" means *Apium graveolens* L. A distinction is made between two principal varieties: leaf celery (petioles) or tall strain (edible part) and turnip-rooted celery whose root (edible part) becomes very large in size. Average percentage composition: (Petioles) water 93; proteins 1; fats 0.1; assimilable carbohydrates 3; crude fiber 1.4; ash 1. (Root): Water 89; proteins 1.5; fats 0.3; assimilable carbohydrates 7; crude fiber 1.2; ash 0.8; ascorbic acid 10 mg.

Celery Extract: see Article 659, numeral 4.

Celery Salt: see Article 623.

Article 409.—The term "Cardoon artichoke" means *Cynara cardunculus* L. the tender petioles of which are edible. Average percentage composition: Water 91; proteins 2.4; fats 0.2; assimilable carbohydrates 4; crude fiber 0.5; ash 1.

Article 410.—The term "Onion" means *Allium cepa* L. The bulbs are usually strung, as garlic bulbs, or packed in bunches. Onions which do not form bulbs but have a thick stem are called scallions. The small bulbs of early varieties (e.g. multiplicans, Bailey) the watering of which is suspended when they reach the size of a marble, are called "miniature onions" or "pickling

onions." Average percentage composition: (Fresh): water 88; proteins 1.5; fats 0.2; assimilable carbohydrates 9; crude fiber 0.6; ash 0.4; ascorbic acid 10 mg. (Dehydrated): Water 10; proteins 14; fats 2; assimilable carbohydrates 61; crude fiber 9; ash 4.

Onion Salt: is prepared like Garlic salt: see Article 623.

Article 411.—The term "Shallot" means the bulb of *Allium ascalonicum* L., which has a sweet onion flavor. Average percentage composition: Water 80; proteins 2.6; fats 0.1; assimilable carbohydrates 15.7; crude fiber 0.7; ash 0.8; ascorbic acid 1 mg.

Article 412.—The term "Asparagus" means the shoots (spears) of the rhizome of *Asparagus officinalis* L. Average percentage composition: Water 93; proteins 2; fats 0.2; assimilable carbohydrates 3; crude fiber 0.6; ash 0.5; ascorbic acid 5 mg.

Article 413.—The term "Fennel" means *Foeniculum officinale* All, and other species. The seeds are used as a spice (see Article 638). The fleshy base of the petioles is edible. Average percentage composition: Water 94; proteins 1.5; fats 0.2; assimilable carbohydrates 2.5; crude fiber 0.7; ash 1.

Article 414.—The name "Leek" means the bulb of *Allium porrum* L. Average percentage composition: Water 89; proteins 2; fats 0.3; assimilable carbohydrates 6; crude fiber 1; ash 0.8; ascorbic acid 8 mg.

Article 415.—The name "Rhubarb" means the fleshy petioles (stems) of various varieties of *Rheum rhabonticum* L. Average percentage composition: Water 95; proteins 0.6; fats 0.1; assimilable carbohydrates 2; crude fiber 0.6; ash 1; ascorbic acid 10 mg.

Cabbages

Article 416.—Cabbages belong in the family *Cruciferae*, and all cabbage varieties derive from *Brassica oleracea* L. The edible parts are:

The Leaves:

1. Cabbage which comes in a single head of smooth leaves: *Brassica oleracea*, var. *capitata* L., White Cabbage, white, red, curly or crispy cabbage. Milan Cabbage. Average percentage composition: Water 92; proteins 1.2; fats 0.2; assimilable carbohydrates 4; crude fiber 1; ash 1; ascorbic acid 35 mg. Chinese Cabbage *Brassica pekinensis* Rupr. Average percentage composition: Water 96; proteins 0.5; fats 0.1; assimilable carbohydrates 2; crude fiber 0.4; ash 0.7; ascorbic acid 18 mg.

2. Brussels Sprouts: *Brassica oleracea* L., var. *gemmifera* Z. Average percentage composition: Water 85; proteins 4; fats 0.3; assimilable carbohydrates 7.5; crude fiber 1.3; ash 1.4; ascorbic acid 20 mg.

3. Kale: *Brassica oleracea* L. var. *acephala*.

The Flowers:

4. Cauliflower: white head or an ensemble of small stems. *Brassica oleracea* var. *botrytis* L. Average percentage composition: Water 91; proteins 2.5; fats 0.1; assimilable carbohydrates 4; crude fiber 0.9; ash 1.2; ascorbic acid 10 mg.

5. Broccoli: green or violet-colored head, *Brassica oleracea* var. *botrytis* L. Average percentage composition: Water 90; proteins 3; fats 0.2; assimilable carbohydrates 4; crude fiber 1.3; ash 1; ascorbic acid 90 mg.

6. Turnip Greens: flowers of *Brassica napus* L. Average percentage composition: Water 88; proteins 2.1; fats 0.2; assimilable carbohydrates 7.5; crude fiber 0.9; ash 1; ascorbic acid 95 mg.

Fleshy stem:

7. Kohlrabi, white and violet-colored.

Fleshy root:

8. White Turnip (white root), *Brassica caulorapa* D. C. and Rutabaga (yellow root). Average percentage composition: (White Turnip): water 90; proteins 2; fats 0.1; assimilable carbohydrates 5.5; crude fiber 1; ash 1. (Rutabaga): Water 89; proteins 1; fats 0.1; assimilable carbohydrates 7.5; crude fiber 1.2; ash 1; ascorbic acid 80 mg.

Salad Vegetables

Article 417.—The name "Salad Vegetables" designates vegetables usually eaten raw with a dressing. They belong in the family *Compositae*: chicory, dandelion, endive, lettuce; the family *Cruciferae*: watercress, nasturtium, etc.; the family *Valerianaceae* such as "canonigo"; and the family *Leguminosae*, such as alfalfa.

1. The chicory (*Cichorium intybus* L.) varieties used for salads are those with fine tender leaves. Average percentage composition: Water 93; proteins 1.5; fats 0.3; assimilable carbohydrates 3; crude fiber 0.7; ash 1; ascorbic acid 9 mg.

2. The parts of alfalfa (*Medicago sativa* L.) used for salads are the tender leaves and petioles. Average percentage composition: Water 85; proteins 8.5; fats 0.2; assimilable carbohydrates 1.5; crude fiber 3; ash 1; ascorbic acid 160 mg.

3. The name "Watercress" designates the leaves and stems of *Nasturtium officinale* R. Br. Average percentage composition: Water 94; proteins 2; fats 0.1; assimilable carbohydrates 1.5; crude fiber 0.6; ash 1.1; ascorbic acid 30 mg.

4. The name "Canónigo" designates the leaves of *Valerianella olitoria* Pall and its golden green, round varieties. Average percentage composition: Water 94; proteins 1.8; fats 0.3; assimilable carbohydrates 2; crude fiber 0.5; ash 0.8.

5. The name "Dandelion" means the leaves of *Taraxacum officinale* Weber. Average percentage composition: Water 86; proteins 2.8; fats 0.7; assimilable carbohydrates 7; crude fiber 1.5; ash 1.8; ascorbic acid 25 mg.

6. The names "escarole" and "endive" mean the two varieties of the leaves of *Cichorium endivia* L.: "Crispa," which has trim curly leaves, and "latifolia," which has lobular dented leaves. Average percentage composition: Water 93; proteins 1.5; fats 0.2; assimilable carbohydrates 3; crude fiber 0.8; ash 0.8; ascorbic acid 8 mg.

7. The names "lettuce," "Boston lettuce," "romaine lettuce" mean the leaves of different varieties of *Lactuca sativa* L. Average percentage composition: Water 95; proteins 0.5; fats 0.2; assimilable carbohydrates 2; crude fiber 0.5; ash 0.8; ascorbic acid 8 mg.

8. The name "Cress" means the leaves and petioles of *Lepidium sativum* L. and *Coronopus pinatifidus*. Average percentage composition (*Lepidium sativum* L.): Water 88; proteins 4; fats 1.2; assimilable carbohydrates 4; crude fiber 1; ash 1.3; ascorbic acid 20 mg.

Legumes

Article 418.—The term "Legumes" means the fruits (pods) and seeds (beans) of several species of plants, especially of the family *Leguminosae*. Some are eaten fresh (peas, string beans, shell beans, etc.) and the others sun-dried, with the seeds separated from the pods and the seeds used as food (chick peas, lentils, beans, etc.).

1. The term "Lupines" means the seeds of *Lupinus albus* L. (white Lupine), *Lupinus luteus* L. (yellow Lupine), *Lupinus angustifolius* L. (blue Lupine) and *Lupinus mutabilis* L. ("Tarhui"). Average percentage composition—Dried bitter lupines: Water 13; proteins 35; fats 5; assimilable carbohydrates (sugars 8) 26; crude fiber 7; ash 13.5. Dried sweet lupines: Water 10; proteins 51; fats 6; assimilable carbohydrates (sugars 9) 25; crude fiber 2.5; ash 5; ascorbic acid 0. Fresh Tarhui: Water 47; proteins 17; fats 17; assimilable carbohydrates 13; crude fiber 3.5; ash 1.6; ascorbic acid 5 mg.

2. The name "Pea" means the fruits of many varieties of *Pisum arvense* L. (field pea) and *Pisum sativum* L. (garden pea). Average percentage composition — Fresh pea: Water 71; proteins 8; fats 0.4; assimilable carbohydrates (sugars 2) 17; crude fiber 2; ash 1; ascorbic acid 20 mg. Dried pea: Water 11; proteins 21; fats 3; assimilable carbohydrates (sugars 8) 59; crude fiber 3.5; ash 2.4; ascorbic acid 0 mg.

3. The name "Jack bean" means the seeds of *Cucurbita maxima Duchesne*. Average percentage composition: Water 3.5; proteins 32; fats 48; assimilable carbohydrates 10; crude fiber 1; ash 5; ascorbic acid 0 mg.

4. The name "Pigeon pea" means the seed of *Cajanno bicolor D. C.* Average percentage composition: Water 69; proteins 7; fats 0.6; assimilable carbohydrates 18; crude fiber 3.5; ash 1.2; ascorbic acid 40 mg.

5. The names "Beans," "Shell beans," "String beans" and "Snap beans" mean the seeds of different varieties of *Phaseolus vulgaris* L., which are eaten fresh or dried, and also in their green pods. Average percentage composition of white, black and red beans: Fresh beans: Water 62; proteins 10; fats 0.2; assimilable carbohydrates 24; crude fiber 2.3; ash 1.5; ascorbic acid 8 mg. Dried beans: Water 12; proteins 22; fats 2; assimilable carbohydrates (sugars 3) 56; crude fiber 4; ash 3.5; ascorbic acid 0 mg. Fresh string beans: Water 89; proteins 2.2; fats 0.1; assimilable carbohydrates 6; crude fiber 1; ash 0.7; ascorbic acid 15 mg.

6. The name "Chick-pea" means the dry seed of *Cicer arietinum* L. and its varieties. Average percentage composition: Water 13; proteins 17; fats 4.5; assimilable carbohydrates (sugars 9) 60; crude fiber 3; ash 2.4; ascorbic acid 0 mg.

7. The name "Okra" means the fruits of *Hibiscus esculentus* L. and its varieties; it is eaten fresh and green, like string beans, and its seeds are eaten dried, like dried beans. Average percentage composition: Water 88; proteins 2; fats 0.4; assimilable carbohydrates 8; crude fiber 0.5; ash 0.8; ascorbic acid 25 mg.

8. The name "Guaba" designates the seed of *Inga edulis* L. Average percentage composition—Fresh: Water 63; proteins 10; fats 0.7; assimilable carbohydrates 23; crude fiber 1.5; ash 1.2; ascorbic acid 10 mg. Dried: Water 10; proteins 20; fats 2; assimilable carbohydrates 61; crude fiber 2.8; ash 3.5; ascorbic acid 0 mg. (See Article 381, numeral 11.)

9. The term "Broad Bean" means the fruit of several varieties of *Vicia faba* L. Average percentage composition—Fresh: Water 70;

proteins 7; fats 0.5; assimilable carbohydrates 19; crude fiber 2; ash 1.2; ascorbic acid 26 mg. Dried: Water 13; proteins 25; fats 1.7; assimilable carbohydrates (sugars 28) 55; crude fiber 1.6; ash 3; ascorbic acid 3 mg. Roasted: Water 5; proteins 26; fats 2; assimilable carbohydrates 62; crude fiber 1.2; ash 3; ascorbic acid 0.

10. The terms "Lablab" and "Black Bean" mean the seed of *Dolichos lablab* L. Average percentage composition: Fresh: Water 90; proteins 2.8; fats 0.2; assimilable carbohydrates 4.5; crude fiber 1.5; ash 0.7; ascorbic acid 25 mg. Dried: Water 13; proteins 18; fats 1; assimilable carbohydrates 58; crude fiber 7.4; ash 2.6; ascorbic acid 2 mg.

11. The term "Lentil" means the seed of *Lens esculenta* Moonch and its varieties. The common lentil has a diameter of 4 to 5 millimeters, the large lentil a diameter of 6 to 9 millimeters. Average percentage composition: Water 12; proteins 22; fats 1.5; assimilable carbohydrates 58; crude fiber 4.2; ash 2; ascorbic acid 3 mg.

12. The term "Cashew nut" means the seed of *Anacardium occidentale* L. Average percentage composition: Water 6.5; proteins 21; fats 40; assimilable carbohydrates 28; crude fiber 0.9; ash 2.8; ascorbic acid 0 mg. (See Art. 381, numeral 43.)

13. The term "Round chick-pea" means the seed of *Crescentia alata* H.B.K. Average percentage composition: Water 5; proteins 28; fats 34; assimilable carbohydrates 29; crude fiber 0.8; ash 3; ascorbic acid 0 mg.

14. The term "Soy bean" means the seed of *Glycine max* L. and its varieties. Average percentage composition: Water 10; proteins 34; fats 19; assimilable carbohydrates 27; crude fiber 4.5; ash 5; ascorbic acid 0 mg.

15. The term "Lima bean" means the seed of *Phaseolus lunatus* L. Average percentage composition: Fresh: Water 61; proteins 9; fats 0.1; assimilable carbohydrates 27; crude fiber 1.7; ash 1.2; ascorbic acid 3 mg. Dried: Water 12; proteins 21; fats 1.3; assimilable carbohydrates 61; crude fiber 1; ash 3.2; ascorbic acid 0 mg.

16. The term "Cowpea" means the seed of *Vigna unguiculata* L. Average percentage composition: Water 10; proteins 22; fats 1.5; assimilable carbohydrates 58; crude fiber 4.7; ash 3.2; ascorbic acid 0 mg.

17. The name "Sesame" means the seed of *Sesamum orientale* L. Average percentage composition: Water 4; proteins 17; fats 49; assimilable carbohydrates 15; crude fiber 10; ash 4.5; ascorbic acid 0 mg.

Leaves, Flowers, Fruits, Algae

Article 419.—The term "Sorrel" means the leaves of *Rumex acetosa* L. which are usually consumed fresh, in salads or cooked.

Average percentage composition: Water 92; proteins 2; fats 0.3; assimilable carbohydrates 3.5; crude fiber 0.6; ash 0.8.

Article 420.—The term “Chard” means the ribs and leaves of *Beta vulgaris* L. var. *cicla* Moq. Average percentage composition: (Ribs:) Water 94; proteins 0.6; fats 0.5; assimilable carbohydrates 2.3; crude fiber 1; ash 1.5. (Leaves:) Water 91; proteins 2; fats 0.3; assimilable carbohydrates 4.2; crude fiber 0.6; ash 1.5; ascorbic acid 30 mg.

Article 421.—The term “Artichoke” means the fully developed flowering top of *Cynara Scolymus* L. Average percentage composition: Water 92; proteins 2.5; fats 0.2; assimilable carbohydrates 2; crude fiber 1.5; ash 1; ascorbic acid 5 mg.

Article 422.—The term “Eggplant” means the fruit of *Solanum melongena*, var. *esculentum* Nees. Average percentage composition: Water 88; proteins 1; fats 0.8; assimilable carbohydrates (sugars 3) 8; crude fiber 1.3; ash 0.5; ascorbic acid 5 mg.

Article 423.—The term “Spinach” means the leaf of *Spinacia oleracea* L. and its varieties. Average percentage composition: Fresh: Water 91; proteins 2.3; fats 0.4; assimilable carbohydrates 3; crude fiber 1; ash 1.4; ascorbic acid 40 mg. Dehydrated: Water 8; proteins 18; fats 3; assimilable carbohydrates 55; crude fiber 8; ash 7; ascorbic acid 12 mg.

Article 424.—The term “Pepper” means the red or green fruits of different varieties of *Capsicum annum* L. The round sweet varieties are called “bell peppers” and the long ones “chilies.” Average percentage composition: Water 91; proteins 1; fats 0.5; assimilable carbohydrates 5; crude fiber 1.5; ash 0.6; ascorbic acid 90 mg.

Article 425.—The term “Tomato” means the ripe fruit of *Lycopersicon esculentum* Mill. and its varieties. Average percentage composition: Water 92; proteins 1; fats 0.3; assimilable carbohydrates 5; crude fiber 0.7; ash 0.6; ascorbic acid 30 mg.

Article 426.—The terms “Pumpkin” and “Squash” mean the fruits of many varieties of the genus *Cucurbita*, especially the families: *Cucurbita pepo* L., *Cucurbita maxima* Duchesne and *Cucurbita ficifolia* Bouché. When intended for human con-

sumption, they are harvested immature and still tender. Average percentage composition: Pumpkin: Water 91; proteins 0.7; fats 0.2; assimilable carbohydrates 6; crude fiber 0.5; ash 0.8; ascorbic acid 8 mg. Squash: Water 94; proteins 0.9; fats 0.1; assimilable carbohydrates 3; crude fiber 0.8; ash 1; ascorbic acid 18 mg. Calabash leaves: Water 89; proteins 5; fats 0.5; assimilable carbohydrates 3; crude fiber 1.5; ash 1.5; ascorbic acid 50 mg.

Article 427.—The term “Julienne” means a mixture of dehydrated vegetables cut in strips for use in the preparation of soups. All vegetables used in the mixture must require the same soaking and cooking time, which must be stated in the labeling.

Article 428.—The name “Algae” means the cellular tissue of more than 3,500 species of brown or red sea plants of the families: *Laminaria*, *Fucus*, *Porphyra*, *Roðophita*, *Macrocystis*, *Chondrus*, *Gracilaria*, *Clopteryx*, *Amanori*, *Schizymania*, *Halymenia*, *Lessonia*, *Laurencia*, *Durvilloea*, *Enteromorpha*, *Desmaristia*, *Ulva*, *Turbinaria*, *Caulerpa*, *Eucheuma*, etc. which may be used as food for humans and cattle.

Canned Vegetables and Fruits

Article 429.—Vegetables and fruits intended for canning must comply with the following requirements:

1. They must meet the specifications fixed in Article 378 and 405;
2. They must be harvested before reaching full maturity (industrial maturity);
3. They must be clean and fresh, and must be processed not later than 72 hours after harvesting. This time limit does not apply to vegetables and fruits which are kept under refrigeration under suitable conditions of humidity, ventilation and temperature;
4. The gradings with which they are sold must meet the established standards;
5. Their green color is prohibited from being reinforced artificially with salts of nickel, copper, coloring matters, sodium bicarbonate, etc. To fix their color, only ascorbic acid and citric acid may be added;
6. Canned vegetables and fruits shall not be considered stabilized, i.e., ready for sale to the public, until ten days after processing.

Article 430.—The term “canned peas” (tiny, small or medium) or “Petits Pois” may be used only for canned peas prepared with the fruits of *Pisum arvense* L. and *Pisum sativum* L. harvested before full maturity. They are graded as follows:

1. Tiny: very tender round peas of uniform color, with barely incipient seeds, without strings, free from defects and not more than 8.5 mm. in diameter.

2. Small: tender round peas, reasonably uniform in color, which may have slight defects and already formed small seeds, which have not reached full maturity, however, and whose diameter does not exceed 10.5 mm. Up to 10 percent of pod tips and 5 percent of pieces or strings are permitted.

3. Medium: reasonably tender peas with small defects, which may have well-developed, but no hard seeds. Their diameter may exceed 10.5 mm. Up to 15% of pod tips and 10% of pieces with strings are permitted.

Average percentage composition: Water 86; proteins 3.5; assimilable carbohydrates 8.5; fats 0.2; crude fiber 1; ash 0.4.

Peas processed in a different manner ("French style," "battered," etc.) shall have a statement to that effect in the labeling.

Canned peas made with soaked dried peas shall be labeled as follows: "Canned soaked dried peas" and no reference to their size ("tiny," "small," "medium," etc.) may be contained in their labeling. Sprouted peas are not permitted to be used.

Article 431.—The following names designate the canned products listed hereinafter:

1. Natural Chard: a canned product prepared with the joints (ribs) and fresh leaves of *Beta vulgaris* L., cicla Moq. variety, with or without ascorbic and citric acid, preserved, with or without sugar, in a brine whose salt content varies between 1 and 3 grams per hundred (See Article 420).

2. Artichokes: a canned product prepared with the flower heads of *Cynara scolymus* L. (See Article 421), picked when still tender. To prevent blackening, sodium bisulfate in a proportion of not more than 2,500 p.p.m., water, ascorbic acid and citric acid may be added to it; the brine in which it is packed must contain salt in a proportion of not less than 1 and not more than 3 per cent, and the amount of citric acid added may not exceed 0.2 percent.

Natural Artichokes: a canned product prepared with the flower heads of *Cynara scolymus* L., picked while still tender and before they turn fibrous, and packed whole, quartered, in hearts (centers) or bases (floral receptacles), with sweetened or unsweetened brine, citric acid and/or ascorbic acid. Flower heads which have opened, have hair in the heart or immasticable fibrous bracts are not permitted to

be used. Average percentage composition: Water 89; proteins 2.6; fats 0.2; carbohydrates 5; crude fiber 2.2; ash 1.

3. Natural String Beans: a canned product prepared with the tender whole, cut or sliced fruits of the cylindrical varieties of *Phaseolus vulgaris*, with or without strings. The labeling must state whether the beans packed are fancy (not more than 6 mm. broad), fine (not more than 9 mm. broad), or medium (more than 9 mm. broad). Average percentage composition: Water 89; proteins 2.5; fats 0.2; assimilable carbohydrates 6; crude fiber 1.3; ash 0.8. (See Article 418, numeral 5.)

4. Sweet Corn or Natural Corn: a canned product prepared with whole (whole grain) or crushed (creamed) grains of sweet varieties of *Zea mays L.* or the *Saccharata* variety, with or without the addition of salt and/or sugar. Starch may be added in a proportion of up to 2 percent without a declaration. Average percentage composition: Water 77; proteins 2.5; assimilable carbohydrates 18; crude fiber 0.4; ash 0.5. (See Article 265.)

5. Sauerkraut: This is a special product with a characteristic sour flavor, in a good state of preservation, prepared by allowing finely chopped leaves of various garden varieties of hard white cabbage (*Brassica oleracea*) to ferment and macerate for some time with 2 to 3 percent of salt and condiments. Its acidity must exceed 1 percent expressed as lactic acid. The tubs or vats used for it must be stored in suitable places and be kept in good condition, and each time the liquid covering the product is changed the brine to be used must first have been boiled.

Average percentage composition: Water 93; proteins 1.2; fats 0.2; assimilable carbohydrates 3; crude fiber 1.4; ash 0.5. (See Article 416.)

6. Natural Asparagus: the canned product thus named is made with the whole, sound, clean, non-fibrous stalks of *Asparagus officinalis L.*

Average percentage composition: Water 93; proteins 1.6; fats 0.1; assimilable carbohydrates 3; crude fiber 0.5; ash 0.7. (See Article 412.)

In American-style canned asparagus only the edible parts are used.

7. Natural Spinach: a product prepared with the fresh leaves of *Spinacia oleracea L.* (See Article 423.)

8. Natural Palm Cabbage: a canned product prepared with the terminal buds of various species of palm trees. Average percentage

composition: Water 89; proteins 3; fats 0.5; assimilable carbohydrates 5; crude fiber 1; ash (sodium chloride 1) 1.4.

9. Natural Peppers: the canned product made with the fruits of different *Capsicum varieties*. (See Article 424.)

The name "Large Sweet peppers" means the fruits of different varieties of *Capsicum annum grossum*, which are medium-sized, bright red, heart-shaped, smooth peppers with a thick pulp. "Calahorra"-type canned peppers are made by using only the pericarp of the fruit, free from seeds, which, to remove the skin, has first been subjected to a heat or alkali treatment. They may not contain salt in a proportion of more than 1 percent or added sugars in a proportion of more than 1 percent. Their pH may not exceed 4.5. They are usually canned whole or in chunks. Whole large sweet peppers are graded as follows:

1. Select: uniform, bright red fruits consistent in structure, which have no tendency to decompose. Fruits whose skin is sticking to them and fruits which are broken may not be used for this grade. The net content of the can shall not be less than 66 percent of the total content.

2. Common: reasonably uniform fruits. Scratches in the skin may not cover more than 60 percent of the length of the fruit. The percentage of reasonably discolored fruit may not exceed 30 percent.

Sweet peppers in chunks must have a surface of not less than 12 cm² and shall always be graded as "common." The name "Pepper purée" means a cooked product obtained from the fruit of different varieties of *Capsicum annum*, with or without sugar and/or salt (not more than 1 percent of either).

Average percentage composition: Water 92; proteins 1.2; fats 0.3; assimilable carbohydrates 4.5; crude fiber 1.4; ash 0.4.

10. Beans: the canned product made with the tender, fresh, sweet seeds of *Phaseolus lunatus L.* and its varieties, with or without the addition of salt and/or sugar. The canned product made with steeped dried beans shall be named: "Steeped dried beans." Sprouted beans are not permitted to be used. Canned beans prepared with bacon, salt pork or tripe shall contain at least 5 percent of such products. (See Article 418, numerals 4, 5, 15 and 16.)

11. Natural Beets or Canned Beets: a product obtained from the tender root of the red varieties of *Beta vulgaris L.*, with or without salt and/or vinegar. It is prepared with the whole roots ("Whole beets"), or cut into chunks, cubes or slices ("Cut beets," "Sliced beets," "Cubed beets"). (See Article 406, numeral 13.)

12. Natural Carrots: a canned product prepared with the whole, cubed or sliced roots of *Daucus carota L.*, to which salt has been added in a proportion of between 1 and 3 percent. Green or purple necks are not tolerated, but slight flaws caused by handling and cleaning are permitted. (See Article 406, numeral 16.)

Article 432.—Canned tomato products shall be made with fresh fruits of the different varieties of *Lycopersicon esculentum Mill.* (See Article 425.) Depending upon their shape, a distinction is made between “smooth and pear-shaped” (Italian variety) and “crannied and round” (Morglose, Manzanita, Sioux, etc. varieties) tomatoes. Depending upon their grade, they are classified into:

1. Select: fruits which by way of exception, due to poor peeling, have some of the peel clinging to them (4 percent). No pieces of loose peel may be found in the container. The net content of the container shall not be less than 65 percent of the total content.

2. Common: fruits which may still have up to 10 percent of their peel and contain up to 20 percent of discolored tomatoes. The net content of the container shall not be less than 55 percent of the total content.

Canned tomato products shall be designated and labeled as follows according to their characteristics:

1. The name “Natural Whole Tomatoes” means whole, ripe, firm fruits which were washed, scalded and peeled, with or without the addition of salt and sugar, and sterilized in their own juice. The name “Natural Chopped Tomatoes” distinguishes the canned product prepared in a similar manner with chopped tomatoes. The name “Crushed tomatoes” means ripe fruits which were washed and crushed, or cut into pieces, without peeling, with or without the addition of salt and sugar and sterilized in their own juice. The name “Natural Tomatoes in the peel” means a similar product prepared with selected tomatoes canned whole with their skin.

2. The name “Tomato Juice” means the juice extracted from ripe red tomatoes, free from seeds and peel, with or without the addition of salt and sugar, which may or may not have been subjected to homogenization before packing and sterilization.

Average percentage composition: Water 95; proteins 1; fats 0.2; assimilable carbohydrates 3; crude fiber 0.2; ash 0.2; acids, expressed as citric acid 0.6; density at 15° C. 1.028. Sugar and not more than 2 percent of salt may be added to it. It must contain soluble solids in

a proportion of between 3.5 and 6.5 percent, free from sugars and added sodium chloride. Its color must be the red typical of the ripe fruit, "faded" juices being prohibited. When passed by natural gravity (without pressure) through a 0.6 mm. mesh at a temperature of between 15 and 20° C., it must all have run through after 30 minutes. Its pH may vary between 4.2 and 4.8, and the cryoscopic index between $-0^{\circ}.10$ and $-0^{\circ}.12$.

3. The name "Tomato Pulp" means the product obtained by sifting tomato pulp (mesocarps), with or without the addition of salt and sugar, and free from peel and seeds. Tomato pulp shall contain tomato solids in a proportion of between 5 and 8.36 per cent and may contain sodium chloride in a proportion not exceeding 5 percent.

4. The name "Tomato Purée" means the product obtained by concentrating tomato pulp and juice, with or without the addition of salt. Its dry residue, free from sodium chloride, must amount to between 8.37 and 12 percent. It may contain added sodium chloride in a proportion of not more than 5 percent.

5. The name "Tomato Sauce" means the slightly concentrated cooked canned product whose dry residue, free from sodium chloride, amounts to not less than 12 and not more than 16 per cent. Its added sodium chloride content may not be more than 5 per cent.

6. The names "Tomato Paste" and "Raw Tomato Paste" mean the raw product canned cold on covered premises with a waterproof floor.

The tubs or vats in which tomato paste is prepared shall be covered with a wire mesh with 2 mm. openings, and when draining bags are used they must be suspended at a height of not less than 25 centimeters from the floor. This canned product may not contain added sodium chloride in a proportion of more than 15 per cent.

7. The names "Plain Tomato Concentrate" and "Plain Tomato Extract" mean the preparation whose salt-free dry residue does not amount to less than 16 or more than 28 per cent. Its added sodium chloride content may not exceed 5 per cent.

8. The term "Double Strength Tomato Extract" means a tomato extract whose salt-free dry residue amounts to not less than 28 and not more than 36 per cent. The amount of sodium chloride added to it may not be more than 5 per cent.

9. The name "Triple Strength Tomato Extract" means a tomato extract whose salt-free dry residue amounts to not less than 36 per cent. The amount of sodium chloride added to it may not be more than 5 per cent.

10. The name "Dried (or Dehydrated) Tomato Extract" means tomato extract containing water in a proportion of less than 20 per cent. Its added sodium chloride content may not exceed 10 per cent.

11. The names "Ketchup," "Catchup" or "Tomato Catsup" mean a sauce made from the juice and pulp of sound ripe tomatoes to which various condiments have been added, such as: onions, sweet peppers, salt, sugar, mustard, mushrooms, pepper, vinegar, etc. No vegetable color may be added to it, and its dry residue may not be less than 35 per cent.

All canned tomato products (juice, sauce, purée, extract, catsup) shall meet the requirements fixed herein and when examined under the microscope by the Howard and Stephenson method in a dilution in which the sample has a dry residue of between 8.37 and 9.37 grams per centum, may not show mold filaments in an amount of more than 60 fields per centum, except products prepared from "Select" tomatoes whose positive mold fields may not number more than 50.

Canned tomato products shall be considered adulterated: if they are misnamed, i.e. if the composition of the product fails to meet the specifications fixed herein for products bearing the name used; if they contain waste material, insoluble ash in a proportion of more than 0.5 per cent, or starch in a proportion of more than 6 per cent calculated on the dry residue, or if they are products in which the ratio between total dry residue and organic matter is above 1.4 or below 1.2 per cent.

Article 433.—The name "Vegetables under Vinegar" (chilis, cucumbers, gherkins, cocktail onions, eggplants, cauliflower, carrots and vegetable mixtures, etc.) means the canned product prepared by placing the whole or cut vegetables into vinegar without first pickling them, with or without aromatics. The expolition liquid shall have an acidity of more than 1 per cent expressed as acetic acid. Vegetables under vinegar shall be sold in hermetically sealed containers which were sterilized in the autoclave at a temperature of above 100° C.

The name "Pickles" means fruits and vegetables which, after brine curing or lactic fermentation under special conditions, have been preserved in vinegar and salt, with or without the addition of condiments, turmeric and sugars (sour pickles) or in vinegar to which sugars and condiments have been added (sweet pickles).

All substances used in the preparation of pickles shall meet the requirements of this Code.

The expolition liquid of pickles must contain salt in a proportion of not less than 3 per cent and have an acidity of not less than 2 per cent expressed as acetic acid.

The name "Pickled chilis" means the stretched fruits of *Capsicum annum L.*, cured in brine and thereafter preserved in vinegar. There are two types of pickled chilis: Sweet and hot.

The name "Chutney" means a pickled product prepared from various vegetables and fruits, dressed with a sauce made of malt vinegar, sour apples, sugars, ginger and mustard.

The name "Chowchow" means a pickle prepared from different vegetables to which mustard has been added.

The name "To:mato Chowchow" means a preparation made with a base of tomatoes, onions, sweet peppers, sugars and salt which is cooked in vinegar before packing.

The name "Piccalilli" means a pickle prepared from various vegetables and vinegar, seasoned with mustard, turmeric or curry powders.

Moreover, pickles shall meet the following specifications:

a. they may not contain traces of sulfurous acid or bisulphites, even when this type of product was used to bleach the vegetables used in their preparation;

b. the acidity of the liquid may not be below 2 per cent, expressed as acetic acid, and its sodium chloride concentration may not be below 2.5 per cent, except in the case of pickles which were sterilized in their own container.

Article 434.—The designation "Natural Canned Fruits" means, in general, canned products made with sound fresh fruits, still in their peel or peeled by hand, by machine or with lye, with or without their seeds or stones and immersed in a light syrup. They shall always be named after the fruit used: Natural Mazzards, Pears, etc. When the fruit is packed with the seed or stone, the labeling shall read: Whole Mazzards, Whole Peaches, etc.

1. The name "Natural Pineapple" designates the canned product made with different pineapple varieties (see Article 381, numeral 4), peeled, freed of its fibrous central part and eyes, cut into slices, half slices, or chunks, and graded according to their quality as:

1. Select: only whole or half slices which are firm, uniform in size and color, not crushed, broken, clipped, or spotted, and have no black tips (eyes). In the can, the syrup, which may be slightly clouded by the fruit, shall have a minimum concentration of 24° Brix or 13.5° Beaumé.

2. Common: slices may have up to two black points (eyes)

in the center, half slices one and chunks none. The syrup in the can may be slightly cloudy from the fruit and shall have a minimum concentration of 20° Brix or 11.3° Beaumé.

2. The name "Natural Peaches," with the addition "white" or "yellow," in "halves," "sliced," "in chunks" or "whole with stones" designates the canned product made from the peeled fruits of *Prunus persica* L., graded according to their quality as:

1. Fancy: fully ripened fruits, which must be firm, however, and have no tendency to decomposing, are even in color and uniform in size, free from spots and imperfections. The syrup in the container shall be clear or clouded slightly by the fruit and shall have a minimum concentration of 22° Brix or 12.4° Beaumé.

2. Select: ripe fruits, of firm consistency, even color and uniform size, practically free from spots and imperfections. The syrup in the container shall be clear or clouded slightly by the fruit and shall have a minimum concentration of 18° Brix or 10° Beaumé.

3. Common: fruits which are neither hard nor too soft, reasonably even in color and size. Spots caused by the sun, handling or oxidation are tolerated in a proportion of not more than 20 per cent of the fruit, always provided that no tissues have decomposed and that the defect covers not more than one-fifth of the spotted fruit. The syrup in the container shall be clear or clouded slightly by the fruit and shall have a minimum concentration of 16° Brix or 9° Beaumé.

3. The name "Natural Apricots" designates the canned product made with the peeled or unpeeled pitted fruits of *Prunus armeniaca* L., graded according to their quality as:

1. Select: fully ripened fruits which have no tendency towards decomposing, are even in color, uniform in size and free from defects. The syrup in the container shall be clear or clouded slightly by the fruit and shall have a minimum concentration of 22° Brix or 12° Beaumé.

2. Common: fruits which are neither hard nor too soft, reasonably even in color. A can may have defective fruits in a proportion not exceeding more than 10 per cent, but may not contain disintegrated pieces. The syrup in the container shall be clear or clouded slightly by the fruit and shall have a minimum concentration of 16° Brix or 9° Beaumé.

4. The name "Natural Cherries" designates the canned product made with whole pitted or unpitted fruits of *Prunus capuli* Ca., free

from peduncles, without disintegrated pieces in the container and graded according to their quality as:

1. Select: fruits free from any spots or defects, uniform in color and size. Each fruit shall be not less than 20 mm. in diameter. The syrup in the container may be slightly cloudy from the fruit and shall have a minimum concentration of 24° Brix or 13.5° Beaumé.

2. Common: fruits reasonably free from spots which may be slightly discolored. Each fruit shall be not less than 15 mm. in diameter. The syrup in the container may be slightly cloudy from the fruit and shall have a minimum concentration of 20° Brix or 11.3° Beaumé.

Pitted natural cherries shall meet the above grading requirements, but may have some splits caused by pitting.

1. Select: splits may not cover more than 30 per cent of the length of the fruit, measured from the base of the peduncle to the tip. Up to 1 per cent of the cherries may have stones.

2. Common: splits may not cover more than 50 per cent of the length of the fruit, measured from the base of the peduncle to the tip. Up to 3 per cent of the cherries may have stones.

5. The name "Natural Mazzards" designates the canned product made from the fruits of *Prunus cerasus* L. or Sour Cherry, canned whole, pitted or unpitted, free from peduncles, not containing disintegrated pieces and graded according to their quality as:

1. Select: fruits free from any spots or flaws, uniform in color and size. Each fruit shall be not less than 20 mm. in diameter. The syrup in the container may be slightly cloudy from the fruit and shall have a concentration of not less than 24° Brix or 13.5° Beaumé.

2. Common: fruits reasonably free from spots which may be slightly discolored. Each fruit shall not be less than 6 mm. in diameter. The syrup in the container, which may be slightly cloudy from the fruit, shall have not less than 20° Brix or 11.3° Beaumé.

Pitted natural Mazzards shall meet the above grading requirements, but may have some splits due to pitting.

1. Select: the splits may not cover more than 30 per cent of the length of the fruit measured from the base of the peduncle to the tip. Up to 1 per cent of the fruits may have stones.

2. Common: the splits may not cover more than 50 per cent

of the length of the fruit, measured from the base of the peduncle to the tip. Up to 3 per cent of the fruits may have stones.

6. The name "Natural Pears" designates the canned product made with the cleaned fruits of *Pyrus Communis L.*, free from peduncles, calyxes, seeds, cores, and central vascular clusters, cut into halves, slices, or chunks and graded according to their quality as:

1. Select: fully ripened fruits which are neither hard nor too soft in consistency, have no tendency towards decomposing, are uniform in size, even in color, white or slightly amber, free from spots or other defects. The syrup in the container may be slightly cloudy from the fruit and shall have not less than 18° Brix or 10° Beaumé.

2. Common: fruits which are neither hard nor too soft, reasonably uniform in color and size. 20 per cent of the fruit may have spots or defects, always provided that they do not cover more than 20 per cent of the fruit. The syrup in the container may be slightly cloudy from the fruit and shall have not less than 15° Brix or 8.5° Beaumé.

Natural pears cut into halves, slices, or chunks shall always be packed separately and are not permitted to be mixed.

7. The name "Natural Apples" designates the canned product made with the cleaned fruits of *Pyrus malus L.*, free from peduncles, calyxes, seeds, cores and central vascular clusters, cut into halves, slices or chunks and graded according to their quality as:

1. Select: fully ripened fruits, whose consistency is neither hard nor too soft, which have no tendency towards decomposing and are uniform in size, even in color, free from spots or other defects. The syrup in the container shall be clear or slightly cloudy from the fruit, and shall have a concentration of not less than 24° Brix or 13.5° Beaumé.

2. Common: fruits which are neither hard nor too soft, reasonably uniform in color and size. Up to 20 per cent of pieces with spots or defects are tolerated, always provided that such spots or defects do not cover more than 20 per cent of each fruit. The syrup in the container shall be clear or slightly cloudy from the fruit and shall have a concentration of not less than 15° Brix or 8.5° Beaumé.

Natural apples cut into halves, slices or chunks may not be mixed in the same container, but each type shall be packed separately.

8. The name "Natural Quince" means the canned product made with the cleaned fruits of *Cydonia vulgaris Pers.*, free from peduncles.

calyxes, seeds, cores and central vascular clusters, cut into halves, slices or chunks and graded according to their quality as:

1. Select: fully ripened fruits, whose consistency is neither hard nor too soft, which have no tendency towards decomposing, and are uniform in size and color, free from spots or other defects. The syrup in the container shall be clear or slightly cloudy from the fruit, and shall have a concentration of not less than 30° Brix or 16.8° Beaumé.

2. Common: fruits which are neither hard nor soft, reasonably uniform in color and size. Up to 20 per cent of the fruits may have spots or defects, always provided that such spots or defects do not cover more than 20 per cent of each fruit. The syrup in the container shall be clear or slightly cloudy from the fruit and shall have a concentration of not less than 20° Brix or 11.3° Beaumé.

Natural quinces, cut into halves, slices or chunks may not be mixed in the same container, but each type shall be packed separately.

9. The name "Natural Plums" designates the canned product made with the whole, cleaned or uncleaned fruits of *Prunus domestica* L., in halves, with or without the stone, graded according to their quality as:

1. Select: fruits which are reasonably uniform in color and size and free from peduncles. The syrup in the container may be slightly cloudy from the fruit and shall have a concentration of not less than 24° Brix or 13.5° Beaumé.

2. Common: fruits free from peduncles, of which up to 20 per cent may have defects, always provided that such defects do not cover more than 20 per cent of each fruit. The syrup in the container may be slightly cloudy from the fruit and shall have a concentration of not less than 18° Brix or 10° Beaumé.

10. The name "Natural Strawberries" designates the canned product made with the whole hypertrophied receptacle of various species of the genus *Fragaria*, free from peduncles, calyxes and other vegetable waste, graded according to their quality as:

1. Select: fruits of firm consistency, uniform in size, without any flattened or crushed fruits. The syrup in the container which may be slightly cloudy from the fruit, shall have a concentration of not less than 24° Brix or 13.5° Beaumé. The natural color may be reinforced with a color permitted by this Code.

2. Common: fruits of firm consistency, without flattened or crushed pieces, reasonably uniform in size, so that the difference

between the fruits largest and smallest in diameter is not more than 5 mm. The syrup used in packing which may be slightly cloudy from the fruit shall have a concentration of not less than 20° Brix or 11.3° Baumé. The natural color may be reinforced with a color permitted by this Code.

The name "Crushed Strawberries" designates the canned product prepared from cleaned, sound strawberries, free from peduncles, calyxes and other vegetable parts, and crushed. Their color may be reinforced with a color permitted by this Code. They may be packed with or without sugar.

11. The name "Natural Figs" designates the canned product prepared with the fruits of *Ficus carica* L. The same product, but prepared with fruits of various species of the genus *Opuntia*, shall be named "Natural Prickly Pears." Only one grade shall be permitted, i.e., Select: firm fruits which are uniform in size and color and free from spots and other defects. The syrup used in packing shall have a concentration of not less than 30° Brix or 16.8° Baumé. The syrup shall be clear, slightly cloudy from the fruit, and somewhat dark in the case of black figs.

12. The name "Natural Grapes" designates the canned product made with the ripe, sound fruits of *Vitis vinifera* L., free from peduncles and other vegetable waste, graded according to their quality as:

1. Select: fruits which are uniform in size and color, free from spots and other defects. The syrup used in packing, which may be slightly cloudy from the fruit, shall have a concentration of not less than 30° Brix or 16.8° Baumé.

2. Common: fruits reasonably uniform in size. The syrup used in packing, which may be slightly cloudy from the fruit, shall have a concentration of not less than 20° Brix or 11.3° Baumé.

13. The names "Natural Fruit Salad," "Natural Mixed Fruits" and "Natural Fruit Cocktail" designate the canned product prepared with various fruits, such as peaches, pears, plums, cherries, grapes, of firm consistency, not crushed or disintegrated, some whole, others sliced, halved or cubed, candied or uncandied, which may have been steeped in sweetened or alcoholic liquids and shall be graded according to the quality of the fruits used as:

1. Select: The syrup used in packing shall have a concentration of not less than 22° Brix or 12.4° Baumé.

2. Common: For this grade, the concentration shall be not less than 18° Brix or 10° Baumé.

[The End]

Building Tomorrow's System

By JAMES L. GODDARD, M.D.

The following article was presented as a speech to members of the National Association of Chain Drug Stores on April 22, 1968, at Bal Harbour, Florida. Dr. Goddard is Commissioner of the Food and Drug Administration.

I AM OFTEN STRUCK by the contradictions we live under: that groups such as the National Association of Chain Drug Stores and the Food and Drug Administration (FDA), groups that literally live with each other day in and day out, have so little opportunity to discuss the big issues in a context that is apart from the immediate, panic problems of that very day-to-day coexistence.

So, I am happy that you—as businessmen involved with the delivery of vital health products and services—and I, as your Commissioner of Food and Drugs, can talk about where we are going, how we are going to get there, and why. Above all, *why*.

And I am delighted that the theme of this year's convention is forward-looking: "68 plus ten." As you know, I had occasion not too long ago to make predictions looking ahead 20 years. Let's say that the reaction was mixed. But today at least I am in "predicting"—if not altogether predictable—company.

I won't set any time limits on some of the things I would like to share with you. But I say they are coming. They are on the way. I would urge you to consider them not narrowly—just in terms of your own chain operation—but broadly, in terms of where the Nation is heading in organizing its health services and where business might be going in order to better participate—and profit from—these new directions. Am I speaking of things to happen in the next ten years? Yes, I am. And of things to happen, I believe, well within that time period as well.

Health Care

First, where are we? What is our take-off point? I would like to discuss this in terms of health care, because it is just not pos-

sible any longer to segment out bits and pieces of health and talk about them as if they could and do exist by themselves. Yes, we will get down to specifics in terms of drugs—which would be, of course, my major topic of discussion with a group such as this. However, we cannot understand the future of drug development and marketing unless we know the kind of health system within which drugs will be needed and used.

Today, health care is booming. Although nobody's estimates are exact, most economists agree that this Nation is passing the \$50 billion mark this year in health expenditures, both public and private. And the line on the graph is still going up. I think that good health care is now something that every American wants and expects to get. It is considered a right. That does not necessarily mean it is free and I don't believe that Americans are confused on that score.

They know, for example, that their children have a right to get the best education available—and they accept the fact that they will pay for it through property taxes, sales taxes, income taxes, or—for private schools—out-of-pocket. There is a cost attached to all our rights and privileges; we need not argue that fact.

But today we are including among those rights and privileges an area that has more often been considered exclusive. In his Health Message to the Congress, President Johnson proposed a program with which, he said, "We can move closer to our goal of decent health care for every American. This is a program to assure that American medicine will continue to build on its great record, and that its benefits will enrich and improve the life of every citizen."

The President's proposals to the Congress on March 4 were based upon a national commitment that is already quite firm. The eighty-ninth and ninetieth Congresses have passed nearly 30 new pieces of important health legislation. The Federal Government's investment in health care has jumped in these three years from \$6 billion to nearly \$14 billion. The private sector has invested close to three times as much. In terms of action, in terms of money, in terms of actual programs that are now serving the American people—there can be no question that health is a booming, growth segment of our society.

And right here, it is time to pause and step back. I know that there is not one executive in this audience who has not gone through the experience of fast, back-breaking growth. From all the literature that Bob Bolger sent my way over the past few months, I am con-

vinced that I am speaking to a group who knows both the excitement—and the stress—of moving ahead and moving up with speed.

Examining Our Present System

As you have done many times during the past few years, so now do we—in the Government—do the same: we are taking a closer, harder look at our total system to see how efficient it is, how responsive, how much of an additional load it can carry. Let's be realistic about that load, too.

The life expectancy of the average American today is 70 years.

With Medicare, about 20 million Americans over the age of 65 can get health service that was not available to them before.

Twenty million children have been vaccinated against measles, and 30 million have been protected against diphtheria, polio, tetanus and whooping cough.

Under the maternal and child health program, 300,000 women are now receiving family planning services; another 390,000 are receiving maternity care; and 680,000 infants are being helped through those crucial first few months of life.

Through Medicaid, another 3.5 million children from our rural and urban ghettos are getting the health care they ought to receive, as American citizens.

And we are going to do more. This is not a full picture of our total health effort today. Nor is it in any way an indication that we have reached the peak of our effort. Quite the reverse. We have just begun to understand how serious—and how immediate—the task of building a broad, national program of better health care really is.

So we have taken a look at our system of health care—at its potential, as well as its present capacities. And we are distressed to find that hospitalization is antiquated, that medical practice is grossly uneven from city to city and even from neighborhood to neighborhood, that prices for health products and services are not only confusing—they are based on a logic that doesn't seem to have much to do with health at all. We find that we need manpower of a new kind and quality, trained in new techniques for new careers—and we need this manpower quickly.

In many of these areas, your particular industry is not involved, I understand. But you are part of the overall "health business," so to speak. When I say we need to do something about expanding

our supply of health manpower, I am including our supply of pharmacists, pharmacy aides, and patient advisors, or, as I prefer to call them, "drug therapy advisors." And when I say that medical practice itself is changing, I mean that it is shifting from solo to group, back and forth, with new techniques, methods, and payment plans exerting greater and greater influence for change.

And, as I indicated when I spilled out all those statistics about millions of older people, of women, and of children receiving health care—the patient population itself is changing. We've got more people into the system, in a shorter period of time, with less understanding among them of what to expect from the system than in any other peaceful mobilization that I can recall.

I am willing to say, also, that for every statistic I can rattle off for the expansion of our health care system in this Nation, you can match me with one that illustrates the expansion of your own industry. Because, ladies and gentlemen, you are part of that system—and we need you, I can tell you that—but you are part of that system and you are just going to grow along with it.

If that is the case, then both of us—you in the private sector and we in the Government—must keep aware of the stresses to come and what we can do to avoid collapse at any point. I think we can make a start by seeing how several different activities that the FDA is now carrying on are beginning to come together. As they converge, they may produce—in concert—a solution to a major problem within our system of health care delivery.

Findings of the Drug Efficacy Review

You are all familiar with the Drug Efficacy Review, I know. When we had our large orientation meeting last January, Dr. R. Keith Cannan, of the National Academy of Sciences-National Research Council noted that 237 different pharmaceutical firms had submitted the labeling claims for 3,600 different drug formulations that were first introduced between 1938 and 1962. Because many of these drugs have multiple labeling claims, Dr. Cannan reported that "something like 10,000 independent therapeutic judgments will have been made when the task is completed" by the 30 panels of experts the Academy brought together.

You are aware, of course, that for every drug product that went to the Academy, we estimate that there are about five "me-too's" in the marketplace. So we are not talking about a modification in

our national drug supply involving only 3,600 products. We are talking about changes involving as many as 16,000 different products.

The findings of the Academy are flowing into our Agency and we are taking all the steps necessary to insure that these findings are translated into regulatory language that is in the spirit of promoting "honesty and fair dealing" in the marketplace, as our basic statute, the Food, Drug, and Cosmetic Act instructs us to do. We are very concerned that this be an orderly process, that it not be disruptive either to the practice of medicine or to the drug industry as a whole. But above all, I must tell you that we are moving forward on this project in the same spirit in which it was begun: to bring about more rational drug therapy among our citizens by influencing the development of a more rational drug supply. Drugs that work ought to remain in the market. Drugs that don't work ought not to clutter up your shelves and warehouses or the insides of our people either.

During the rest of this year, the results of the Academy will come in to us, will be processed by our medical and regulatory personnel, and published in the *Federal Register*. All the administrative machinery for all affected parties will, naturally, be available. But we don't anticipate too much difficulty. But I do want you to remember that the goods on your shelves this year—thousands of different products—do not reflect what may be on your shelves next year. And one reason is the completion of the Drug Efficacy Review.

Drug Directory and Compendium

As this is going on, we have been lending our support and technical assistance to many health and medical care programs handled by the Department of Health, Education, and Welfare. The Department currently finances drug programs for out-patients which run to 70 million prescription claims a year. We anticipate that, as present programs expand and new ones are enacted, the number of claims to be processed could rise to 350 million a year.

When we talk in this order of magnitude, we immediately see that the present methods of inventorying our drug supply are inadequate and that the ways we projected for working out re-payment to insurance carriers and others have to be re-evaluated as well. One thing we have done already is to put our Agency's new Science Information Facility at work on a way of coding drug products uniformly, so that they can be incorporated into electronic data processing systems. Earlier this month, the FDA published its pilot

edition of what we call a "National Drug Code Directory." Let me emphasize that it is a pilot issue and lists only about 4,000 individual drug products, both prescription and over-the-counter.

Next week, we are holding a workshop with members of the drug industry in order to move ahead toward the printing of the first official—that is, "nonpilot"—edition later this year. So far, cooperation has been excellent and I see this as one of our most exciting projects involving close industry-Government relationships.

With the National Drug Code Directory—this numerical control system over the entire drug supply on a product-by-product basis—and with the Drug Efficacy Review results coming out in the course of this year, also, you can begin to see that the system of ordering, storing, and delivering drugs is in a transitional state. However, the transition is toward a more rational, more manageable, and more understandable delivery system. We no longer need to be unnerved by predictions of masses of new people purchasing drugs in unusually high volume within a matter of a year or two. We merely have to take a second look at the inefficiencies that exist in the drug delivery system and set them aside—hopefully, for good. In place of those inefficiencies we can establish a better drug supply that is organized to exploit today's technology.

But let us understand that no one part of the system can move forward without the rest of the system responding in much the same way. And here we come upon the heart of the matter, as far as prescription drugs are concerned.

Throughout my remarks thus far may have been implicit the fact that when the label claims for drugs are changed, as a result of the Academy review, doctors will know about the changes and will adjust their prescribing habits accordingly. This could be the case, if doctors had some efficient way of getting all the information they need about all the drugs available. But they don't.

That is why we are taking yet another step that is related and will, in time, contribute so very much to a more efficient health system that can serve all Americans. I am speaking, of course, of the proposed United States Drug Compendium.

The Compendium was included in President Johnson's Health Message to the Congress on March 4. The President said:

To make sure that doctors have accurate, reliable and complete information on the drugs which are available, *I recommend that the Congress authorize this year publication of a United States Compendium of Drugs.*

This Compendium would be prepared by the Secretary of Health, Education, and Welfare, in cooperation with pharmaceutical manufacturers, who would bear the cost of its publication, and with physicians and pharmacists.

It will give every doctor, pharmacy, hospital, and other health care institution complete and accurate information about prescription drugs—use and dosage, warnings, manufacturer, generic and brand names, and facts about their safety and effectiveness.

The Drug Compendium is not a new idea. It has been discussed quite seriously by the medical profession and the drug industry since early in this decade. Many physicians—myself included—were long ago convinced that a compendium would be of great help to us in our work. In 1966, when I became Commissioner of Food and Drugs, I talked over this matter with representatives of the American Medical Association and the Pharmaceutical Manufacturers Association, among others. They expressed interest, but also noted the many “problems” that a compendium might present.

Well, I agree that there may be problems—but in light of the overall problem of getting the best information to the physician as soon as it becomes available—in light of that overriding problem, I just could not see the FDA retreating from a position of leadership. So we have in the Congress today—two years after my personal plea to private medicine and private industry to take the lead—we have in Congress the President’s proposal. Senator Lister Hill and Representative Harley O. Staggers are sponsoring the compendium legislation. I urge each of you to write these gentlemen for a copy of the bill, to study it, and to see if it does—as we maintain—bring an additional element of good sense and order to our health system.

Delays in Labeling Changes

Let me give you a concrete example of how imbalanced this part of the system is. Between March 26 and April 1, we collected samples of a number of drugs at the retail pharmacy level. This was done for information purposes. Each of the drugs had gone through the supplemental New Drug Approval process for a change in labeling. That is, each of the drugs we had sampled was to have had different prescribing of usage information accompanying it. The changes in labeling were all approved during the first quarter of 1967. Let me repeat, the labeling changes—changes that were made to help the physician prescribe or to help the patient use the drug—were approved during January, February, and March of 1967, over a year ago.

One would think that in a year's time, the label changes would all be in the marketplace. But such is not the case. We sampled a handful of drugs. Most of them are in the market, but do not dominate the market. Still, there they are—on pharmacy shelves, either on yours or in institutions.

For example, in our cross-country check—one sample per FDA District Office, how random can you get?—We picked up 14 bottles of Betadine Aerosol Spray. It's available over the counter. Among the labeling changes were these: "Keep away from the eyes," "keep out of the reach of children," "contents under pressure . . . never throw container into fire or incinerator," plus some new language in the indications-for-use section. Samples picked up in five FDA Districts had the proper, revised labeling approved last year. Samples picked up in nine districts still had the old labeling.

Or take Zolyse. Eight samples were collected. In Chicago and Detroit, the new insert was not with the sample. The new insert has two new contraindications and four side effects listed.

Or take Aquatag. This one had already been brought into conformance with the other standardized thiazide labeling. But a standard pregnancy warning was added in March 1967. That change did not appear in the inserts accompanying five of six samples picked up.

Then there is Oxylone. In eight districts, the samples had the wrong insert; in two districts, no insert was available with the sample; and in the remaining six districts, the proper, up-to-date insert did accompany the sample.

As I say, we sampled a number of drugs to see what the problem was. We found that some high-volume sellers, such as Indocin, which had an insert change during the first quarter of 1967, had the proper insert with every sample. But clearly we cannot rely on market position to be the guide as to whether a drug unit is properly labeled and ready to be given to a patient or not.

How long should it take for a drug that has new indications, new precautions, new warning statements, or other new prescribing information—how long should it take for that drug to be properly labeled? Should there be a time limit? Should lots that are not properly labeled and still in the market be recalled after that time limit? How will the time limit be set? And by whom? Who will pay for the exchange of inserts in each little box? Who will pay for the recalling of the lots themselves?

The NDA supplemental process is an important process. It keeps up to date whatever we know about any drug. It helps the doctor function better, which benefits his patients. And—in the last analysis—it is good patient care for this entire Nation that we are talking about today.

That is why I think the President's proposed United States Compendium of Drugs will be reviewed by the Congress this year and enacted into law. It makes sense medically. With the quarterly updating that we envision, it would be possible to get to the practicing physician the information he needs much sooner than he is getting it now. And he would get it on time, regardless of his geographical area of practice. And he would get the information updated regardless of the volume prescribing practices of his colleagues.

I think the proposal will pass because industry cannot afford the estimated 6 to 7 million dollars they now spend on the package insert for prescription drugs—and then very possibly pay for recalling improperly labeled drug lots or pay for labeling changes in your stores and warehouses either. Something has to give. It cannot be the welfare of the patient. It cannot be the professional judgment of the doctor. It cannot be the professional responsibility of the pharmacist.

But it *can* be the archaic organization of drugs and drug information. We *can* get the inefficiencies out of the delivery system and, as I have tried to sketch out for you this morning, I think we can do this together and with a sense of real accomplishment—from your viewpoint, accomplishment in the best business sense: good management, good organization, good controls. From our point of view, it is an accomplishment that means contributing to better health care for every man, woman, and child in this country.

Meeting the Challenges

Recently, Secretary Wilbur Cohen spoke to members of our Department and reminded us that "We are being challenged with many new assignments. We have tapped new resources and we have worked together in new ways to meet the challenges. Together, we are tackling the age-old problems of poverty, deprivation, ignorance, and ill health. And we are making progress in dealing with them. Now, we must continue with an even deeper commitment..."

I join Secretary Cohen in that spirit of meeting challenges and I hope that each of you here this morning will join with us in this deeper commitment to the well-being of America. [The End]



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By Alan E. Morrill

With an Introduction by Melvin Belli

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