

10.3 Appendix – Answer Key

10.1.2.1 Canned Vegetables and Fruits

- 1. What are Food Standards? How do they differ from grade standards?** “Food Standards” is FDA’s common designation for Standards of Identity, Standards of Quality, and Standards of Fill of Container promulgated under the FD&C Act. They are written to promote honesty and fair dealing in the interest of consumers. Food Standards are written by FDA and are found in 21 CFR 130-169; industry must comply with these or their products are deemed misbranded. The US Department of Agriculture establishes Grade Standards for fruits and vegetables to designate quality: "U.S. Grade A" and "U.S. Grade B". Industry compliance is voluntary. The U.S. Department of the Interior also uses these grade designations for fishery products. Such grade designations are not required by the Federal Food, Drug, and Cosmetic Act to be stated on the labels, but if they are stated, the product must comply with the specifications for the declared grade.
- 2. What consumer protection was presumed in the promulgation of food standards?** Consumers are protected from adulterated and misbranded foods by use of standards.
- 3. When is the packing liquid included in net weight calculations?** The packing liquid is included in the net weight calculations when it is also used by the consumer.
- 4. Define edible portion.** Edible portion is any portion of a food product that is fit to be eaten.
- 5. What is the basis for determining the solids content by use of the refractive index?** The refractive index is used in determining the solids for liquid samples containing only soluble solids. A refractometer is used and the observed value is corrected to 20 °C. This reading is compared to the same refractive index value of a standard sucrose concentration; solids in the sample solution are reported as percent by weight of sucrose.
- 6. Why isn't the product allowed to "drain" completely in a drained weight determination? Why are two minutes specified in 21 CFR 145.3(n)?** For the analyst “drained” completely is an empirical term that would be impossible for an analyst to time accurately and results would vary for one lab to another. Products are not drained completely in order to avoid leaving products on a sieve for a non-uniform time and to prevent evaporation. Two minutes are specified in the CFR in order to insure a constant basis for measurement and comparison.
- 7. What is the basis for the determination of alcohol-insoluble solid in canned vegetables?** The basis for determination of alcohol-insoluble solid in canned vegetables is consistency and to determine if product is excessively liquid which would make the product substandard. In this method the definition of Solids in Canned Peas is alcohol insoluble material.

8. **What are the requirements for the fill of container?** Food containers must be so made, formed, or filled so they are not misleading (FD&C Act, Sec. 403(d)). Fill of container is the minimum quantity of the solid food in the container after processing: not less than 90 percent of the total capacity of the container.
9. **Can the net contents be satisfactory and fill of container fail?** When the volume of product settles during shipment the correct net contents may no longer properly fill the container. When this is expected, the manufacturer may include a comment on the label to that effect.
10. **Define "degrees Brix."** A unit of measure on the Brix scale for measuring the density or concentration of sugar (sucrose) in solution, determined as percent by weight. It is used to measure the density of the packing medium of fruits and vegetables, or strength of juices.

10.1.2.2 Cheese

1. **Why is speed essential in sample preparation?** Speed is essential in sample preparation to prevent moisture loss, which would affect the results in the fat calculations of cheeses.
2. **Differentiate between a cheese spread and cheese food.** A cheese food is the food prepared by comminuting and mixing, *without* the aid of heat, one or more optional ingredients into a homogeneous mass. A cheese spread is the food prepared by comminuting and mixing, *with* the aid of heat, one or more optional ingredients into a homogeneous mass.
3. **Why are preservatives added? Must they be declared on labels?** Preservatives are added to slow or prevent growth of microorganisms which spoil food or cause disease. They must be declared on label according to 21 CFR 101 and 130.
4. **List two kinds of cheese in which sorbic acid is permitted and include the conditions under which it might be used. List two kinds of cheese for which sorbic acid is not permitted.** Sorbic Acid is permitted for use in cold pack cheeses in an amount not to exceed 0.3 percent by weight and in pasteurized process cheeses in an amount not to exceed 0.2 percent by weight. Sorbic Acid is not permitted for use in Nuworld and Roquefort cheeses.
5. **What is a processed cheese?** A processed cheese is the food prepared by comminuting and mixing, with the aid of heat, one or more of the optional cheese ingredients, into a homogeneous mass that is spreadable.
6. **In the CFR procedure, is the moisture content directly determined?** The CFR procedure uses an indirect method and moisture loss is determined, not content.
7. **In the cheese fat extraction, what other substances may be found?** Other product ingredients, such as oil-soluble natural colors, may be extracted if present.

8. **Why is petroleum ether used for the extraction?** Petroleum ether is used because fats and oils are readily soluble in this solvent and it is easily evaporated.

10.1.2.3 Jams, Jelly, and Orange Juice

1. **What is jam?** A viscous or semi solid food, from a mixture of one or more fruits, mixed with or without water, and concentrated with or without heat. The soluble solids content of the finished product should not be less than 65 per cent. The standards of identity for jams and jellies (21 CFR 150) require that these products be prepared by mixing not less than 45 parts by weight of certain specified fruits (or fruit juice in the case of jelly), and 47 parts by weight of other designated fruits, to each 55 parts by weight of sugar or other optional nutritive carbohydrate sweetening ingredient.
2. **What is an imitation jelly?** A food is an imitation if it is a substitute for, and resembles another food, but is nutritionally inferior to that food (21 CFR 101.3(e)). Nutritional inferiority includes any reduction in the content of an essential nutrient that is present in a measurable amount.
3. **What orange products are standardized?** Orange juice that is fresh, pasteurized, or with preservatives; or made from concentrate. Also juice that is frozen, concentrated, canned, frozen concentrated, canned concentrated, or un-concentrated for manufacturing. Refer to 21 CFR 146.
4. **Why are K_2O and ash used as criteria to determine fruit content?** K_2O is a pyrolysis product of the predominant mineral found in fruits. The ash content reflects the pyrolysis product of all minerals found in the fruit.
5. **Are the literature values of K_2O and Ash definitive for fruit?** The authentic literature values for K_2O and Ash data are fairly uniform for a given fruit. They may be used as a guide for sample data evaluation.

10.1.2.4 Mixed Nuts

1. **Be prepared to discuss the sections of the Act that apply to the examples of cheating given in the Introduction.** (To discuss with the trainer.)
2. **Differentiate between misbranding and adulteration in regard to question 1.**

A food shall be deemed to be “adulterated” if:

It bears or contains any poisonous or deleterious substance which may render it injurious to health.

It bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical in or on a raw agricultural commodity; or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406 of The Act.

It consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.

It has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

A food shall be deemed to be “misbranded” if:

Its labeling is false or misleading in any particular, or in the case of a food to which section 411 of the Act applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2).

It is offered for sale under the name of another food.

Its container is so made, formed, or filled as to be misleading.

In the case of nuts with misleading vignettes, misrepresentation of product, and incorrect net weight, misbranding charges apply.

3. **Why do the standards specify both amount and type of nuts?** Standards specify amount and type of nuts to prevent misbranding and economic fraud.
4. **How does the shape of the container affect the net weight determination?** The shape of the container dictates the method used to determine the net volume in cubic centimeters to calculate the net weight for the container.
5. **What is the maximum amount of peanuts allowed in mixed nuts?** In mixed nuts, each nut ingredient shall be present in a quantity not less than 2 percent and not more than 80 percent by weight of the finished food.
6. **What, if any, is the relationship between the vignette and the contents?** If the label bears any pictorial representation (vignette) of the mixture of nuts, it must depict the relative proportions of the nut ingredients contained in the finished food.

10.1.2.5 Egg Noodles

1. **Are eggs the only possible source of cholesterol in this product?** In egg noodles, concentrated glyceryl monostearate may be another possible source of cholesterol. Any fat ingredient obtained from an animal may be a source of cholesterol.

2. **Does the label have an ingredient statement? Why?** The label of an egg noodle must have an ingredient statement *when optional ingredients* such as onions, garlic salt, gum gluten, or glyceryl monostearate are added.
3. **Do all noodle products contain eggs?** As defined in the standard, all noodle products should contain egg; in noodles, the total solids of egg or egg yolk are not less than 5.5 percent.
4. **Compare the two drying methods. Which must be used to determine compliance with the standard for total solids?** One method uses a vacuum oven with drying to a constant weight at temp 98-100 ° C (~ 5 hrs.) and the second uses an air oven at 130 ° C for 1 hour. CFR 21.139.150(a)4 specifies the vacuum oven method.
5. **What is accomplished in AOAC 954.03?** Quantification of sterols (mostly cholesterol) by extraction and precipitation of the unsaponifiable fat portion of the macaroni product.
6. **Why is there a precaution in AOAC 954.03 to retain solid material in the separator?** To avoid loss of cholesterol before the extraction is completed, and to help keep insoluble material from causing an emulsion.
7. **How would one cope with an emulsion if it formed?** If an emulsion forms, leave it in the separatory funnel and wash, by swirling gently, the ether solution using two portions of water. Discard the aqueous phase and continue the analysis on ether solutions.
8. **What is the difference between macaroni and noodles?** The difference between macaroni and noodles is the egg content. In macaroni the total solids from egg white, frozen egg white, or dried egg white is not less than 0.5 and not more than 2.0 percent. In noodles, the total solids of egg or egg yolk are not less than 5.5 percent.

10.2.2.1 Salt and Sodium Nitrite in Smoked Fish

1. **What are the three requirements that must be met for a preservative to be used according to good manufacturing practices?** The three requirements for preservative use are the following: generally recognized as safe for such use (a food additive is covered by food additive regulations prescribing conditions of safe use); not used in such a way as to conceal damage or inferiority or to make the food appear better or of greater value than it is; and proper declaration on the food label in which used.
2. **List 10 standardized foods for which the addition of chemical preservatives has been permitted by regulation.** Milk and milk products, cereal, fish, macaroni, cheeses, canned vegetables, nuts, fruits bakery goods, and cacao.
3. **Which fish or fish products may legally contain nitrates or nitrites? List the maximum**

legal level for each product and describe how the retail container must be labeled. The fish or fish products that may contain nitrates or nitrites are smoked cured sablefish, salmon, shad, and chubs at levels not to exceed (NTE) 200 ppm sodium nitrite and NTE 500 ppm sodium nitrate. In smoked tuna fish products the level of sodium nitrite is NTE 10 ppm. The container label must bear the name and concentration of the additive.

4. **Where is "water phase salt" defined?** Water phase salt (WPS) is defined as the salt content of the water phase portion of the edible portion of the finished smoked product, as measured in the loin muscle (21 CFR 172.177). Generally, WPS should not be less than 3.5%. However, consult Compliance Programs 7303.844 and 7303.842 Domestic/Imported Fish and Fisheries Products for specific requirements, or the HACCP program (Fish and Fisheries Products Hazards & Controls Guide). **How does water phase salt vary with moisture content?** The water phase salt content is inversely proportional to the moisture content. **Write the equation used for calculating the salt concentration in the water phase.**

$$\% \text{ salt in water phase} = \% \text{ salt} / (\% \text{ salt} + \% \text{ water}) \times 100.$$

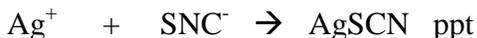
5. **Why is water added to the portion taken for analysis by AOAC method 952.08A?** Water is added for the purpose of mixing and to help uniformly distribute the sample portion across the surface of the drying pan. A smooth layer of sample promotes even drying.
6. **How would one show that all the volatile components had been evaporated from the tissue?** If no significant change in weight is observed after an additional period of drying then all volatiles have been evaporated.
7. **Show the reactions involved in the titrimetric analysis for total chloride.**

The procedure uses a modification of the old Volhard Titration.

For fish and fish products, the organic matter is oxidized by heating with HNO₃; the Cl⁻ is precipitated by the addition of Ag⁺. This results in an excess of Ag⁺.



The excess Ag⁺ is then titrated with SCN⁻ (thiocyanate).



One drop past the end point there is an excess of SCN⁻. This excess SCN⁻ then reacts with the Fe⁺³ to produce a colored ferric thiocyanate complex:



So, the total amount of Ag⁺ is known and the excess Ag⁺ after AgCl formation is known

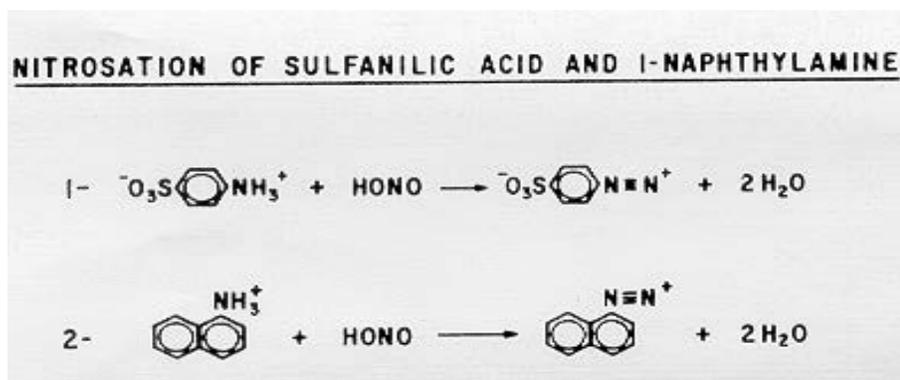
from the titration. Subtracting the moles of each yields the amount of Ag^+ that reacts with the Cl^- , which in turn tells us the amount of Cl^- . The Fe^{+3} does not do anything until there is an excess of SCN^- ; then it reacts and produces the colored FeSCN^{+2} complex which is used for the end point. The reddish-brown FeSCN^{+2} actually has a more complex formula. Bromide, iodide and cyanide are interferences. Also, if one does not do the titration quickly, then there will be an interference from the AgCl ($K_{sp} = 1 \times 10^{-10}$) reacting with the SNC^- since AgSCN has a $K_{sp} = 1 \times 10^{-12}$). The analyst should get an RSD of $< 5\%$ and a relative error of $< 2\%$.

8. **Why is the HNO_3 solution to be boiled before the indicator is added?** The HNO_3 solution is used to digest the protein and liberate the chloride in solution before the indicator is added.
9. **AOAC method 937.09B(b) states "With 10g sample each mL 0.1N $\text{AgNO}_3 = 0.058\%$ NaCl." How is this factor obtained?**

Assuming a 10.000 gram sample is used:

$$\frac{100\% \times 58.44 \text{ mg NaCl/meq N SCN}}{10,000 \text{ mg sample}} = 0.058\%$$

10. **What is the structure of the colored product formed during the nitrite analysis? Show the reactions involved.** The nitrosation of sulfanilic acid to form the diazonium salt of sulfanilic acid which then couples with 1-naphthylamine to form a pink azo compound.



11. **How has the order of addition of reagents been shown to affect this type of analysis?** Nitrite was added to sulfanilic acid and the mixture was allowed to stand 20 minutes before 1-naphthylamine was added. The resulting amount of azo dye was the same as that formed when nitrite was added to a mixture of sulfanilic acid and 1-naphthylamine.
12. **What is the correlation between pH and color stability?** Use of more acid and substitution of acids were investigated and the amount of dye compound formed was not affected.

10.2.2.2 Sulfites

1. **Why doesn't the HCl distill into the sulfur dioxide absorber? What is an azeotrope?**
The risk of interfering substances reaching the hydrogen peroxide trap (sulfur dioxide absorber) by aerosolization, co-distillation, or steam distillation has been reduced by condenser coolant temperatures, reflux rates, and nitrogen flow. The HCl is trapped in the reflux column. An azeotrope is a mixture of liquids that has a constant boiling point and cannot be separated by distillation.
2. **What reaction occurs in the distilling flask? In the sulfur dioxide absorber?** An oxidation reaction, $\text{SO}_2 \rightarrow \text{SO}_3$.
3. **What is the purpose of the gravimetric determination?** The gravimetric determination serves as a confirmatory test specific for sulfites.
4. **What purpose does the pyrogallol/KOH gas wash serve?** The pyrogallol/KOH wash serves as an oxygen scrubbing solution.

10.2.2.3 Monosodium Glutamate

1. **What other names are used for "monosodium glutamate?" What name must be used on a food label? Cite the regulation that supports the answer.** MSG is the sodium salt of the amino acid glutamic acid and a form of glutamate. "L-glutamic acid, sodium salt," and "sodium glutamate" are other names for MSG. When MSG is added to a food it must be included on the ingredient list as "monosodium glutamate," as required by 21 CFR 101.22(h)(5).
2. **How much monosodium glutamate is permitted in foods?** MSG is generally recognized as safe when used as a salt substitute in accordance with good manufacturing practice.
3. **Why is monosodium glutamate titrated in a non-aqueous solvent system and not in water? Show the chemical reactions involved.** MSG is titrated in a non-aqueous solvent because this condition is needed to protonate the amine; if water is present it will compete with this process:



4. **Define: optical activity, optical rotation, angular rotation and specific rotation.** *Optical*

activity is a measure of the ability of substances to rotate plane-polarized light. Optical activity results from polarized light emerging in a continuum of planes at different intensities such that the plane of maximum intensity forms a measurable angle with the plane of incident light. Where this effect is large enough for precise measurement it serves as the basis for an assay or an identity test (and is expressed in degrees). *Optical rotation* is the change of direction of the plane of polarized light to either the right or left as it passes through a molecule containing one or more asymmetric carbon atoms. Substances that rotate the light plane clockwise (dextrorotatory) are designated by “+” or “*d*.” Substances that rotate the light plane counterclockwise (levorotatory) are designated by “-” or “*l*.” *Angular rotation* is the observed optical rotation, measured in degrees. *Specific rotation* is the angular rotation divided by length of the path in decimeters x concentration of solute in grams in 100 cc solution. The wavelength and temperature are usually specified. For a pure liquid, concentration is replaced by its density.

10.2.2.4 Artificial Sweeteners

1. **The referenced TLC method is for beverages, what modification would be made for a non-liquid sample? What potential problems may be incurred using a modified method?** For a non-liquid sample, add a suitable portion of hot water, let stand and then filter through filter paper. The problem of emulsions, change of salt content, etc. - preventing suitable extractability of the analyte of interest - can be encountered when modifying the method.
2. **In terms of the TLC extraction procedure, what is the purpose of adding 5 ml of 50% NaOH solution?** Modification of the nature of the aqueous phase to basic changes the solubility of the 4 analytes. This will promote their extracting into the ethyl acetate organic phase.
3. **In terms of HPLC, what may occur if there is a change in the composition of the mobile phase?** The chromatographic elution pattern will change and possibly the peak shape; the resolution between peaks may not meet the performance criteria, components may elute in the void volume or greatly increase elution time resulting in poor chromatography and efficiency.
4. **In terms of HPLC how critical is the detection wavelength?** The wavelength at which the analyte of interest absorbs is critical information. When using HPLC with a UV/VIS fixed detector and attempting to chromatograph several analytes at once, a wavelength that is common for the group of analytes should be selected. However, modern instrumentation allows for different wavelengths to be simultaneously or sequentially monitored throughout the course of a chromatographic run.
5. **What is the salt of benzoic acid? Sodium or potassium benzoate. What pH does sodium benzoate optimally function? pH 2.5 – 4.0 Which is more soluble, sodium benzoate or benzoic acid?** Sodium benzoate is 180 times more soluble than benzoic acid.

- 6. What is meant by a regulated food additive? Provide examples.** Benzoic acid, sodium benzoate, calcium benzoate, sorbic acid potassium sorbate, sodium sorbate and calcium sorbate. Their maximum allowable in a food product is regulated at 0.1%.

10.2.2.5 Borates

- 1. "Caviar" is made from what type of fish?** Originally the name "caviar" was applied only to the eggs of the sturgeon prepared by a special process. [The eggs first prepared and most extensively used were those of the sturgeon, and to many people the term caviar was synonymous with sturgeon caviar.] The term caviar can properly be applied to any kind of fish eggs prepared by this special method.
- 2. When the roe of other fish types are used, what labeling requirement must be followed?** The term "caviar" can be used on a product prepared according to the usual caviar method and made from the roe of whitefish - provided the name of the fish is given in conjunction with the word caviar on the product label.
- 3. What is the purpose of adding boric acid?** Boric Acid is added to retard spoilage and to promote color retention (a color fixative). It is not allowed in caviar sold in the U.S.

10.2.3 Color Additives

- 1. What is a color additive?** A color additive is a specific category of Food Additive defined as a dye, pigment or other substance - whether synthetic or derived from a vegetable, animal, mineral, or other source - which is added to impart color to a food, drug, cosmetic, or applied to the human body.
- 2. Define these terms: straight color, lake and diluent.** A *straight color* is a color additive that has not been mixed or chemically reacted with any other substance. Straight colors subject to certification are listed in 21 CFR Part 74. Straight colors exempt from certification are listed in 21 CFR Part 73. In addition, 21 CFR Section 81.10 and 81.30 identify straight colors whose listings or certain uses have been terminated or whose certificates have been cancelled. *Lakes* are pigments prepared by precipitating a soluble dye onto an insoluble reactive or adsorptive substratum or diluent. They are water-insoluble and more stable than straight dyes, and are ideal for product in which leaching of the color is undesirable (coated

tablets and hard candies, for example). A *diluent* is any component of a color additive mixture that is not of itself a color additive and has been added to facilitate the use of the mixture as a coloring agent. The term *mixture* means a color additive made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

3. **What are "certified" colors?** Certified colors are Color Additives from certified batches analyzed by FDA's Color Certification Branch, CCB, to assure the Code of Federal Regulations (*21 CFR Part 74*) specifications are met. These Certifiable Color Additives are synthetic organic dyes, pigments or lakes of a dye. In order to be used in foods, drugs, cosmetics, and medical devices manufactured or sold in the United States, the color additives must meet the following criteria: come from a certified batch, be allowed in the respective product, and the color additive name must be listed in the ingredients label.
4. **Under what conditions may color additives be used in the area of the eye, in injections, or in surgical sutures?** Color additives may be used in the area of eye, injections, or in surgical sutures only if the color additives are specifically certified for such use.
5. **List the restrictions, if any, for the following colors:**
 - a. **Citrus Red No.2** - Permanently listed for use only in coloring of skins of mature oranges. Limit of 2 ppm calculated on basis of whole fruit weight.
 - b. **Orange B** - Permanently listed for use in coloring surfaces and casings of frankfurters or sausages. Limit of 150 ppm by wt. of finished product.
 - c. **Titanium dioxide** - Limit: of 1.0% by wt of food.
 - d. **FD&C Blue No. 1** - For food, drug and cosmetic use, including drugs and cosmetics for eye area - GMP - 74.101, 74.1101, 74.2101, 82.101.
 - e. **FD&C Red No. 3** - For food and ingested drugs - GMP - 74.303, 4.1303. Lake use terminated 2-1-90; All cosmetic uses terminated 2-1-90.
 - f. **FD&C Red No. 40** - For food, drug and cosmetic use, including drugs and cosmetics for eye area - GMP - 74.340, 74.1340, 74.2340.
 - g. **FD&C Yellow No. 5** - For food, drug and cosmetics, including drugs and cosmetics for eye area - GMP - 74.705, 74.1705, 74.2705, 82.705.
6. **What are chromophores and auxochromes? Identify the chromophores and auxochromes in two of the colors listed in the previous question.** *Chromophores* are groups of one or more unsaturated bonds that absorb light (in the ultraviolet or visible region) and thus produce colored substances. They are, in most cases, covalent unsaturated groups such as C=C, C=O, C=NH, CH=N, and N=N. Examples are FD&C Yellow No. 5 (N=N) and

FD&C Blue No. 1 (N=CH). *Auxochromes* are functional groups that do not confer color to a substance themselves, but increase the coloring power of a chromophore. They contain functional groups, such as -OH, -NH₂, -SO₃H, -COOH, that don't exhibit absorption in visible wavelengths (however, auxochromes may absorb strongly in the far-ultraviolet region). When an auxochrome is combined with a chromophore in the same molecule, the chromophore absorption will typically shift to a longer wavelength (a bathochromic shift) and show an increase in intensity (a hyperchromic shift). Auxochromes provide an unshared pair of electrons in conjunction to the chromophore. Examples are FD&C Blue No. 1 (-SO₃) and Citrus Red 2 (-OH).

7. **What is hypsochromic shift? Give the effect of hypsochromic shift for two of the colors in question 5.** Hypsochromic shift is a change in wavelength maxima to a shorter wavelength, and thus change in color. For FD&C Red No. 40 and Citrus Red 2, the addition of base produces a change in color from red to orange and a wavelength maxima shift of approximately 50 nanometers.
8. **Give one example of a triphenylmethane color.** Brilliant Blue FCF (CI 42090, certifiable as FD&C Blue No.1) is an example of a triphenylmethane color. [Other triphenylmethane dyes, such as malachite green or gentian violet, are sometimes used as fungicides in the food industry.] Triphenylmethane colors consist of a common moiety of three phenyl groups attached to a central carbon (hence "methane"). Other functional groups are then attached to the phenyls and these determine the different colors.
9. **List the Color Index Number (C.I. No.) and common name for FD&C Red No. 1, FD&C Red No. 3, D&C Orange No. 3, FD&C Green No. 3, D&C Yellow No. 7, D&C Yellow No. 9, FD&C Blue No. 2, and FD&C Violet No. 1.**

FD&C Red No.1	CI 16155	Ponceau 3R
FD&C Red No.3	CI 45430	Erythrosine
D&C Orange No.3	CI 16230	Orange G
FD&C Green No.3	CI 42053	Fast Green FCF
D&C Yellow No. 7	CI 45350	Fluorescein
D&C Yellow No.9	CI 45350	Uranine K
FD&C Blue No.2	CI 73015	Indigotine
FD&C Violet No.1	CI 42640	Wool Violet 5BN

10. **A label of a food product declares "...E123..." as an ingredient. Is this product permitted in the U.S.?** E123 is the European code designation for Amaranth (a.k.a. CI 16185, former FD&C Red No.2) which is not permitted for use in the U.S.
11. **A label of a food product declares "...Sunset Yellow FCF, Erythrosine Lake, Allura Red AC." Is this product correctly labeled? If not, why? If the importer re-labels the product would it be permitted in the U.S.?** Artificial colors must be declared on the labels by listing the color additive name (*i.e.* Red 40) among the list of ingredients (21 CFR

101.22(k)(1)). When colors are declared using their common names (*i.e. Allura Red AC*), it is assumed that the colors used were not from a certified lot and the product can be detained based on adulteration. Use of Erythrosine Lake is not permitted in the U.S. and the product would not be permitted to be sold even if relabeled.

12. **How many synthetic colors are approved for use in cosmetics? Which of these colors are permitted in eye area cosmetics?** Presently there are thirty four synthetic colors approved for use in cosmetics, of which only four are permitted in eye area cosmetics – FD&C Yellow No.5, FD&C Red No. 40, FD&C Blue No.1, and D&C Green No.5.
13. **A lipstick sample was analyzed using Newburgers, 19.1. One bright pink band of color, exhibiting orange fluorescence, was detected. Using Table 12 in Newburgers (page 119), what color(s) was(were) detected? Are the possible color(s) detected, permitted for use?**
A bright pink band of color exhibiting orange fluorescence under UV light can be due to either D&C Red No. 27, which is permitted for use in cosmetics, or it can be due to D&C Red No. 19, which is not permitted for use in the U.S.
14. **Discuss solubility in terms where one would expect to find the following colors:**
Natural color such as riboflavin or saffron- in the chloroform
Tartrazine- as it is water soluble, in the Resin in hexane solution
Sudan 1 – in the chloroform
D&C Red 19 or DC Red 28 – as it is oil soluble, in the chloroform
Red #3 – in the chloroform layer, once the solution is made basic in order to see the red color