TELEPHONE HUDSON 3-6126

Manufacturing Chemists' Association, Inc.

(FOUNDED 1872)
1825 CONNECTICUT AVENUE, N. W.
WASHINGTON, D. C. 20009

June 25, 1968

TO: FOOD, DRUG, AND COSMETIC CHEMICALS COMMITTEE

SUBJECT: FDA's Plant Evaluator System

Gentlemen:

Enclosed is General Delmore's letter of June 14, 1968 with enclosures for your information.

Sincerely yours,

M. M. Hoover

MMH:sjg

Enclosures

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

June 14, 1968

Gentlemen:

This special issue of the Newsletter is to acquaint trade associations with the FDA's new Plant Evaluator System (PEV). FDA has received numerous requests for details on this system.

The PEV system is a long-term project to accumulate data on manufacturing practices in specific industries. The data will be obtained by the FDA inspectors during establishment inspections. By analyzing the data FDA will be able to identify problem areas in specific industries. The PEV system will not be used to rate individual firms or determine their compliance status.

Many of your member firms may have their operations reported under the PEV system. We believe it will be to their benefit if they are aware of the details of the PEV system. We are asking your assistance in making available to your member firms copies of the PEV's as they become available. Your association may wish to reproduce additional copies for distribution to your members. Because of the large number of firms that will undoubtedly be interested in the PEV system, the FDA is not able to make copies available to individual firms.

We believe these PEV's will be useful to individual firms in developing and/or improving their self-inspection programs. The ability of a firm to take a critical objective look at itself is very important if quality is to be maintained or improved. However, these firms must understand that key indicators do not encompass all of the problem areas nor are they a substitute for other guidelines.

The first group of PEV's are enclosed with this Newsletter as an example of their format and content. We are attaching a complete list of PEV's, including those that have issued as well as those in preparation. If you are interested in receiving specific ones, please advise. A limited supply will be mailed to you as they issue.

Your comments and suggestions concerning the value of this system in your member firms' quality control programs will be most welcome, and should be addressed to; Bureau of Voluntary Compliance (VC-1), Food and Drug Administration, 200 C St., S.W., Washington, D.C. 20204.

Sincerely,

Fred J. Delmore, Director
Bureau of Voluntary Compliance

PEV No.02,16,18,21,22
List of PEV's

LIST OF PEV's ISSUED AND IN PREPARATION

PEV Title	PEV Number
Small Volume Injectables	1 (Human)
	23 (Veterinary)
Smoked fish	2
Animal By-Products for Feeds	3
Dry Milk Products	4
Frozen Egg	5
Shelled Tree Nuts	6
Dried Yeast	7
Natural Cheese	8
Dried Egg	9
Canned Infant Formula	10
Canned Fish	11
Fresh Blue Crab Meat	12
Large Volume Parenterals	13 (Human)
	27 (Veterinary)
Breaded Shrimp	14
Canned Vegetables	15
Food Warehouses	16
Fresh & Frozen Fish	17
Frozen Potato Products	18
Macaroni & Noodles	19
Filled Bakery Specialties	20
Standardized Chocolate Products	21
Cosmetics	22
Sterile Disposable Devices	24
Drugs not Represented as or Required to be Sterile	25 (Human)
	26 (Veterinary)

June 14, 1968

PEV

PLANT EVALUATOR

Food and Drug Administration

PEV No. 16

Food Warehouses

This PEV does not apply to salvage dealers and similar establishments.

RAW MATERIALS

1. - 8. Not Used.

MANUFACTURING AND PROCESSING

9. Are all lots visually examined before being placed in storage and if contamination is found or suspected, is the lot segregated, and either adequately reconditioned or rejected?

10. Are proper precautions taken in warehouse storage and in loading carriers (trucks, rail, etc.) to prevent chemical contamination of food products by effectively segregating toxic chemicals from foodstuffs?

11. Is the warehouse free of any evidence of the presence of dogs, cats, birds and vermin (including but not limited to rodents and insects)?

12. Does the firm have a formal (written schedules and instructions) sanitation and pest control program including at least weekly inspections made by a trained, qualified, and designated employee?

13. Are all rodenticides, used in the warehouse, approved for such use in food plants; kept in secure tamper-proof containers, if warranted; and located an adequate distance from all food items susceptible to contamination?

14. Are all other toxic substances, such as insecticides which are used in the warehouse, approved for such use and employed in a manner to prevent contamination of foods?

This PEV covers Commodity Codes:

47-0

Date Issued: May 27, 1968

15. Are all cold storage units equipped with an accurate and easily visible thermometer with the sensing element located at least five feet above the floor?

16. Are all cold storage refrigeration units maintained at a temperature equal to or less than 40°F?

17. Are all cold storage freezer units maintained at 0°F or less?

18. Is there walk-through space between stored items and walls, and are items stored on pallets or the equivalent to avoid direct contact with the floor?

19. Does the firm maintain a morgue area for damaged and returned goods, which is adequately separated from the storage area?

20. Does the firm maintain a program of timely and proper disposal of morgue items to prevent the development of pest breeding places and harborages?

21. Does the firm maintain a program of stock rotation, including adequate identification of each lot, to assure both a rapid and proper rotation of goods?

22. Is there adequate physical separation of bagged animal feeds, if stored by the firm, from human food storage?

23. Is the building suitable for food storage from a structural standpoint (protection from elements and vermin)?

24. - 45. Not Used.

FINISHED PRODUCT

46. - 55. Not Used.

LABELING AND PROMOTIONAL

56. - 60. Not Used.

PEV

PLANT EVALUATOR

Food and Drug Administration

PEV No: 18

Frozen Potato Products

RAW MATERIALS

1. Are raw potatoes inspected upon recaipt for mold, rot or other defects that render them unfit for human consumption?

2. Is the storage location for raw materials sufficiently separated from the processing area to prevent its contamination?

3. Does the firm control the application of pesticides to raw materials, or require a guarantee from the supplier that raw materials do not contain illegal pesticide residues?

4. - 8. Not Used.

MANUFACTURING AND PROCESSING

9. Is the plant free of any evidence of the presence of dogs, cats, birds and vermin (including but not limited to rodents and insects)?

10. Do all persons handling food ingredients, or their contact surfaces, wear clean outer garments, including hair-nets, headbands or caps, maintain a high degree of personal cleanliness and conform to hygienic practices?

11. Are hand dip solutions maintained at 100 ppm available chlorine, or equivalent, and are they used by employees?

12. Are surfaces of all equipment in direct contact with the food product thoroughly cleaned and sanitized each day prior to operation, between work shifts, and when necessary, during processing?

This PEV covers Commodity Codes:

43-9

Date Issued: May 27, 1968

13. Are potatoes adequately sorted, peeled, washed and trimmed to remove all peel, rot, mold, parasitic damage, and other defects?

14. Are the storage locations for potentially dangerous chemicals (e.g. caustic solutions for peelings, sanitizing chemicals, insecticides, etc.) sufficiently separated from the manufacturing area and are chemicals handled only by authorized personnel?

15. Is the water, in contact directly or indirectly with the product, from an approved source (municipal supply or tested private source)?

16. Does the firm have an adequate solid and liquid waste disposal system?

17. Is the operation properly controlled through to the testing of the finished product to prevent time-temperature abuses?

18. Are the cooking oils in use properly filtered and replaced as necessary to prevent a build-up of foreign material and rancidity?

19. Is the forced air used in the retrogradation and drying tunnels, precoolers, and freezers properly filtered?

20. Do temperature controls reveal that freezing is uniform throughout the product?

21. Are quality control records maintained?

22. Are bacteriological examinations routinely made of "in-line" samples?

23. Does the firm have a written, scheduled, sanitation program and is it being followed?

24. Are food and color additives used in accordance with the Regulations?

25. - 45. Not Used.

FINISHED PRODUCT

46. Is the internal temperature of the frozen product maintained at $0^{\circ}F$ or lower?

47. Are recording thermometers used in strategic locations in the storage area?

48. Does the firm have microbiological specifications to which the product must comply?

49. Does firm withhold from distribution lots which do not meet the microbiological specifications?

50. Are products found to be contaminated, destroyed or reconditioned to eliminate the contamination prior to shipment?

51. Are storage containers for in-process, bulk and final products maintained under sanitary conditions?

52. Are products shipped under proper refrigeration (0°F or lower)?

53. - 55. Not Used.

LABELING AND PROMOTIONAL

56. Does the firm maintain an adequate inventory control system, which reflects the history of each lot from its raw material stage through distribution of the finished product?

57. - 60. Not Used.

PEV

PLANT EVALUATOR

Food and Drug Administration

PEV No. 21

Standardized Chocolate Products

RAW MATERIALS

1. Is the receiving and storage location for raw materials sufficiently separated from the processing area to prevent its contamination?

2. Are all incoming raw materials inspected for evidence of mold, insect, animal, bird, and other contamination?

3. Are critical raw materials, (e.g. scrap or salvage chocolate, dried milk, etc.) received under the supplier's guarantee, or examined for bacteriological contamination prior to use?

4. Are raw materials quarantined pending results of analysis?

5. Are rejected raw materials segregated and then either disp sed of, or reprocessed to eliminate the contamination?

6. Does the firm record and control the fumigation process of cocoa beans to ensure that residues are below tolerance?

7. Are all raw materials, and collateral materials used in their processing, stored under controlled temperature and humidity to prevent bacterial and mold contamination?

8. Are potentially dangerous chemicals (e.g. fumigants, boiler compounds, etc.) properly stored and handled in a manner to preclude contamination of the raw materials?

MANUFACTURING AND PROCESSING

9. Is the plant free of any evidence of the presence of dogs, cats, birds, and vermin (including but not limited to rodents and insects)?

This PEV covers Commodity Codes:

13-2

Date Issued: May 27, 1968

10. Does the firm maintain a scheduled sanitation program for the plant, including but not limited to the inspection and examination of air filters, dust collectors, vacuum and floor sweepings, and floor drains?

11. Are potentially dangerous chemicals (e.g. insecticides, sanitizing solutions, etc.) properly stored and handled in a manner to preclude contamination of the food?

12. Is the plant so designed and the equipment arranged to preclude cross-contamination of in-process products?

13. Is traffic within the plant restricted and controlled to prevent unnecessary cross-traffic between raw material and processing areas?

14. Are the bags of raw materials brushed off before emptying?

15. Is the equipment furnished with dust collectors where necess ry?

16. Are sorting and stoning machinery operating properly to remove foreign material?

17. Are magnets strategically located in the conveyor belts and other equipment to prevent the incorporation of metal particles in the finished product?

18. If fluid milk is used, is it pasteurized?

19. Is chocolate material, that drops on machinery or on the floor, destroyed rather than reclaimed?

20. Is the equipment constructed and positioned to avoid "dead spots" which hinder inspection and are not readily cleaned?

21. Are chutes, leading to mixers and cleaners, shielded or screened to prevent the introduction of foreign material?

22. Are implements (e.g. brooms, shovels, etc.) identified for use in specific plant areas and not interchangeably used?

23. Does the firm refrain from using wooden utensils which come in contact with the product?

24. Are utensils properly stored and used to preclude contamination of the product and other equipment?

25. Is static material removed from equipment between batches on a routine basis?

26. Are floors in all processing areas readily cleanable and sloped to permit complete washing and drainage?

27. Are cocoa beans roasted at minimums of 180°F (internal bean temperature) for 15 minutes or an equivalent time-temperature ratio?

28. Are roasting ovens equipped with continuous recording thermometers?

29. Is the time-temperature ratio for each roast checked by a responsible individual?

30. Are precautions taken in the cooling area to prevent microbial recontamination?

31. Is the cracking process accomplished promptly after the cooling process?

32. Are bean cleaning and roasting equipment adequately isolated and partitioned off from other operations to prevent air-borne contamination of the roasted product?

33. Are all lights above the mixing, grinding, and conveying equipment shielded?

34. Are the storage tanks and hoppers covered?

35. Is scrap chocolate collected and stored in closed, clean, sanitary containers?

36. Does the management prevent any person affected with boils, sores, infected wounds or other sources of potential pathogenic organisms from working in direct or indirect contact with the food product?

37. - 45. Not Used.

FINISHED PRODUCT

46. Are all lots of finished products aseptically sampled for bacterial examination?

47. Are representative samples collected from each lot to provide a minimum of 10 subsamples and is each of sufficient size to conduct appropriate microbial analyses?

48. Are the samples analyzed for bacterial contamination, especially Salmonella?

49. Is the finished product withheld from distribution until quality control tests are completed?

50. Are finished products which are found to be contaminated, segregated and then destroyed or reprocessed to eliminate the contamination?

51. Is the finished product handled and stored in a manner which precludes contamination?

52. - 55. Not Used.

LABELING AND PROMOTIONAL

56. Does the firm maintain an adequate inventory control system, which reflects the history of each lot from its raw material stage through distribution of the finished product?

57. - 60. Not Used.

PEV

PLANT EVALUATOR

Food and Drug Administration

PEV No. 02

Smoked Fish

This PEV is not applicable to the "cold smoked" fish industry.*

RAW MATERIALS

1. Are all fish received at the plant inspected and only wholesome fish processed?

2. Are all fresh round and dressed fish thoroughly washed in potable water upon receipt?

3. Are holding temperatures for fresh fish maintained at 38°F or below to prevent spoilage?

4. Is the raw material area free of any evidence of dogs, cats, birds, and vermin (including rodents and insects)?

5. - 8. Not Used.

MANUFACTURING AND PROCESSING

9. Are all frozen fish defrosted at recommended temperatures (water defrosting at 70°F or below; air defrosting at 45°F or below)?

10. Is evisceration of all round fish performed with a minimum disturbance of intestinal tract content?

11. Is the removal of viscera complete?

12. Is the water used for washing fish from an approved source (municipal supply or tested private source)?

13. Does the firm have an adequate solid and liquid waste disposal system?

14. Are the eviscerated fish washed in potable water prior to brining?

This PEV covers Commodity Codes:

23-1*

Date Issued: May 27, 1968

15. Are equipment and washing surfaces cleaned and sanitized between different lots of fish?

16. Is the temperature of the brining solution maintained at 38°F or below?

17. Are analyses conducted to determine if the salt content in the aqueous phase of the loin muscle of the finished product is in excess of three percent?

18. Are all food additives used permitted and are their restrictions for use observed?

19. Is the cooling room used after smoking, a single purpose room?

20. Are the smoked fish cooled to a temperature of 38°F or below immediately following smoking?

21. Does the management prevent any person affected with boils, sores, infected wounds, or other sources of bacterial contamination from working in direct or indirect contact with the food?

22. Is the process area free of any evidence of dogs, cats, birds and vermin (including rodents and insects)?

23. - 45. Not Used.

FINISHED PRODUCT

46. Is the finished product handled, stored and packed in a sanitary manner?

47. Is packaging performed in a single purpose room?

48. Does the packaging adequately protect the finished product from contamination?

49. Is the finished product stored at a temperature of 38°F (internal temperature) or below?

50. Are delivery trucks clean and refrigerated?

51. Is the finished product area free of any evidence of the presence of dogs, cats, birds and vermin (including rodents and insects)?

52. - 55. Not Used.

LABELING AND PROMOTIONAL

56. Does the firm adequately label the product to indicate its perishable nature and to ensure its storage at 38°F (internal temperature) or below during shipment and while being held for sale?

57. Does the firm code its product to indicate the date of manufacture?

58. - 60. Not Used.

PEV

PLANT EVALUATOR

Food and Drug Administration

PEV No. 22

Cosmetics

RAW MATERIALS

1. Has the firm established specifications (microbiological, chemical, physical, etc.) for the raw materials used?

2. Are raw materials checked to determine compliance with the specifications, and rejected when they do not meet the specifications?

3. Are records maintained which relate the history of each lot of raw materials, including origin, amounts received, quality control checks, use, etc.?

4. Are raw materials properly labeled or identified (including necessary warnings and cautions) to prevent mix-ups or misuses?

5. Do proper temperature and humidity conditions exist in the storage areas to maintain acceptable quality?

6. Are raw materials protected from contamination by animals, insects, and other sources?

7. - 8. Not Used.

MANUFACTURING AND PROCESSING

9. Does the batch record include an accurate reproduction of the master formula, and does the record accompany the product through the entire production process?

10. Do batch formula instructions provide information such as, processing temperatures, mixing times, screen sizes, etc.?

11. Does the firm retain an adequate record of the formulation, weighings, and processing temperatures, etc. for each batch produced?

This PEV covers Commodity Codes:

94-1/9

Date Issued: May 27, 1968

12. Are the colors used safe for use in cosmetics (exempt from certification, or from certified batches)?

13. Is the plant so designed and so arranged to prevent cross-contamination of products?

14. Are product contact surfaces adequately cleaned and sanitized prior to use and between batches?

15. Are employees properly attired?

16. Are hand dip solutions maintained at 100 ppm available chlorine, or equivalent, and are they used by employees?

17. Is the water, in contact directly or indirectly with the product, from an approved source (municipal supply or tested private source)?

18. Are quality control tests made to ensure an homogeneous product?

19. Are quality control tests conducted at critical points in the processing to detect bacteriological contamination in the equipment?

20. Is label control adequate to prevent mix-ups?

21. Are controls employed during packaging adequate to ensure accurate quantity of contents and identity of the labeled product?

22. Where batches are reworked, does the firm maintain adequate rec rds to determine the production and analytical history of the product including that of the original batch?

23. - 45. Not Used.

FINISHED PRODUCT

46. Has the firm established specifications (microbiological, chemical, physical, etc.) for the finished product, and is any batch not meeting the specifications withheld from distribution?

47. Are finished products handled and stored in a suitable manner to maintain quality?

48. Is the product tested prior to distribution to ensure the effectiveness of added preservatives against the growth of microorganisms?

49. Are pharmacological and chemical studies conducted prior to distribution on new products, or when significant formula changes are made in those products previously marketed?

50. Does the firm retain reserve samples for determining microbiological quality, effectiveness of preservatives, stability tests, etc.?

51. Does the firm review each complaint received, attempt to find its cause, and make necessary changes in processing, formulation, etc.?

52. - 55. Not Used.

LABELING AND PROMOTIONAL

56. Are the products labeled with adequate directions for use (e.g., preliminary patch test) and proper caution legends and warnings?

57. Does the firm maintain an inventory control system that can be used to facilitate rapid and effective recall if necessary?

58. - 60. Not Used.