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BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

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Problems In Preventing The Marketing Of Raw Meat And Poultry Containing Potentially Harmful Residues

GAO estimates that 14 percent by dressed weight of the meat and poultry sampled by the Department of Agriculture between 1974 and 1976 contained illegal and potentially harmful residues of animal drugs, pesticides, or environmental contaminants. Many of these substances are known to cause or are suspected of causing cancer, birth defects, or other toxic effects.

Actions taken by the Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture to protect consumers from illegal and potentially harmful residues have not been effective because:

--The extent of public exposure to illegal residues has not been accurately estimated.

--Contaminated meat and poultry are generally marketed before the violation is discovered and some cannot be recalled.

--Efforts to prevent future shipments of meat and poultry containing illegal residues have been inadequate.

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To the President of the Senate and the
Speaker of the House of Representatives

This report discusses the need for additional legislative authority to more effectively protect consumers from illegal and potentially harmful residues in raw meat and poultry. The Food and Drug Administration, Department of Health, Education, and Welfare; the Department of Agriculture; and the Environmental Protection Agency are responsible for administering the activities discussed in this report.

We are sending copies of this report to the Secretary of Health, Education, and Welfare; the Secretary of Agriculture; the Administrator, Environmental Protection Agency; and the Director, Office of Management and Budget.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

PROBLEMS IN PREVENTING THE MARKETING OF RAW MEAT AND POULTRY CONTAINING POTENTIALLY HARMFUL RESIDUES

D I G E S T

Federal efforts to protect consumers from illegal and potentially harmful residues of animal drugs, pesticides, and environmental contaminants in raw meat and poultry have not been effective. GAO estimated that 14 percent by dressed weight of the meat and poultry sampled by the Department of Agriculture (Agriculture) between 1974 and 1976 contained illegal residues.

Although residues do not often pose an immediate threat to human health, many of the drugs, pesticides, and environmental contaminants to which food-producing animals are exposed are known to cause or are suspected of causing cancer, birth defects, or other toxic effects. Residues of many of these substances have been found in raw meat and poultry, often at levels exceeding established tolerances. Residues have also been found in human tissues and fluids, including mothers' milk.

Of 143 drugs and pesticides GAO identified as likely to leave residues in raw meat and poultry, 42 are known to cause or are suspected of causing cancer; 20 of causing birth defects; and 6 of causing mutations. (See pp. 12 to 14.)

The Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and Agriculture (USDA) share responsibility for making sure that only safe levels of drugs, pesticides, and environmental contaminants will be present in raw meat and poultry.

The Food and Drug Administration is responsible under the Federal Food, Drug, and Cosmetic Act for (1) insuring the safety of drugs given to food-producing animals, (2) setting a limit, or tolerance, on the amount of an animal drug or environmental contaminant allowable in food, and (3) preventing the marketing of raw meat and poultry containing residues above tolerance levels.

The Environmental Protection Agency is responsible for (1) insuring the safety and effectiveness of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act, (2) setting tolerances for pesticide residues in food under the Federal Food, Drug, and Cosmetic Act, and (3) regulating under the Toxic Substances Control Act the introduction into the environment of most chemical substances not regulated as drugs, pesticides, or food additives.

Agriculture is responsible under the Federal Meat Inspection Act and the Poultry Products Inspection Act for preventing the marketing of adulterated raw meat and poultry, including those containing residues in excess of tolerances. (See pp. 2 to 6.)

F.I.C.

Efforts by the three agencies to protect consumers from illegal and potentially harmful residues have not been effective because

--the extent to which the public is exposed to illegal residues has not been accurately estimated,

--meat and poultry from violative animals is generally marketed before the violation is discovered and cannot be recalled, and

--actions taken to prevent future shipments of residue-contaminated meat and poultry have been inadequate.

PUBLIC EXPOSURE
UNDERESTIMATED

Agriculture reports that it found illegal residues in only about 2 percent of the raw meat and poultry sampled between 1974 and 1976.

~~This~~ estimate ~~however,~~ does not adequately reflect the incidence of ~~illegal~~ residues likely to be present in raw meat and poultry because:

--Each animal was tested for only one individual or class of animal drug, pesticide, or environmental contaminant rather than all 54 substances included in Agriculture's monitoring program.

--Only 46 of 143 drugs and pesticides likely to leave residues were monitored.

To agree to Agriculture's 2-percent violation rate is to assume that there is no illegal residue of a substance in an animal not tested for that substance.

A more appropriate assumption would be that animals not analyzed for a particular substance would contain about the same percentage of illegal residues as tested animals. Accordingly, GAO's analysis of Agriculture's data indicates that the incidence of illegal residues of drugs, pesticides, and environmental contaminants included in Agriculture's testing may have actually ranged from as high as 2.6 percent in sheep and goats to almost 16 percent in swine.

Because of questions concerning the statistical validity of Agriculture's sampling methods, GAO has not projected the violation rates to all slaughtered animals. (See pp. 7 to 12.)

CONTAMINATED PRODUCTS
MARKETED

With few exceptions, neither Agriculture nor the Food and Drug Administration can locate

and remove from the market raw meat and poultry found to contain illegal residues because:

--Animals are marketed and probably consumed before sample analysis is completed.

--Agriculture does not have the authority to detain raw meat and poultry pending results of sample analysis unless it has reason to believe the animal is violative.

--Meat and poultry from violative animals usually cannot be identified once the animal has been slaughtered.

Residue analysis must be completed before the animal is divided into wholesale cuts at the packing house--about 24 hours after slaughter--if Agriculture is to prevent the marketing of meat containing illegal residues. However, it generally takes Agriculture 6 to 25 days to complete this analysis, using current detection methods.

Only in cases such as turkeys, where the carcass is coded, frozen, and stored for a lengthy period, can the contaminated animal be identified and removed from the market.

Several methods are available or are being developed which would enable Agriculture to complete sample analysis on some drugs and pesticides within 24 hours. However, Agriculture does not currently have the laboratory facilities or equipment to use such methods at slaughterhouses. (See ch. 2.)

INADEQUATE EFFORTS TO PREVENT FUTURE SHIPMENTS

Because of the overwhelming problems in identifying and removing from the market raw meat and poultry found to contain illegal residues, a major part of the Government's efforts must be directed to preventing future shipments of violative animals. However, such efforts have not been effective.

After Agriculture identifies illegal residues in a sample of raw meat or poultry, the Food and Drug Administration and the Environmental Protection Agency should determine the cause of the violation and Agriculture should determine whether needed corrective actions have been taken.

During the 4-year period ended December 1976, the Food and Drug Administration's district offices reported such investigations on only 37 percent of the cases referred to it by Agriculture for followup.

Agriculture operates a program to test animals of growers previously identified as marketing violative animals. Before shipping additional animals to slaughter, such growers are asked to provide a small lot from the herd or flock for residue analysis. If residues are within tolerances, the entire herd or flock is approved for slaughter.

Many growers, however, do not comply with the pretest. GAO's review at three Agriculture offices indicated that about 600 of 1,100 growers required to submit animals between 1974 and 1976 had not complied. Growers can easily avoid pretest by shipping animals to an auction house or to a different slaughterhouse.

Agriculture officials believe that quarantine authority would enable it to prevent moving animals from a grower's farm before pretest.

Agriculture and the Food and Drug Administration cannot always follow up on residue violations because Agriculture cannot require growers to put identification tags on their animals before marketing them. (See pp. 40 to 44.)

The Food and Drug Administration generally issues information letters--the agency's mildest enforcement action--for serious violations, such as deliberate misuse of drugs by growers, when prosecution, injunction, or seizure actions may be warranted.

The agency in many cases has not been able to take stronger measures against violators because:

--Agriculture's monitoring program is not designed to enable the Food and Drug Administration to develop the case histories needed to support stronger regulatory actions.

--Raw meat and poultry from animals found to contain illegal residues generally cannot be identified for seizure action.

--Residue detection methods adequate to support regulatory actions do not exist for many animal drugs and pesticides.

--Misuse of an animal drug does not, in itself, violate the Federal Food, Drug, and Cosmetic Act--the Agency must prove that such misuse resulted in the marketing of adulterated raw meat and poultry.

--The agency cannot levy civil penalties for residue violations. (See pp. 44 to 51.)

RECOMMENDATIONS

To enable the responsible agencies to more effectively prevent the marketing of raw meat and poultry containing illegal residues, GAO is recommending that the Congress amend the

--Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize Agriculture to (1) quarantine animals from a violative grower and (2) require growers to place an identification tag on animals before they are marketed;

--Federal Food, Drug, and Cosmetic Act to make misuse of an animal drug illegal and to authorize the use of civil penalties for residue violations; and

--Federal Insecticide, Fungicide, and Rodenticide Act to better enable the Environmental Protection Agency to identify the possible misuse of pesticides. (See pp. 52 and 53.)

Rec to Ags

The Secretaries of Agriculture and of Health, Education, and Welfare and the Administrator, Environmental Protection Agency, should improve their programs for preventing the marketing of raw meat and poultry containing illegal residues. (See pp. 21, 36, and 52.)

AGENCY COMMENTS

The Food and Drug Administration, the Department of Agriculture, and the Environmental Protection Agency agreed that improvements are needed in Federal efforts to control the marketing of raw meat and poultry containing illegal residues, but disagreed with some of GAO's specific recommendations. The agencies' comments are discussed in the report. (See pp. 21, 36, and 53.)

Contents

ABBREVIATIONS

EBDC	Ethylene bisdithiocarbamate
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
MCA	alpha-monocarboxylic acid
NADA	new animal drug application
NIOSH	National Institute for Occupational Safety and Health
PBB	polybrominated biphenyl
PCB	polychlorinated biphenyl
ppm	parts per million
RPAR	rebuttable presumption against registration
TSCA	Toxic Substances Control Act
USDA	U.S. Department of Agriculture

CHAPTER 1

INTRODUCTION

Animal drugs, pesticides, and environmental contaminants, which represent three dissimilar classes of chemicals, share a common potential for residues in raw meat and poultry. Residues of some of these substances may pose hazards to consumers. The manner in which animals are exposed to drugs, pesticides, and environmental contaminants and the regulatory distinctions between these classes of substances affect the Government's ability to identify and remove from the market animals containing illegal and potentially harmful residues.

The success of Federal efforts to insure the safety of raw meat and poultry depends on the effectiveness of programs to (1) regulate the drugs, pesticides, and other toxic substances to which food-producing animals are exposed and (2) control the marketing of food-producing animals exposed to such substances.

In prior reports (see app. I) we have identified numerous deficiencies in the regulation of animal drugs, pesticides, and other toxic substances. This report examines Federal efforts to control the marketing of food-producing animals containing illegal and potentially harmful residues.

HOW ARE ANIMALS EXPOSED?

Food-producing animals, including cattle, sheep, swine, chickens, and turkeys, are exposed, either intentionally or unintentionally, to a wide variety of drugs, pesticides, and environmental contaminants.

Drugs are administered to food-producing animals to promote growth as well as to treat or prevent animal diseases. According to the Food and Drug Administration (FDA), more than 80 percent of the meat and poultry consumed in the United States comes from animals that were given drugs in their feed.

Some pesticides may be administered to food-producing animals to control insects or worms. However, most animal exposure to pesticides is unintentional and results from the use of pesticides to (1) keep animal dwellings free from rodents and insects, (2) control insects on crops used as livestock feed, (3) control weeds on grazing and pasture lands, and (4) control insects and bacteria in silos and other

feed storage facilities. Both intentional and unintentional use of pesticides may ultimately result in residues in meat and poultry.

Animals are exposed to environmental contaminants such as polychlorinated biphenyls (PCBs) through industrial pollution. Sludge from wastewater treatment plants containing PCBs or other industrial chemicals used as fertilizer may ultimately contaminate crops used as animal feed. Although environmental contaminants can find their way into the animal and become tissue residues by many routes, one of the most highly publicized cases involved the accidental mixing of polybrominated biphenyls (PBBs)--a fire-retardant chemical--into animal feed.

HOW ARE THESE SUBSTANCES REGULATED?

FDA and the Environmental Protection Agency (EPA) share responsibility for regulating drugs, pesticides, and environmental contaminants.

FDA is responsible under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended (21 U.S.C. 301 et seq.), for (1) ensuring the safety of drugs given to food-producing animals and (2) setting a limit, or tolerance, on the amount of an animal drug or environmental contaminant allowable in food. 1/ FDA may establish a withdrawal period prior to slaughtering an animal or taking any food yielded or derived from the animal during which time certain animal drugs may not be administered (21 U.S.C. 360(i)). FDA must also ensure that animal feeds are free from illegal levels of drugs, pesticides, and environmental contaminants.

EPA regulates the introduction into the environment of pesticides and toxic substances. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 (7 U.S.C. 135), as amended by the Federal Environmental Pesticide Control Act of 1972 (7 U.S.C. 136 et seq.), EPA approves pesticide products for safety and effectiveness before they can be marketed. In addition, under the FD&C Act, EPA establishes

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1/Except for tolerances for residues of poisonous or deleterious substances resulting primarily from pesticide use of the substance. Such tolerances are set by EPA.

safe tolerance levels for pesticides likely to leave residues in food. 1/ Like FDA, EPA may establish a withdrawal period during which time the pesticide may not be administered. The introduction of most chemical substances not regulated as drugs, pesticides, or food additives is regulated by EPA under the Toxic Substances Control Act of 1976 (15 U.S.C. 2601 et seq.).

According to FDA, the statutory distinctions between animal drugs, pesticides, and environmental contaminants affect the Government's ability to control their residues in raw meat and poultry. For example:

--Statutory guidance for establishing tolerances varies significantly among animal drugs, pesticides, and environmental contaminants.

--Premarket clearance procedures, and their relevance to raw meat and poultry, vary widely for animal drugs, pesticides, and environmental contaminants.

--Pesticides and environmental contaminants unintentionally contaminate animal diets and consequently are subject to different degrees of use control than are drugs added intentionally to animal diets.

--Animal drug manufacturers are required to develop methods for detecting animal drugs in raw meat and poultry, but there is no clear statutory requirement that manufacturers of pesticides and other toxic substances develop methods to detect residues in raw meat and poultry.

Appendix II discusses the statutory distinctions between animal drugs, pesticides, and environmental contaminants in more detail.

WHAT IS A TOLERANCE?

A tolerance is the maximum residue of a drug, pesticide, or environmental contaminant that is legally allowed

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1/Authority for administering FIFRA was transferred from the Department of Agriculture along with responsible organizational elements to EPA on Dec. 2, 1970, pursuant to Reorganization Plan No. 3 of 1970 which established EPA. The reorganization plan also transferred authority for establishing pesticide tolerances and related responsibilities from FDA to EPA.

in food. A tolerance is not, however, a safe or no-risk residue level. Rather, it is a residue level which has been determined to pose an acceptable risk.

In setting tolerances, consideration is given to the nature, level, and toxicity of the residues. According to EPA, a pesticide tolerance is set at the level at which residues are expected to occur if good agricultural practices have been followed in applying the pesticide in order to minimize residues in food and feed, and thus in animals and humans. EPA said that this level may, in fact, be less than the limits of reasonable risk, which is a theoretical calculation based on toxicology data. EPA also said that it would not establish a tolerance if available toxicity data indicated that the anticipated residues presented too great a hazard.

According to FDA, tolerances for animal drugs usually include an additional safety factor of 100 to 2,000 times the dosages found to be toxic to laboratory animals. FDA also said that tolerances are set at the level expected to occur when the animal drug is used as directed--a level that may be significantly lower than the level that could be supported by toxicity data.

If residues in excess of tolerance are present in any edible animal tissue, the raw meat or poultry is considered adulterated and is prohibited from being shipped in interstate commerce. Because a margin on the side of safety is built into the tolerance, over-tolerance residues do not necessarily constitute an immediate health hazard.

Chapter 2 discusses the extent of illegal residues present in raw meat and poultry and the potential health effects of those residues.

HOW ARE TOLERANCES ENFORCED?

Both FDA, under the FD&C Act, and the U.S. Department of Agriculture (USDA), under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), are responsible for preventing the marketing of raw meat and poultry containing residues in excess of tolerances set by FDA or EPA.

USDA has conducted a national monitoring program for chlorinated hydrocarbon and arsenic residues since 1967. In 1972 USDA structured its residue monitoring program to assure a statistical basis for the reported results, and the

program has since been expanded to include monitoring for the presence of many other compounds which can be detected by current technology. According to USDA, the program is still under development and can be improved in a number of ways.

USDA's residue monitoring program has two phases. Under the first, or monitoring phase of the program, a random sample of animals is identified in a computer printout, and USDA inspectors collect samples from them at slaughtering plants. The samples, which may be of fat, liver, kidney, muscle, or a combination of these, are submitted to USDA laboratories for residue analysis. The sample may be analyzed for a number of different animal drugs, pesticides, or environmental contaminants. The residue to be tested for is also identified in the computer printout. While the sample is being analyzed, the carcass continues moving through the slaughtering and marketing process. Samples are taken from 18,000 to 20,000 animals annually under the monitoring phase.

If the laboratory analysis indicates that residues are present in raw meat or poultry at levels in excess of tolerance, USDA refers the case to FDA for investigation. If illegal pesticide residues are found, the case is also referred to EPA. FDA and EPA inspectors investigate at the grower level to determine the cause of the residue problem and to take regulatory action, if warranted.

Under the second, or surveillance phase of the program, animals are sampled because USDA has reason to believe the animal carcass is violative. The carcass can be detained for up to 20 days. The surveillance phase provides for sampling (1) if there are outward signs, such as injection lesions, that the animal may contain illegal residues, (2) if the grower has previously shipped animals containing illegal residues, or (3) as part of special surveys. In 1977 the surveillance phase consisted of the sampling of 4,000 to 6,000 animals.

Under the FD&C Act FDA may initiate, through the Department of Justice, action to (1) prosecute an individual who violates provisions of the act, (2) enjoin a grower from violating the act and FDA regulations, and (3) seize raw meat and poultry that is adulterated or misbranded.

In cases of minor violations, FDA generally issues information letters notifying the alleged violator of the problem and requesting that corrective action be taken.

If FDA's followup indicates that the illegal residue resulted from misuse of a pesticide, FDA refers the case to EPA for regulatory action. EPA can prosecute or levy a civil money penalty against an applicator who is found to be using a pesticide in a manner inconsistent with its labeling.

SCOPE OF REVIEW

Our objective was to evaluate the effectiveness of Federal efforts to prevent the marketing of raw meat and poultry containing illegal and potentially harmful residues. We reviewed pertinent laws, regulations, policies, and procedures and examined USDA, FDA, and EPA records. We interviewed officials of USDA, FDA, EPA, industry and trade associations, and Michigan and Indiana and reviewed reports by Government and private researchers concerning residues and their toxic effects.

Our review was made at FDA headquarters in Rockville, Maryland, and at Washington, D.C.; at FDA district offices in Atlanta, Dallas, Detroit, Kansas City, and Nashville; at USDA and EPA headquarters in Washington, D.C.; at USDA regional offices in Atlanta, Dallas, and Des Moines; and at EPA regional offices in Atlanta, Chicago, Dallas, and Kansas City.

CHAPTER 2

RESIDUE MONITORING PROGRAM INEFFECTIVE

Illegal residues may not cause immediate toxic effects. However, residues of drugs, pesticides, and environmental contaminants known to cause or suspected of causing chronic adverse effects, including cancer and birth defects, may pose a hazard to consumers. Residues of many substances found to cause chronic adverse effects in animals have been found in raw meat and poultry at levels exceeding established tolerances. Residues have also been found in human tissues and fluids, including mothers' milk.

From various sources, including FDA, USDA, and EPA officials, we identified at least 143 drugs and pesticides likely to leave residues in food-producing animals. In addition, there are an unknown number of environmental contaminants likely to leave residues. USDA's monitoring program tests for only 46 of the 143 drugs and pesticides and for 8 environmental contaminants.

The extent to which the public is exposed to illegal residues has not been adequately estimated by USDA. On the basis of data developed under the residue monitoring program, USDA reports that it found illegal residues in only about 2 percent of the raw meat and poultry samples tested between 1974 and 1976. Based on the same data, we estimate that 14 percent by dressed weight of the raw meat and poultry sampled by USDA between 1974 and 1976 contained illegal residues. However, because most animal drugs, pesticides, and environmental contaminants were not included in the monitoring program, the actual incidence of illegal residues was probably higher.

ACCURACY OF USDA VIOLATION RATE QUESTIONABLE

USDA's estimate--that only 2 percent of the raw meat and poultry sampled in the United States contain illegal residues--does not reflect the actual incidence of illegal residues likely to be present in these products because:

--Each animal sampled was tested for only one individual or class of animal drug, pesticide, or environmental contaminant rather than all 54 substances included in the monitoring program.

--Most drugs, pesticides, and environmental contaminants to which food-producing animals may be exposed were not included in the monitoring program.

Animals not tested for all substances in monitoring program

USDA arrived at a 2-percent violation rate by dividing the number of violations identified by the number of animals sampled.

The results of this calculation, in our view, do not accurately estimate overall consumer exposure to illegal residues of the drugs, pesticides, and environmental contaminants included in the monitoring program because each meat and poultry sample was not tested for each substance. Instead, each animal sampled was tested for only one substance or class of substances.

Between 1974 and 1976 USDA analyzed samples from over 57,000 animals. Table 1 shows (1) the number of animals analyzed for each of the drugs, pesticides, and environmental contaminants in the monitoring program that we identified as likely to leave residues in raw meat or poultry and (2) the percentage of animals analyzed for each substance or class of substances that was found to contain illegal residues. Appendix III lists the reported toxic effects of the drugs and pesticides in the monitoring program.

To use USDA's 2-percent violation rate as an overall estimate of the incidence of illegal residues, an assumption must be made that there is no illegal residue of a substance in an animal if the animal was not tested for that particular substance. For example, of the approximately 57,000 animals sampled, USDA tested only about 8,000 for sulfa residues. Even though USDA's tests showed that about 4 percent of the 8,000 animals tested contained illegal sulfa residues, the assumption would have to be made that none of the remaining 49,000 animals contained illegal sulfa residues.

In our opinion, a more appropriate assumption would be that animals not analyzed for a particular substance or class of substances would generally contain about the same percentage of illegal residues as did the animals that were analyzed for the substance. On this basis, the overall violation rate would more closely approach the sum of the violation rates for each of the substances or class of substances included in the monitoring program, assuming that those violation rates were statistically valid.

Table 1

	Animals sampled	Samples violative	Percent violative
Pesticides:			
Chlorinated hydrocarbons (note a)	13,534	232	1.71
Organophosphates (note b)	800	3	.38
Animal drugs:			
Antibiotics (note c)	12,420	436	3.51
Arsenic	6,986	69	.99
Carbadox	2,148	13	0.61
Clopidol	382	-	0.00
Decoquinate	97	-	0.00
Diethylstilbestrol	7,502	47	.63
Ipronidazole	820	17	2.07
Levamisole hydrochloride	4	-	0.00
Monensin	910	1	0.11
Robenadine hydrochloride	763	9	1.18
Sulfas (note d)	8,016	300	3.74
Thiabendazole	149	-	0.00
Zeranol	249	-	0.00
Environmental contaminants:			
Cadmium, copper, lead, and mercury	2,414	34	1.41
Iron	178	-	0.00
PBB	39	-	0.00
	57,411	1,161	

a/Includes the pesticides aldrin, benzene hexachloride, chlordane, DDT, dieldrin, endrin, heptachlor, lindane, methoxychlor, mirex, and toxaphene, and the environmental contaminants polychlorinated biphenyls and hexachlorobenzene.

b/Includes coumaphos, diazinon, dichlorovos, dioxathion, ethion, gardona, malathion, methyl parathion, parathion, ronnel, and trichlorofon. Dichlorovos is both a pesticide and an animal drug.

c/Includes chlortetracycline, erythromycin, neomycin, oxytetracycline, penicillin, streptomycin, and tetracycline.

d/Includes sulfachlorpyridazine, sulfadimethoxine, sulfaethoxypyridazine, sulfamethazine, sulfanitran, and sulfathiazole.

Further analysis of the data developed under USDA's monitoring program indicates that the actual incidence of illegal residues in the animals tested between 1974 and 1976 may have ranged from 2.6 percent in sheep and goats to almost 16 percent in swine. (See table 2.) Because of questions raised about the statistical validity of USDA's sampling methods in an earlier GAO report, 1/ we have not attempted to project the violation rates to the universe of animals slaughtered between 1974 and 1976. However, we believe the violation rates offer a more reasonable indication of the magnitude of the residue problem than does the USDA computed figure.

Table 2

Species	GAO-calculated violation rate
Cattle	14.96
Calves	8.84
Sheep and goats	2.60
Swine	15.83
Horses	6.71
Chickens	5.08
Turkeys	8.46
Ducks and geese	12.51
Rabbits	6.64

Based on straightline projections of the violation rates shown in table 2, we estimate that 14 percent by dressed weight of the animals sampled between 1974 and 1976 contained illegal residues. (See table 3.) It should be noted, however, that the number and weight of animals sampled for each species is not proportionate to the number and weight of animals slaughtered for those species. For example, cattle represent about 32 percent (78 percent by weight) of the animals sampled between 1974 and 1976 but only about 1 percent (50 percent by weight) of the animals slaughtered in 1976. The number and dressed weight of animals slaughtered in 1976 is also shown in table 3.

1/In a June 8, 1977, report "Federal Efforts To Protect Consumers From Polybrominated Biphenyl Contaminated Food Products" (HRD-77-96), we questioned the statistical validity of the sampling methods used in USDA's surveys of PBB residue in meat because they involved judgment rather than random sampling. In those surveys, as in the National Residue Monitoring Program, the selection of animals to be sampled was left to the inspector's judgment.

Table 3

Estimated Dressed Weight of Violative Animals Sampled 1974 Through 1976 and Number and Weight of Animals Slaughtered During 1976

Species	A Number sampled	B GAO-calculated violation rate	C Number of violative animals sampled (A x B)	D Average dressed weight (note a)	E Weight of animals sampled (A x D)	F Weight of violative animals sampled (C x D)	Number slaughtered 1976	Weight of animals slaughtered 1976
		(percent)		----------(pounds)----------				(tons)
Cattle	16,780	14.96	2,510	610	10,235,800	1,531,100	42,644,700	13,006,634
Calves	8,217	8.84	726	128	1,051,776	92,928	5,351,200	342,477
Sheep	b/3,315	2.60	86	54	179,010	4,644	6,718,900	181,410
Swine	8,613	15.83	1,363	187	1,610,631	254,881	73,783,200	6,898,729
Chickens	9,157	5.08	465	2.8	25,640	1,302	3,432,882,000	4,806,035
Turkeys	6,743	8.46	570	14.6	98,448	8,322	134,337,000	980,660
	52,825		5,720		13,201,305	1,893,177	3,695,717,000	26,215,945
						(14.3%)		

a/Based on average dressed weight of animals slaughtered during 1976.

b/Includes unknown number of samples from goats.

Most substances not included in monitoring program

Because USDA does not test for most drugs and pesticides likely to leave residues in food-producing animals, the actual incidence of illegal residues was probably even higher than our estimate. USDA tested for only 46 of the 143 drugs and pesticides we identified as likely to leave residues in raw meat and poultry. In addition, food-producing animals are exposed to an unknown number of environmental contaminants, but only eight were included in the monitoring program.

Among the 97 drugs and pesticides not included in USDA's monitoring program are 24 known to cause or suspected of causing cancer and 17 suspected of causing birth defects. In some cases a drug or pesticide is known to cause or is suspected of causing both cancer and birth defects. Drugs and pesticides not included in the monitoring program include:

--Phenoxy herbicides, including 2,4,5-T and Silvex, which are suspected of causing cancer and birth defects due to dioxin contaminants.

--Ethylene bisdithiocarbamate (EBDC) fungicides (including Maneb, Zineb, and Polyram), whose decomposition product, ethylene thiourea, has been shown to cause cancer in laboratory animals. EBDC fungicides are also suspected of causing birth defects.

--Furazolidone, which is an animal drug shown to cause cancer in rats and mice.

Some drugs and pesticides are not included in the monitoring program because residue detection methods are not available; however, methods do exist for detecting some of the drugs and pesticides not included. The need for detection methods for certain drugs and pesticides is discussed in chapter 4.

POTENTIAL TOXIC EFFECTS OF RESIDUES

Because of safety factors built into the tolerance-setting procedures by FDA and EPA, residues will generally not cause immediate toxic effects in consumers even if the tolerance is exceeded. A further margin of safety is provided by the fact that most of the raw meat and poultry consumed contain residues below the established tolerance.

Although residues do not often pose an immediate threat to human health, many of the drugs, pesticides, and environmental contaminants to which food-producing animals are exposed are known to cause or are suspected of causing cancer or other adverse effects in laboratory animals. Thus, repeated exposure of consumers to low levels of certain residues may pose a hazard to their health.

Using the 1976 National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances, together with data obtained from EPA and FDA, we identified known or suspected toxic effects for 55 of the 143 drugs and pesticides identified as potential sources of residues.

Of the 55 drugs and pesticides for which reported toxic effects were identified

--42 are known to cause or are suspected of causing cancer,

--20 are suspected of causing birth defects,

--6 are suspected of causing mutations,

--6 are suspected of causing adverse effects on reproduction,

--4 are suspected of causing adverse effects on the fetus, and

--11 are reported to cause other toxic effects.

Many drugs and pesticides were suspected of causing more than one adverse effect. Appendix III identifies the 143 drugs and pesticides that may remain as residues in raw meat and poultry and their possible toxic effects.

Other adverse effects

A pamphlet published by FDA, "We Want You To Know What We Know About Drugs for Food-Producing Animals," states

> "One potential hazard of medicated feeds is that, just as some animal diseases can be transmitted to man, so many of the drugs that affect animals can also affect man.

"If significant residues of the drugs fed to an animal are still present when the meat and poultry products reach the consumer's table, some problems may arise:

--A person may be allergic to the drug residue.

--Bacteria in the intestinal tract of the person may develop resistance to the drug. Then, if a physician prescribes the same drug for fighting a human disease, the drug may not work as well as it should."

A 1973 article 1/ by a Kansas State University researcher notes that as many as 20 million Americans may be sensitive to antibiotics and other chemotherapeutic drugs which may leave residues in raw meat and poultry. The article also states that only minute quantities of an antibiotic or its degradation products need be present in raw meat and poultry to initiate an allergic reaction ranging from mild responses to severe and sometimes fatal anaphylactic shock. The article notes that documentation of the effects will become more frequent as mechanisms for the reactions become better understood and more complete reporting of adverse effects occurs.

With respect to drug resistance, FDA has recently initiated action to withdraw approval to market penicillin and tetracyclines for most of their animal feed uses and is reviewing the use of other antibiotics in animal feeds.

EXTENSIVE CONSUMER EXPOSURE TO SUSPECTED CARCINOGENS

Although there is no known safe level for exposure to residues of a carcinogen, finite tolerances or action levels have been established for most of the suspected carcinogens included in USDA's monitoring program. Residues of these substances up to the tolerance level may legally remain in raw meat and poultry. As a result, violation rates determined on the basis of USDA's monitoring program do not reflect total consumer exposure to residues of suspected carcinogens. In some cases, most animals tested were found to contain residues of a suspected carcinogen.

1/Oehme, F. W., "Significance of Chemical Residues in United States Food-Producing Animals," Toxicology, vol. 1 (1973), pp. 205-215.

Tolerances or action levels have been established for most of the suspected carcinogens not because the residue levels were determined to be safe, but because (1) a final determination had not been made that the substance causes cancer or (2) residues of the substance are unavoidable due to the persistence of the substance in the environment.

Animal drugs

Finite tolerances, ranging from 0.1 parts per million (ppm) to 2 ppm, have been established by FDA for three (arsenic, sulfamethazine, sulfathiazole) of the six animal drugs included in USDA's monitoring program that are suspected of causing cancer. No residue of the other three animal drugs (carbadox, diethylstilbestrol, ipronidazole) may legally remain in raw meat or poultry.

If an animal drug is found to cause cancer, the Delaney Clause 1/ to the FD&C Act precludes the use of that drug in food-producing animals unless it can be demonstrated that no residues will be present in food taken from those animals. To be treated as a carcinogen under the Delaney Clause, appropriate tests must produce evidence that the chemical in question definitely causes cancer. Chemicals only suspected of causing cancer are not subject to the Delaney Clause. Therefore, although one or more studies have indicated that arsenic, sulfamethazine, and sulfathiazole may cause cancer, and thus they are suspected carcinogens, residues of these drugs may legally remain in raw meat and poultry.

According to a June 28, 1973, Federal Register notice (38 FR 17000) that increased the tolerance for residues of arsenic in uncooked edible byproducts of chickens and turkeys from 1 ppm to 2 ppm, long-term studies submitted to FDA on roxarsone, an organic arsenical, support the safety of arsenical drugs. However, EPA considers both organic and inorganic arsenicals suspect carcinogens, and workers at arsenic-producing plants have been shown to have a greater risk of developing cancer than the general population.

USDA tests for arsenic in 1976 showed that 27 (24 percent) of the cattle, 161 (29 percent) of the swine, and 391 (74 percent) of the chickens tested had measurable levels, but only 9 animals contained illegal residues.

1/The Delaney Clause provides that no regulation be issued permitting the use of an animal drug found to induce cancer when ingested by man or animal unless it can be shown that no drug residues will be found in food.

In the case of sulfamethazine and sulfathiazole, we identified only one article concerning a study on their possible carcinogenicity. We did not review the adequacy of the study, which was published in 1952, or its appropriateness for evaluating the safety of an animal drug.

According to the Department of Health, Education, and Welfare (HEW), when there are questions about potential carcinogenicity of an animal drug prior to its approval by FDA, the burden of proving safety clearly rests with the petitioner and the approval process obligates the petitioner to resolve such questions. HEW pointed out, however, that after a drug is approved, FDA shoulders the responsibility for demonstrating that there is sufficient question of safety to warrant requiring the producers to reconfirm the safety of a previously approved chemical and/or removing the product from the market. HEW said that continuing advances in the scientific bases and techniques for determining carcinogenicity of chemicals commonly generate questions about the validity and adequacy of prior tests.

FDA, according to HEW, is devoting systematic effort to reappraising previously approved animal drugs. HEW said that, at any given moment, the continuing advancement of scientific knowledge results in growing doubt about some previously approved products.

Pesticides

EPA has established finite tolerances or action levels ranging from 0.3 ppm to 10 ppm for 10 1/ of the 12 pesticides included in the USDA monitoring program that are suspected of causing cancer. Negligible residue tolerances of 0.1 ppm have been established for the other two pesticides (trichlorofon and mirex) suspected of causing cancer.

Tolerances, or action levels, have been set for some of the pesticides suspected of causing cancer, not because the levels have been proven safe, but because residues are unavoidable due to the persistence of the pesticides in the environment. For example, both DDT in 1972 and dieldrin in 1974 were banned by EPA for agricultural uses because they were suspected to cause cancer, yet residues are still in meat and poultry as a result of prior usage of these chemicals. USDA tests in 1976 showed that:

1/Aldrin, benzene hexachloride, chlordane, DDT, dieldrin, endrin, heptachlor, lindane, ronnel, and toxaphene.

--1,117 (63 percent) of the cattle, 165 (37 percent) of the swine, and 763 (82 percent) of the chickens tested for DDT residues had measurable residues, but only 2 animals had illegal residues.

--924 (52 percent) of the cattle and 580 (63 percent) of the chickens tested for dieldrin residues had measurable levels, but only 13 animals had illegal residues.

An attempt to prevent the sale of any raw meat and poultry containing residues of DDT or dieldrin would eliminate the sale of most meat and poultry in the United States. Thus tolerances or action levels are set at a level which will permit the marketing of most raw meat and poultry while preventing the marketing of animals containing exceptionally high residue levels.

Environmental contaminants

USDA tests in 1976 also showed that extensive contamination of raw meat and poultry occurs from two environmental contaminants (cadmium and hexachlorobenzene) suspected of causing cancer, mutations, and birth defects.

--67 (82 percent) of the cattle, 71 (57 percent) of the chickens, and 139 (70 percent) of the swine tested for cadmium residues had measurable levels, but none contained illegal residues.

--720 (40 percent) of the cattle, 168 (18 percent) of the chickens, and 22 (5 percent) of the swine tested for hexachlorobenzene residues had measurable levels, but only one animal contained illegal residues.

Cadmium is a trace element in the environment, but it is also a byproduct of the smelting industry and is used in a wide variety of commercial enterprises. According to a USDA official, there is about 100 times as much cadmium used today as was used at the beginning of the century. EPA is currently contemplating action against the pesticide uses of cadmium because of its potential to cause cancer.

Hexachlorobenzene is a waste byproduct of the manufacture of chlorine and chlorinated hydrocarbon chemicals including carbon tetrachloride, trichloroethylene, and several pesticides. Although it is believed that the production and disposal of industrial waste is responsible for

the vast majority of hexachlorobenzene entering the environment, other potential sources of environmental contamination include its use as a fungicide and as a component of hand and road flares. Hexachlorobenzene residues are relatively stable in the environment, remaining unaltered for up to 1 year in soil.

The Toxic Substances Control Act authorizes EPA to regulate the manufacture, processing, use, distribution in commerce, and disposal of chemicals which may harm human health or the environment.

RESIDUES IN HUMANS

Recent studies have demonstrated the presence of some drugs, pesticides, and environmental contaminants in human tissue, urine, and milk. For example:

--A 1975-76 study 1/ of chlorinated hydrocarbon pesticide residues in breast milk taken from more than 1,400 women found that 63 to 80 percent of the samples contained residues of one or more of the following: dieldrin, heptachlor epoxide (a metabolite of heptachlor), and oxychlordane (a metabolite of chlordane).

--An EPA survey 2/ of chlorinated hydrocarbon pesticide residues in breast milk in Arkansas and Mississippi between September 1973 and February 1974 found DDT, PCB, and DDE (a metabolite of DDT) residues in all samples. From 28 to 46 percent of the samples were also found to contain one or more of the following: dieldrin, heptachlor epoxide, oxychlordane, and betabenzenehexachloride (an isomer of benzene hexachloride).

1/Savage, E. P., "National Study To Determine Levels of Chlorinated Hydrocarbon Insecticides in Human Milk," unpublished (1976), EPA contract no. 68-01-3190.

2/Strassman, S. C., Kutz, F. W., "Insecticide Residues in Human Milk from Arkansas and Mississippi, 1973-74," Pest. Monit. J., vol. 10, no. 4, pp. 130-133, 1977.

--Harvard University researchers reported in 1977 1/ that they had found residues of dioxin (2,3,7,8-tetrachlorodibenzo-p-dioxin) in 4 of 18 samples of breast milk taken from women living in areas where the herbicide 2,4,5-T is commonly used. Dioxin, a contaminant of 2,4,5-T, Silvex, Ronnel, and certain industrial chemicals, is one of the most toxic substances known to man.

--A draft EPA report on hexachlorobenzene notes that about 95 percent of the human fatty tissue and 75 percent of the mothers' milk samples collected in the United States by EPA have been found to contain hexachlorobenzene.

--Preliminary data from a joint survey by EPA's Ecological Monitoring Branch and HEW's National Center for Health Statistics 2/ reveals the presence of dimethyl phosphate in 11.5 percent of the human urine sampled, diethyl phosphate in 7.9 percent, dimethyl phosphothionate in 6.5 percent, and diethyl phosphothionate in 10.8 percent. The four substances detected are metabolites of organophosphorus insecticides.

--Preliminary data from the EPA/HEW survey also revealed the presence of the pesticide pentachlorophenol in 84.8 percent of the human urine samples analyzed. The survey found residues of 3,5,6-TC-2-P, a metabolite of chlorpyrifos, in 16.1 percent of the samples analyzed, and 2,4,5-TCP, a metabolite of certain organochlorine insecticides in 1.7 percent of the samples.

--Preliminary data from the EPA/HEW survey also revealed the presence of two metabolites of the insecticide malathion in human urine. Alpha-monocarboxylic acid (MCA) was detected in 9.4 percent of the human urine samples and dicarboxylic acid in 2.8 percent of the samples.

1/Meselson, M., and Baughman, R., "The Evaluation of Possible Health Hazards from TCDD in the Environment," unpublished, 1978.

2/Kutz, F. W., Murphy, R. S., and Strassman, S. C., "Survey of Pesticide Residues and Their Metabolites in Urine from the General Population," Pentachlorophenol, edited by K. R. Rao, Plenum Publishing Corporation, New York, 1978, pp. 363-369.

The above studies demonstrate the existence of residues in humans but do not identify the particular sources of the residues. While the legal use of pesticides and the resulting legal residues in food and feed are undoubtedly a major source of the residue ultimately found in people, illegal and over-tolerance residues also contribute to the burden of residue in the environment and in humans.

CONCLUSIONS

Consumers are exposed to toxic residues of animal drugs, pesticides, and environmental contaminants in the meat and poultry they eat. However, USDA has not accurately assessed the extent to which consumers are exposed to illegal and potentially harmful residues because:

--The methods used by USDA to compute residue violation rates assume that there is no illegal residue of a substance in an animal if the animal was not tested for that particular substance.

--Most substances likely to leave residues in raw meat and poultry were not included in USDA's monitoring program.

We estimate that 14 percent by dressed weight of the meat and poultry sampled by USDA between 1974 and 1976 contained illegal residues.

Many of the drugs, pesticides, and environmental contaminants likely to leave residues in raw meat and poultry are known to cause or are suspected of causing cancer. Although residues of some of the substances cannot be avoided because of the persistence of banned pesticides in the environment, actions could be taken to reduce consumer exposure to some suspected carcinogens.

FDA should reevaluate data on the carcinogenicity of arsenical drugs and take appropriate action to remove them from the market if they are found to cause cancer. Similarly, EPA should examine available data on the safety of cadmium and hexachlorobenzene and take appropriate action to restrict their manufacture, use, and distribution if they are found to cause cancer.

RECOMMENDATIONS TO THE SECRETARIES OF AGRICULTURE AND HEW AND THE ADMINISTRATOR OF EPA

We recommend that the Secretary of Agriculture revise the methods currently being used to compute residue violation rates to more accurately reflect the extent to which consumers are exposed to illegal residues in raw meat and poultry.

We also recommend that USDA expand its monitoring efforts to include, at least periodically, all the animal drugs, pesticides, and environmental contaminants for which detection methods exist.

We recommend that the Secretary, HEW, direct the FDA Commissioner to reevaluate available data on the possible carcinogenicity of arsenical drugs and take appropriate steps to withdraw approval of the drugs if they are found to cause cancer.

We recommend that the EPA Administrator review available data on the safety of cadmium and hexachlorobenzene and take appropriate steps to restrict their manufacture, use, and distribution if they are found to cause cancer.

AGENCY COMMENTS AND OUR EVALUATION

USDA agreed (see app. IV) that its monitoring efforts should be expanded but took exception to our estimate of the extent of public exposure to illegal residues from animal and poultry sources. HEW said (see app. V) that FDA is reassessing the safety of animal drugs, and EPA said (see app. VI) it is currently assessing the safety of cadmium and hexachlorobenzene. Specific comments on our recommendations are discussed below.

Revise USDA methods for computing residue violation rates

USDA explained that while its data show that 2 percent (by count) of its 1974-76 monitoring samples of meat, poultry products, and byproducts contained illegal levels of the residue or class of residues tested for, the figure was not represented, or intended, as an estimate of total public exposure. USDA said, however, that its program gives a reliable estimate of the incidence of illegal residues in its total population of animals, but only on an individual specific compound-animal species pairing.

According to USDA, our 14-percent estimate of public exposure to violative residues in the meat and poultry supply may be misleading because:

--The summing of violation rates for individual compounds within a species as a means for determining the violative residues rate for that species represents a worst-case basis, as it does not take into account the multiple residue violations that do occur. Therefore, the true violation rate lies at a level below the sum of the violation rates for a particular species; however, the extent of multiple residue violations is unknown.

--We projected the sum of violation rates to obtain an estimate by carcass weight when many of the residues tested for concentrate in the kidneys or liver and this may not be representative of the residue present in the whole carcass. Therefore, many violative samples represented only the weight of the target organ, not the weight of an entire carcass which was otherwise free of the residue. For example, USDA has never found diethylstilbestrol in carcass meat.

We recognize that the overall residue violation rates would be reduced when an animal contained illegal residues of more than one substance. However, we could not consider multiple residue violations in our computations because USDA does not have data on the extent of multiple violations. We believe any downward adjustment to the violation rates due to possible multiple violations probably would be balanced by increases that would result if USDA tested for all substances that are potential sources of illegal residues. (See p. 12.) Moreover, even if the true violation rate were less than the sum of the violation rates for a particular species, we believe, as stated on page 8, that the sum of the violations is a more reasonable basis than the USDA basis for estimating the violation rate.

We believe an accurate estimate, which USDA acknowledges it does not now have, of total public exposure to illegal residues is important so that USDA and FDA can reliably determine the extent of the residue problem and make appropriate decisions concerning resource commitments to deal with the problem. Therefore, USDA should revise its method for computing residue violation rates so that the rate is more representative of the actual situation.

With regard to USDA's contention that a finding of an illegal residue in liver or kidney tissue may not necessarily mean that illegal residues are present in other edible tissues, USDA regulations state that, when a sample is found to contain illegal residues, the entire carcass must be considered adulterated unless it can be shown that illegal residues are not present in other edible tissues.

Although USDA may test for residues in only one specific organ, its regulations provide that

> "All carcasses and edible organs and other parts thereof, in which are found any biological residues which render such articles adulterated shall be marked as 'U.S. Condemned' and disposed of * * *."

USDA regulations further state that

> "Carcasses, organs, or other parts of carcasses of livestock shall be condemned if it is determined that they are adulterated because of the presence of any biological residues."

and

> "That no product shall be passed for human food * * * unless it is found to be otherwise not adulterated."

Thus, when USDA finds illegal residues in liver or kidney tissue, the entire animal is to be condemned unless it can be shown that the remainder of the animal is free from illegal residues. While USDA has said that it has never found diethylstilbestrol, a known carcinogen, in carcass meat, it should be noted that USDA usually does not test for it. For example, although USDA found illegal diethylstilbestrol residues in 47 liver samples between 1974 and 1976, it did not test any carcass meat for this residue during the 3-year period.

Furthermore, if, as USDA contends, there may be no correlation between the finding of illegal residues in liver or kidney tissue and the presence of illegal residues in other edible tissues, then USDA is expending its limited resources to test for residues in meat byproducts constituting only a small portion of the American diet. For example, of approximately 3,600 swine sampled during 1976, USDA tested only about 1,000 for residues in muscle or fat tissues; these tissues comprise most of the edible tissues. The prudence of using such resources in this manner is questionable.

Contrary to USDA's contention, in many cases there is a close correlation between residues in liver or kidney tissue and residues in muscle tissue. For example, USDA tested kidney tissues from 1,493 swine for sulfa residues in 1976 and found 141 animals with violative residues. In tests of muscle tissue from 143 animals for which kidney tissues were found to contain sulfa residues close to or above tolerances, 131 were found to contain illegal residues.

Expand USDA monitoring efforts

USDA agreed that its residue program should be diversified and substantially expanded through a much larger volume of samples. USDA said it intends to devote more resources in the coming year, and will continue to concentrate attention on those harmful residues that are most likely to enter the food supply. According to USDA, it is also important to remember that some compounds lack regulatory analytical methods that are feasible for routine monitoring. USDA said it is attempting to develop better methods, but greater attention by other agencies is also needed. USDA said it now gives priority attention to those residues for which analytical methods are sufficiently reliable to support legal actions.

HEW believes our analysis is simplistic and misleading, in that it fosters the erroneous notion that the number of chemicals monitored is a valid indicator of the effectiveness of the program. HEW believes that (1) such factors as volume, use, relative toxicity, and comparative costs of tests should be considered in determining what chemicals should be included in the USDA monitoring program and (2) monitoring efforts should be concentrated on selected chemicals to maximize public protection at any given level of resources.

While the factors cited by HEW should be considered in determining the extent to which USDA should concentrate its monitoring efforts on a particular drug, pesticide, or environmental contaminant, we believe that all substances for which tolerances have been established should be included in the monitoring program--at least periodically. In planning future monitoring efforts, USDA should consider not only the factors cited by HEW but also the extent to which illegal residues have been found in prior monitoring efforts.

Reevaluate the safety of arsenical drugs

HEW said that FDA will review the carcinogenicity of arsenical drugs.

HEW pointed out that illegal residues in raw meat and poultry pose a difficult and complex problem to which it has devoted considerable time and effort. According to HEW, the information presented in our report, and in related hearings by the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, has been carefully considered in formulating current efforts to alleviate the problem. HEW said that recent initiatives included:

--A strengthened toxicological program within HEW to enhance assessment of suspected carcinogens.

--A cyclical review of the safety data supporting previously approved new animal drug applications.

--Establishment of a Residue Task Force within FDA to analyze and improve residue-related regulatory efforts.

--Initiation of a Food Safety Task Force within FDA to study possible changes and improvements in food regulatory programs.

--Efforts by an interagency regulatory liaison group to improve regulatory cooperation and coordination between FDA and EPA.

HEW said that while the cited initiatives reflect its concern and commitment, HEW recognizes that its unilateral efforts cannot achieve an effective solution to this inherently complex problem. HEW believes the solution depends, in large part, on all concerned parties--regulators, legislators, producers, processors, and consumers--arriving at some common appreciation of the various facets of the problem, so that all may contribute to a collective solution. According to HEW, these facets include an understanding of statutory authorities, regulatory procedures, organizational relationships, production techniques, marketing systems, and scientific capabilities.

With regard to arsenical drugs, HEW said that it is aware of EPA's finding that arsenic is a carcinogen based on occupational exposure and on epidemiological studies in regions where high arsenic levels are observed in the water supply, but that the observations are certainly inconclusive and controversial in that competing factors were often present. HEW also said that to its knowledge, the carcinogenicity of

arsenicals has never been confirmed in animal feeding studies. HEW has assigned arsenicals a high priority in its cyclical review of animal drugs.

According to HEW, FDA is closely monitoring the developing information on all aspects of arsenic toxicity, including carcinogenicity, teratogenicity, and mutagenicity, as well as the growing body of evidence that arsenic is an essential element, with the objective of modifying its current regulatory position should the facts warrant.

Review safety of cadmium and hexachlorobenzene

EPA said that it is reviewing both cadmium and hexachlorobenzene to determine whether regulatory action is appropriate under the Toxic Substances Control Act. EPA stated that cadmium and hexachlorobenzene are also a part of the EPA Office of Pesticide Programs' intensive risk/benefit review process for pesticides. This review process is known as rebuttable presumption against registration (RPAR).

According to EPA, an RPAR notice was issued for cadmium on October 26, 1977, identifying risks associated with its pesticide uses and soliciting public input and comment. The possible effects identified were tumors, mutations, birth defects, toxic effects on the fetus, and metabolic effects. EPA said that it is currently analyzing the information received in response to the notice in order to reach a decision on the risks and benefits of cadmium pesticides.

Depending on the results of its analysis, EPA may either continue, restrict, or cancel the registrations of cadmium pesticides. EPA pointed out that it cannot take action solely upon a finding of risk but that its action must be based on a finding of unreasonable adverse effects as determined by balancing economic, social, and environmental risks and benefits.

According to EPA, hexachlorobenzene is in a pre-RPAR stage during which EPA reviews and evaluates data available in-house to decide whether the potential risks associated with its use are sufficiently great to warrant a full RPAR review.

CHAPTER 3

PROBLEMS IN IDENTIFYING AND REMOVING FROM THE MARKET RAW MEAT AND POULTRY CONTAINING ILLEGAL RESIDUES

An objective of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the FD&C Act is to prevent the marketing of adulterated raw meat and poultry. However, with few exceptions, neither USDA nor FDA can locate and remove from the market raw meat and poultry found to contain illegal residues.

The Government is unable to prevent the marketing of the contaminated animals because:

--USDA does not have the authority to detain raw meat and poultry pending results of sample analysis unless it has reason to believe the animal is violative.

--Animals are marketed and probably consumed before sample analysis is completed.

--Meat from violative animals usually cannot be identified once the animal has been slaughtered.

Before USDA and FDA can establish an effective program to identify and remove residue-contaminated raw meat and poultry from the market after it has left the slaughterhouse, it would be necessary to establish a "tagging" system whereby meat taken from slaughtered animals would be coded for identification purposes. However, such a program may not be feasible and would not greatly increase consumer protection.

Other alternatives, including residue analysis prior to slaughter and dependence on producers to monitor the animals slaughtered at their plants, might increase the probability of removing animals containing violative residues.

CONTAMINATED PRODUCTS SOLD TO THE PUBLIC

By the time samples are analyzed and a violation discovered, the products have been distributed and, in many cases, sold to the public. Even in those cases where raw meat and poultry have not yet been sold to the public, USDA

usually cannot identify the animal from which a violative sample was taken in order to remove it from the market.

Except for cause, neither the Federal Meat Inspection Act nor the Poultry Products Inspection Act authorizes USDA to detain carcasses of slaughtered animals until routine analysis of animal samples is completed. Therefore, the carcass of an animal randomly selected under the monitoring phase of USDA's program continues through the slaughtering and marketing process while the sample is being analyzed. Meat and poultry are usually not held at the slaughterhouse for more than 48 hours. By contrast, USDA officials estimate that it takes 6 to 25 days to complete a residue analysis.

USDA inspectors send raw meat and poultry samples to a USDA laboratory. Samples are frozen and shipped by airmail to the appropriate laboratory for analysis.

However, once the sample reaches the laboratory it is not always analyzed promptly. According to a USDA laboratory official, the laboratory staff tries to maintain a 3- or 4-day backlog of samples in order to keep the laboratory running efficiently.

The official said the following timetable for analysis of swine tissue for sulfa residues (a class of animal drugs) is typical of the delays encountered in the monitoring program.

--April 7, 1977, sample collected at slaughterhouse.

--April 11, 1977, sample mailed to laboratory.

--April 13, 1977, sample received at laboratory.

--April 22, 1977, residue analysis begun.

--April 27, 1977, residue analysis completed.

Thus, 20 days after the animal was slaughtered and about 18 days after the carcass was marketed, USDA determined that the animal contained illegal sulfa residues.

Because raw meat or poultry from a slaugthered carcass is not normally stamped or tagged to identify the animal of origin, contaminated products cannot usually be identified and removed from the market. Therefore, USDA could not locate meat and poultry from most of the approximately 1,200 food-producing animals it found under its monitoring

program between 1974 and 1976 to contain illegal residues. These animals represented about 250,000 pounds of raw meat and poultry.

Only in those cases such as turkeys, where the carcass is coded, frozen, and stored for a lengthy period, can the contaminated animal be identified and removed from the market. However, even when contaminated animals are located, they are not always removed from the market.

For example, in 1975 USDA identified illegal residues of the animal drug ipronidazole, a suspected carcinogen, in a flock of turkeys. The lot of turkeys from which the sample was collected was combined with other lots and processed into turkey rolls. Although FDA was able to identify the recipients of the turkey rolls made from the contaminated turkeys, it did not recall the products. Nor did FDA notify USDA of the problem to enable it to take action to remove the contaminated turkey rolls from the market.

The above case was discussed in detail in March 1976 hearings before the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce. At that time, the FDA Commissioner disavowed the agency's actions in the case and said that they did not represent FDA policy.

WHAT CAN BE DONE?

To remove raw meat and poultry containing illegal residues from the market, USDA must either (1) develop a "tagging" system whereby the carcasses of slaughtered animals will be marked for future identification or (2) develop residue detection methods which can be completed before the animal carcass leaves the slaughterhouse. Because tagging appears infeasible, emphasis should be placed on developing quicker detection methods.

A third alternative for improving the current monitoring program would be to place greater emphasis on residue detection by industry. Industry efforts, however, may suffer from the same limitations as the USDA monitoring program unless quicker detection methods are developed.

Feasibility of a "tagging" system

Under the current monitoring program, residue violations are not normally discovered until after the animal has been

slaughtered and the carcass distributed. Although maintaining a "tagging" system capable of tracing the identity of a contaminated animal through the marketing chain might enable USDA to remove some contaminated meat from the market, such a program may not be cost effective because of the complexity of the marketing system and the limited nature of the monitoring program.

The chart on page 31 illustrates the livestock marketing process from grower to consumer. Beginning with the earliest phase of the marketing process, the auction house, and continuing to the retail level, animals from a violative grower are constantly being mixed with animals from other growers. To maintain the identity of the animal through to the retail level, the carcass would have to be tagged at least four times.

--When the animal is sent from the grower to an auction house or slaughterhouse, an ear tag, brand, or other external tag would be required.

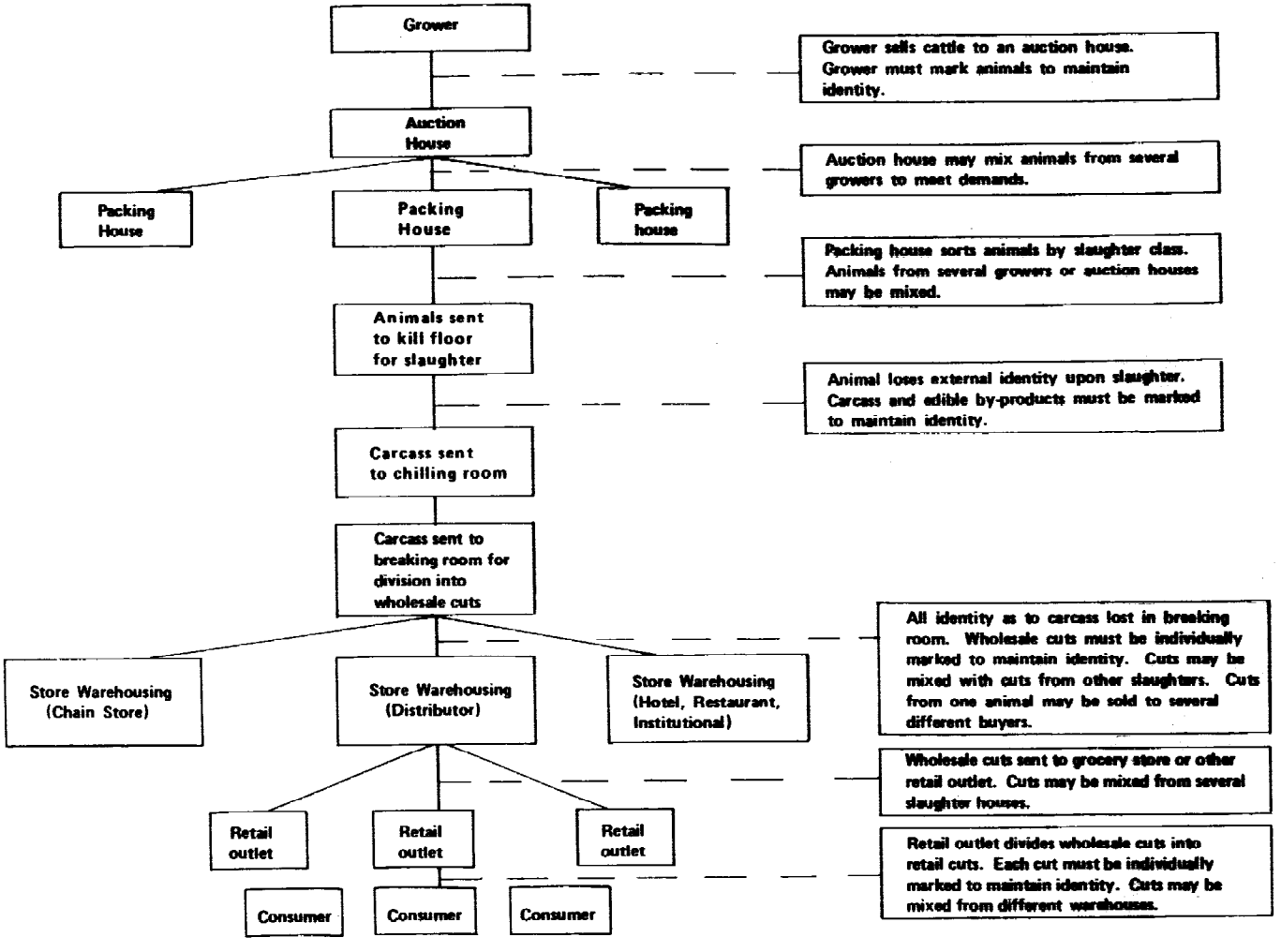
--When the animal is slaughtered, external identification is lost. Separate tagging would be required for the carcass and the edible byproducts such as kidney and liver.

--When the packing house divides the carcass into wholesale cuts, separate tagging of each cut would be required.

--When the wholesaler or retailer divides the carcass into retail cuts, each cut would have to be tagged.

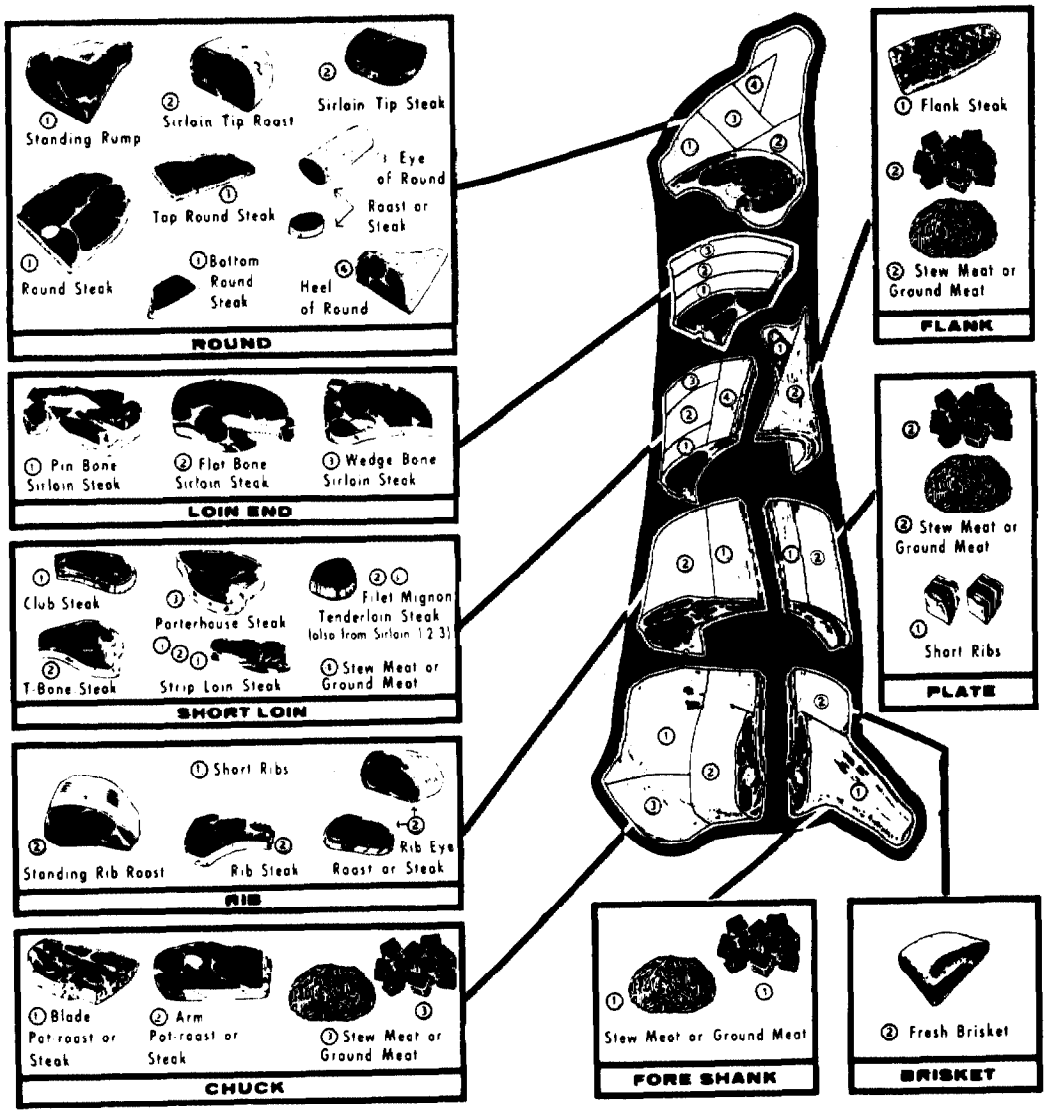
The chart on page 32 identifies the wholesale and retail cuts for beef cattle. Each cut would have to be separately tagged. According to one packing house official, one animal may yield several hundred retail cuts.

Before meat from an animal found to contain illegal residues could be identified and removed from the market, USDA would have to trace through four separate tagging processes. By the time the violation was discovered and the locations to which meat from the violative animal was shipped were identified, the meat would probably have been consumed. In addition, if all animals in the lot sold by the grower were assumed to contain illegal residues, each animal carcass would have to be independently traced.


Grower
Grower sells cattle to an auction house. Grower must mark animals to maintain identity.
Auction House
Auction house may mix animals from several growers to meet demands.
Packing House
Packing House
Packing house
Packing house sorts animals by slaughter class. Animals from several growers or auction houses may be mixed.
Animals sent to kill floor for slaughter
Animal loses external identity upon slaughter. Carcass and edible by-products must be marked to maintain identity.
Carcass sent to chilling room
Carcass sent to breaking room for division into wholesale cuts
All identity as to carcass lost in breaking room. Wholesale cuts must be individually marked to maintain identity. Cuts may be mixed with cuts from other slaughters. Cuts from one animal may be sold to several different buyers.
Store Warehousing (Chain Store)
Store Warehousing (Distributor)
Store Warehousing (Hotel, Restaurant, Institutional)
Wholesale cuts sent to grocery store or other retail outlet. Cuts may be mixed from several slaughter houses.
Retail outlet
Retail outlet
Retail outlet
Retail outlet divides wholesale cuts into retail cuts. Each cut must be individually marked to maintain identity. Cuts may be mixed from different warehouses.
Consumer
Consumer
Consumer

BEEF CHART

Showing the 9 Wholesale Cuts and the Retail Cuts Obtained From Them



Source: U. S. Department of Agriculture

During calendar year 1976, over 128 million livestock and 3.5 billion poultry were slaughtered in the United States. However, only 1 of every 11,000 livestock slaughtered and 1 of every 575,000 poultry slaughtered were sampled. The cost of establishing a tagging system and maintaining the paperwork necessary to locate and remove violative meat from the market would appear to be prohibitive in light of the limited consumer protection that would be afforded.

USDA officials said that it might be feasible to tag carcasses until they are shipped to the breaking room and divided into wholesale cuts; however, beyond that point, the animal loses all identity.

Need for quicker assay methods

The FD&C Act requires that manufacturers develop "practicable" analytical methods for detecting residues of pesticides and animal drugs in raw meat and poultry. FDA and EPA are responsible for insuring that manufacturers develop adequate methods.

FDA regulations (21 CFR 500.90) state that:

> "The assay shall be considered practicable only if it is suitable for routine use in a government regulatory laboratory. The time required to complete the assay must be consistent with regulatory objectives (monitoring, compliance, etc.). All supplies, equipment, reagents, standards, and other materials necessary to conduct the assay must be commercially available except that reference standards may be supplied by the petitioner if they are not commercially available."

The regulations also state that:

> "The Commissioner will withdraw approval of any assay method and initiate regulatory action against the sponsored compound [animal drug], if the petitioner breaches such a condition of the compound's approval."

Residue analysis must be completed before the animal is divided into wholesale cuts at the packing house, if USDA is to prevent the marketing of meat containing illegal

residues. Because animals are generally divided into wholesale cuts about 24 hours after slaughter, a practicable method would appear to be one that can be run at the slaughterhouse within a 24-hour period. However, even if the administrative delays in mailing and handling tissue samples were eliminated, sample analysis using existing methods would not be completed within 24 hours.

Several methods, including testing of live animals, are available or are being developed which would enable USDA to complete sample analysis on some drugs and pesticides within 24 hours. However, the senior staff officer of USDA's Epidemiology, Residue Evaluation, and Science Services Staff said that USDA currently has neither laboratory facilities nor personnel to use such methods.

USDA has contracted with the University of Georgia to develop a quicker method for detecting residues of sulfa drugs. When completed, the method will enable USDA to test animals as quickly as they are slaughtered. USDA officials believe the method can be adapted to detect other residues.

Methods are currently available which would enable USDA to detect residues of many substances within 2 hours after the sample is collected. According to a researcher from Michigan State University, thin layer or gas chromatography methods can be used to detect residues in tissue, blood, and urine, making possible the completion of residue analysis prior to slaughter. However, the researcher said that problems exist in detecting residues in blood and urine because the residue will be far less concentrated than in tissue samples.

To take advantage of these or other quick detection methods, USDA must develop laboratory capability--possibly mobile laboratories--at the slaughterhouse.

Monitoring by private industry

USDA has recently entered into agreements with two large poultry producers to have the producers operate their own residue detection programs under USDA supervision. Before approving the industry testing programs, USDA officials reviewed the companies' testing procedures, comparing test results obtained in the company laboratory to results obtained on a portion of the same tissue sample in a USDA laboratory.

After approving a company's monitoring program, USDA continues to spot check the company's products. USDA will decrease its monitoring of the substances covered by the company's program.

One of the companies having a USDA-approved monitoring program produces about 4.5 million chickens a week. The company owns its own laying hens, hatcheries, feed mills, and processing plants. Growers raise chickens for the company under contract, the company providing both the medicated and nonmedicated feed.

The company's residue monitoring program includes only pesticides and environmental contaminants. According to a company official, drug residues will not be present in chickens as long as the manufacture of the medicated feed is controlled and withdrawal periods are followed. Every day, six fat samples are collected from one flock at each of the company's eight slaughterhouses. The samples are analyzed for 13 pesticides or environmental contaminants, including polychlorinated biphenyls, DDT, dieldrin, and mirex.

If the residue content of a sample is close to the established tolerance, USDA is to be notified. Intensified sampling with USDA involvement is to be initiated to identify the scope and cause of the problem.

The second company with a USDA-approved monitoring program provides the turkeys--but no feed--to the growers. The company's monitoring program includes both chlorinated hydrocarbon pesticides and animal drugs such as ipronidazole, penicillin, and tetracyclines.

The company samples six turkeys before slaughtering the rest of the flock. If residues are found to be below tolerance, the rest of the flock is slaughtered.

CONCLUSIONS

Raw meat and poultry are generally marketed and probably consumed by the public before USDA can identify a violation. Because meat taken from a violative animal cannot normally be identified once the animal has been slaughtered, and a "tagging" system to make such identification possible does not appear feasible, USDA needs to develop the capability to complete residue testing of animals at the slaughterhouse before the animal carcass is divided into wholesale cuts.

However, even if USDA tested samples at the slaughterhouse, sample analysis under existing residue detection methods would not be completed before the animal carcass was marketed. FDA and EPA should work with USDA in assuring that manufacturers develop more practicable detection methods.

Encouraging large meat and poultry producers to develop residue monitoring programs could help USDA broaden the residue monitoring program at minimal expense to the Government. It might also enable USDA to expand its monitoring to include more substances not included in industry monitoring efforts.

RECOMMENDATIONS TO THE SECRETARIES OF AGRICULTURE AND HEW AND THE ADMINISTRATOR OF EPA

We recommend that the Secretary of Agriculture develop the capability to conduct residue analyses at the slaughterhouse and encourage the expansion of private residue monitoring efforts.

We recommend that the Secretary of HEW direct the FDA Commissioner to require animal drug manufacturers to develop residue detection methods which can be completed at the slaughterhouse within 24 hours after slaughter.

We recommend that the EPA Administrator require pesticide manufacturers to develop residue detection methods which can be completed at the slaughterhouse within 24 hours after slaughter.

AGENCY COMMENTS AND OUR EVALUATION

Developing slaughterhouse testing capability

USDA said it strongly supports the view that USDA or the other concerned agencies must conduct or foster research to speed advancement of residue analysis technology and agreed that private monitoring efforts should be expanded.

USDA also agreed that onsite analysis is ordinarily advantageous only if it can be completed within 24 hours. USDA said that it and most other governmental and private organizations involved in analysis of highly perishable foods are always keenly interested in speedier yet reliable methods of analysis. USDA will implement a swab test in

early 1979 by which onsite inspectors can detect antibiotic drug residues in dairy cattle kidney tissue. Also, a swab test that may enable quick on-the-farm screening for antibiotic residues is under development and USDA study. USDA said it is also testing a laser beam system that analyzes meat extracts for certain residues and identifies them. According to USDA, this method probably will not be suitable for use in slaughtering plants, but will allow it to do as many samples in 3 days as are now done manually in 1 month. USDA said these results are encouraging, but recognized that much more research and development work in residue detection and analysis needs to be done.

Development of faster residue detection methods

HEW and EPA agreed that the ultimate solution to the problem of illegal residues awaits the development of quick, simple, and accurate assay methods for use at the point of slaughter, but did not believe that manufacturers should be required to develop such methods at this time. EPA questioned the cost effectiveness of performing residue analysis at the slaughterhouse even if faster detection methods are developed.

According to HEW, significant advances in instrumentation and methodology must be developed by the scientific community before regulatory agencies can translate research methods into effective, reliable, and simple test methods for widespread operational use. HEW said that the state of the art in methodology is not sufficiently advanced to permit development of assay methods for use at the point of slaughter.

According to HEW, FDA is investing resources in developing assay methods as well as requiring the regulated industry to submit methods that are accurate and that can be used to sustain regulatory action. HEW said that it is fully committed to continuing FDA's efforts, but believes the capability cannot be quickly or easily developed.

HEW said that, if it were to require animal drug manufacturers to develop residue detection methods which can be completed at the slaughterhouse within 24 hours after slaughter at this time, the present state of analytical technology would be unable to produce analytical methods of sufficient precision and reliability suited to use under slaughterhouse conditions. According to HEW, research laboratories have methods which some slaughterhouses

are experimenting with that can detect and confirm specific drug residues at the extremely low levels permitted to remain in meat and poultry, but they are not generally practical for widespread in-plant use because of the sophisticated equipment needed and the special expertise required.

HEW also said that, although some screening methods are under development that could be performed in 24 hours, these methods will not be adequate to support regulatory actions and would require substantial investment of new laboratory capability in or very near all federally inspected slaughterhouses.

EPA said that residue detection methods are available for all pesticides for which tolerances in raw meat and poultry have been established, and that many of these methods can be completed within 24 hours even though a 24-hour methodology has never been a requirement for establishing a pesticide tolerance.

EPA said that the real problem is that the residue methods required for tolerances apply only to individual pesticides, but USDA and FDA have found it necessary to use multiresidue methods in order to perform their routine responsibilities. According to EPA, it would be more practical to develop rapid, multiresidue methods than to impose a 24-hour completion criterion on methods for individual pesticides, but the agency has no clear legal authority under the FD&C Act to require tolerance petitioners to develop 24-hour, multiresidue methods suitable for the particular pesticides for which they wish to establish a tolerance.

EPA said that it lacks the resources to develop the methods itself, but that it would be willing to share its considerable expertise in the development of analytical methods with FDA and USDA and work with them to develop rapid, multiresidue methods where feasible if such methods would make a substantial contribution to public health protection. EPA believes that residue testing at the slaughterhouse on a 24-hour turnaround would be quite costly and that a determination must be made as to whether a substantial additional expense would be justified by whatever additional protection of the public health such testing might provide. According to EPA, the high expense would have to be borne by either the meat packing industry (and ultimately the consumer through higher prices) or the Government.

EPA said that determining whether the additional expense would be justified would require a careful survey to determine the rate of tolerance violations, the amount by which the violative residues exceed the tolerances, the

health problems that may result from the consumption of meat and poultry with these levels of residues, and the technical feasibility of developing such residue-testing techniques for enforcement purposes. According to EPA, the benefits of onsite residue analysis could then be compared meaningfully with the additional costs.

While we recognize that the development of residue detection methods which can be completed at the slaughterhouse within 24 hours cannot be accomplished in the short term and is limited by the present state of analytical technology, we believe that, consistent with the FD&C Act, the responsibility should be placed clearly on animal drug and pesticide manufacturers to develop faster methods. (See p. 33.) FDA and EPA should consider establishing target dates for the development of new methods which could spur developments in the area of analytical technology.

By placing greater emphasis on industry for development of faster detection methods for individual drugs and pesticides, FDA and EPA could concentrate their limited resources on assisting USDA in developing rapid, multiresidue screening methods. The use of rapid screening tests, such as the swab test cited by USDA, for detecting antibiotic residues in cattle kidney tissue may lessen, rather than increase, the costs of residue analysis as EPA suggests. Currently, USDA must complete quantitative and qualitative residue analysis for each sample collected because it has no way of knowing what residues may be present. With the use of a screening method to identify the presence of a drug or pesticide in an animal, USDA could limit the use of the more complex and expensive quantitative methods to those animals actually known to contain residues. Thus, USDA may be able to expand its monitoring efforts through the use of screening methods without increasing the cost.

Expansion of private residue monitoring

USDA said that its activities in the area of private residue monitoring are in the early stages. USDA referred to the two large poultry operations mentioned in this report (see p. 34), which conduct a cooperative residue program with USDA, and said that the program is now sufficiently tested to allow USDA to encourage expansion to other operations and species. USDA noted that a number of other large operators conduct residue analysis but do not wish to participate in the USDA cooperative program. USDA said the program has resulted in detection of problems in the early stages of development and allowed rapid corrective action.

CHAPTER 4

EFFORTS TO PREVENT FUTURE SHIPMENTS OF RESIDUE-CONTAMINATED ANIMALS NEED STRENGTHENING

Because of the problems in identifying and removing raw meat and poultry containing illegal residues from the market, a major part of FDA, EPA, and USDA efforts concerning residues must be directed to preventing future shipments of residue-contaminated raw meat and poultry. However, the Government's efforts in this regard have not been effective because:

--FDA does not follow up on most residue violations to identify the cause of the violation and the corrective action taken.

--USDA's pretest program to determine whether residue violations have been corrected can easily be avoided by growers.

--FDA generally issues information letters because of difficulties in using stronger regulatory alternatives.

--USDA's monitoring program is not designed to enable FDA to develop case histories to support prosecutions.

--Residue detection methods adequate to support regulatory actions do not exist for many drugs and pesticides.

--Misuse of an animal drug is not a violation of the FD&C Act.

--FDA cannot seek civil penalties against violators; its authority is limited to criminal penalties.

INEFFECTIVE FOLLOWUP

After USDA identifies illegal residues in a sample of raw meat or poultry, followup should be performed (1) by FDA and EPA to determine the cause of the violation and (2) by USDA to determine whether needed corrective actions have been taken. However, followup efforts have not been effective.

Followup to determine cause of violation

USDA reports findings of illegal residues to FDA for followup to determine the cause of the violation and the corrective action needed. According to FDA officials, an animal containing illegal residues is considered contaminated food from the moment it leaves a "premise of origin" for a slaughtering plant involved in interstate commerce. Thus FDA inspectors visit the feedlot or farm, i.e., the premise of origin, from which a violative animal went to slaughter. If FDA inspectors determine that the residue violation occurred because of misuse of a pesticide, the case is referred to EPA for further followup.

During the 4-year period ended December 1976, USDA reported 3,124 residue violations to FDA for followup. However, FDA district offices reported followup investigations on only 1,161, or 37 percent, of the cases. Investigations were not reported on the remaining 1,963 cases.

According to FDA officials, some residue violations were not followed up because

--the data received from USDA were too old,

--the grower could not be identified,

--the residue varied only slightly from the tolerance,

--the case was referred to FDA by mistake, or

--the residues were of substances, such as copper and lead, for which FDA has no program.

One FDA district office official said that FDA does not follow up on some residue violations because the data the agency receives from USDA are too old. He said that FDA generally does not follow up on referrals that are received more than 35 days after collection of the sample because of the difficulty involved in trying to identify the cause of the violation so long after it occurred. In an effort to speed the reporting of residue violations to FDA district offices, USDA, in July 1976, began reporting the results of its sample analysis directly to the appropriate FDA district office in addition to reporting the violation to FDA headquarters. Previously, violations were reported to FDA headquarters, which in turn referred the cases to the district offices.

However, the new procedure has not resulted in an increase in the number of residue violations investigated. Between July 1976 and December 1976, only 99 of 494 violations (20 percent) reported to FDA were investigated. In the 6 months preceding implementation of the new reporting procedures, 154 of 334 violations (46 percent) had been investigated.

We did not review the adequacy of EPA's followup efforts.

Ineffective pretest

The pretest portion of USDA's surveillance program provides for USDA to test animals from growers previously identified as marketing animals containing illegal residues. Before shipping additional animals to slaughter, a violative grower is asked to provide a small lot from the herd or flock for residue analysis. The carcasses of the sampled animals are normally held at the slaughterhouse until the sample analysis is completed.

If the sample analysis shows that residues are within tolerance levels, the remainder of the herd or flock is approved for slaughter. An additional sample is collected by USDA when the main herd or flock is slaughtered to verify that the residue problem has been cleared up, but the animals are not detained pending completion of sample analysis.

Many growers, however, do not comply with USDA's pretest requirements. Review of records at USDA regional offices in Atlanta, Dallas, and Des Moines indicated that pretest had not been completed by about 600 of the approximately 1,100 growers required to submit animals for pretest between 1974 and 1976.

According to the senior staff officer at USDA's Epidemiology, Residue Evaluation, and Science Services Staff, regional office personnel should follow up on every residue case until pretest has been successfully completed. However, USDA regional office officials advised us that USDA headquarters has never established guidelines for following up on growers who do not complete pretest.

USDA officials acknowledge that growers can easily avoid pretest by shipping animals to an auction house or to a different slaughterhouse. Because USDA lacks authority to require growers to "tag" their animals for grower identification, the identity of the owner cannot

always be determined. Our review of 31 open cases at three USDA regional offices indicated that at least five of the growers may have shipped additional animals to market without completing pretest.

USDA officials believe quarantine authority would strengthen the pretest program. Such authority would enable USDA to prevent the movement of animals from a grower's farm until pretest has been successfully completed.

Even if a grower complies with the pretest requirement, however, USDA does not know whether the animals are representative of the herd or flock. Because the grower--not USDA--selects the animals to be tested, USDA cannot even determine whether the animals are from the same herd or flock as those the grower proposes to market. USDA's only way to assure that the animals submitted for pretest are representative of the herd or flock is to collect an additional sample when the whole herd or flock is slaughtered.

In a September 11, 1978, audit report, USDA's Office of the Inspector General confirmed our findings with respect to the pretest program. The Inspector General's report stated that

> "The Food Safety and Quality Service (FSQS) had not fully implemented the hold and test requirements when violative levels of biological residues were found in edible tissues of animals slaughtered for human consumption. We attributed this primarily to the lack of authority within USDA to quarantine animals that could contain residues, and also to the need for FSQS to more closely work with the states in the absence of quarantine authority. Consequently, the benefits of this $1.1 million program were not fully realized, in that, animals containing high levels of residues could be slaughtered for human consumption."

Need for grower identification

For a followup program to be effective, USDA must be able to identify the grower who shipped a violative animal. Because large commercial growers generally ship their animals directly to a slaughterhouse, the grower can be readily identified. However, according to a USDA official, the small farmer--from whom the majority of meat and poultry comes--generally sends his animals to slaughter through a

stockyard or auction house. At the auction house the grower's animals may be mixed with animals from other growers before they are sent to a slaughterhouse. Because growers do not have to place identifying tags on the animals they market, the identity of the grower may be lost during the marketing process. Thus, FDA cannot follow up to identify the cause of the violation, and USDA cannot pretest animals from that grower to ensure that the grower does not market other violative animals.

The American Meat Institute, a trade association representing about 300 federally inspected slaughterhouses processing about 75 to 80 percent of the meat produced in the United States, favors establishment of a national animal identification program. According to its officials, the Institute has drafted a proposal for its members to require growers to place identification on each animal before it is accepted for slaughter. The officials indicated, however, that the proposal was not adopted because of opposition from growers who feel that slaughterhouses might use the data to blacklist growers with residue violations.

USDA currently lacks the authority to require growers to tag their animals before marketing them.

LIMITED USE OF REGULATORY ALTERNATIVES

Because of difficulties in using stronger regulatory alternatives, FDA generally issues information letters even when the violation occurred due to deliberate misuse of an animal drug.

Enforcement alternatives

Under the FD&C Act, FDA may initiate, through the Department of Justice, action to:

--Prosecute an individual who violates provisions of the act.

--Enjoin a grower from violating the act and FDA regulations.

--Seize raw meat and poultry that is adulterated or misbranded when introduced into interstate commerce.

The act does not require that FDA initiate one of the above actions in the case of a minor violation if the public interest will be adequately served by a suitable written notice of warning.

Although FDA is not provided authority under the FD&C Act to require a recall, FDA may request slaughterhouses to voluntarily recall products which are alleged to violate the FD&C Act.

When a violation of the FD&C Act is alleged to have occurred, FDA initiates action through issuance of a citation, regulatory letter, or information letter. A citation, or Notice of Hearing, is required by the FD&C Act when criminal proceedings are contemplated. It provides an alleged violator an opportunity, through a hearing, to explain any extenuating circumstances or corrective actions taken, which would eliminate the need for prosecution.

FDA issues regulatory letters for violations which do not create a danger to health. According to the acting director of the Bureau of Foods' Division of Regulatory Guidance, failure to take corrective action following receipt of a regulatory letter would probably result in a seizure or injunction but not in a prosecution. The regulatory letter warns the alleged violator that, unless he notifies FDA of the corrective actions taken, the agency is prepared to take additional regulatory action.

In cases of minor violations, FDA issues information letters notifying the alleged violator of the problem and requesting that corrective action be taken.

Use of information letters

FDA generally issues information letters to growers even if the violation was caused by the grower's deliberate misuse of drugs.

For example, a grower treated a cow with oxytetracycline, an antibiotic, and sold the animal the next day, ignoring the required 18-day withdrawal period. USDA found that the animal contained illegal residues. When questioned by FDA, the grower stated that he was afraid the cow would die if he followed the required 18-day withdrawal period before marketing the animal. Although the violation occurred because of intentional misuse of an animal drug, and the illegal residues could have posed a health hazard to antibiotic-sensitive individuals, FDA issued an information letter to the grower rather than a citation or regulatory letter.

In another case, a grower shipped about 600 turkeys, which were being treated for cholera with a sulfa drug, to slaughter. USDA collected a sample from one of the turkeys and found that it contained illegal sulfa residues. During FDA's followup investigation, the FDA inspector noted that the grower was evasive when he was asked for paperwork concerning the shipment of the flock. The inspection also revealed that the grower did not maintain medication records on his flocks to prevent the shipment of animals during the withdrawal period.

When the FDA inspector asked the grower whether procedures had been written to prevent such an incident from happening again, the grower originally stated that they had. However, when the inspector asked for a copy of the procedures, the grower told him that no procedures had been written, but that he had told his managers to make sure a similar incident did not occur.

FDA issued an information letter to the grower and asked him to report in writing on the medication record system that had been implemented. Although the grower responded with a brief statement that medication records are now being kept, FDA performed no followup to determine the adequacy of the corrective action.

The FD&C Act provides for the use of a written notice of warning, i.e., an information letter, only in cases involving minor violations. Residue violations occurring because of intentional misuse of an animal drug, or violations occurring in large numbers of animals because of the grower's failure to establish adequate procedures to ensure proper withdrawal, would seem to be serious violations.

However, several factors make it difficult for FDA to initiate stronger regulatory actions. Specifically:

--USDA's monitoring program is not designed to enable FDA to develop the case histories needed to support stronger regulatory actions.

--Raw meat and poultry from animals found to contain illegal residues generally cannot be identified for seizure action.

--Residue detection methods adequate to support regulatory actions do not exist for many animal drugs and pesticides.

--Misuse of an animal drug is not a violation of the FD&C Act, thus FDA must prove that misuse of a drug resulted in the marketing of adulterated raw meat and poultry.

--FDA lacks authority to levy civil penalties for violations of the FD&C Act.

Case histories not developed

Because only 1 out of every 11,000 livestock slaughtered and 1 out of every 575,000 poultry slaughtered were sampled by USDA in 1976, FDA was not able to develop the case histories needed to support strong regulatory actions. FDA officials told us that the agency generally will not prosecute a grower for the first violation. However, because animals sampled under USDA's monitoring program are randomly selected, it is unlikely that a grower will be sampled frequently enough to enable FDA to develop a case history. Moreover, there is little likelihood that adequate followup data on violative growers can be accumulated through USDA's pretest program to support a prosecution, since the program can easily be avoided.

Product not available for seizure

Because raw meat and poultry from animals found to contain illegal residues cannot normally be identified once the animal has been slaughtered, seizure cannot be accomplished. Before seizure could be made an effective enforcement alternative, a tagging system would have to be developed to enable FDA to identify contaminated products on the market. However, as pointed out earlier, such a tagging system does not appear feasible.

Detection methods not adequate

Many of the residue detection methods used in USDA's monitoring program are not adequate to support legal action against a violative grower. Data provided to us by the FDA Bureau of Veterinary Medicine's chief chemist indicate that as of March 1977 detection methods adequate to support legal action against a violative grower were available for only 3 of the 25 animal drugs included in USDA's monitoring program between 1974 and 1976. EPA officials advised us that the methods used to detect residues of the 21 pesticides included in USDA's monitoring efforts are adequate to support legal actions. However, adequate methods to support legal actions are lacking for many animal drugs and pesticides not included in the monitoring program.

The Assistant to the Associate Director for Sciences of FDA's Bureau of Foods told us that, before passage of the Food Additive Amendments to the FD&C Act in 1958, most drugs used in animals were also used in human medicine and their safety was being judged primarily upon data supporting human use and the lack of adverse effects in the farm animals under the proposed use conditions. At that time regulatory methods of analysis for residues were generally not required for drug approval.

The assistant added that, between 1958 and 1968 food additive petitions were required for animal drugs, but that these petitions were often approved on the basis of "zero residue," meaning that no residue could be detected using the best available method of analysis. She said that the early tissue residue methods were generally adaptations of methodology for the parent drug in animal feed, rarely possessing a sensitivity below 1 part per million during the 1950s.

Further, according to the assistant, methods of analysis which at one time were considered acceptable may no longer be valid for several reasons. She said that one factor was the enactment of the Delaney Clause and the approval of diethylstilbestrol use with a method of analysis capable of detecting 2 parts per billion of diethylstilbestrol. Two parts per billion then became the operational definition of "no residue" for carcinogenic animal drugs until publication in February 1977 of the "Sensitivity of Methods Document." (See p. 49.) She said that 2 parts per billion was generally accepted as a practical level of insignificance and in 1962 represented the threshold of analytical achievement.

A second factor affecting the acceptability of detection methods, according to the assistant, was the development of the "negligible tolerance" concept by the National Academy of Sciences' National Research Council in 1965 and 1966 to replace the "zero tolerance" basis for registering pesticides. Under the concept, the results of the 90-day toxicity studies were used to compute an acceptable daily intake using a safety factor of 2,000 and a negligible tolerance was established. Residues below this level would be considered insignificant. FDA adopted the negligible residue concept for animal drugs but imposed an additional requirement that a negligible residue tolerance not exceed 0.1 parts per million. Residues above that level had to be supported by more extensive toxicological testing before a tolerance was set.

She said that some drugs previously approved, based on a showing of no residue by the best methods then available, no longer met the new criteria. She also said that, while better methods have been developed for most of the older products, FDA is in the process of requiring updating methods for all drugs.

A third factor she cited was the acceptance between 1965 and 1971 of most detection methods on the basis of a desk review of procedures and data developed by the drug's sponsor. When some of these procedures were subjected to trial at FDA laboratories, it was found that methods that appeared adequate in a desk review did not provide reliable results in the agency's trials. Since 1972 the practice of validation trials has gradually been developed. In 1973 criteria for evaluating regulatory methods of analysis were revised and strengthened. In addition, the need for procedures to confirm the identity of the substances being assayed was recognized, and more adequate standards for confirmatory tests were adopted.

A fourth factor, according to the assistant, was that FDA in 1973 focused on the problems associated with evaluation of drug metabolite residues and the need for adequate consideration of all potentially significant residues. Beginning in 1974, more emphasis was placed on the total residue present, including the parent drug and and its metabolites, and tolerances were established as an upper allowable level of total residue of potential significance.

The assistant said this change has necessitated the development of more sensitive methods of analysis, but implementation of the total residue concept has evolved gradually since 1974 because of unresolved technical problems and resource constraints.

The fifth factor she cited was the development of the "Sensitivity of Methods Document" which became effective on March 21, 1977. The document provides a new basis for determining the (1) operational definition of "no residue" for known and suspected carcinogens and (2) criteria by which an analytical method will be deemed acceptable to meet the Delaney Clause. The assistant added that in 1973 FDA began to notify some sponsors of marketed drugs that are known or suspected carcinogens of the need to develop data to meet the anticipated new standards. In the case of diethylstilbestrol and nitrofurans, FDA has initiated administrative proceedings to withdraw approval to market the drugs because FDA believes the available data show that the approved uses are not shown to be safe.

The assistant told us that because of the substantial changes in food safety criteria, particularly since 1973, most of the drug uses approved before that time do not meet the newer standards now required for determining the adequacy of analytical methods. She said that the agency is currently devoting manpower to review the supporting data on each marketed drug in sequence, based on a designated priority.

Misuse of drugs not a violation

Misuse of an animal drug is not a violation of the FD&C Act, thus FDA must prove that misuse resulted in the marketing of adulterated raw meat or poultry. Residue violations frequently occur because growers fail to adhere to established withdrawal periods or fail to clean feed bins when switching from medicated to nonmedicated feed. If misuse of an animal drug were a violation of the FD&C Act, FDA could establish a monitoring program to identify and correct conditions which could cause residue violations.

Another major cause of residue violations is misuse of pesticides. Although use of a pesticide in a manner inconsistent with its labeling violates the Federal Insecticide, Fungicide, and Rodenticide Act, EPA does not have authority to inspect a grower's premises without the grower's permission unless it has reason to believe a violation has occurred.

Need for civil penalties

The marketing of raw meat and poultry containing illegal residues is punishable by criminal penalties under the FD&C Act. However, for the reasons cited earlier, criminal penalties are not assessed for most residue violations. One alternative that could help FDA enforce the provisions of the FD&C Act would be the authority to assess civil money penalties for residue violations.

The 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act authorized EPA to assess civil money penalties for violation of the act's provisions. Since then, EPA has used civil money penalties extensively in its enforcement of the act. An EPA official told us that the agency often assesses civil money penalties for pesticide violations rather than attempting to institute criminal action against first-time offenders.

In a 1972 recommendation, the Administrative Conference of the United States--established to study the efficiency, adequacy, and fairness of Federal agencies' administrative

procedures--expressed the desirability of regulatory agencies making greater use of civil money penalties. The conference stated that civil money penalties are an important and useful enforcement tool that should enable agencies to (1) obtain quicker corrective action for violations and (2) demonstrate greater consistency in their judicial rulings. Criminal penalties would remain available for use when appropriate.

The Administrative Conference said that the use of civil money penalties would not reduce or eliminate the due process protection now provided under criminal penalty situations. Civil money penalties would be assessed in accordance with the Administrative Procedure Act (5 U.S.C. 551 et seq.), which provides for review, on appeal, by the U.S. Court of Appeals (5 U.S.C. 706(E)). Also, the conference suggested that agencies be allowed to compromise or mitigate any civil money penalty settlement either before or after assessment.

CONCLUSIONS

Efforts to prevent future shipments of raw meat and poultry containing illegal residues have not been effective. FDA does not follow up on most residue violations to identify the cause of the violation. Although USDA has a pretest program to determine whether residue violations have been corrected, the program can easily be avoided by growers. FDA enforcement actions have generally been limited to the issuance of information letters because of difficulties in using stronger regulatory alternatives.

Although some improvements in the USDA and FDA enforcement efforts could be accomplished under existing legislative authority, additional authority (1) authorizing FDA to levy civil penalties for violations of the FD&C Act, (2) making misuse of an animal drug a violation of the FD&C Act, (3) authorizing USDA to quarantine animals from a violative grower until the grower demonstrates that corrective action has been taken, and (4) authorizing USDA to require growers to place identification tags on animals before they are shipped to slaughter, would significantly expand enforcement alternatives.

By making misuse of an animal drug a violation of the FD&C Act, the Congress could enable FDA to establish a separate monitoring program designed to identify and correct conditions which could cause residue violations before a grower ships animals to slaughter.

EPA's authority to monitor the use of pesticides that might leave residues in raw meat and poultry should be expanded to enable that agency to routinely inspect a grower's premises to detect misuse without obtaining the grower's permission for the inspection.

RECOMMENDATIONS TO THE SECRETARIES OF AGRICULTURE AND HEW

We recommend that the Secretary of Agriculture develop (1) a sampling program designed to enable FDA to develop case histories on violative growers and (2) a more effective pretest system to prevent growers from shipping additional violative animals.

We recommend that the Secretary of HEW direct the FDA Commissioner to:

--Make more effective use of available enforcement alternatives.

--Hasten the development of detection methods suitable for regulatory action.

--Establish guidelines to ensure effective followup on residue violations.

RECOMMENDATIONS TO THE CONGRESS

To enable USDA, FDA, and EPA to more effectively prevent the marketing of raw meat and poultry containing illegal residues, we recommend that the Congress:

--Amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide USDA quarantine authority to prevent the marketing of additional animals by a violative grower until corrective action has been taken.

--Amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize USDA to require growers to place identification tags on animals before they are sent to an auction house or slaughterhouse.

--Amend the FD&C Act to make the misuse of an animal drug a violation of the act.

--Amend the FD&C Act to provide FDA authority to levy civil penalties for violations of the act's provisions.

--Amend FIFRA to provide EPA authority to inspect a grower's premises for the purpose of identifying possible misuse of pesticides likely to result in residues in food.

AGENCY COMMENTS AND OUR EVALUATION

USDA comments

While USDA generally agreed with the need for sampling programs designed to enable FDA to develop case histories and a more effective pretest program, it did not believe significant improvements could be made at this time. USDA said that under currently available resources and analytical methods, it is not able to give FDA the volume of cases it needs on a timely basis, but that changes in the monitoring phase of the USDA residue program oriented to FDA's need would destroy the randomness of the monitoring program. To develop case histories, we believe USDA could establish a sampling program to follow up on violative growers under the surveillance phase of its overall residue monitoring program without affecting the randomness of the program's monitoring phase. (See p. 5.)

According to USDA, it has a strong incentive to cooperate with FDA because the success of USDA efforts to keep potentially harmful residues out of meat and poultry partially depends on FDA's success in keeping them out of live animals and birds. USDA said it has agreed with FDA and EPA to reexamine the current memoranda of understanding to strengthen enforcement procedures and avoid duplication of effort. In addition, according to USDA, it has requested FDA's cooperation in developing a comprehensive approach to drug residue prevention by jointly examining all facets of the total approval and control process. USDA said this is planned to assure that FDA's new drug approval and cyclical review processes include monitoring and enforcement considerations.

With regard to its pretest system, USDA said that our finding that 54.5 percent of the growers submitted pretest animals on request is probably as good as can be expected of a voluntary arrangement, since growers may move suspect animals without identification tags to other Federal- or State-inspected slaughtering plants, directly or through livestock dealers. Nevertheless, USDA said that it should

follow up on all pretest cases and it plans to improve its record by shifting resources into that activity over the next year.

However, USDA was not optimistic about improving the pretest system without the legislative amendments we recommend relating to the tagging and quarantine of animals at the farm level. USDA favors the legislative amendments we propose providing it tagging and quarantine authority. However, USDA said that to make such authorities practicable, other changes relating to access to premises and records and to intrastate commerce would also be necessary. According to USDA, the meat and poultry inspection acts provide USDA with little authority over live animals before they reach an inspected slaughterhouse, thus the pretest program presently depends on voluntary cooperation.

HEW comments

HEW generally agreed with our recommendations and said that FDA is

--studying ways to improve its enforcement procedures,

--reviewing available methodology and will recommend changes and priorities, and

--considering modifications to its guidelines for followup on residue violations.

FDA, according to HEW, has established a Residue Task Force to review the enforcement procedures used to regulate residues and to make recommendations for improvements. HEW said that the task force is expected to submit its report to the FDA Commissioner for review in early 1979.

HEW does not believe hastening efforts to develop detection methods is practical because HEW's new analytical methods cannot always be expedited simply by redoubling resolve or increasing developmental resources, particularly when the technological state of the art is the limiting factor.

FDA, according to HEW, is, and has been for the past several years, working to develop rapid screening methodology that could be used at the slaughterhouse to indicate where more specific and accurate assay methodology should be employed. HEW said that the screening tests would not be appropriate for regulatory purposes because this relatively

unsophisticated methodology lacks specificity and has not yet been developed to the point that it can be used. HEW said that the much more highly sophisticated methodology required to support regulatory action is even more difficult to develop, and in many instances cannot be adequately developed without significant breakthroughs in technology. However, according to HEW, FDA is working toward this goal. HEW said that one of the functions of the Residue Task Force is to review available methodology and recommend changes and priorities when appropriate.

With respect to guidelines to ensure effective followup on residue violations, HEW pointed out that guidelines currently exist in the form of agreements between USDA, EPA, and FDA and the "Compliance Program" and "Program Circulars" that have been issued to FDA field offices. HEW said that as part of FDA's study and reevaluation of its residue programs and in particular the development of alternative enforcement strategies in this area, it expects that the current guidelines will require some modification. According to HEW, the alternative enforcement strategies coupled with a means to positively identify animal carcasses will help to assure more effective followup.

As mentioned on page 47, detection methods adequate to support legal action against a violative grower were available for only 3 of the 25 animal drugs included in USDA's monitoring program between 1974 and 1976. The FD&C Act requires that animal drug manufacturers develop practicable detection methods adequate to support regulatory action as a condition of FDA's approval to market the drug. As stated on page 33, FDA regulations state that a method is practicable only if it is adequate for regulatory purposes. Although the technological state of the art may prevent some animal drug manufacturers from developing such methods, the FD&C Act does not grant those manufacturers an exemption from the act's requirements. FDA should (1) promptly require animal drug manufacturers to develop detection methods suitable for regulatory action and (2) withdraw approval to market those drugs for which adequate methods cannot be developed within an established time period.

With respect to our legislative recommendations, HEW said that the proposed revisions merit careful consideration by the Congress and concerned agencies. HEW said that it has not conducted a comprehensive analysis of the implications and effect of all the proposals, but that some clearly warrant further study.

HEW said that making misuse of an animal drug a violation of the act might not achieve the intended results. According to HEW, to implement an adequate program for discovering instances of misuse and documenting them sufficiently to support regulatory action on that basis alone would require a significant increase in resources. HEW said that to prove misuse would often require a witness willing to testify that the user did not follow the approved labeling of the product. HEW also said that, because it would be dealing with individual farmers in many cases, the Department of Justice and the courts would very likely expect evidence of repeated misuse before they would be willing to prosecute.

If misuse of animal drugs were a violation of the FD&C Act, FDA could establish and enforce regulations requiring proper use of drugs, including procedures for cleaning feed bins and withdrawing animals from medicated feeds. Evidence of noncompliance with regulations obtained through grower inspections would eliminate the need for witnesses and would enable FDA to develop case histories through followup inspection of violative growers. By performing the inspections as part of the followup inspections of growers found to be shipping violative animals under USDA's monitoring program, FDA should be able to limit the additional resources required.

With respect to the need for authority to levy civil penalties, HEW said that it has recently sought such authority for drugs and believes similar authority would probably be desirable in the regulation of foods.

GAO REPORTS DEALING WITH ANIMAL DRUGS, PESTICIDES, AND ENVIRONMENTAL CONTAMINANTS

ANIMAL DRUGS

1. "Need To Establish Safety and Effectiveness of Antibiotics Used in Animal Feeds" (report to the Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, HRD-77-81, June 27, 1977).

2. "Use of Cancer-Causing Drugs in Food-Producing Animals May Pose Public Health Hazard: The Case of Nitrofurans" (report to the Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, MWD-76-85, Feb. 25, 1976).

PESTICIDES

1. "Special Pesticide Registration by the Environmental Protection Agency Should Be Improved" (report to the Congress, CED-78-9, Jan. 9, 1978).

2. "Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately From Pesticide Hazards?" (report to the Congress, RED-76-42, Dec. 4, 1975).

3. "Questions on the Safety of the Pesticide Maleic Hydrazide Used on Potatoes and Other Crops Have Not Been Answered" (report to Congresswoman Julia B. Hansen, B-133192, Oct. 23, 1974).

4. "Pesticides: Actions Needed To Protect the Consumer From Defective Products" (report to the Congress, B-133192, May 23, 1974).

5. "Environmental Protection Agency Efforts To Remove Hazardous Pesticides From the Channels of Trade" (report to the Congress, B-133192, Apr. 26, 1973).

APPENDIX I

ENVIRONMENTAL CONTAMINANTS

1. "Federal Efforts to Protect Consumers From Polybrominated Biphenyl Contaminated Food Products" (report to the Chairman, Senate Committee on Commerce, Science, and Transportation; the Chairman, Subcommittee on Science, Technology, and Space, Senate Committee on Commerce, Science, and Transportation; and Senator Donald W. Riegle, Jr.; HRD-77-96, June 8, 1977).

2. "Sewage Sludge Disposal on Agricultural Land" (report to the EPA Administrator, CED-77-78, May 23, 1977).

3. "An Incident of Contamination of Livestock Feed and Certain Consumer Products" (report to the Chairman, Senate Committee on Agriculture and Forestry, B-164031(2), Dec. 1, 1972).

REGULATION OF ANIMAL DRUGS, PESTICIDES, AND TOXIC SUBSTANCES

ANIMAL DRUGS

Basic legal authority for regulating animal drugs is contained in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). FDA, a part of HEW, administers the act.

The FD&C Act requires that a person (a manufacturer or other individual or group seeking to ship a new animal drug in interstate commerce) file a new animal drug application (NADA) with FDA and obtain its approval before introducing such a product into interstate commerce. FDA must approve the drug for both safety and effectiveness. If the new animal drug is to be used in food-producing animals, FDA must also approve the safety of any drug-related residues in food.

The FD&C Act (21 U.S.C. 321(w)) defines a new animal drug as any drug intended for use in animals other than humans

> "(1) the composition of which is such that such drug is not generally recognized * * * as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof * * * or
>
> "(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions; or
>
> "(3) which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug * * *."

FDA's regulatory authority over new animal drugs was broadened by the Food Additive Amendments of 1958 (Public Law 85-929) and the Drug Amendments of 1962 (Public Law 87-781) to the FD&C Act. The 1958 amendments authorized FDA to issue regulations prescribing the conditions under which an animal drug may be safely used in food-producing animals. The 1962 amendments required drug sponsors to demonstrate the effectiveness of animal drugs.

FDA regulations (21 CFR 514.1 et seq.) require that any animal drug residue in meat, milk, or eggs be proven safe and that FDA set a limit, or tolerance, on the amount of the drug allowable in food. FDA may establish a withdrawal period before slaughtering an animal or taking any food yielded by or derived from the animal during which time the animal drug may not be administered (21 U.S.C. 360(i)).

In addition, the FD&C Act provides that no regulation be issued permitting an animal drug to be used if it is found to induce cancer when ingested by man or animal unless it can be shown that no drug residues will be found in food. This prohibition is known as the Delaney Clause (21 U.S.C. 360b(d)(1)(H)).

FDA's Bureau of Veterinary Medicine has primary responsibility for reviewing NADAs which are submitted to demonstrate the safety and effectiveness of new animal drugs. FDA's Bureau of Foods assists the Bureau of Veterinary Medicine by reviewing data submitted to demonstrate the safety of any drug-related residues in food. 1/

FDA regulations (21 CFR 514.1) specify that the NADA must include

--copies of all labeling to be used for the new animal drug;

1/The Bureau of Veterinary Medicine was established on Jan. 1, 1966. Before then, the Bureau of Medicine had responsibility for regulating both human and animal drugs.

The Bureaus of Foods and Drugs were established on Feb. 1, 1970. Before then, the functions of the Bureaus of Foods and Drugs were divided among the former Bureaus of Medicine, Science, and Compliance.

--a complete list of all articles used in producing the drug, including a list of each article's composition;

--a full description of the methods used in, and the facilities and controls used for, manufacturing, processing, and packaging the drug;

--a description of practicable methods for determining the quantity, if any, of the drug in or on food, any substance formed in or on food through its use, and any tolerance or other use restrictions required to assure that, when used as proposed, the drug will be safe; and

--full reports of investigations regarding the drug's safety and effectiveness.

After a NADA has been approved, additional uses for the drug or changes in the directions for its use must be approved through a supplemental NADA. FDA has not been willing to approve a supplemental NADA unless the drug's safety and effectiveness could be established under the conditions of use contained in the supplemental NADA.

A holder of an approved NADA is required to submit periodically a "Drug Experience Report," including information on (1) any new studies relating to the drug, (2) any adverse reactions to the drug that have been reported to the holder, and (3) the amount of the drug distributed during the preceding year (21 U.S.C. 360b(l)(l); 21 CFR 510.300).

If experience or new scientific data show an animal drug to be unsafe or ineffective under its approved conditions of use, the FDA Commissioner is required, after notifying the NADA holder of the findings and affording him an opportunity for a hearing, to issue an order withdrawing approval of the NADA (21 U.S.C. 360b(e)(1)).

A Notice of Opportunity for Hearing, which is published in the Federal Register, affords the NADA holder and other interested parties 30 days to file objections to FDA's proposed actions and to request a hearing to discuss their objections. FDA can either grant a hearing if it determines that the request raises issues of fact or deny a hearing if it finds that the request raises no valid issues (21 CFR 514.200).

Under the FD&C Act (21 U.S.C. 360b(e)(1)) and FDA regulations (21 CFR 514.115), the Secretary, HEW, can suspend approval of a NADA upon determining that use of the animal drug as intended creates an imminent hazard to human health. The holder of the NADA must receive prompt notification of this action and an opportunity for an expedited hearing on the suspension.

PESTICIDES

The basic legal authority for regulating pesticides is in the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (7 U.S.C. 135), as amended by the Federal Environmental Pesticide Control Act of 1972 (7 U.S.C. 136) and in the FD&C Act. Authority for administering FIFRA was transferred from USDA along with the responsible organizational elements to EPA on December 2, 1970, pursuant to Reorganization Plan No. 3 of 1970 which established EPA. At the same time, authority for establishing pesticide tolerances and related requirements under the FD&C Act was transferred from FDA to EPA.

FIFRA generally requires that a person (a manufacturer or other individual or group seeking to market a pesticide) file an application with EPA and obtain its approval before introducing such a product in intrastate or interstate commerce. EPA registers a pesticide when it determines that

--the pesticide's composition is such as to warrant its proposed claims (product efficacy);

--the pesticide's labeling and other material required to be submitted comply with requirements;

--the pesticide will perform its intended function without unreasonable adverse effects on the environment (product safety); and

--when used in accordance with widespread and commonly recognized practice, the pesticide will not generally cause unreasonable adverse effects on the environment. (FIFRA defines unreasonable adverse effects as any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.)

FIFRA requires that EPA classify all pesticides for general or restricted use on the basis of the degree to which they adversely affect the environment.

If a pesticide remains in or on food, the FD&C Act requires that a tolerance be established for that pesticide. Tolerances are established on the basis of data submitted by the petitioner on the nature, level, and toxicity of the pesticide's residues. The Registration Division in EPA's Office of Pesticide Programs establishes all tolerances for pesticide residues remaining in food either under section 408 (pesticide chemicals in or on raw agricultural commodities) or section 409 (pesticide food additives) of the FD&C Act. A pesticide is classified as a food additive if it is applied to processed foods or if the concentration of the pesticide increases as the raw agricultural commodity is processed.

Under FIFRA, registration is valid for 5 years and must, by law, be renewed at the end of this period, or it is canceled. EPA is required to review registered pesticides to determine if they are still safe and effective in the light of developing scientific data.

If EPA determines that a pesticide, its labeling, or other material required to be submitted does not comply with FIFRA or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the EPA Administrator may issue a notice of his intent to (1) cancel its registration or change its classification or (2) hold a hearing to determine whether its registration should be canceled or its classification changed.

Registrants and other interested parties are given 30 days to comment on the proposed action. If a registrant appeals a notice of cancellation, the pesticide may continue to be marketed pending the completion of the administrative review process.

The Administrator of EPA may immediately suspend the registration of a pesticide if he determines that the action is necessary to prevent an imminent hazard to the public. The registrant may appeal the suspension order; however, shipments of pesticides affected by the suspension are prohibited as of the date of the suspension notice.

TOXIC SUBSTANCES

Basic legal authority for regulating the introduction into the environment of chemical substances not including drugs, pesticides, food additives, and certain other substances is in the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) and in the FD&C Act.

TSCA authorizes EPA to (1) collect information on chemicals, (2) require testing of chemicals before they are marketed, (3) require testing, where necessary, of chemicals already on the market, and (4) regulate the manufacture, processing, use, distribution in commerce, and disposal of chemicals which may harm human health or the environment.

The term "chemical substance" is defined as any organic or inorganic substance of a particular molecular identity including any combination of such substances occurring as a result of a chemical reaction or in nature, and any element or uncombined radical. The term does not include mixtures of substances, or substances such as pesticides, food additives, and drugs regulated under other laws.

TSCA sets up a committee composed of representatives from various Federal biological research agencies and regulatory agencies concerned with the effects of chemicals on health and a representative from the Department of Commerce to publish and maintain a list of chemicals and their priority for testing. The EPA Administrator may publish a rule requiring the testing of certain chemicals or classes of chemicals. Such rules set out the health effects to be tested for and give some general suggestions on how the tests are to be done.

Manufacturers are required to notify EPA 90 days before marketing a new chemical or a significant new use of an existing chemical. On the basis of data supplied by the manufacturer, EPA determines whether the chemical requires testing or regulation.

If EPA determines that a chemical, either new or existing, may cause harm to human health or the environment, the EPA Administrator may initiate formal regulations to restrict the chemical's manufacture, distribution, or use. When he determines that serious harm could occur to humans or the environment during the time necessary to promulgate such regulations, the Administrator may declare the chemical an imminent hazard and seek a court injunction to restrict its manufacture until the safety questions are resolved through a formal rulemaking.

Section 406 of the FD&C Act authorizes FDA and EPA to set tolerances for poisonous or deleterious substances, including environmental contaminants, in food. 1/ In setting such tolerances, FDA and EPA are to take into account the extent to which use of such substances is required or cannot be avoided in the production of the food item, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

1/ If the poisonous or deleterious substance is present in food primarily as a result of its use as a pesticide, EPA is responsible for establishing any tolerance for the substance in food. Any other regulations under section 406 are established by FDA.

APPENDIX III

ANIMAL DRUGS AND PESTICIDES WHICH MAY RESULT IN RESIDUES IN RAW MEAT AND POULTRY

Included in USDA monitoring between 1974 and 1976	Suspected toxic effects (Agency reporting effect)
Animal drugs	
1. Arsenic	Cancer (EPA)
2. Carbadox	Cancer (FDA)
3. Chlortetracycline	(a)
4. Clopidol	(a)
5. Decoquinate	(a)
6. Dichlorvos	Blood effects (NIOSH)
7. Diethylstilbestrol b/	Cancer (FDA, NIOSH) Glandular (NIOSH)
8. Erythromycin	(a)
9. Ipronidazole	Cancer (FDA)
10. Levamisole hydrochloride	(a)
11. Monensin	(a)
12. Neomycin	(a)
13. Oxytetracycline	Skin (NIOSH)
14. Penicillin	(a)
15. Robenidine hydrochloride	(a)
16. Streptomycin	(a)
17. Sulfachlorpyridazine	(a)
18. Sulfadimethoxine	(a)
19. Sulfaethoxypyridazine	(a)
20. Sulfamethazine	Cancer (NIOSH)
21. Sulfanitran	(a)
22. Sulfathiazole	Cancer (NIOSH)
23. Tetracycline	(a)
24. Thiabendazole	(a)
25. Zeranol	(a)
Pesticides	
	(a)
26. Aldrin c/	Cancer (EPA, NIOSH)
27. Benzene Hexachloride	Cancer (EPA) Fetotoxicity (EPA) Reproductive effects (EPA)
28. Chlordane c/	Cancer (EPA)
29. Coumaphos	(a)
30. DDT c/	Cancer (EPA, NIOSH) Mutations (NIOSH) Central nervous system (NIOSH)

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Included in USDA monitoring between 1974 and 1976	Suspected toxic effects (Agency reporting effect)
Pesticides	
31. Diazinon	(a)
32. Dieldrin c/	Cancer (EPA, NIOSH)
	(a)
33. Dioxathion	(a)
34. Endrin	Cancer (EPA)
	Birth defects (EPA)
35. Ethion	Central nervous system (NIOSH)
	Blood (NIOSH)
36. Gardona	(a)
37. Heptachlor c/	Cancer (EPA)
38. Lindane	Cancer (NIOSH, EPA)
	Fetotoxicity (EPA)
	Reproductive effects (EPA)
39. Malathion	(a)
40. Methoxychlor	(a)
41. Methyl parathion	(a)
42. Mirex	Cancer (EPA, NIOSH)
43. Parathion	(a)
44. Ronnel	Cancer (EPA)
	Birth defects (EPA)
45. Toxaphene	Cancer (EPA)
46. Trichlorofon	Cancer (EPA)
	Birth defects (EPA)
	Mutations (EPA)
	Bone marrow effects (EPA)
Not included in USDA monitoring	
Animal drugs	
1. 2-Acetylamino-5-nitrothiazole	(a)
2. Alkomide	(a)
3. Ampicillin	(a)
4. Amprolium	(a)
5. Bacitracin	(a)
6. Buquinolate	(a)
7. Carbomycin	(a)
8. Cephapirin	White blood cells (NIOSH)
9. Chlorhexadine	(a)
10. Chlormadinone acetate	Cancer (FDA)
	Birth defects (NIOSH)
11. Cloxacillin	(a)
12. Dihydrostreptomycin	(a)

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Not included in USDA monitoring between 1974 and 1976	Suspected toxic effects (Agency reporting effect)
Animal drugs	
13. Dimetridazole	Cancer (FDA)
14. 3,5-Dinitrobenzamide	(a)
15. Estradiol benzoate	Cancer (FDA, NIOSH)
16. Estradiol monopalmitate	Cancer (FDA)
17. Ethopabate	(a)
18. Furazolidone d/	Cancer (FDA) Respiratory (NIOSH)
19. Gentamicin sulfate	(a)
20. Gentian violet e/	Cancer (FDA)
21. Haloxon	(a)
22. Hygromycin B	(a)
23. Lasalocid sodium	(a)
24. Lincomycin	(a)
25. Melengestrol acetate	Cancer (FDA)
26. Metoserpate hydrochloride	(a)
27. Nequinate	(a)
28. Novobiocin	(a)
29. Nystatin	(a)
30. Oleandomycin	(a)
31. Ormetoprim	(a)
32. Progesterone	Cancer (FDA, NIOSH)
33. Pyrantel tartrate	(a)
34. Reserpine	Birth defects (NIOSH) Psychotropic (NIOSH)
35. Sodium sulfachloropyrazine monohydrate	(a)
36. Spectinomycin	(a)
37. Testosterone	Cancer (FDA)
38. Testosterone propionate	(a)
39. Tylosin	(a)
40. Virginiamycin	(a)
41. Zoalene	(a)
Pesticides	
42. Acephate	(a)
43. Aldicarb	(a)
44. Atrazine	(a)
45. Azinophosmethyl	(a)
46. Benomyl	Mutagenic (EPA) Birth defects (EPA) Reproductive effects (EPA)
47. sec-Butylamine	(a)

APPENDIX III

Not included in USDA monitoring between 1974 and 1976	Suspected toxic effects (Agency reporting effect)
Pesticides	
48. Captan	Cancer (EPA) Birth defects (NIOSH, EPA) Mutations (EPA)
49. Carbaryl	Cancer (NIOSH) Birth defects (NIOSH, EPA)
50. Carbofuran	(a)
51. Carbophenothion	(a)
52. Chlordimeform	(a)
53. Chlorobenzilate	Cancer (EPA, NIOSH)
54. Chlorpyrifos	(a)
55. Crufomate	(a)
56. 2,4-D	Birth defects (NIOSH)
57. Dalapon	(a)
58. Daminozide	Cancer (EPA) Neurotoxicity (EPA)
59. Def	Birth defects (NIOSH)
60. Demeton	(a)
61. Dialifor	Cancer (EPA) Mutations (EPA) Fetotoxicity (EPA) Reproductive effects (EPA)
62. Dimethoate	Birth defects (NIOSH)
63. Diphenylamine	(a)
64. Disyston	(a)
65. Diuron	(a)
66. Dodine	(a)
67. Endosulfan	Birth defects (NIOSH)
68. Fenthion	(a)
69. Ficam	(a)
70. Guthion	(a)
71. Hexakis	(a)
72. Linuron	Cancer (EPA, NIOSH) Birth defects (EPA, NIOSH)
73. Maneb	Cancer (EPA) Mutations (EPA)
74. Methanearsonic acid	(a)
75. Methoprene	(a)
76. Naled	Birth defects (EPA, NIOSH) Reduced fertility (EPA) Respiratory effects (EPA)
77. Paraquat	Fetotoxicity (EPA) Birth defects (EPA)
78. Pentachlorophenol	Cancer (EPA) Reproductive effects (EPA)
79. Perthane	

APPENDIX III

Not included in USDA monitoring between 1974 and 1976	Suspected toxic effects (Agency reporting effect)
Pesticides	
80. Phorate	(a)
81. Phosolone	(a)
82. Piperonyl butoxide	Cancer (EPA)
83. Plictran	(a)
84. Polyram	Cancer (EPA) Birth defects (EPA)
85. Propachlor	(a)
86. Propargite	(a)
87. Pyrethrins	(a)
88. Sencor	(a)
89. Silvex f/	Cancer (EPA) Birth defects (EPA)
90. Simazine	(a)
91. Stam	(a)
92. 2,4,5-T f/	Cancer (EPA) Birth defects (EPA, NIOSH)
93. Terbacil	(a)
94. TDE	Cancer (EPA, NIOSH)
95. Tetradifon	(a)
96. Zinc ion and maneb coordination product	(a) Cancer (EPA) Birth defects (EPA)
97. Zineb	Cancer (EPA, NIOSH) Birth defects (NIOSH, EPA)

a/None identified in 1976 NIOSH Registry of Toxic Effects of Chemical Substances.

b/Hearing on proposed withdrawal completed. Awaiting ruling by administrative law judge as of Aug. 18, 1978.

c/Registration canceled for most uses but residues persist in the environment.

d/Hearing on proposed withdrawal pending.

e/Not an approved drug, but reported by USDA as being used in poultry feed.

f/Cancellation hearing delayed.

APPENDIX IV

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND QUALITY SERVICE
WASHINGTON, D.C. 20250

DEC 18 1978

Mr. Henry Eschwege
Director, Community and
Executive Development Division
General Accounting Office
Washington, DC 20548

Dear Mr. Eschwege:

We appreciate the opportunity to comment on your proposed report entitled "Problems in Preventing the Marketing of Raw Meat and Poultry Containing Illegal Residues." We have conducted a national program for chlorinated hydrocarbon and arsenic residues since 1967. Our current residue monitoring program format was adopted in 1972 to assure a statistical basis for the reported results.

Since that time the program has expanded its activities to include monitoring for the presence of many other compounds which can be detected by current technology. Clearly, the program is still under development and can be improved in a number of ways.

We are aware of the need for a national commitment to the allocation of resources for development of better and more rapid test technology, a national animal identification system, authority to control sources of animals contaminated with violative residues, and the need for governmental agencies and industry to develop a comprehensive strategy to prevent residue adulteration of our food supply. We appreciate your interest in bringing to the attention of Congress these problems, their causes, and the means by which this Department and other agencies with related responsibilities may become more effective in keeping residues of pesticides, antibiotics, and environmental contaminants out of meat and poultry products.

We strongly support the view that the Department of Agriculture (USDA) or the other concerned agencies must conduct or foster research to speed advancement of residue analysis technology. We also favor the proposal to amend the meat and poultry inspection acts to provide USDA with authority to quarantine animals and to require growers to place identification tags on animals before marketing. However, to make such authorities practicable, other changes relating to access to premises and records and to intrastate commerce will also be necessary.

We believe you should reconsider your estimate of the extent of public exposure to illegal residues from animal and poultry sources. The USDA data shows that 2 percent (by count) of its 1974-1976 monitoring samples

of meat, poultry products, and byproducts contained illegal levels of the residue or class of residues tested for. This figure was not represented nor intended as an estimate of total public exposure. The approach taken by your reporter was to first sum the violation rates for individual compounds within a species as a means of determining the violative residue rate for that species. This represents a worst case basis as it does not take into account the multiple residue violations that do occur, the extent of which is unknown. Therefore, the true violation rate lies at a level below the sum of the violation rates for a particular species.

Next, your reporter used the sum of the violation rates and projected that the estimate of public exposure to violative residues in the meat and poultry supply amounted to 14 percent by carcass weight. Projecting results of tests on specific organ tissues to the entire carcass may be misleading. Many of the residues tested for concentrate in kidneys or livers. Therefore, many violative samples represented only the weight of a target organ, not the weight of an entire carcass which was otherwise free of the residue. For example, we have never found diethylstilbestrol in carcass meat.

Several specific comments concerning technical data in your report are attached. Other comments on proposed recommendations for USDA are as follows:

1. Expand residue monitoring to include, at least periodically, all animal drugs, pesticides, and environmental contaminants for which detection methods exist.

We agree that our residue program should be diversified and substantially expanded through a much larger volume of samples. We intend to devote more resources in the coming year. We will continue to concentrate attention on those harmful residues that are most likely to enter the food supply. It is also important to remember that some compounds lack regulatory analytical methods that are feasible for routine monitoring. We are attempting to develop better methods, and this needs greater attention by other agencies as well. We now give priority attention to those residues for which analytical methods are sufficiently reliable to support legal actions.

2. Develop the capability to conduct residue analysis at the slaughterhouses.

As your proposed report indicates, on-site analysis is ordinarily advantageous only if it can be completed within 24 hours. We and most other governmental and private organizations involved in analysis of highly perishable foods are always keenly interested in speedier yet reliable methods of analysis. In early 1979 we will implement a swab test by

which on-site inspectors can detect antibiotic drug residues in dairy cattle kidney tissue. Also, a swab test which may enable quick on-the-farm screening for antibiotic residues is under development and USDA study. We are also testing a laser beam system that analyzes meat extracts for certain residues and identifies them. Although this method probably will not be suitable for use in slaughtering plants, it will allow us to do as many samples in 3 days as are now done manually in a month. These results are encouraging, but we recognize that much more research and development work in residue detection and analysis needs to be done.

3. Encourage private monitoring.

Our activities in this area are in the early stages. Your proposed report mentions two of the large poultry operations which conduct a cooperative residue program with USDA. This program is now sufficiently tested to allow us to encourage expansion to other operations and species. This program has resulted in detection of problems in the early stages of development and allowed rapid corrective action. We are aware that a number of other large operators conduct residue analysis but do not wish to participate in the USDA cooperative program.

4. Develop a sampling program designed to enable the Food and Drug Administration (FDA) to develop case histories on violative growers.

Since our degree of success in keeping potentially harmful residues out of meat and poultry products partially depends on FDA's success in keeping them out of live animals and birds, we have a strong incentive to cooperate. However, under currently available resources and analytical methods, we are not able to give FDA the volume of cases it needs on a timely basis. Changes in the monitoring phase of our residue program oriented to FDA's need would destroy the randomness of the monitoring program. We have agreed with FDA and EPA to reexamine the current memoranda of understanding to strengthen enforcement procedures and avoid duplication of effort. In addition, we requested that FDA work with us to develop a comprehensive approach to drug residue prevention by jointly examining all facets of the total approval and control process. This is planned to assure that FDA's new drug approval and cyclic review processes include monitoring and enforcement considerations.

5. Develop a more effective pretest system to prevent growers from shipping additional violative animals.

The pretest system presently depends on voluntary cooperation. The meat and poultry inspection acts provide USDA with little authority over live animals before they reach an inspected slaughterhouse. Your finding that

54.5 percent of the growers submitted pretest animals on request is probably as good as can be expected of a voluntary arrangement, since growers may move suspect animals without identification tags to other Federal or State inspected slaughtering plants, directly or through livestock dealers. We are not optimistic about improving the pretest system without the recommended legislative amendments surrounding the tagging and quarantine of animals at the farm level. We should follow up on all pretest cases and plan to improve our record by shifting resources into this activity over the next year.

I hope our comments will be helpful in preparing the final report and look forward to its publication.

Sincerely,

Donald L. Houston
Acting Administrator

Enclosure

APPENDIX IV

Additional Comments

Bottom of page six of the proposed report--"In 1977 about 800 animals were sampled under the surveillance phase." We actually had about 800 individual cases. The numbers of animals tested under each case generally ranged upward from five. The total number would probably be around 4,000 to 6,000 individual animals.

Table one, page 12--Combining data for all years in calculating the percent of violations and combining all animals sampled tends to be misleading. Violation rates tend to be correlated almost specifically with the specific animal species or subspecies, not all animals.

Regarding the use of USDA testing data in terms of total public exposure to violative levels of residues, page iii and elsewhere, we do not assume that if an animal is not tested, it does not have an illegal residue. In fact, we consider our program to give a reliable estimate of the incidence of illegal residues in our total population of animals, but only on an individual specific compound-animal species pairing.

Page 46, just above "CONCLUSIONS:" --"The company samples six chickens--." We believe this should read turkeys, not chickens.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

JAN 12 1979

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Problems in Preventing the Marketing of Raw Meat and Poultry Containing Illegal Residues." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Thomas D. Morris
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE ON THE COMPTROLLER GENERAL'S DRAFT REPORT ENTITLED "PROBLEMS IN PREVENTING THE MARKETING OF RAW MEAT AND POULTRY CONTAINING ILLEGAL RESIDUES"

General Comments

Illegal residues in raw meat and poultry pose a difficult and complex regulatory problem to which the Department has devoted considerable time and effort. The information presented in this report and in related hearings by the House Interstate and Foreign Commerce Committee, Subcommittee on Oversight and Investigations has been carefully considered in the formulation of current efforts to alleviate the problem. Recent initiatives have included:

- A strengthened toxicological program within HEW to enhance assessment of suspected carcinogens.
- A cyclical review of the safety data supporting previously approved new animal drug applications.
- Establishment of a Residue Task Force within FDA to analyze and improve residue related regulatory efforts.
- The initiation of a Food Safety Task Force within FDA to study possible changes and improvements in food regulatory programs.
- Efforts by the Interagency Regulatory Liaison Group to improve regulatory cooperation and coordination between FDA and EPA.

While these efforts reflect our concern and commitment, we recognize that our unilateral efforts cannot achieve an effective solution to this inherently complex problem. We believe the solution depends, in large part, on all concerned parties--regulators, legislators, producers, processors, and consumers--arriving at some common appreciation of the various facets of the problem, so that all may contribute to a collective solution. These facets include an understanding of statutory authorities, regulatory procedures, organizational relationships, production techniques, marketing systems, and scientific capabilities. Independent from our reaction to specific conclusions and recommendations in this report, we view the body of the report as a valuable opportunity to promote this essential common understanding of the problem; but we are concerned that, in its present form, the report advances some misconceptions and simplifications of the problem.

APPENDIX V

We believe that the potential of this report, as a step toward the solution to this problem, could be significantly enhanced by a more accurate presentation of certain legal and scientific considerations. The following items summarize the most serious deficiencies:

1. The commingled presentation of animal drug, pesticide, and environmental contaminant residues obscures important statutory distinctions between these categories of chemicals, and generally overstates the commonality in the regulatory approaches used to control such residues.

   The report analyzes the regulation of three dissimilar classes of chemicals from the perspective of a single common attribute, i.e., the potential for residues in raw meat and poultry. While this approach offers the prospect of an integrated solution not apparent by separate discussion of animal drug, pesticide or environmental contaminant residues; it is an ambitious undertaking in that it must maintain sensitivity of the readers to the statutory and regulatory distinctions between these classes. The report seeks to engender this sensitivity by including a discussion of the responsibilities of FDA, EPA, and USDA in the initial portions of the text and appending a more complete exposition of the relevant statutes, but the body of the report contains only infrequent mention of statutory distinctions between these chemical classes. This approach tends to obscure the distinctions at the very point in the analysis where they are most necessary and it allows readers to infer or sustain misunderstandings about the regulation of different chemical residues in raw meat and poultry. Some of the regulatory distinctions that need greater emphasis throughout the report are:

   - Tolerances - statutory guidance for establishing tolerances varies significantly among animal drugs, pesticides, and environmental contaminants.

   - Preclearance Requirements - preclearance procedures, and their relevance to raw meat and poultry vary widely for animal drugs, pesticides, and environmental contaminants.

   - Use Control - animal drugs are intentionally added to the diet of animals, but pesticides and environmental chemicals unintentionally contaminate animal diets and consequently are subject to different degrees of use control.

Responsibility for Detection Methods - the burden of responsibility of developing assay methodology for animal drugs in raw meat and poultry rests with the manufacturer, but there is no comparable manufacturer responsibility for developing assay methodology for pesticides or environmental contaminants in raw meat or poultry.

2. The report fails to distinguish adequately between legal residues and illegal (or violative) residues.

By its title and introductory chapter, the report declares a focus on illegal residues, but the body of the report repeatedly muddles the distinction between legal and illegal residues by characterizing all residues, even those that are legal, as unsafe. For example, the report explains in Chapter 2 how legal tolerances are established, but it does so in a section titled "Extensive Consumer Exposure to Suspected Carcinogens." This shifting of focus between illegal residues and residues which GAO considers unsafe has the potential for both confusing and alarming readers without contributing to an understanding of what action regulatory agencies can, or should take, against violative residues.

3. The report omits consideration of the procedures, burden of responsibility and weight of evidence necessary to confirm the carcinogenicity of a suspected chemical; and by doing so, the report lends credence to the notion that any suspicion, regardless of its veracity, origin or degree, should cause FDA to regulate the chemical as a known carcinogen.

When there are questions about potential carcinogenicity of an animal drug prior to its approval by FDA, the burden of proving safety clearly rests with the petitioner and the approval process obligates the petitioner to resolve such questions. But after an approved product is marketed, it is not uncommon that continuing advances in the scientific bases and techniques for determining carcinogenicity of chemicals will generate questions about the validity and adequacy of prior tests. In such cases, FDA shoulders the responsibility for demonstrating that there is a sufficient question of safety to warrant requiring the producers to reconfirm the safety of a previously approved chemical and/or removing the product from marketing. FDA recognizes this responsibility and is devoting systematic effort to

the reappraisal of previously approved animal drugs. But at any given moment, the continuing advancement of scientific knowledge means that there will be some previously approved products about which there are gathering doubts. The report's line of reasoning that immediate reappraisal by the FDA of several specific chemicals can alleviate the dilemma of suspected carcinogens is largely superficial since it omits consideration of the substantial implications of a continuing advancement in scientific knowledge for all prior decisions.

4. The report fosters excessive optimism regarding advancements in analytical methodology and the feasibility of operational use of such advances.

Virtually every knowledgeable group that has examined the problem of illegal residues agrees that the ultimate solution to this problem awaits the development of quick, simple, and accurate assay methods for use at the point of slaughter.

The GAO report joins this consensus, but it does so in a way that suggests a lack of haste by regulators is the key obstacle to development of these assay methods. In an extremely brief discussion, the report states that gas chromatography methods can detect residues, that some companies have monitoring programs, and that both USDA and FDA are working on improved methods. By capping this series of facts with a recommendation to regulatory agencies to hasten residue detection methods, the report effectively obscures the significant advances in instrumentation and methodology which the scientific community must supply before regulatory agencies can translate research methods into effective, reliable and simple test methods for widespread operational use. In short, the state-of-the-art in methodology is not sufficiently advanced to achieve this.

FDA is investing resources in developing assay methods as well as requiring the regulated industry to submit methods that are accurate and that can be used to sustain regulatory action. While we are fully committed to continuing this effort, we do not believe that the capability proposed by GAO can be developed with the ease or promptness suggested by the report.

5. The report decries the absence of monitoring for many drugs and pesticides, but it avoids consideration of the benefit or practicality of the implied alternative.

The report bases its analysis of the present monitoring program on statistical observations about the number of chemicals monitored in existing programs, e.g., 46 out of 143 drugs and pesticides. This numerical analysis is simplistic and misleading in that it fosters the erroneous notion that the number of chemicals monitored is a valid indicator of the effectiveness of the monitoring program.

Without consideration of factors such as the volume, use, relative toxicity of substances and the comparative cost of tests, this approach has limited value in measuring the effectiveness of current efforts. When these factors are considered, we believe that, at any given level of resources, concentration of effort on selected chemicals maximizes public protection.

We hope the final report can reflect the preceding observations because we believe their inclusion will significantly enhance the prospects for a collective understanding of the problem by all concerned parties. The degree of this understanding will dictate the extent of cooperation and initiative supplied by other parties, and that in turn will decisively influence the ultimate impact of the Department's actions described below.

GAO Recommendation

We recommend that the Secretary, HEW, direct the Commissioner, FDA to reevaluate available data on the possible carcinogenicity of arsenical drugs, and take appropriate steps to withdraw approval of the drugs if they are found to cause cancer.

Department Comment

We concur. We are aware of EPA's finding that arsenic is a carcinogen based on occupational exposure and on epidemiological studies in regions where high arsenic levels are observed in the water supply. These observations are certainly inconclusive and controversial, i.e., competing factors were often present. To our knowledge, they have never been confirmed in animal feeding studies. FDA is closely monitoring the developing information on all aspects of arsenic toxicity including carcinogenicity, teratogenicity and mutagenicity, as well as the growing body of evidence that arsenic may be an essential nutrient, with the objective of modifying its current regulatory position should the facts warrant. The arsenicals have been assigned a high priority in the cyclic review of animal drugs to resolve these questions.

GAO Recommendation

We recommend that the Secretary, HEW, direct the Commissioner, FDA to require animal drug manufacturers to develop residue detection methods which can be completed at the slaughterhouse within 24 hours after slaughter.

Department Comment

We do not agree that this requirement should be imposed at this time. If the Agency were to impose this requirement now, the present state of analytical technology would be unable to produce analytical methods of sufficient precision and reliability suited to use under slaughterhouse conditions. While research laboratories have methods that can detect and confirm specific drug residues at the extremely low levels permitted to remain in meat and poultry, and some slaughterhouses are experimenting with such methods, they are not generally practical for widespread in-plant use because of the sophisticated equipment needed and the special expertise required. Some screening methods are under development that could be performed in 24 hours, but they will not be adequate to support regulatory actions, and they would require substantial investment of new laboratory capability in or very near all federally inspected slaughterhouses.

GAO Recommendation

We recommend that the Secretary, HEW, direct the FDA Commissioner to:

-- Make more effective use of available enforcement alternatives.

Department Comment

We concur. FDA has established a Residue Task Force to review the enforcement procedures used to regulate residues and to make recommendations for improvements. This Task Force is expected to submit its report for review by the Commissioner of Food and Drugs in early 1979.

GAO Recommendation

-- Hasten the development of detection methods suitable for regulatory action.

Department Comment

We do not agree that hastening current development efforts is practical. As mentioned in the general comments, new analytical methods can not always be expedited simply by redoubling resolve or increasing developmental resources, particularly when the technological state-of-the-art is the limiting factor. At the present time, and for the past several years, FDA has been working to develop rapid screening methodology that could be used at the slaughterhouse to indicate where more specific and accurate assay methodology should be employed. The screening tests would not be appropriate for regulatory purposes because they lack specificity. This relatively unsophisticated methodology has not yet been developed to the point that it can be used. The much more highly sophisticated methodology required to support regulatory action is even more difficult to develop and in many instances cannot be adequately developed without significant breakthroughs in technology. Nevertheless, FDA is working toward this goal. One of the functions of the Residue Task Force is to review available methodology and recommend changes and priorities when appropriate.

GAO Recommendation

-- Establish guidelines to ensure effective followup on residue violations.

Department Comment

Guidelines currently exist in the form of agreements (MOU's) between USDA, EPA, and FDA and the Compliance Program and Program Circulars that have been issued to the FDA field offices. However, as part of FDA's study and reevaluation of its residue programs and in particular the development of alternative enforcement strategies in this area, we expect that the current guidelines will require some modification. The alternative enforcement strategies, coupled with a means to positively identify animal carcasses, will help to assure more effective followup.

Department Comments on the GAO Recommendation to the Congress

The proposed revisions to the statutes merit careful consideration by the Congress and concerned agencies. The Department has not conducted, nor does the report provide, a comprehensive analysis of the implications and effect of all the proposals. Some clearly warrant further study.

For example, making misuse of an animal drug a violation of the Act might not achieve the intended result. To implement an adequate program for discovering instances of misuse and documenting them sufficiently to support regulatory action on that basis alone would require a significant increase in resources. To prove misuse, would often require a witness willing to testify that the user did not follow the approved labeling of the product. Because we would be dealing with individual farmers in many instances, past experience suggests that the Department of Justice and the courts would very likely expect evidence of repeated misuse before they would be willing to prosecute. With respect to the need for the authority to levy civil penalties, the Department has recently sought this authority for drugs in the proposed Drug Regulation Reform legislation. Similar authority would probably be desirable in the regulation of foods.

The Department will be assessing these proposals, as well as others for improving FDA's authorities for the regulation of foods in the previously mentioned Food Safety Task Force.

APPENDIX VI

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 26 1979

OFFICE OF
PLANNING AND MANAGEMENT

Honorable Henry Eschwege
Director, Community & Economic
Development Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Eschwege:

The Environmental Protection Agency (EPA) has reviewed the General Accounting Office (GAO) draft of a proposed report entitled "Problems In Preventing The Marketing Of Raw Meat And Poultry Containing Illegal Residues." The report makes two recommendations to the Administrator of EPA which I will comment on briefly.

The first recommendation is to "review available data on the safety of cadmium and hexachlorobenzene, and (to) take appropriate steps to restrict their manufacture, use, and distribution if they are found to cause cancer." The Agency is reviewing both the substances under the authority of the Toxic Substances Control Act to determine whether regulatory action is appropriate. In addition, cadmium and hexachlorbenzene are part of the Office of Pesticide Programs' intensive risk/benefit review process for pesticides known as rebuttable presumption against registration (RPAR). A fact sheet on the RPAR process is enclosed.

A RPAR notice was issued for cadmium on October 26, 1977, identifying risks associated with the pesticidal use of this compound (oncogenicity, mutagenicity, teratogenicity, fetotoxicity, and metabolic effects) and soliciting public input and comment. A copy of the RPAR notice is enclosed. The Agency is now in the process of analyzing the information received in order to reach a decision on the risks and the benefits of cadmium pesticides. Depending on the results of this analysis, the Agency may either continue, restrict, or cancel the registrations of cadmium pesticides. I might note that under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) the Agency is authorized to take administrative action against a pesticide upon a finding

not of risk alone, but of unreasonable adverse effects as determined by balancing economic, social, and environmental risks and benefits.

Hexachlorobenzene is in a pre-RPAR stage during which the Agency reviews and evaluates data available in-house to decide whether the potential risks associated with its use are sufficiently great to warrant a full RPAR review such as the cadmium review now underway.

The second recommendation is for the Administrator "to require pesticide manufacturers to develop residue detection methods which can be completed at the slaughterhouse within 24-hours after slaughter." Methods of residue detection are available for all pesticides for which tolerances in meat or poultry have been established. Many of the pesticide residue methods could be completed within 24-hours, although a 24-hour methodology has never been a requirement for establishing a pesticide tolerance. Current EPA/United States Department of Agriculture (USDA) interagency agreement calls for EPA to submit advance notice of the establishment of a tolerance, including analytical methods, to USDA. Also, all analytical methods for residues in meat or poultry are available in the Pesticide Analytical Manual published by the Food and Drug Administration (FDA).

The real problem, however, is that the residue methods required for tolerances apply only to individual pesticides, but USDA and FDA have found it necessary to use multi-residue methods in order to perform their routine enforcement responsibilities. It would be more practical to develop rapid, multi-residue methods than to impose a 24-hour completion criterion on methods for individual pesticides. EPA has no clear legal authority under the Federal Food, Drug, and Cosmetic Act to require tolerance petitioners to develop 24-hour, multi-residue methods suitable for the particular pesticides for which they wish to establish a tolerance. EPA also does not have the resources to develop suitable methods on its own. However, because of our tolerance setting responsibilities we do have considerable expertise in the development of analytical methods and would be willing to work with USDA and FDA to develop rapid, multi-residue methods where feasible if such analytical methods would make a substantial contribution to public health protection.

The report proceeds on the assumption that only residues less than or equal to a tolerance are safe, and any over-tolerance residues are not safe. A tolerance is not, however, a safe or no risk residue level; rather it is a residue level which has been determined to pose an acceptable risk. The tolerance is set at a level no higher than that at which residues are expected to occur if good agricultural practices have been followed in applying the pesticide in order to minimize residues in food and feed, and thus in animals and man. This level may in fact be less than the limits of reasonable risk which is a theoretical calculation based on toxicology data. (I should note that the Agency would not establish a tolerance at all, if available toxicological data indicated that anticipated residues presented too great a hazard.) There is, therefore, a margin on the side of safety built into the tolerance, and over-tolerance residues do not necessarily constitute a serious health hazard. I am enclosing a paper describing the current tolerance setting system for more information.

It is our assumption that residue testing at the slaughter-house on a 24-hour turnaround would be quite costly. The high expense would have to be borne by someone - either the meat packing industry (through higher consumer prices) or the government. The real question - which the report does not address - is whether what may be a substantial additional expense would be justified by whatever additional protection of the public health that might result.

Answering this question would require a careful survey to determine the rate of tolerance violations, the amount by which the violative residues exceed the tolerances, the health problems that may result from the consumption of meat and poultry with these levels of residues, and the technical feasibility of developing such residue testing techniques for enforcement purposes. The benefits of the suggested on-site residue analysis/carcass detention approach then could be compared meaningfully with the additional costs of the approach.

We appreciate the opportunity to comment on the report prior to its issuance to Congress.

Sincerely yours,

William Drayton

for William Drayton, Jr.
Assistant Administrator for
Planning and Management

Enclosures
(10870)

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