SECTION 5. PLANNING THE 2002 FSIS IMPORT MONITORING PLAN: VETERINARY DRUGS

PHASE I - GENERATING AND RANKING LIST OF CANDIDATE COMPOUNDS

LIST OF CANDIDATE COMPOUNDS

The candidate veterinary drugs of concern selected by members of the Surveillance Advisory Team (SAT) for the import Monitoring plan are the same as those listed in Section 4. Furthermore, in ranking drugs for inclusion in the Import Monitoring Plan, FSIS employed the ranking scores generated for the Domestic Monitoring Plan (see Section 4), because FSIS does not have sufficient historical data on drugs in imported products to predict their violation rates. However, if FSIS has reason to believe that a compound is being misused in a foreign country then it would add that compound/country pair to the Import Monitoring Plan.

PHASE II - SELECTING DRUGS FOR INCLUSION IN THE 2002 NRP

As stated in Section 4, from the list of ranked veterinary drugs, FSIS selected compounds and compound classes, based purely on their relative public health concern, which should be included in the 2002 NRP. FSIS and FDA decided that those compounds and compound classes ranked 34th or higher represented a potential public health concern sufficient to justify their inclusion in the 2002 NRP.

Once the high-priority compounds and compound classes had been identified, FSIS applied other practical considerations to determine the compounds FSIS should sample. The principal consideration was the availability of laboratory resources, especially the availability of appropriate analytical methods within the FSIS laboratories. Where the laboratory resources were limited, FSIS decided that more resources should be used to test domestic products since imported products have been inspected previously by the importing country. Based on these considerations, the following compounds will be included in the 2002 FSIS Import Monitoring Plan.

--Antibiotics:

- Those antibiotics quantitated by the FSIS Bioassay multiresidue method (MRM) and associated follow-up methodologies [1] [tetracycline, oxytetracycline, chlortetracycline, beta-lactams (penicillins and cephalosporins; not differentiated within this category), gentamicin, streptomycin/spectinomycin

[1] FSIS quantitates most antibiotics using a 7-plate Bioassay that measures microbial inhibition. The pattern of inhibition (i.e., the combination of plates showing inhibition) is used to identify the antibiotic. However, there are some antibiotics that share the same pattern of inhibition. In these cases, it is necessary to undertake follow-up testing (HPLC or mass spectrometry) to identify the compound. The compounds that share patterns of inhibition, and which are thus individually identified through follow-up testing, are:
tetracycline/oxytetracycline/chlortetracycline - compounds individually identified by follow-up with HPLC method for tetracyclines
tilmicosin/tylosin - differentiated by mass spectrometry

(not differentiated), erythromycin, tilmicosin, tylosin, neomycin, flavomycin, bacitracin, hygromycin, novobiocin, lincomycin*, pirlimycin*, clindamycin*, spiramycin*, oleandomycin*] *identification by mass spectrometry; not quantitated

- Choramphenicol
- Fluoroquinolones

--Other Veterinary Drugs:

- Arsenicals (detected as elemental arsenic)
- Avermectins in FSIS MRM (doramectin, ivermectin and moxidectin)
- Carbadox
- MGA
- Phenylbutazone (detected in the CHC3 method)
- Ractopamine
- Sulfonamides (sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachloropyridazine, sulfadoxine, sulfamethoxypyridazine, sulfaquinoxaline, sulfadimethoxine, sulfisoxazole, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfaethoxypyridazine, sulfaphenazole, and sulfatroxazole)

The 2002, FSIS Import Monitoring Plan will employ 10 methodologies and analyze for over 50 veterinary drugs. Five of these are single-compound methodologies, and five are MRMs (phenylbutazone is detected by the FSIS MRM for chlorinated hydrocarbon and chlorinated organophosphate compounds).

PHASE III - IDENTIFYING THE COMPOUND/PRODUCT CLASS PAIRS

SAT participants from the FDA identified, for each of the drugs and drug classes to be included in the 2002 NRP, product classes in which they had a concern. The results are presented in Table 5.1, *Product Classes Considered for Each Drug/Drug Class.* Compound/product class pairs included in the 2002 NRP are designated by a "✯." Those compound/product class pairs that are of potential public health concern, but that are not included in the 2002 NRP because of laboratory resource constraints, are marked with a "✉." Since all product classes will be sampled by the chlorinated hydrocarbon/chlorinated organophosphate (CHC/COP) method (see Section 7), and since this method also detects phenylbutazone, the latter, by default, will be sampled in all product classes. However, phenylbutazone is not of regulatory concern in all product classes. Those product classes in which phenylbutazone will be sampled, but where it is not of regulatory concern, are designated by a "▤."

PHASE IV - ALLOCATION OF SAMPLING RESOURCES

ALLOCATION OF SAMPLING RESOURCES AMONG DIFFERENT PRODUCT CLASSES

EGG PRODUCTS

The samples for residue analysis for imported egg products are selected in a different manner than the other product classes. As stated in Section 2, in order to establish a history of compliance with the U.S. requirements for each category of egg product, the first ten shipments from individual foreign establishments are subjected to 100 % reinspection. If the egg product is in compliance, the rate of

inspection is reduced to a random selection of one reinspection out of eight product lots from each foreign establishment. This reinspection rate will continue as long as the product is in compliance.

ANIMAL PRODUCT CLASSES

Table 5.2**,** *Estimated Annual Amount (in lbs.) of Product Imported,* lists the estimated amount of all the product classes imported into U.S. and includes the percentage of each of the product classes. The data for the product classes is obtained from Automated Import Information System. The percent of each product class imported annually is calculated using the following formula:

$$\% \text{ Product Class Imported } (P_C) = \frac{\text{Amount Product Class Imported}}{\text{Total Product Imported}} \times 100 \qquad (5.1)$$

The relative sampling priority is obtained by multiplying the percent product class (P_C) by the drug scores obtained in Phase I, using the following equation

$$\text{Relative Sampling Priority} = (P_C) \times \text{Drug Score} \qquad (5.2)$$

Based on the scores, one of the following sampling options is chosen: (1) very high regulatory concern (460 analyses/year); (2) high regulatory concern (300 analyses/year); (3) moderate regulatory concern (230 samples/year); or (4) low regulatory concern (90 samples/year). This is indicated in Table 5.5, *Number of Drug Samples/Product Class,* in the column labeled "Number of Samples."

Starting this year, FSIS in its Import Monitoring Plan will not test (1) processed products from eligible foreign countries that also ship fresh products to the United States; and (2) processed products from countries that source all their raw materials from other foreign countries that are eligible to ship fresh product and are actively exporting to the United States. Processed chicken products from Hong Kong and Mexico, processed turkey products from Hong Kong, and processed pork products from Belgium will not be sampled since the raw materials used are from countries that are eligible to ship raw products to the U.S.

If a product class represents less than one percent (by weight) of total combined U.S. imports of meat, poultry and egg products, then the total number of samples analyzed for any compound or compound class is eight times the number of countries from which that product is imported. For example, if fresh goat is imported from only three countries and the amount imported is 0.24 % relative to the total U.S. import, twenty-four samples of fresh goat would be taken for each analysis, eight from each country.

The adjusted numbers of samples is listed in Table 5.5, in the column labeled "Adjusted Number of Samples." The final number of samples for a compound/product class is obtained after the allocation of samples among different countries is completed. The final number of samples is listed in Table 5.5 in the column labeled "Final Number of Samples." Based on the laboratory capacity, the number of samples for carbadox and chloramphenicol were adjusted downwards.

ALLOCATION OF SAMPLES AMONG DIFFERENT COUNTRIES

The total number of samples chosen for each compound/product class pair was subdivided among the different countries. The number of samples for each country was based on the relative amount of total product class imported: less than one percent and greater than one percent.

Allocation of Samples in Product Classes Whose Total Volume Imported is less than 1%

As stated above, if the amount of an import product class was less than 1%, eight samples per compound/compound class were taken from each country. The relative amounts of fresh goat, fresh chicken, processed beef/pork, fresh and processed turkey, fresh and processed other fowl, processed lamb/mutton, and processed veal were less than 1%. Also, as stated above if a country is exporting both fresh and processed products or sources all their raw materials from eligible sources then no residue samples will be scheduled for processed products from that country. The unadjusted numbers of samples are listed in the columns labeled, "Unadjusted Number of Samples" in Tables 5.6 to 5.15. The adjusted numbers of samples per country/per product class is listed in the column labeled, "Final Number of Samples" in Tables 5.6 to 5.15.

Allocation of Samples in Product Classes Whose Total Volume Imported is Greater Than 1%

For major product classes, the number of samples was allocated to each country depending upon the relative amount of product imported from that country. Table 5.3, *Estimated Annual Amount (in lbs.) of Product Imported/Country,* lists the amount of product imported from each country. The percent of a product class imported from a country was calculated as follows and is in Table 5.4, *Relative Annual Amount of Product Imported/Country.*

$$\text{Percent Product Class Imported per Country } (P_{C/C}) = \frac{\text{Amount of Product Class from Country}}{\text{Total Amount of Product Class}} \times 100 \quad (5.3)$$

Based upon the relative amount of product class imported per country, the number of samples that should be taken at the port-of-entry was calculated using the following formula:

$$\text{Unadjusted Number of Samples per Country } (U_{C/S}) = \text{Total Number of Samples} \times \frac{(P_{C/C})}{100} \quad (5.4)$$

This is indicated in the column labeled "Unadjusted Number of Samples ($U_{C/S}$)," in Tables 5.16 to 5.23 (except 5.18b and 5.20b).

After determining the number of samples required from each country, each country with less than eight samples was assigned a minimum of eight samples. This is indicated in the column labeled "Adjustment #1" in Tables 5.16 to 5.22 (except 5.18b and 5.20b). The results of this adjustment are in the column labeled "Initial Adj #." If the total number of samples for a compound/product class resulted in more than the total number of samples allocated to that compound/product class pair, then a second adjustment had to be made, so that the total number of samples would be within an allocated number. This adjustment was made only to those countries from which greater than eight samples were to be taken. This was accomplished using the following equations:

$$\text{Number of Samples after Adjustment \#2} = (U_{C/S}) - \frac{(N \times P_{C/C})}{(P_{T/C})} \quad (5.5)$$

where ,

$N = (N_1) - (N_T)$
N_1 = Total Number of Samples after Adjustment #1
N_T = Total Number of Samples Allocated
$P_{T/C}$ = Total Percent of Product Class from the Countries That Had Greater Than Eight Samples
$P_{C/C}$ = Percent Product Class Imported Per Country
$U_{C/S}$ = Unadjusted Number of Samples

As mentioned above, if a country is exporting both fresh and processed products or sources all their raw materials from eligible sources then no residue samples will be processed from that country. The final numbers of products sampled are indicated in Tables 5.17 to 5.23 (except 5.18b and 5.20b) in the column labeled "Final Adj.#."

Notes:

Because of limited laboratory resources 24 samples were allocated for chloramphenicol in fresh veal, and 92 samples for ractopamine in fresh pork.

Since the U.S. imports processed pork from seventeen countries, the total number of samples tested for arsenicals were adjusted from 90 to 104, i.e. 8 samples/country.

Phenylbuatzone is detected by the FSIS CHC/COP method. Therefore, all product classes that are sampled for CHC/COP are sampled for phenylbutazone. The number of samples/product class/country is discussed in Section 7.