samples are to be run, calibrating at the beginning and end of the run is sufficient.

VI. CALCULATIONS

Area values are obtained on known mixtures and samples by multiplying the net peak height by the peak width at half height or by counting squares. Area values obtained on knowns are plotted versus zeranol concentration. Calibration plots indicate a near linear function in the 0–10 microgram range. Area values obtained on samples are converted directly to microgram quantities using the curve. Control tests demonstrated a 70 percent recovery of zeranol from spiked wet beef liver and muscle necessitating a correction factor.

$$\text{Zeranol, parts per billion} = \frac{\text{Micrograms of zeranol found A1,000}}{\text{W A0.7}}$$

Where:

0.7=Correction factor for 70 percent recovery.

W=Grams of tissue examined.

VII. RECOVERY STUDY

A. Fortification of reagent blank.

1. For those using this method for the first time either for recovery study or tissue assay, a solvent blank and solvent fortified with zeranol should be processed through the entire procedure. This preliminary operation will establish whether or not the procedure is free from contamination arising from solvents and glassware and demonstrate the level of recovery of the standard zeranol. Level of recovery should be in the same range as the samples.

2. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2*N* HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate.

3. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2*N* HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate. Spike the concentrate with 1.0 milliliter of stock solution D.

4. Assay both samples as described in the procedure beginning extraction step V–E1.

B. Fortification of samples.

1. Transfer 100-gram portions of partially thawed tissues into 250-milliliter homogenizing flasks and set half of them aside to serve as tissue blanks.

2. Add to the remaining samples 1 milliliter of stock solution D to serve as fortified samples to which 20 parts per billion zearalanol have been added.

3. Assay both fortified and unfortified tissue as described in the procedure section beginning with V–C1.

[40 FR 13942, Mar. 27, 1975, as amended at 54 FR 31950, Aug. 3, 1989]

§ 556.770 Zoalene.

Tolerances are established for residues of zoalene (3,5-dinitro-*o*-toluamide) and its metabolite 3-amino-5-nitro-*o*-toluamide in food as follows:

(a) In edible tissues of chickens:

(1) 6 parts per million in uncooked liver and kidney.

(2) 3 parts per million in uncooked muscle tissue.

(3) 2 parts per million in uncooked fat.

(b) In edible tissues of turkeys: 3 parts per million in uncooked muscle tissue and liver.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Subpart A—General Provisions

Sec.

Subpart B—Specific New Animal Drugs For Use in Animal Feeds

AUTHORITY: 21 U.S.C. 360b, 371.

SOURCE: 40 FR 13959, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 558.3 Definitions and general considerations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a ''no-residue'' basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required, or are a veterinary feed directive drug.

(2) A ''Type A medicated article'' is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under § 514.105 of this chapter.

(3) A ''Type B medicated feed'' is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term ''highest continuous use level'' means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would