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In response to HHS Advance Notice of Proposed Rulemaking on Import Tolerances, and the December 7, 2001 extension of the public comment period to March 11, 2002 (FR 63519), the Catfish Farmers of America are pleased to submit the following comments.

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01N-0284

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## COMMENTS BY THE CATFISH FARMERS OF AMERICA ON IMPORT TOLERANCES

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### **Issue 1:**

FDA asked for input on different approaches that the agency could use to find a safe import tolerance.

Answer:

There should be absolutely no variation from the requirements for a tolerance of a drug approved in this country for many reasons, many of which are given below. To do otherwise will result in an *incentive* to manipulate the system of approval and enforcement in order to produce food products in a way that would be prohibited in the United States, resulting in the introduction of residues of unapproved drugs into the US food supply.

### **Issue 2:**

Are there analytical techniques or other approaches that would allow us to determine whether a residue is due to the use of the drug product for which the tolerance is approved?

Answer:

We do not know of any methods that FDA could use beyond what is normally used to detect residues in the tissues. We should not be expending valuable and limited resources on the task of looking for analytical methods that make it easier for an import tolerance to be established than what is required for a domestic tolerance.

### **Issue 3:**

How can FDA inform the public of the import tolerance process while also ensuring that the agency does not disclose trade secrets and confidential commercial information?

Answer:

The FDA should not have a different process or requirement for import tolerances with regard to the protection of trade secrets and confidential commercial information. It should not consider any process that provides producers of products exported to the United States with more favorable, or less favorable, protections of their information.

Question a:

Should FDA disclose to the public that the agency is considering an import tolerance for a new animal drug?

Answer: Yes.

Question b:  
If so, when?

Answer: Notice should be provided sufficiently early for interested parties to have meaningful input. This notice should be provided upon receipt of a request.

Question c:  
How should FDA do so?

Answer: Both the Federal Register and the Internet

Question d:  
How much detail should FDA provide?

Answer: The FDA must give enough information so that the public knows what is known for a domestic application, including the drug and its use for what animal species the import tolerance is being considered.

Issue 4: FDA is seeking information on whether import tolerances will have a significant effect on the environment.

Answer: On the surface, it seems that residue of drugs in imported animal *products* for human consumption should not have a significant effect on the environment.

Issue 5: General Comments

1. We need to be assured of the protection of our food supply from unsafe residues. This situation is particularly critical as it relates to the consumption of aquatic species.

Americans consumed 15.6 pounds of seafood per person in 2000, an increase of 0.2 pounds from the 1999 level. In 2000, 68% (>16 billion pounds) of all the seafood we consumed in the United States was imported and that trend has been steadily increasing. At 15.6 pounds of seafood per person, the per capita consumption of imported seafood is 10.6 pounds and is likely to continue to increase. What percentage of that amount is farm raised is unknown, but most or all of the shrimp, salmon, catfish, clams, and scallops in the top ten of seafood consumed is farm raised but so also are trout, tilapia, and mussels.

The potential for exposure to harmful residues of drugs and chemicals imported seafood is greatest in those countries that do not have laws for approving drugs and chemicals for safety. Countries that do not have approvals or have limited requirements and with the greatest potential for exposing Americans to harmful residues include those with aquaculture shipments of (1) more than 1000: Chile, Ecuador, India, Indonesia, and Thailand; (2) 500 to 1000: Bangladesh, Honduras, Mexico, and Philippines; and (3) 100 to 499: China, P.R., Taiwan, and Vietnam.

2. How can we be assured that the import tolerances are not exceeded when FDA does not have enough inspectors now to detect for unsafe residues?

There are approximately 70 to 80 drugs that have been or are being used in aquaculture worldwide. Many of these drugs do not have sensitive enough analytical methods to detect them at low concentrations.

3. We need to ensure that US consumers are not subjected to the consumption of imported products that do not ensure the same level of food safety that is expected of our domestic food animal producing industries. Special care needs to be given to ensure that incentives are not provided through *less rigorous safety requirements for imported products*, especially those that are in the development phase here and abroad (e.g., aquaculture), that will place unfair competition on the production of safer domestic products to the eventual detriment of the safety of safety of products consumed in the United States.

Aquaculture production is growing at 11% annually on a global basis. The U.S. is the second largest seafood market in the world but the domestic aquaculture industry has not kept pace with the rest of the world because of high costs, lack of commercialized production, cost of regulations, lost markets from imports, and skilled labor shortage. Allowing import tolerances for unapproved drugs for use on aquatic species would increase the uneven playing field more than it already is. From a food safety perspective, the United States market risks becoming dependant on foreign supplies of seafood which does not have equivalency agreements similar to meat and poultry, and because of that and the sheer number of processors, results in an expanding risk of bio-terrorism.

4. If import tolerances were established, then our domestic food animal producing industries should also be able to use these same drugs since they are considered to be safe. The argument that the drug in question is used to treat animal disease that does not occur in the United States is not valid. For example, an oral antibacterial drug will usually control a broad spectrum of bacterial diseases, some of which are surely in this country. There is no valid reason that an *unapproved* treatment should be allowed just because one bacteria not present in the US.

5. FDA states that “Some of these drugs may not be easily approved in the United States, because drug sponsors may not be able to meet one or more requirements of the NADA (21 U.S.C. 360b (b)).” If a company wants an import tolerance, it should be willing and able to gain an approval of that drug for that use in this country. That is not too much to ask.

6. Import tolerances should never be established for substances that are banned in the United States. In addition, FDA should establish enforcement mechanisms to ensure that food safety is equivalent for imported products that are produced in countries where such drugs are not banned, or where enforcement of such bans is not adequate and effective. USDA requires foreign *governments* to provide for meat and poultry a certification that ensures that the banned substance is not used or present in the growth or production. It should be noted that USDA also maintains equivalency agreements with exporting countries (in addition to HACCP requirements) that provide for a far higher level of food safety than exists for seafood. We also note that other countries register foreign seafood processors, and subject each to on-site inspections. In addition, the percent of entries of seafood in other countries

that are subjected to physical inspections are an order of magnitude greater than exists in the United States. For example, the United Kingdom inspects products from countries with equivalence agreements at a rate of entry inspection that is similar to that which FDA maintains for *all* countries. FDA places great reliance on HACCP for imported seafood, a reliance that has been called into question by the General Accounting Office's report GAO-01-204, a report which was characterized by the Center for Science in the Public Interest as "GAO Gives Failing Grade to Seafood HACCP Program", (CSPI Press Release, 2/13/01).

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