This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs for a processor that holds live lobster in a lobster pound, using control during holding. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards for this product.

Updated: 9/23/04

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for each Preventive Measure**	**Monitoring**				**Corrective Action(s)**	**Records**	**Verification**
			What	**How**	**Frequency**	**Who**			
Holding	Aquaculture drugs	Lobster will be withheld from distribution for 30 days after treatment with oxytetracycline in accordance with the labeled directions for use No other aquaculture drugs will be used	Type of aquaculture drug used	Visual observation of drug use	Every time aquaculture drugs are used	Production employee	Hold the product AND Collect a sample of the finished product and have analyzed for oxytetracycline residue by contact laboratory. If 2.0 ppm or less, release. If higher than 2.0 ppm, hold product an additional 5 days and then retest AND Destroy the lot when unapproved drugs are used AND Modify drug use practices	Drug use record	Review monitoring and corrective action records within one week of preparation
			Date and quantity of drug use	Visual observation of drug use	Every time aquaculture drugs are used	Production employee		Drug use record	
			Date of finished product distribution	Visual observation of drug use	Every time aquaculture drugs are used	Shipping supervisor		Shipping record	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for each Preventive Measure**	**Monitoring**				**Corrective Action(s)**	**Records**	**Verification**
			What	**How**	**Frequency**	**Who**			
Receiving	Aquaculture Drugs	Third party certificate indicating that the producer operates under a third party audited Quality Assurance Program that covers aquaculture drug usage	Presence of third party certificate	Visual, for presence of certificate	Each lot checked to see if covered by certificate, which is renewed annually	Receiving dock employee	Reject lot AND Discontinue use until a certificate is obtained	Third party certificate of operation Receiving record	Review monitoring and corrective action records within one week of preparation

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	**Significant Hazard**	**Critical Limits for each Preventive Measure**	**Monitoring**				**Corrective Action(s)**	**Records**	**Verification**
			What	**How**	**Frequency**	**Who**			
Pre-harvest	Aquaculture drugs	Animal drugs used on fish only if the drugs have been: a) approved by FDA and used in accordance with proper withdrawal times and other labeled conditions; b) approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guidelines; c) listed on the "low regulatory priority aquaculture drug" list; or,	On farm drug usage procedures	Survey farm husbandry procedures, ask questions, and review drug records	Once per year for each aquaculture site	Field agent	Reject AND Discontinue use of supplier until evidence is obtained that drug treatment practices have changed	On-site audit report	Review monitoring and corrective action records within one week of preparation
		d) permitted by FDA for use in food fish under the conditions of an INAD (as evidenced by a lot-by-lot written certificate from the grower)	Certificate indicating proper INAD usage	Visual	Same	Same	Reject	Certificate of INAD usage	

(1)	(2)	(3)	(4)	(5)		(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	**Significant Hazard**	**Critical Limits for each Preventive Measure**	**Monitoring**					**Corrective Action(s)**	**Records**	**Verification**
			What	**How**		**Frequency**	**Who**			
Receiving	Aquaculture Drugs	No fish will be accepted that contains unapproved drug residues (other than those used under an INAD application or included on the "low regulatory priority aquaculture drug" list)	Fish flesh for drug residues	Obtain samples and analyze for drugs using rapid screening methods Note: A limited number of drug screening tests for aquaculture are available, and these have not been validated by FDA or AOAC. This topic is further discussed in Step #12 (Identify the CCPs.)		Each lot received	Quality assurance personnel	Reject lot AND Discontinue use of supplier until evidence is obtained that drug treatment practices have changed	Analytical results	Review monitoring and corrective action records within one week of preparation

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	**Significant Hazard**	**Critical Limits for each Preventive Measure**	**Monitoring**				**Corrective Action(s)**	**Records**	**Verification**
			What	**How**	**Frequency**	**Who**			
Receiving	Aquaculture Drugs	Certificate indicating proper drug usage accompanying all lots of incoming pond-raised shrimp	Presence of a certificate indicating proper drug usage	Visual	Each lot received	Receiving dock employee	Reject lot AND Discontinue use until supplier agrees to provide certificate for each lot.	Grower's drug usage certificate Receiving record	Visit all new pond-raised shrimp suppliers within the year and all existing suppliers at 25% per year on a rotating basis to review the grower's drug usage procedures Review monitoring, corrective action, and verification records within one week of preparation

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	**Significant Hazard**	**Critical Limits for each Preventive Measure**	**Monitoring**				**Corrective Action(s)**	**Records**	**Verification**
			What	**How**	**Frequency**	**Who**			
Receiving	Aquaculture Drugs	Animal drugs used on fish only if the drugs have been: a) approved by FDA and used in accordance with proper withdrawal times and other labeled conditions; b) approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guidelines; c) listed on the "low regulatory priority aquaculture drug" list; or d) permitted by FDA for use in food fish under the conditions of an INAD (as evidence by a lot-by-lot written certificate)	On-farm drug usage procedures	Review drug records at receipt	Each lot received	Production supervisor	Reject lot AND Discontinue use of supplier until evidence is obtained that drug treatment practices have changed	Grower's drug usage records Receiving record	Review monitoring and corrective action records within one week of preparation
			Certificate indicating proper INAD usage	Visual	Same	Same	Same	Certificate of INAD usage	

FDA. 2001. Aquaculture Drugs (A Chemical Hazard). Ch. 11, In *Fish and Fishery Products Hazards & Controls Guidance: Third Edition*. 127-144. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Seafood, Washington, DC.