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Joan Claybrook, President

July 21, 2004

Division of Dockets Management (HFA-305)
The Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To: Division of Dockets Management (HFA-305)

**Re: Program Priorities in the CFSAN, Request for Comments
Docket No. 1998N-0359**

Public Citizen is providing you public comments for the program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2005. Public health concerns exist concerning imported farm raised shrimp; and therefore, and we recommend that the U.S. Food and Drug Administration **prioritizes imported shrimp inspections for FY 2005.**

Shrimp is currently the number one seafood choice for American consumers. Approximately 80% of the shrimp consumed in the United States is imported, over half of which is farmed raised. Some chemicals, such as chloramphenicol and nitrofurans, are used around the world to raise shrimp in coastal farms for exportation to the United States. As you know, these chemicals are actually banned by the U.S. FDA. (See attached table of all chemicals used in aquaculture.)

Chloramphenicol is linked to human aplastic anemia, intestinal problems, and neurological reactions; while nitrofurans have been found to be carcinogenic. Both are widely used to produce shrimp, but both are also banned in the United States, due to the FDA's commitment to protect American consumers and to secure our country's food supply.

In 2001, the European Union found high levels of chloramphenicol residue in shrimp imported from China, Thailand and Indonesia. As a result, they instituted a rigorous 100% inspection system, until they were able to get the situation under control. Despite the known use of these chemicals overseas, currently, the FDA only inspects less than 1% of imported shrimp. This leaves U.S. consumers completely in the dark as to the health risks associated with consuming farm raised shrimp.

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As outlined in the June 24th, 2004 Federal Register Notice request for comments, imported shrimp inspections fall under the FY 2004 workplan and program areas, which are to be followed for the FY 2005 workplan, as well. Imported shrimp inspections uphold the FDA's domestic health standards, as well as ensure international compliance for U.S. food safety. In order to guarantee that imported shrimp is safe for American consumers and that it adheres to the current FDA guidelines on chemical usage in foods, shrimp inspection should be a priority, and placed on the FDA CFSAN "A-list" for FY 2005.

Even the House Committee on Appropriations is focused on the public health concern surrounding imported shrimp. The recent House Report 108-584, which accompanied the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill - H.R. 4766, stated:

The Committee continues to have serious concerns regarding seafood safety issues posed by banned antibiotic contamination in farm-raised shrimp imports. The Committee recommends that the FDA, in cooperation with any state testing programs, continue testing of farm-raised shrimp imports for chloramphenicol and other related harmful antibiotics used in the aquaculture industry and ensure that any adulterated shrimp that tests positive for chloramphenicol or other banned antibiotics will be destroyed or exported from the United States.

The Food and Drug Administration is responsible for ensuring a safe food supply for American consumers, I urge you to recognize this mandate and to prioritize imported shrimp inspections and to institute the following:

1. For one entire year, inspect 100% of shrimp imported into the United States for banned chemicals, such as chloramphenicol and nitrofurans. This will allow the FDA to better understand the extent of the problem.
2. Once the year of 100% testing is complete, the agency will devise a testing program for imported farm raised shrimp that is based on the prevalence of banned chemicals found during the total testing period.
3. If shrimp entering the US is detected with residues of banned chemicals, the contaminated shrimp must be destroyed, rather than dumped back to consumers in the country of origin or for use in animal feed.

Sincerely Yours,



Wenonah Hauter
Director
Critical Mass, Energy and Environment Program

Attachment

				cooked prawns imported to UK from Malaysia and Thailand	http://ntp-server.niehs.nih.gov/hdocs/CHEM_H&S/NTP_Chem7/Radian738-70-5.html	
Triphenyl tin acetate CAS: 900-95-8	Fentin acetate, Brestan	Organotin compound	Previously used as antifoulant on fish cages and to remove molluscs from shrimp ponds in SE Asia	Immunotoxicity in mammals Possible neurotoxicity Residues accumulate in fish cultured in treated ponds and persist for many months	Budavari (1996), GESAMP (1997)	Use banned in USA and Europe, as well as in Philippines and Indonesia
Triphenyl tin chloride CAS: 639-58-7	Fentin chloride, Aquatina	Organotin compound	Previously used as antifoulant on fish cages and to remove molluscs from shrimp ponds in SE Asia	Immunotoxicity in mammals Possible neurotoxicity	Budavari (1996), GESAMP (1997)	Use banned in USA and Europe, as well as in Philippines and Indonesia

			antibacterial action			
Sulfadimethoxine (6-Sulfanilamido-2,4-dimethoxy-pyrimidine) CAS: 122-11-2	Dinosol	Sulfonamide antibiotic	No specific information	No information available	[MSDS available at http://www.vedco.com/VedcoCatalog.html]	Residues detectable in fish tissues. Use is allowed in U.S. aquaculture.
Teflubenzuron (N-(((3,5-dichloro-2,4-difluorophenyl)amino)carbonyl)-2,6-difluoro-benzamide) CAS: 83121-18-0	Nomolt, Dart, Diaract, Tefluron	Benzoyl phenyl-urea insect growth regulator	Control of sealice in finfish culture in Norway, Canada and Chile	No information available	Roth (2000)	Residues detectable in vegetables and fruits following agricultural use
Tricaine methane-sulphonate (Ethyl 3-aminobenzoate, methanesulfonic acid salt) CAS: 886-86-2	Metacaine, Finquel, MS-222		Anaesthetic	Persistent residues in fish tissues	Meinertz <i>et al.</i> (1999)	
Trichlorfon CAS: 52-68-6	Dipterex, Neguvon	Organophosphate	Used against monogenean ectoparasites in Mediterranean seabass and sea bream, though also has application in shrimp culture in SE Asia	Acetylcholine esterase inhibition Hydrolyses to form more toxic and persistent dichlorvos	Budavari (1996), GESAMP (1997), Graslund and Bengtsson (2001)	
Trifluralin CAS: 1582-09-8	Treflan	Organonitrogen compound	Fungicide used in bath treatments in shrimp aquaculture	Possible human carcinogen Induces thyroid and liver tumours in mammals	Budavari (1996), GESAMP (1997), Hurley <i>et al.</i> (1998), Gunier <i>et al.</i> (2001)	
Trimetoprim (trimethoprim) CAS: 738-70-5	Proloprim, Trimpex plus many others			Potential development of antibiotic resistance Residues detected in	Willis <i>et al.</i> (1999), Graslund and Bengtsson (2001) [MSDS available at	

5-(4,5-dimeth-oxy-2-methyl-benzyl)-2,4-diaminopyrim-idine CAS: 6981-18-6	Ormetoprim - one component of ROMET-30	Diaminopyri-midine antibiotic	Applied in feed to treat furunculosis, enteric red mouth disease and vibriosis	No information on toxicity	GESAMP (1997),	Cooking does reduce tissue residues in fish (Xu <i>et al.</i> 1996). Used in U.S. aquaculture combined with sulfadimethozinc
Oxolinic acid CAS: 14698-29-4	Gramurin, Dioxacin plus others	4-quinolone antibiotic	Used against gram-negative bacteria	Development of resistant strains Residues resistant to degradation	GESAMP (1997)	
Oxytetracycline CAS: 79-57-2	Terramycin, plus many others	Tetracycline antibiotic	Probably the most widely used antibacterial agent in shrimp aquaculture, especially in SE Asia	Development of strains resistant to oxytetracycline and other related antibiotics	Baticados <i>et al.</i> (1990), Primavera <i>et al.</i> (1993), GESAMP (1997), Graslund and Bengtsson (2001)	Use recently allowed in U.S. aquaculture.
Polyvinyl pyrrolidone iodine complex CAS: 25655-41-8	Povidone iodine	Iodophore	Antibacterial and antiviral agent, used to treat fish eggs		Budavari (1996), GESAMP (1997)	
Rifampicin CAS: 13292-46-1	Rifampin plus many others		Antibacterial, effective against mycobacterial infections	Rapid development of resistant strains	Primavera <i>et al.</i> (1993), Graslund and Bengtsson (2001)	Rifampicin resistance very common in fish and prawn from South India (Vivekanandhan <i>et al.</i> 2002)
Romet 30	See Ormetoprim and Sulfadiazine					
Simazine CAS: 122-34-9	Simadex, Aquazine plus many others	Triazine herbicide	No specific information	Toxic by ingestion Effects on liver and thyroid in humans Potential reproductive toxin	Goldburg <i>et al.</i> (2001)	
Sulfadiazine CAS: 68-35-9	One component of ROMET-30	Sulphonamide antibiotic	Commonly used in combination with diamino-pyrimidine to yield broad spectrum	Development of resistant strains	Budavari (1996), GESAMP (1997)	Cooking does reduce tissue residues in fish (Xu <i>et al.</i> 1996)

			in UK, Ireland, Canada and Chile			
Malachite green oxalate CAS: 569-64-2	Malachite green Basic Green 4 Diamond Green	Organonitrogen compound	Antifungal and antiprotozoal bath treatment, primarily in shrimp hatcheries	Respiratory poison Persistent residues in tissues of seafood	Primavera <i>et al.</i> (1993), Dierberg and Kiattisimkul (1996), GESAMP (1997), Graslund and Bengtsson (2001)	Prohibited for use in USA, EU and in Thailand
Methylene blue CAS: 61-73-4			Used as antifungal and antiprotozoal treatment, though less frequently than malachite green	Can produce haemolytic anaemia in laboratory animals	GESAMP (1997), Hejtmancik <i>et al.</i> (2002)	
Malathion CAS: 121-75-5		Organophosphate	Control of ectoparasitic crustaceans (seallice) and trematode infections in shrimp hatcheries	Acetylcholine esterase inhibition	Budavari (1996), GESAMP (1997), Graslund and Bengtsson (2001)	
Metronidazole CAS: 443-48-1		Imidazole	Used against protozoan infections, though mainly for the aquarium trade	Reasonably anticipated to be a human carcinogen	GESAMP (1997) NTP (2001)	
6-[2-(5-nitrofuranyl)ethenyl]-2-pyridinemethanol CAS: 13411-16-0	Nifurpirinol	Nitrofurans	Broad spectrum and potent antibacterial and antiprotozoal agent	Suspected human carcinogen	GESAMP (1997), Graslund and Bengtsson (2001)	In 1990, one of the most common therapeutic agents used in shrimp hatcheries in the Philippines (Baticados <i>et al.</i> 1990)
Norfloxacin CAS: 70458-96-7	Noroxin	Organonitrogen compound	Antibiotic	Used as human drug, but only for severe infections (and never for children or pregnant women)	Budavari (1996), GESAMP (1997)	

(Thiosulfan) CAS: 115-29-7			farming in Thailand (precise use not listed)	and immunotoxicant in humans Suspected endocrine disruptor	(1986), ATSDR (1993), Vonier <i>et al.</i> (1996), Graslund and Bengtsson (2001)	countries, and variously classified as "toxic" and "hazardous". Breakdown product, endosulfan sulphate, is more persistent and exhibits similar toxic traits
Enrofloxacin CAS: 93106-60-6		Fluoroquinolone antibiotic	Broad spectrum antibacterial	Causes retinal degeneration in cats Potentially highly persistent	GESAMP (1997), Graslund and Bengtsson (2001)	
Erythromycin CAS: 114-07-8		Macrolide antibiotic	Used against bacterial kidney disease and streptococcosis in yellowtail in Japan and in SE Asia shrimp hatcheries	Development of resistant strains	Primavera <i>et al.</i> (1993), GESAMP (1997), Graslund and Bengtsson (2001)	
Ethoxyquin CAS: 91-53-2		Organonitrogen antioxidant	Commonly used in feed preservation	Harmful by ingestion Irritant	GESAMP (1997) [MSDS available at http://ntp-server.niehs.nih.gov/htdocs/CHEM_H&S/NTP_Chem9/Radian91-53-2.html]	
Furazolidone CAS: 67-45-8		Nitrofurantoin antibiotic	Broad spectrum antibacterial and antiprotozoal activity	Possible human carcinogen Has been used as drug for AIDS patients	GESAMP (1997), Graslund and Bengtsson (2001)	Use for food animals prohibited within EU
Ivermectin CAS: 70288-86-7	Ivomec	Avermectin	Used against crustacean (sea lice) and nematode infestations in salmonids, including	Neurotoxic in mammals "Safe" residue levels in low ppb range for meat products	Baynes <i>et al.</i> (1999), Grant and Briggs (1998), Roth (2000)	

			in Norway			
Diazinon CAS: 333-41-5	Dimpylat	Organophosphate	Removal of mysids from shrimp ponds in Indonesia	Acetylcholine esterase inhibition	GESAMP (1997), Graslund & Bengtsson (2001)	
Dichlorvos CAS: 62-73-7	DDVP, Nuvan	Organophosphate	Widely used to control crustacean ectoparasites (sealice) in fish, especially salmonids in NW Europe and Chile – discontinued in Norway and Faroes in 1998	Acetylcholine esterase inhibition	Budavari (1996), GESAMP (1997), Roth (2000), Graslund & Bengtsson (2001)	Di-n-butyl phthalate may be used as carrier (Burrige and Haya 1995). Some preparations may contain epichlorohydrin as a stabiliser (GESAMP 1997)
Diflubenzuron CAS: 35367-38-5	Dimilin, Difluron plus many others	Difluorobenzoyl urea insect growth regulator	Control of sealice in finfish culture in Norway and Chile	Cytotoxicity in human and rat cell lines	De Sousa <i>et al.</i> (1997), Roth (2000)	
Diquat bromide (1,1-ethylene-2,2'-bipyridinium dibromide) CAS: 85-00-7	Aquacide plus many others		No specific information	Possible reproductive toxicant and effects on kidneys in humans Highly toxic by skin contact	Goldburg <i>et al.</i> (2001) [MSDS available at http://www.state.nj.us/health/eoh/rtkweb/0808.pdf]	
Dimethyl-5-nitroimidazole CAS: 551-92-8	Dimatridazole	Imidazole	Used against protozoan infections, though mainly for the aquarium trade	No information	GESAMP (1997)	
Doramectin CAS: 117704-25-3		Avermectin	Broad spectrum endo- and ectoparasiticide, listed as used in Chile	Reproductive toxin in rabbits Relatively persistent as parent compound in liver	Baynes <i>et al.</i> (1999), Roth (2000)	
Emamectin benzoate CAS: 137512-74-4	Emamectin, MK-0244	Avermectin	Used against ectoparasites on salmonids in Norway, UK, Canada and Chile	Possible neurotoxicity in mammals, though not in birds	O'Grodnick <i>et al.</i> (1998), Roth (2000), Duston and Cusack (2002)	
Endosulfan	Thiodan	Organochlorine	Used in shrimp	Possible reproductive	Banerjee and Hussain	Banned in numerous

Carbaryl CAS: 63-25-2	Sevin	Organophosphate/Carbamate	Control of burrowing shrimp in shrimp ponds in Central and S. America, and in bottom oyster culture in NW USA	Teratogen Acetylcholine esterase inhibition	GESAMP (1997), Dumbauld <i>et al.</i> (2001)	
n-Chloro- <i>p</i> -toluene sulfonamide, sodium salt CAS: 127-65-1	Chloramine-T	Chlorinated sulphonamide	Treatment of bacterial gill disease and protozoan ectoparasites in salmonids Disinfectant used for tank and equipment cleaning	Harmful by ingestion Active ingredient is 20% available chlorine – no information on residues	[MSDS available at http://www.cris.com/~hschem/msdscht.html]	
Chloramphenicol CAS: 56-75-7		“Phenicol” antibiotic	Broad spectrum antibiotic	Aplastic anaemia Resistant strains develop readily	Primavera <i>et al.</i> (1993), Budavari (1996), GESAMP (1997) Graslund & Bengtsson (2001)	
Chlorpyrifos CAS: 2921-88-2	Dursban plus many others	Organophosphate	Control of ectoparasites in freshwater fish and of monogenetic trematode infections in shrimp hatcheries	Acetylcholine esterase inhibition Neurotoxicity greater in juvenile animals	GESAMP (1997), Chanda <i>et al.</i> (2002)	
Cotrimoxazole (Sulfamethoxazole) CAS: 723-46-6		Sulphonamide antibiotic	General antibacterial	Toxic epidermal necrolysis in sensitive individuals	GESAMP (1997), Nassif <i>et al.</i> (2002)	
Cypermethrin CAS: 52315-07-8	EXCIS plus many others	Synthetic pyrethroid	Net pen treatment of sea lice on salmonids in USA, UK, Norway, Faroes and Ireland	Neurotoxicity, possibly enhanced by co-presence of organophosphates	Roth (2000), Ernst <i>et al.</i> (2001), Haya <i>et al.</i> (2001)	Weakly antiestrogenic and antiandrogenic May degrade to produce oestrogenic residues (Tyler <i>et al.</i> , 2000)
Deltamethrin CAS: 52918-63-5	Alpha Max plus many others	Synthetic pyrethroid	Net pen treatment of sea lice on salmonids	Neurotoxicity	Roth (2000)	

Table 1: Summary of chemicals used in the culture of finfish and/or shrimps which are, or may be, of concern with respect to residues in the final seafood product based on their intrinsic properties and/or reported detection of residues in foodstuffs.

Chemical	Trade names	Chemical type	Use Category	Hazards	References	Notes
Acriflavine neutral (mixture of 3,6-diamino-10-methylacridinium chloride and 3,6-diamino-acridine) CAS: 8048-52-0	Euflavine, Gonacrine, Neuroflavine, Trypaflavine		Antibacterial and external topical treatment for protozoan infection – used on fish eggs and fry	Irritant Inhibitor of DNA activity in human cell lines (has been used as anti-inflammatory drug)	GESAMP (1997) Choi <i>et al.</i> (2000) [MSDS available at http://www.koivet.com/acriflavine_msdsh.html]	Acroflavine hydrochloride (CAS 8063-24-9) is a suspected teratogen, but appears to be used less frequently
Amoxicillin (Amoxicillin) CAS: 61336-70-7		β -lactam antibiotic	Antibacterial administered in feed or, more rarely, by direct injection	Exposure of consumers sensitive to β -lactam (penicillin-type) antibiotics Development of resistant strains	GESAMP (1997)	
Azamethiphos CAS: 35575-96-3	Salmosan 50% plus several others	Organophosphate	Treatment against preadult and adult sealice in European and North American salmon culture	Acetylcholine esterase inhibition	Pretti <i>et al.</i> (2002)	
Azinphos ethyl CAS: 2642-71-9	Gusathion A	Organophosphate	Previously used to remove molluscs from shrimp ponds in Philippines, but now banned. Use in other countries not documented	Acetylcholine esterase inhibition	Budavari (1996), Graslund & Bengtsson (2001)	
Benzocaine (ethyl <i>para</i> -amino-benzoate) CAS: 94-09-7	Anesthone, Orthesin, Cepacaine plus many others	Aminobenzoate	Anaesthetic used during egg and milt-stripping and as preparation for transport	Harmful if swallowed Residues can be detected in fish tissue, though more rapidly cleared than other anaesthetics	GESAMP (1997), Meinertz <i>et al.</i> (1999)	Developed in response to concerns about tricaine methane-sulphonate (Meinertz <i>et al.</i> 1999)