

# BIOTERRORISM, THE FDA & YOU

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I read the brochures on the new FDA requirement to register food facilities, because I'm a beekeeper, and I was not sure if I needed to comply or not. The brochures can be found on the FDA website at: [www.cfsan.fda.gov/~acrobat/fsbtreg.pdf](http://www.cfsan.fda.gov/~acrobat/fsbtreg.pdf); [www.cfsan.fda.gov/~acrobat/fsbtgn.pdf](http://www.cfsan.fda.gov/~acrobat/fsbtgn.pdf)

I noticed that these brochures included disclaimers at the bottom of the inside covers.

I thought I'd translate and explain the disclaimer for other beekeepers from the point of view of one who pronounces "government" as "gummit," as I KNOW it can get very sticky at times:

The brochures say:

*"This guidance document is a restatement of the Food and Drug Administration's (FDA's) current requirements for registration of food facilities presented in simplified format and language."*

**TRANSLATION** The wording of the law is complete gibberish, so we thought we'd try to explain it in plain English.

*"As guidance, it is not binding on either FDA or the public."*

**TRANSLATION** But don't hold us to anything we say here.

The law itself, even though an incomprehensible muddle of jargon and legalese, is the law, and it must somehow be obeyed, even if no one ever successfully translates it into plain English.

*"FDA notes, however, that the regulation that is the basis for this pamphlet establishes requirements for all covered activities."*

**TRANSLATION** So, no matter who you are, you have to stop what you are doing and make a choice: either (A) read this, do what it says, and hope that what we say is accurate, or (B) hire a team of lawyers, and hope that THEY can understand it and explain it to you. Either way it is a gamble, and you are betting your livelihood.

*"For this reason, FDA strongly recommends that affected parties consult the regulation at 21 CFR Part*

*1, Subpart H, in addition to reading this pamphlet."*

**TRANSLATION** On second thought, don't believe a single word we say in this fancy color brochure, printed at taxpayer expense. This brochure is useless, as only the language of the law itself is "the law." Never mind that you can't understand it, the law says what it says, and it will certainly be explained in detail through enforcement actions, court rulings, fines, and other processes that we use to inform you if you don't comply with any of the laws you don't understand.

(If it is any consolation, we here at the FDA think that even Congress itself does not understand this law. Think about it! How could anyone "poison" a large number of people unless they poison a LARGE food supply? Any random reservoir would be a more effective target for poisoning a large group. Why bother tracking small-scale operations at all? We kinda like our existing recall process, and we know it works, but we have to do as we are told.)

*"The Food and Drug Administration has prepared this guidance to restate the legal requirements set forth in 21 CFR 1.225 through 1.243 concerning registration of food facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."*

**TRANSLATION** We had better give you a citation to the actual wording of the law. We've only written two paragraphs so far, but we have realized that we are wasting our time, and maybe mis-informing people who could be fined, criminally prosecuted, and maybe even have their inventory confiscated.

*"This guide is intended to help..."*

**TRANSLATION** Yeah, 'help.' That's the ticket! We are 'helping.'

*"...any entity, regardless of size, to comply with the regulations..."*

**TRANSLATION** The immigrant street-corner hot dog and ice cream vendors who have yet to master English beyond 'You want onions?,' let alone

hear of this new regulation, will be easy to arrest, hold without due process, and/or deport. This may be the actual fear over at Homeland Security – a low-yield battlefield tactical nuclear device, bought from a rouge supply Sergeant in a breakaway Soviet republic, smuggled in via Canada in a 55-gallon drum of maple syrup, and deployed in an ice cream vendor's cart in Lafayette Park, right across Pennsylvania Avenue from the White House. (We here at the FDA think that those guys at Homeland Security have been reading far too much Tom Clancy, but we aren't going to argue with John Ashcroft. We don't want to be held without due process as 'enemy combatants' either. We have families too, ya know.)

*"...that require domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA."*

**TRANSLATION** Yes, we are imposing requirements even on people who are governed by the laws of other countries, not even citizens or residents of the USofA. Don't like it? Then don't try and ship us any food. Did you really think that we were going to comply with any of those "World Trade" agreements, and submit our biosecurity and health concerns to the WTO's 'Office International des Epizooties' (OIE) for their consideration? Come on! Even their name is in French, for Pete's sake!

*"This document also serves as FDA's Small Entity Compliance Guide (SECG), in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121)."*

**TRANSLATION** This is all you are gonna get from us, so don't try to complain that you are a small business, and can't afford to spend the money required to figure out if you have to comply with this law, or are exempt. Yes, we know that we are required by law to make life easier for small businesses like beekeepers, bakers, and hot dog vendors, but the bottom line is that we can't clearly explain something that we ourselves don't understand. **BC**