

Topics for RCAC Discussion - February 28, 2008

We have discussed how FDA does risk communication in the context of its various authorities. Our goal is to be most effective: to achieve timely, transparent and useful communication while staying within regulatory and legal constraints. Below are some characteristics of scenarios we might encounter. Please consider how we might approach different combinations of factors to communicate better. Keep in mind that we are not discussing problems focused on any particular product, but on products in general. Please also know that these lists are not intended to be all-inclusive.

Some product types	Risk characteristics	Exposure characteristics
<ul style="list-style-type: none"> • Packaged food • Perishable food • Pet food • Livestock feed • Veterinary medicines • Human non-prescription medicines • Human prescription medicines • Home use medical devices • Blood or tissues • Human vaccines • Radiation-emitting electronic products 	<ul style="list-style-type: none"> • Contamination by infectious organism • Contamination by industrial chemical • Intentional contamination • Clear manufacturing violations • Imported product (vs. domestic) • Potential adverse effect, uncertain link with product • Potential adverse effect, established link with product • Negative outcome is permanent (vs. outcome is temporary) • Effects appear immediately (vs. appear over time) • Effects severe (vs. effects mild) 	<ul style="list-style-type: none"> • Effects or exposure geographically wide-spread • Effects or exposure limited to identifiable subpopulation or species • Effects or exposure unclear • Effects or exposure greater in children • Effects or exposure greater in pregnant women • Effects or exposure greater in elderly persons