

From: France Capon <france.capon@epmf.be>
Subject: **FW: More information concerning the FDA study**
Date: 22 Jun 2015 07:33:10 GMT+02:00
To: Katrien Arijs <katrien.arijs@arche-consulting.be>

FYI
France

-----Original Message-----

From: Rosalind Volpe [mailto:rvolpe@ilzro.org]
Sent: samedi 20 juin 2015 01:45
To: france.capon@epmf.be
Cc: Michael DiRienzo
Subject: More information concerning the FDA study

Dear France,

Today, I received the following update from Erin Tesch concerning the FDA study and what FDA is doing concerning the reprotox situation.

Best Regards,
Rosalind, SNWG

FDA is working to address some questions that remain following review of the study and there is now some uncertainty as to whether or not the study will actually be published. While FDA still has concerns regarding the reproductive toxicity, the FDA is lifting the moratorium on FCNs (food contact numbers) for silver. FCNs that do not increase the Cumulative Estimated Dietary Intake (CEDI) will be processed as they have been in the past. FCNs that increase exposure may need additional safety data and companies are encouraged to meet with FDA to discuss what type of testing to do (it will be some type of reproductive toxicity study).

One of the reasons for this reversal is that FDA has re-assessed dietary exposure and determined that it is much less than they had previously thought. One large contributor to the calculation of dietary exposure was the use of silver as a wash for poultry, fruits, and vegetables. The FDA has since confirmed that USDA FSIS has not approved use on poultry. Because approvals by both USDA and FDA are needed for this use, FDA was able to determine that silver was not being used in this manner. FDA was therefore able to remove the carcass wash from their calculations. A second contributor, the paper slimicide use (a regulation), is also thought not to be active. The FDA is continuing to work on determining which uses are active and their calculations may change further.

The FDA is talking with EPA about the need for further reproductive toxicity testing. They are actively discussing study designs that could be acceptable to both agencies (the EPA guidelines and the FDA Red Book reproductive tox guidelines have significant differences). If a reproduction study is required it will likely be requested using EPA Data Call In authority.

Sent from my iPhone