

Message

From: Deziel, Dennis (DR) [DRDeziel@dow.com]
Sent: 8/1/2017 7:21:42 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Marshall, Venus [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbd81a18f6ad447f90b8abbc90fe9db-Venus Ashton]
Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

We are here!

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From: Deziel, Dennis (DR)
Sent: Wednesday, July 19, 2017 10:01:48 AM
To: Beck, Nancy; Marshall, Venus
Cc: Witt, Mike (M)
Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Venus,

We can be available on August 1 at either 11am or anytime 3:30pm or later. 30 minutes would be great. Thank you!

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Tuesday, July 18, 2017 5:44 PM
To: Deziel, Dennis (DR) <DRDeziel@dow.com>
Cc: Marshall, Venus <Marshall.Venus@epa.gov>
Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Dennis—

I'm happy to meet with Mike Witt and can invite our leads for the development of our alternatives strategy. Please work with Venus to find a 30 minute window that will work.

Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: **Ex. 6**
beck.nancy@epa.gov

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]
Sent: Tuesday, July 18, 2017 1:18 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Nancy,

Dow is a leader in non-animal testing methods, including extensive, collaborative work with EPA's National Center for Computational Toxicology. We want to engage on this issue in as helpful way as possible. One of our leaders on this issue, Mike Witt, head of our toxicology center, will be in town August 1st. Would you be available to meet when he is here to discuss this issue? Or we could meet with others as you recommend.

Thank you, Dennis

Dennis Deziel Government Affairs
The Dow Chemical Company
500 North Capitol Street, NW Suite 200
Washington, DC 20001
Ex. 6 (office) | Ex. 6 (cell)
E-Mail: DRDeziel@dow.com



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Bloomberg News

Chemical Makers Urge EPA to Accept Non-Animal Safety Data

By Pat Rizzuto

Chemical manufacturers want the EPA to be more receptive than they say the European Chemicals Agency has been in accepting chemical safety data derived from non-animal tests.

"We've had challenges in the EU getting many of these alternatives accepted. We hope the U.S. will be a more friendly place," Athena Keene, a senior toxicologist at Afton Chemical Corp., said at a recent science policy meeting.

Afton, a subsidiary of the NewMarket Corp., which makes fuel and lubricant additives, has registered chemicals under the EU's registration, evaluation, authorization and restriction of chemicals, or REACH, law. REACH encourages the use of non-animal tests, yet animal welfare groups and chemical manufacturers have appealed many decisions in which the European Chemicals Agency rejected non-animal data the companies sought to submit.

The Environmental Protection Agency soon will invite chemical manufacturers, trade associations, animal welfare advocates, and academic and other scientists to help shape an agency strategy to develop and use the results from non-animal, or "alternative," tests for chemical decision making, said Tala Henry, who directs the risk assessment division of the EPA's Office of Pollution Prevention and Toxics. Keene and Henry were among the speakers at a July 12 Toxicology Forum meeting that discussed the Lautenberg Chemical Safety Act, which amended the Toxic Substances Control Act in 2016.

TSCA's amendments require the EPA to develop a non-animal testing strategy by June 22, 2018, to promote the development and use of new scientifically valid test methods that don't use mammals or other vertebrates. That strategy is part a broader requirement for EPA to reduce and replace the use of animals at a time when more tests may be required.

The EPA is deciding whether to seek public participation through a workshop, releasing a draft concept document, or some other method, Henry said. The agency expects to invite interested parties to provide input in a few months, she said.

Reducing Liability

Harvey Clewell, a senior scientist at ScitoVation, a research institute specializing in cell-based and computational methods as chemical evaluation methods, echoed Keene's point that some European chemical regulators have not used available non-animal test methods.

The U.S., however, has a growing academic, federal and industry scientific infrastructure supporting their development and use, he said. Clewell pointed to federal agencies such the EPA and National Institute of Environmental Health Sciences (NIEHS), which have been developing and using a spectrum of automated chemical testing systems.

Using alternative tests "just makes good sense," especially in the early stages of a new chemical's development, Clewell said. "There's a lot of liability potential for chemicals. They can cost a company a lot of money once they are out there. Wouldn't it behoove a company to run some quick tests and say 'this has red flags why should we pursue it'."

Suzanne Hartigan, director of science policy and regulatory affairs at the International Fragrance Association North America, said fragrance makers already have developed strategies to obtain chemical safety data from alternative tests, so they could comply with the EU's Cosmetics Products Regulation and its predecessor—the Cosmetics Directive—which phased out the use of animal tests on cosmetics and their ingredients.

The Research Institute for Fragrance Materials, Inc., which assesses fragrance safety, has developed a phased in, or "tiered," testing strategy that begins with evaluating existing data for a particular fragrance, proceeds to examining information about similar compounds, and builds toward in vitro and computer-modeled tests, Hartigan said. After such alternative data sources have been utilized, animal tests can be considered, she said, urging EPA to consider some of these strategies.

No Double Standard

Henry said EPA already would review non-animal chemical safety data if companies submitted it but added, "It's not flooding into us."

The more companies submit alternative data, the more it will help the agency understand their uses and limitations, she said.

Richard Denison, lead senior scientist with the Environmental Defense Fund, said that group supports the use of alternative tests. Details about tests used to generate data submitted to the EPA should, however, be made available to build public confidence in the tests' predictions, he said. Protocols used for statutorily required animal tests are publicly available.

Many of the assays the EPA uses for its automated chemical testing program, called ToxCast, and that the NIEHS uses for a similar program called Tox21, are proprietary, Denison said.

Alternative test advocates also should avoid a double standard, Denison said.

There's a tendency for proponents to want to use data from an alternative test if it suggests a chemical would not raise health or environmental concerns, he said. Yet if such tests show a problem, then the proponents argue the tests aren't valid because they don't reflect the "real world," Denison said.