

Message

From: Wolf Doug USGR [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DC97C43A0DB8486E9C07FE741DE498BA-WOLF DOUG U]
Sent: 1/31/2018 5:31:22 PM
To: Josh Gilder (JoshuaGilder@gmail.com) [JoshuaGilder@gmail.com]; Jay Byrne (jay.byrne@v-fluence.com) [jay.byrne@v-fluence.com]
Subject: FYI
Attachments: ICHAgChem SYT.pdf; Application of RISK21 SYT and industry.pptx; LtO.FtO visual.pdf; Climate change is real.docx
Sensitivity: Company Confidential

Thank you both for all your help.
doug

From Alexandra in response to Marian, also attached Alexandra's newspaper article but also a quote from Eric Fyrwald.

"thanks for providing this information. It's really insightful. A better risk based scientific testing approach with alternative methods to animal studies will be very helpful for all stakeholders. This is a good piece of work.

I am a bit more split on my feedback on using the ICH pharma approach as a role model for us to better "harmonize" regulations for AI's.

ICH is not really a global framework. It found interest in regulatory environments of already high complexity while usually emerging economies have not adopted this. The US itself only uses it as a guidance, not legally enforced. In emerging economies, such a system is usually way too expensive for local manufactures and the authorities lack the funds and capabilities to apply and enforce this. The benefits I see from my past Pharma experience are also clear as to a certain extent such an approach reduces double work. I always wondered why the Codex could not really fill this gap and ICH was needed. Maybe the Codex is too broad.

I guess our target also should not be to "harmonize" regulations. It's usually as mentioned not acceptable to developing economies and usually national policy differences make it very unlikely. Remember the massive debate about Food Hygiene Standards when we tried to do TTIP. It's more about convergence and mutual acceptance. I was involved in a convergence project in my Feed days. It's a walk in the park to bring Canada and Australia onto an FDA agenda. It's easy to convince Switzerland to follow the EU. Apart from this, we have zero success.

I would suggest that we specify the CLI proposal more before we go forward with a critical view on what ICH and other convergence initiatives really delivered and where they have struggled. Once we have this, we can better specify the scope and deliver success within this."

From: Wolf Doug USGR
Sent: Thursday, December 21, 2017 12:39 PM
To: Stypa Marian USGR <marian.stypa@syngenta.com>
Subject: Follow Up to our FTO conversation

Marian,

Thank you for taking the time to talk with me about my current and future FTO related activities that I lead. Sorry for the long email, but there has been a lot of activities and while I am trying to be brief with only major highlights on the LTO/FTO efforts I and my many colleagues have been engaged in, there are a number of areas where we have been able to make some significant strides forward.

Case ID: 220300429

SYNG-PQ-12572218

This summary follows up our conversation about my LTO/FTO activities on behalf of Syngenta and in collaboration with our industry and other stakeholder partners. From a Syngenta point of view the goal is to drive the streamlining of human health and environmental risk evaluation efforts to speed decision-making and reduce resources needed to obtain registration and re-registration through innovative sustainable processes and effectively and efficiently provide innovative solutions to growers. This will be accomplished through an innovative strategy in the way we evaluate human and environmental safety and best done through collaboration across industry and with government regulatory decision-makers.

The successful outcome I and my partners and collaborators are striving for is that regulatory organizations, globally, use a consistent scientific exposure-based risk assessment and management paradigm for decision making. No one is as far forward in their thinking on this as Syngenta is and I strongly believe Syngenta can be the industry leader in innovative approaches to evaluating the safety for use of AIs and products with speed, efficiency and accuracy. The outcome of this will enable us to achieve our imperative of moving to 2 new AIs/year and successful re-registrations. As you know we have had success at this on our US re-registrations recently.

To best achieve the above goal I have been working collaboratively with and through the regulated community and those regulatory agencies that will actively participate in discussion and projects with registrants. A huge advantage for Syngenta is that this effort perfectly aligns with the goals of project VOLTA and our strategic market segment approach.

Both agencies the US and Canada pesticide regulatory programs have said to “come in and talk early and discuss different approaches to information collection”... doing this will enable “focused testing and avoid unnecessary testing”.

We have definitely capitalized on this opportunity and in so doing receive direct and valuable feedback from key decision-makers at EPA and PMRA. We are directly working with and through the USEPA to effect change in the regulatory paradigm by leveraging USEPA influence in other regions. From EPA’s perspective they want and need to increase the speed of decision-making as directed by their current political leaders. We can directly address this with them.

Examples of effective results through open communication

Ongoing replacement of whole animal acute 6-pack with in vitro assays and calculations

Successful study waivers saving company money, time, and animals

Support of alternative non animal methods to replace repeat-dose studies

Direct feedback early in project development has been used to change project direction before significant investment in unnecessary testing

But I have not only had the opportunity to engage with NA regulatory agencies but have been able to leverage my previous connections I made when I worked at the US EPA and through scientific organizations to further our FTO interactions.

LATAM regulatory agencies across Brasil and LAS:

Facilitated training of ANVISA and IBAMA by USEPA to learn modern risk assessment methods.

Facilitated training in Brasil of industry, academia, government (ANVISA, IBAMA, MAPA) on RISK21 philosophy and application. www.risk21.org

Facilitated training in Argentina of industry, academia, government (Argentina, Paraguay, Uruguay) on RISK21 philosophy and application.

I have also been fortunate to engage with some of our regulatory agency partners in the APAC region as well.

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SYNG-PQ-12572219

Invited training of Chinese Food Safety Authority on RISK21 philosophy and application as they are implementing the approach and associated webtool for decision support of food contaminants in China. Discussed RISK21 philosophy and application with ICAMA and Chinese Ministry of Environment.

Finally I am attaching 3 documents that provide more specifics around the LTO/FTO efforts I have been driving.

A short description of the ICHAgChem proposal which is how I see leveraging the application of the best scientific principles in human health and ecological risk assessment in order to globally move away from hazard based systems by leveraging the influence of risk assessment based regulatory agencies such as US EPA. This has come out of a cross industry partnership sponsored by CLI. I recently presented this idea to EPA senior leadership and they were very supportive and are willing to engage in its implementation.

A short slide set that I presented at a recent meeting of the Scientific Advisory Committee on Alternative Toxicological Methods which illustrates how Syngenta is the industry leader in applying the principles of a problem formulation based exposure driven evaluation strategy (RISK21), which is why I was invited to give the presentation. It also illustrates the broader opportunities and animal and \$ savings which can be achieved if we apply this knowledge based approach in our decision making and not always assume we have to do another study. Please feel free to use any of the slides if you wish.

A single slide which illustrates the conceptual model of the LTO/FTO project I have been leading.

Thanks Marian and again, sorry about the long email. If you wish any additional information on any specific effort please let me know.

Doug

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THS Mission: Provide scientific leadership in toxicology and human health for development and sustainable use of safe products and technologies to meet Syngenta's vision of feeding the world.

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