

## **Victory at Codex Over Dangerous Vet Drug!**

*But Cult Leaders Excoriate NHF for Having Challenged its False Religion*

By Scott C. Tips

Imagine a drug for animals that has no purpose other than to bulk up that animal with muscle so that when it is slaughtered, the rancher (or more likely the ranch industry) can make a few extra dollars off of each animal. The drug has no health benefits, but instead has health detriments, not only for the poor animals but for the poor humans who then unknowingly consume its residue-tainted meat. Add one more toxic residue to the synthetic stew that nowadays comprises the typical human diet.

### **Meet Zilpaterol**

Like its evil twin ractopamine, zilpaterol hydrochloride (tradename Zilmax®) is a beta-adrenergic agonist (bAA) drug that is given to cattle and other food animals to take nutrients away from fat production and push them instead into muscle, creating a leaner and ostensibly more-valuable animal. Zilmax is about 125 times more potent than ractopamine.<sup>1</sup> Although not a steroid, the drug does have steroid-like effects on animals and humans alike. These effects, though, can be devastating.

The drug company Merck, which holds U.S. Patent No. 8,580,772 for Zilmax, had widely marketed and sold the drug in Canada and the United States for many years, after its approval by the U.S. Food and Drug Administration. In fact, its annual sales in North America were \$159 million in 2012,<sup>2</sup> before Merck responsibly suspended sales of Zilmax in 2013 due to broad health concerns about cattle hooves falling off and even worse.

Unfortunately, the “even worse” part of zilpaterol’s “adverse unintended consequences” is “the cumulative risk and incidence rate of death was 75 to 90% greater in animals administered the bAA compared to contemporaneous controls.”<sup>3</sup> Not to even mention that, in humans, elevated heart rates, arrhythmias, myocardial infarctions, and deaths have resulted from bAA drugs.<sup>4</sup>

Another study, published in 2018, confirmed that zilpaterol hydrochloride administration to cattle predisposes them to cardiac disease.<sup>5</sup> Despite attestations to the contrary, then, zilpaterol given to cattle can be harmful both to the animals and to humans consuming their meat.

So, why, then, does Merck irresponsibly and dishonestly pursue establishing a Codex Alimentarius standard for residues in meat? Merck uses human studies and not animal studies to push such a standard, and apparently Merck could not care less about the severe ill effects upon food animals so long as it gets what it wants. An approved Codex standard would be Merck’s golden ticket to worldwide sales. And the cash machine could recommence *chitching*.

### **Merck’s Minions, “Drugs for Animals”**

Think of the *Orcs* in the film *Lord of The Rings*, dress them up in suits and ties and sometimes skirts, and you might get a good feel for the dark servants of Merck. As part of its master plan, Merck long ago spawned an industry front group euphemistically called “Health for

Animals.” For a good laugh, just imagine if J.R.R. Tolkien had named his hideous creatures the “*Brothers of Peace*” instead of *Orcs*. It would be that silly.

This front group has strongly lobbied for regulatory approval of these and other dangerous animal drugs.<sup>6</sup> To be sure, Health for Animals, to my knowledge, has never met a vet drug it didn’t like and shuns natural alternatives to drugs, which is why – if honest labels were required of Codex INGOs – the front group’s real name should be “Drugs for Animals.”

Front groups with impressive names are created by drug companies to endorse drug solutions to health problems that will coincidentally also benefit those companies’ bottom line. I myself see the same type of front groups aplenty populating Codex Alimentarius meetings around the World. Their names – such as Health for Animals for Merck and Crop Life for Monsanto – provide just enough veneer to disguise to the non-discerning viewers their true purpose.

At the recent meeting of the Codex Committee of Residues of Veterinary Drugs in Food (CCRVDF), held in Chicago, Illinois from April 23-27, 2018, at least 14 Merck and other industry representatives were there operating under the umbrella of Drugs for Animals or as members of country delegations. It would not be a stretch or hyperbole to describe industry front groups such as this one as the dark subconscious of Codex.

## **Codex Battleground**

One of the major and most hotly contested issues addressed by the CCRVDF at its April Chicago meeting was zilpaterol, which had been wending its way up the 8-step approval process to – hopefully – final adoption by the Codex Alimentarius Commission. At this meeting it was at Step 4 and it was widely expected by its sponsors to be advanced by the Committee to Step 5 or even Step 5/8, the latter of which would mean almost certain quick adoption by the Commission at its next meeting in Rome this July.

Arrayed against a zilpaterol standard were the European Union (EU), Norway, Switzerland, Russia, Bosnia, Mozambique, Indonesia, Egypt, Kazakhstan, and the National Health Federation (NHF), the only consumer organization in attendance at this meeting. China would have added its voice to oppose any standard being adopted for zilpaterol but the United States government – which strongly supports a zilpaterol standard – for some reason refused to grant the Chinese delegates visas to attend the meeting.<sup>7</sup>

Chairing the meeting was Dr. Kevin Greenlees, Senior Advisor for Science and Science Policy, CCRVDF Chairman and employed by the Center for Veterinary Medicine of the U.S. Food and Drug Administration, which was particularly fortunate because Dr. Greenlees followed in the gracious tradition of the previous CCRVDF Chairman Dr. Steven Vaughn and was equally fair-minded and impartial in running this meeting. From beginning to end, and even in the face of taxing and tedious disputes among the Codex delegates, Dr. Greenlees never once lost his professionalism nor treated anyone, including NHF, unfairly.

Wanting to advance the zilpaterol standard were the usual suspects: the United States, Mexico, and the rest of the entire Western Hemisphere plus those countries who had possibly been cajoled into joining forces with the U.S., such as Ghana, Nigeria, Kenya, South Africa, Japan, Zimbabwe, and Togo.<sup>8</sup> All of them stated that they were relying upon the “science” provided by JECFA on zilpaterol (and clearly without doing their own due diligence).<sup>9</sup> The ostensible leaders of the push for zilpaterol were, of course, those two countries who have never met an unhealthy Codex standard that they did not love: Australia and New Zealand, also known as the regional branch offices for Monsanto and Merck.

At the start of the morning of the second day of the Codex meeting (April 24<sup>th</sup>), the Chairman called for the Committee to discuss the proposed Zilpaterol MRLs (Maximum Residue Levels) in cattle. At Step 4 (out of 8 steps to final adoption), this was a critical time to stop zilpaterol from moving forward to adoption where it would then be Codex-sanctioned for sale and use worldwide with fines levied against those who wished to keep it out of their country.

After the Chairman opened the floor for discussion, the JECFA secretariat spoke first and reaffirmed its position that the proposed MRLs for zilpaterol were safe and that there was no safety reason why the zilpaterol standard could not move forward. The European Union (EU) delegate, Risto Holma, acquiesced in JECFA's risk assessment of zilpaterol, but strongly and articulately opposed having the zilpaterol MRL advance for EU policy reasons. Bosnia, Switzerland, and Russia quickly joined in with the EU's position, while New Zealand argued that the EU's concerns were outside the parameters of Codex. Evidently, New Zealand supports torturing animals for minor profit while poisoning its own people with toxic drug residues to add to the long laundry list of other toxins and contaminants we are all exposed to on a daily basis.

Many delegations spoke out both for and against zilpaterol. The Italian delegate was especially vocal and animated against zilpaterol. Finally, after all of the country delegates had their chance to speak, the Chairman, following Codex procedure, called upon NHF to speak.



The NHF in the Chicago Codex meeting

I told the Committee that growth promoters do not belong in animal husbandry and that zilpaterol's endocrine-disruptive effect on the reproductive capabilities of animals must be considered here; that zilpaterol's use in horses was already banned, so why are we trying to use it in cattle?; that no risk assessment of this compound had been done in connection with other vet drugs given to food animals so there is no information on the cumulative and synergistic effects on humans or animals from the drug residues of zilpaterol and other drugs acting together; that contrary to others, NHF does believe that animal health is pertinent to

consideration at Codex because of its direct and indirect effects upon humans not even to mention our duty to be humane to animals; that consumers must be made aware of what they are consuming and virtually none have any idea that when they are eating meat, they are eating vet-drug residues such as zilpaterol, along with hefty doses of antibiotics, thereby denying consumers the right to know and choose; and that zilpaterol is really no different than ractopamine, which as everyone at Codex must remember, engendered a tremendous and bitter fight for years in this Committee and then again at the Commission level, and that this issue could do the same.

Drugs for Animals then spoke after NHF with a prepared speech that argued that zilpaterol had no impact on animal welfare, that it was the most studied vet drug before the Committee, and that 65 studies have concluded that zilpaterol is safe and effective. Of course, from studies mentioned in this article, we already know that zilpaterol does indeed have a negative impact on animal welfare and the so-called 65 (industry?) studies proving zilpaterol safe have been adequately called into question by others that demonstrate that zilpaterol is not safe with potential cardiac effects. So, Drugs for Animal's statement that zilpaterol "had no impact on animal welfare" was a lie from the pit of Hell since Merck itself had pulled zilpaterol off the market because of its very negative effects on animal health!

The Chairman was in a tough position, with the room almost evenly divided. As mentioned, due to visa refusals by the U.S., the Chinese delegation was not there to weigh in against zilpaterol; but had it been, the collective populations of China, Russia, India, the EU, and other countries far outweighed those of the countries that wanted zilpaterol to move forward.

Sensing the obvious – that there was no consensus in the room – the Chairman quite reasonably stated that "We are clearly divided and cannot come to agreement. There are passionately held positions here, so I suggest that we stop all work on zilpaterol." That set off an angry explosion amidst the pro-zilpaterol crowd, which began pushing the idea that there was a "consensus on the science" and therefore zilpaterol could move forward.

The debate then become focused on what constituted "consensus" or agreement amongst the delegates. If consensus could be found by the Chairman, then the standard should move forward. So, the pro-zilpaterol crowd argued their bizarre theory that there was consensus, while the anti-zilpaterol delegations argued that obviously there was none at all. It went back and forth for a considerable time.

When I again got the chance to speak for NHF, I strongly argued that "Contrary to what others have said, we do not have consensus. Consensus is defined as the absence of sustained opposition. There is sustained opposition to the standard. And that is what counts here. The Committee does not exist to just rubber-stamp JECFA or any other scientific decisions. Otherwise, why do we exist? We might as well adjourn and have a clerk with a rubberstamp in a back room take care of our business. There is no consensus."

The Chairman then announced that "There is no consensus even though we have followed the rules. I find it disappointing that we cannot do here what we have done with the gentian-violet standard. We are closing debate on this at this time."

Then began the objections, a whole litany of them as delegation after delegation cried out in protest. South Africa complained that "it was scary to come all this way to hear science being defeated," while Drugs for Animals spoke about the Committee's "failure" while leveling a thinly veiled threat against Codex: "This will have a chilling effect on sponsors in future work." In other words, no more drugs for you drug-happy regulators! NHF could only wish that it were so.

After all of the pro-zilpaterol delegations who wanted to had registered their reservations against the decision to halt the zilpaterol standard at Step 4, the Chairman then concluded the morning's session with his thanks to the Committee and "we will close this discussion and put aside any passions." His last remarks proved soon enough to be wishful thinking.

Before going to lunch, the Greek and a few other delegates had come over to thank NHF for its strong comments about zilpaterol. While they were doing that, I noticed that the Drugs for Animals executive director was up at the head table showing something on his smartphone to the JECFA secretariat. I thought nothing much of it at the time. After all, we had won.

Coming back from lunch, as the meeting started, I stepped out into the hall to make a telephone call. When I came back into the room and took my seat, I saw and heard that the delegates were giving thunderous applause to the JECFA secretariat. My colleague and NHF's Executive Director, Katherine Carroll, turned to me and said that they had just publicly attacked NHF for having called JECFA science "junk science" on social media.

I had not heard a word of what was said, but just then the Drugs for Animals executive director, came over to the NHF table and acting almost like he had been dropped on his head, managed to chortle in our faces something like "They all hate you in the room now!" With an additional unsolicited "This is really going to go against you now," he dashed away with a look of triumph on his face. I knew then that he must have been the person behind JECFA's public outrage and attack upon NHF.

This was confirmed later when I spoke with Tom Heilandt, the Codex Secretariat, who told me that the same person had just come up to him and shown him a photo on his phone taken of Tom and me somewhere together as if there were presumed collusion or something wrong in having a photo of the Secretariat taken with a Codex INGO delegate. Sheer nonsense. This clear attempt at intimidation of the Codex Secretariat by the Drugs for Animals executive director shows just how angry, vengeful, and desperate these people can be.

But Katherine Carroll, not content to let matters drop, tracked down the Merck drug bully in the hallway as he himself coozied up to the JECFA representative and let him know the facts about why JECFA science has truly been junk science all too often. He refused to hear it and may as well have covered his ears with his hands. ***The ultimate joy, though, came from knowing that NHF had helped stop the zilpaterol MRL from advancing.***

Merck mistakenly thought that NHF needed some friendly affirmation, to be liked. What a serious misjudgment on their parts. NHF has not been attending Codex meetings to win popularity contests; we have been there to protect people from unhealthy standards as well as to advance healthy ones.

And, frankly, NHF has been challenging JECFA on its all-too-frequent pseudo-science since the early 2000s, so for JECFA to only wake up now to that fact speaks volumes about its researching skills and makes me wonder even more about its risk assessments. It is not as if NHF has hidden its opinions from anyone, just ask the Australian Codex office.

## **The New Religion**

NHF has been saying this for two decades: The worship of God has been largely replaced by the worship of Science. At Codex meeting after Codex meeting, I have personally witnessed the majority of vocal Codex delegates being painfully obsequious to the merest pronouncement on a scientific matter by JECFA. Unfortunately for all of us, their collective genuflection at the altar of "Science" is very badly misplaced since JECFA relies in large measure upon unvetted published scientific studies and suspect sponsor-provided (read, Merck) industry research to

reach its conclusions with a lack of transparency due to trade-secrecy claims on the part of the industry sponsor.

When a 2009 study revealed that “up to 72%” of scientists admitted their colleagues were engaged in “questionable research practices,” and that some 14% were engaged in outright “falsification,”<sup>10</sup> we can safely assume that there is a problem with published science.

And when, in 2011, another team at Bayer HealthCare in Germany reported that only about 25% of published preclinical studies could be validated enough to justify projects continuing,<sup>11</sup> we can take even more heed of this problem.

In fact, the problem was further highlighted by a group of scientists at a California biotech firm who took the trouble to double-check the results of 53 published landmark studies in cancer research and blood biology. Only 6 of the 53 studies could be proven valid. So, while almost 90% of the landmark studies were flawed, they had all been passed off to the public as fact.<sup>12</sup>

Others, such as respected medical editor Dr. Marcia Angell, are just as insistent: “It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of *The New England Journal of Medicine*.”<sup>13</sup>

And Dr. Richard Horton, the Editor-in-Chief of *The Lancet*, seconded Dr. Angell’s conclusions when he said that “[t]he case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness....”<sup>14</sup>

But Dr. Horton’s condemnation of published science did not end there. He cautions us that “[t]he apparent endemicity of bad research behaviour is alarming. In their quest for telling a compelling story, scientists too often sculpt data to fit their preferred theory of the world. Or they retrofit hypotheses to fit their data. Journal editors deserve their fair share of criticism too. We aid and abet the worst behaviours. Our acquiescence to the impact factor fuels an unhealthy competition to win a place in a select few journals. Our love of ‘significance’ pollutes the literature with many a statistical fairy-tale ... Journals are not the only miscreants. Universities are in a perpetual struggle for money and talent.”<sup>15</sup>

With so much “junk” science being passed off as “real” science, and with so many professionals and academics meekly accepting counterfeit science, current science is more in the nature of a religion than a method of critical thinking about the World and trying to discover the truth about how it really operates. It is instead a religion, pure and simple; and for any heretic who dares to question it at Codex, the penalty is excommunication by the Codex priests.

### **JECFA Science Too Often Fails Us**

JECFA is highly regarded by most of the Codex delegates, no matter what country. And most of those think that whatever JECFA says, the Codex committees should accept, ***without question***. As I have often argued throughout numerous Codex committee meetings, then why do the delegates even bother to show up? Why not simply have a clerk with a rubber stamp and each time a pronouncement comes down from the Mount where JECFA is seated, then the clerk can rubberstamp “Approved” and the rest of us can all stay at home?

The National Health Federation has challenged and questioned JECFA science for decades. It has also at times supported JECFA science (such as on the recent draft standard for the vet drug gentian violet). So, this most recent incident on zilpaterol was not the first time NHF has criticized JECFA. And it was only because Drugs for Animals – ***bitterly angry*** at its sudden and unexpected loss on the zilpaterol issue – resorted to juvenile revenge-seeking against NHF and made it an issue with the FAO and WHO representatives at the head table that it even flared up at this last Codex meeting.

We have to ask why Codex allowed protocol to be manipulated with a priestly condemnation from the pulpit against free speech directed solely at NHF. Were all other delegations opposed to zilpaterol subjected to a review of their Facebook pages?

Ironically, the fact that Drugs for Animals could even make it an issue reveals the extent to which the drug industry controls or influences the risk assessors (such as JECFA), the risk managers (such as Codex), and the regulators. I personally saw Drugs for Animals Executive Director up at the head table showing the FAO and WHO representatives material off of his smartphone and chumming it up with them, not to mention his sleazy attempt at intimidating the Codex Secretariat.

If alarm bells are not sounding loudly from these industry indiscretions, then perhaps we should be alarmed when one of the Drugs for Animals representatives boldly told the Codex delegates assembled there in Chicago on April 24th, “In my 18 years of attending Codex here, this is the first time that a sponsor is not happy with a change.” Really? In ***eighteen years***, the change that the CCRVDF committee made to the Flumethrin risk assessment was the very first and only time that an industry sponsor was not happy? It takes incredible arrogance and hubris to admit something like that. Clearly, the vet drug industry thinks it owns this Codex Committee and along with it, evidently JECFA as well.

Since JECFA has just publicly anointed itself as the bastion of “real” science, it might be worth a trip down memory lane to see how appropriate that self-anointing is.

### **1. rBGH (or rbST)**

At the 38<sup>th</sup> session of the Codex Alimentarius Commission (CAC) held in July 2015, one of the most important items to be debated on its agenda was the adoption of a Maximum Residue Limit (MRL) for recombinant bovine growth hormone (rBGH) or recombinant bovine somatotropin (rbST).

As with ractopamine and zilpaterol, many Codex member states – such as the European Union, Norway, Switzerland, India, Russia, and China – have banned this genetically modified veterinary drug’s use on animals under a very sensible health policy that prohibits drug use on animals for anything other than therapeutic purposes. The vet drug rBGH, injected into cows, is not therapeutic; it is used to increase milk production. This made for a contentious Codex issue.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has conducted three safety reviews of rBGH and its representative kept insisting to the Codex delegates that these safety reviews have shown the veterinary drug to be safe, with no noticed increase in mastitis (udder infections) or antimicrobial residues from rBGH use.<sup>16</sup> The JECFA representative at this meeting took the same position as she had expressed at the Codex Committee on Residues of Veterinary Drugs in Foods held in Costa Rica in April 2015, that JECFA’s “systematic review of the literature published since the 50<sup>th</sup> JECFA [1998] did not find any significant difference in the incidence of mastitis ... [nor] specific studies correlating the use of rbST with the development of antimicrobial resistance.”

Pro-rBGH delegates at the 2015 CAC meeting were not shy about repeatedly pointing out that this was JECFA's **third** review of rBGH for safety. How could anyone, they hypnotically demanded time and again, possibly have an issue with **three** JECFA reviews that found no safety concerns for rBGH? And besides, they added, since this Codex standard has been on hold for fifteen years, we would be harming Codex's credibility were we to turn our backs on JECFA science and refuse to adopt the MRLs for rBGH that JECFA assures us are safe.

Codex delegates representing **more than half** of the World's population did not believe that the JECFA risk assessment was either sound or scientific. Indeed, many thought the risk assessment was very political and industry-influenced. The NHF had also strongly argued at the previous meeting that JECFA had overlooked negative study results from the industry itself, and even the product warning labeling for Monsanto's rBGH product (Posilac), which cautions users about a possible increase in mastitis in cows injected with Posilac.

Curiously enough, during its own first two reviews, JECFA had specifically excluded any consideration of mastitis issues, conveniently claiming that these safety problems were outside the scope of the JECFA review. So, contrary to pro-rBGH claims, there had not really been three JECFA reviews of all the issues.

NHF member and policy advisor Robert Cohen – an expert on rBGH and its many dangers – has pointed out that a herd of Holstein cows injected with the genetically engineered bovine growth hormone presented extremely shocking results upon autopsy, which the FDA and Monsanto did not make public. It was only upon publication in a dairy magazine that consumers learned that rBGH-injected cows lost an average of 100 pounds after six months, but that their hearts and spleens and other stressed organs had grown abnormally large. JECFA missed this important data, but then it was not made public until recently, so we cannot blame JECFA for that. Still, maybe we should take a look at the sponsor science that was held in secret and without the transparency that good science demands.

However, what JECFA has missed and can be held accountable for is what Dr. Michael Hansen of Consumers International had argued, among other things, at the 2015 CAC meeting, that is, that studies have shown that: (1) rBGH use significantly increases mastitis rates; and (2) the average length of treatment for a case of mastitis is almost six times longer in the rBGH-treated cows compared to untreated cows. And as NHF argued, the JECFA review of rBGH was incomplete in that it had failed to consider the industry's own data showing a marked increase in mastitis after rbST injection, which in turn led to increased antibiotic use to avoid pus and bacteria in milk.

Yet, despite this and an enormous amount of other, unbiased evidence out there, JECFA and its worshippers at Codex continue to insist that rBGH is safe. With antimicrobial resistance (AMR), JECFA had even twisted *the lack of data* on AMR into a conclusion that AMR is not an issue with rBGH use! As every true scientist knows, an absence of data means scientists wait to draw conclusions until they have the data.

Too, we suspect that JECFA's expert body on AMR may not be as disinterested as they should be in making their risk assessments of rBGH. An NHF investigator found that one of the Codex Antimicrobial experts, Y. Tamara, was working for Mead Johnson's GMO division in 2004 where he obtained a U.S. patent for a GMO grain.

All in all, the JECFA review of the safety data on rBGH was incomplete, ignorant of health issues such as mastitis, excess pus, and overuse of antibiotics to try to correct the pus in milk. If JECFA were truly doing its job, then it would be ruthless about tracking down each and every hint of evidence that rBGH poses a human and animal health problem. But, sadly enough,



JECFA's reviews here were third rate and industry walked away richer at the expense of our health.

## 2. Aspartame

Aspartame is a well-known artificial sweetener with less-known, but still-proven deleterious effects upon humans and animals, which can include seizures, brain tumors, dementia, and weight gain.<sup>17</sup> Notwithstanding the considerable and increasingly accumulating evidence of aspartame's toxicity, JECFA declared aspartame "safe" in the early 1980s at a consumption level of 40 mg per kilogram of body weight.<sup>18</sup>

Many of the observations that independent researcher Mark Gold made of the EU Scientific Committee that reviewed aspartame safety also apply to the JECFA review that led to its approval: "Almost all aspartame studies conducted and funded independently of the aspartame manufacturer (and related trade groups) have linked aspartame to adverse effects or adverse biochemical changes. This includes numerous human studies (e.g., clinical, double-blind) and animal studies (Walton 1996). ... [T]he Scientific Committee on Food either ignored many of these independent studies or had negative things to say about almost all of the independent studies that they did mention. ... On the other hand, the Committee accepted almost all of the aspartame industry-funded studies without any negative comment. In fact, the Committee relied heavily on and repeatedly cited parts of books and reviews written and compiled by employees of the aspartame manufacturer (e.g., Stegink 1984, Tschanz 1996, Butchko 1994, Butchko 2001)."<sup>19</sup>

The conflicts of interest that plagued the EFSA "scientific" review of aspartame safety are well documented.<sup>20</sup> NHF is investigating the conflicts of interest that might also exist with JECFA committee members and will report on that later. What is abundantly clear, however, is that industry is not shy in the least about extending its tentacles of undue influence amongst scientific bodies so as to get the commercial results that they seek.

## 3. Glyphosate

Over 1 billion pounds of pesticides are used in the United States each and every year, while approximately 5.6 billion pounds are used worldwide.<sup>21</sup> In many developing countries, programs to control pesticide exposures are limited or non-existent. The agrochemical companies – supported in many cases by JECFA – tell us these compounds are safe and are ensuring adequate food production to feed the World, but the facts tell us another story.

On January 24, 2017, the United Nations (UN) published a report in which it stated that although pesticide use has correlated with a rise in food production, it has had **catastrophic** impacts upon human health and the environment. The report went on to say that "[e]qually, increased food production has not succeeded in eliminating hunger worldwide. Reliance on hazardous pesticides is a short-term solution that undermines the rights to adequate food and health for present and future generations." In fact, the UN blames pesticides for poisoning 200,000 people each year.<sup>22</sup> I think that figure is wildly conservative.<sup>23</sup>

Glyphosate tops the list of poisons applied every day to plants and soil that in turn destroy humans, animals, and our environment. Some 9.4 million tons of glyphosate have been spread on our fields. It is in our water table, our soil, crops, the food industry, and over 90% of Westerners have it in their bodies and even breastmilk. In fact, 33% of our bread contains glyphosate, the World's biggest selling weed killer.<sup>24</sup> Despite industry assurances that glyphosate is "safe" and "environmentally friendly," there is increasing awareness that glyphosate is nothing more than a replay of DDT with its similar pronouncements of "certified safe" and "completely harmless."<sup>25</sup> In fact, some experts attribute tens of thousands of deaths to glyphosate usage.<sup>26</sup>

Worse, as NHF Board member Sayer Ji has said, glyphosate is poisoning our soil, destroying our gut biome, and laying the foundation for destroying our ability to produce healthy foods for future generations.<sup>27</sup> Industry and regulators claim that glyphosate is safe for humans and animals because the means by which it kills weeds (the shikimate pathway) is not present in humans and animals. However, the shikimate pathway is present in bacteria, which dominate human and animal gut biomes. The glyphosate preferentially destroys beneficial gut bacteria, thereby allowing disease and inflammation to take hold.<sup>28</sup> It is also an endocrine-disrupter that has serious effects upon reproductive and hormonal health in humans.<sup>29</sup>

Equally bad, recent scientific studies by U.S. government researchers have discovered that certain popular weed-killing products containing glyphosate are more toxic than the glyphosate alone.<sup>30</sup> The U.S. Environmental Protection Agency sought the testing because the International Agency for Research on Cancer (IARC) in 2015 classified glyphosate as a probable human carcinogen.<sup>31</sup>

Unfortunately, as with other toxic compounds, JECFA has drunk the cool-aid of the industry and delivered yet another pass on toxic glyphosate. Ignoring substantial scientific evidence questioning the safety of glyphosate, JECFA has instead sanctified its use with subpar science. When corporate bonds are subpar, the market calls them “junk” bonds. What do we call science when it is subpar?

#### 4. Ractopamine

Most of the World’s countries (some 160 at last count) wisely do not allow ractopamine-doped meat to be sold within their borders. Especially strict is the European Food Safety Authority (EFSA), which has found that ractopamine constricts blood vessels and quickens the heart.<sup>32</sup> EFSA also has strong concerns about the drug’s carcinogenicity as well as its stressing and other adverse effects on the animals given the drug. As for humans, since there is no clearance period of two weeks prior to slaughter as with other veterinary drugs to rid the meat of drug residues, consumers are being medicated with ractopamine residue when they eat the treated meat.<sup>33</sup> The Chinese Government has spent many millions of Yuan in studies of the health effects of ractopamine and, convinced of its health risks, has banned both its import and export.<sup>34</sup> As a further nail in ractopamine’s coffin, EFSA and its member States have a very sensible public-health policy against drugging healthy animals just for steroid-like effects.

It is important to note that when EFSA pointed out the fatal flaws in the JECFA Report on ractopamine almost a decade ago, JECFA simply declared that EFSA had not presented any “new data” and EFSA’s concerns were summarily rejected.<sup>35</sup> That is *not* how scientific review and debate is conducted in the real world. In the real scientific world, JECFA would have had to respond and/or correct the flaws, regardless of whether EFSA’s critique presented any “new data” or not.

Yet, JECFA conducted its own industry-influenced assessments of the risks of ractopamine and established MRLs for ractopamine residues that have been seized upon by the drug’s promoters as “proof” of its safety.<sup>36</sup> Mentioning JECFA’s reports as frequently and fervently as drug addicts mainlining on heroin, the pro-ractopamine group conveniently overlooked the fact that ***JECFA’s study groups consisted of only six healthy human males and a band of monkeys*** (the embarrassing dog study having been slyly omitted from the reports). They also overlooked the fact that JECFA’s ractopamine science is based only on industry studies. JECFA science is often both political and highly suspect, a fact that surprisingly escapes most Codex delegates.<sup>37</sup>

#### 5. Zilpaterol hydrochloride

The harmful health effects of the vet drug zilpaterol hydrochloride have already been set forth above and will not be repeated in this section, other than to note that, as with its complete failure to recognize and address the health risks of ractopamine, JECFA and its religious adherents have similarly relied too heavily upon industry studies to come to the faulty conclusion that zilpaterol is safe for humans when in fact it is 125 times more potent than even ractopamine.

This is a drug product that even industry (such as Tyson Foods, the largest meat processor in the U.S.) has shunned for health reasons and that Merck's Animal Unit has ceased sales of in the United States and Canada over animal-health and other concerns.<sup>38</sup> One would think that all of these factors, including numerous published studies of zilpaterol's adverse health effects, would signal JECFA to conduct a closer and more careful review of **all** of the science. Critical thinking should be applied to any assessment of this vet drug and not just thinking about untapped markets.

## Conclusion

The JECFA secretariat owes NHF an apology. Essentially, he had tried to shame NHF for not worshipping at its altar. This public shaming was unprofessional, anti-scientific, and even childish. We are all entitled to our opinions and we are all supposedly at Codex to advance the health of humanity. Such attempts as were made by the JECFA secretariat to stifle free discussion at Codex are reprehensible and not in the best interests of Codex or its good works.

Rather than a childish outburst, JECFA should take NHF's opinions of its work in stride and as a challenge to do even better. Not all of JECFA science is wrong, just as not all of its assessors are misguided. There is good with the bad in everything and the wise accept criticism as a challenge instead of a rush to crush its horrible truth.

In all of my many years at Codex, I have **never** seen this kind of attempt to publicly shame a delegation or INGO into compliance by censoring free thought and free speech. Instead of presumed shame for NHF exhibiting critical thinking backed by research, though, it has only highlighted even more NHF's power to educate and persuade the World about Codex and our opponents' fear of the truth.

What is apparent is that JECFA is resistant to any message that challenges their authority. What we have observed coming from JECFA is:

- Inconsistent science
- Insisting there is no science when science clearly exists
- Too often a lack of critical thinking
- Too narrow of a focus
- Making assessments when there are data gaps
- Too heavy a reliance upon self-serving industry "science"

Moreover, conflicts of interest must be avoided at all costs. All scientific assessors must be thoroughly vetted and cleared for industry ties before they can serve with JECFA.

Sadly, it was apparent to me that Drugs for Animals considers that it owns this Codex committee. The chummy relationship the Drugs for Animals delegate enjoyed with the WHO and FAO head-table personnel where he could feel free to share with them that NHF had called JECFA's reviews "junk science" and the subtle threat given by him to the Codex Secretariat, as well as the comment of one speaker for that industry front group that in his 18 years of attending the committee he had never seen a change to a standard that he had not liked "until now," all go

to show the absolute arrogance of an all-too-cozy relationship between industry and its regulators.

Codex is a marvelous institution that has the potential to be even better. But Codex will never be better as long as industry thinks it “owns” Codex and JECFA. JECFA should have enough dignity and self-respect to stop itself from being led around by the nose by industry. The motto of Codex after all is “Safe, Good Food for Everyone” and not “More Sales for Industry.”

All of us at Codex have an absolute duty to work to ensure safe and good food for the World’s people. And that duty is shirked by anyone who meekly accepts without challenge whatever swill is being passed off as “science.”

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<sup>1</sup> Dr. Joseph Mercola, “Zilmax: Slaughterhouse Observations Raise New Concerns about This Growth-Promoting Drug,” *Mercola.com*, Nov 5, 2013, at <https://articles.mercola.com/sites/articles/archive/2013/11/05/zilmax-side-effects.aspx>.

<sup>2</sup> Merck Press Release, “Merck Animal Health Strengthens Commitment to Five Steps to Responsible Beef,” *Merck.com*, Aug 16, 2013, at <http://www.mrknewsroom.com/press-release/animal-health/merck-animal-health-strengthens-commitment-five-steps-responsible-beef>.

<sup>3</sup> Loneragan GH, Thomson DU, Scott HM, “Increased Mortality in Groups of Cattle Administered the b-Adrenergic Agonists Ractopamine Hydrochloride and Zilpaterol Hydrochloride,” *PLOS One*, Vol. 9, Issue 3, March 2014, e91177, at <http://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0091177&type=printable>.

<sup>4</sup> *Ibid.*

<sup>5</sup> Neary JM, Garry FB, Gould DH, *et al.*, “The beta-adrenergic agonist zilpaterol hydrochloride may predispose feedlot cattle to cardiac remodeling and dysfunction,” *F1000Research*, March 2018, 7:399 (doi: [10.12688/f1000research.14313.1](https://doi.org/10.12688/f1000research.14313.1)), at <https://f1000research.com/articles/7-399>.

<sup>6</sup> Health for Animals website, accessed May 19, 2018, at <https://healthforanimals.org/aboutus/about-us.html>.

<sup>7</sup> Per NHF private source of information.

<sup>8</sup> Report of the 24<sup>th</sup> Session of the CCRVDF, Chicago, Illinois, April 2018, Paras. 53-54, at [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-730-24%252FFINAL%252520REPORT%252FREP18\\_RVDFe.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-730-24%252FFINAL%252520REPORT%252FREP18_RVDFe.pdf).

<sup>9</sup> JECFA is the acronym for the Joint FAO/WHO Expert Committee on Food Additives, and is the Codex-spawned expert group upon which Codex Committees rely for expert scientific opinions in forming Codex standards.

<sup>10</sup> Daniele Fanelli, “How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data,” *PLOS One*, May 29, 2009, at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0005738>.

<sup>11</sup> Prinz, F, Schlange, T & Asadullah, K, “Believe it or not: how much can we rely on published data on potential drug targets?” *Nature Rev. Drug Discov.* 10, 712 (2011), at <https://hopecenter.wustl.edu/wp-content/uploads/2012/01/Nat-Rev-Drug-Disc-reproducibility-article.pdf>.

<sup>12</sup> Begley CG & Ellis LM, “Drug development: Raise standards for preclinical research,” *Nature*, 483, 531-533 (29 March 2012); doi:10.1038/483531a, at <https://www.nature.com/articles/483531a>.

<sup>13</sup> Dr. Marcia Angell, “Drug Companies & Doctors: A Story of Corruption,” *NY Review of Books*, January 15, 2009, at <http://www.nybooks.com/articles/2009/01/15/drug-companies-doctors-a-story-of-corruption/>.

<sup>14</sup> Dr. Richard Horton (editor-in-chief of *The Lancet*), “Offline: What is medicine’s 5 sigma?” *The Lancet*, 11 April 2015, Vol 385, No. 9976, p. 1380, at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(15\)60696-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)60696-1/fulltext). A special thanks to Jon Rappoport at <https://jonrappoport.wordpress.com/2018/03/08/shocking-victory-for-proponents-of-alternative-medicine/>.

<sup>15</sup> *Ibid.*

<sup>16</sup> See “Report of the Codex Alimentarius Commission, Geneva, 6-11 July 2015,” Paras. 50-51, at [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-38%252FReport%252FREP15\\_CACe.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-38%252FReport%252FREP15_CACe.pdf).

<sup>17</sup> Mark D. Gold, *Independent Analysis of “Opinion of the European Commission, Scientific Committee on Food: Update on the Safety of Aspartame / E951,”* Feb. 3, 2003, at <http://www.holisticmed.com/aspartame/scf2002-response.htm>.

<sup>18</sup> See, e.g., InChem, "Aspartame," undated, at <http://www.inchem.org/documents/jecfa/jecmono/v15je03.htm>. See also JECFA Evaluation Monograph, dated 2018, at <http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=62>.

<sup>19</sup> Gold, *supra*, at "Aspartame Industry Influence" subsection D.

<sup>20</sup> Corporate Europe Observatory, "Exposed: Conflicts of Interest of EFSA's Experts on Food Additives," 5 June 2011, at <https://corporateeurope.org/efsa/2011/06/exposed-conflicts-interest-among-efsa-experts-food-additives>.

<sup>21</sup> Michael C.R. Alavanja, "Pesticides Use and Exposure Extensive Worldwide," *Rev Environ Health*, 2009 Oct–Dec; 24(4): 303–309, at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2946087/>.

<sup>22</sup> Ryan Rifai, "UN: 200,000 die each year from pesticide poisoning," *Al-Jazeera*, March 8, 2017, at <http://www.aljazeera.com/news/2017/03/200000-die-year-pesticide-poisoning-170308140641105.html>.

<sup>23</sup> Even the somewhat sexist Women in Europe for a Common Future (WECF) stated almost five years ago that "pesticides and harmful chemicals cause more than 900,000 deaths annually." See WECF, "Pesticides and harmful chemicals cause more than 900,000 deaths annually," *WECF website*, Oct. 10, 2012, at <http://www.wecf.eu/english/articles/2012/10/pesticides-africa.php>.

<sup>24</sup> David Noakes, "The Glyphosate Killer," *Health Freedom News*, Summer 2016, Vol. 34, No. 2, at p. 30.

<sup>25</sup> Dr. Joseph Mercola, "Toxic Combo of Roundup and Fertilizers Blamed for Tens of Thousands of Deaths," *Mercola.com*, April 8, 2014, at <http://articles.mercola.com/sites/articles/archive/2014/04/08/roundup-fertilizer.aspx>.

<sup>26</sup> *Ibid.*

<sup>27</sup> Sayer Ji, "Roundup Herbicide Linked to Overgrowth of Deadly Bacteria," *Health Freedom News*, Spring 2013, Vol. 31, No. 1, pp. 12–13.

<sup>28</sup> Dr. Joseph Mercola, "Roundup and Glyphosate Toxicity Have Been Grossly Underestimated," *Mercola.com*, July 30, 2013, at <http://articles.mercola.com/sites/articles/archive/2013/07/30/glyphosate-toxicity.aspx>.

<sup>29</sup> Parvez S, Gerona RR, Proctor C, *et al.*, "Glyphosate exposure in pregnancy and shortened gestational length: a prospective Indiana birth cohort study," *Environmental Health*, 17:23, (<https://doi.org/10.1186/s12940-018-0367-0>) (2018), at <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-018-0367-0>. See also Dr. Charles Benbrook "Coping with Chemical Trespass on a Grand Scale" presentation, May 14, 2018, at <https://prezi.com/view/WVs0gVpq6blQW0layDg5/>.

<sup>30</sup> Carey Gillam, "Weedkiller products more toxic than their active ingredient, tests show," *The Guardian*, May 8, 2018, at <https://www.theguardian.com/us-news/2018/may/08/weedkiller-tests-monsanto-health-dangers-active-ingredient>.

<sup>31</sup> IARC Monograph on Glyphosate, 2015, at <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-10.pdf>. (Note extensive references at the end of the Monograph)

<sup>32</sup> *The EFSA Journal* (2009) 1041, 1–52, at <http://www.efsa.europa.eu/en/scdocs/doc/1041.pdf>, accessed August 1, 2012.

<sup>33</sup> As much as 20% of Paylean (given to pigs for their last 28 days), Optaflexx (given to cattle their last 28 to 42 days), and Tomax (given to turkeys their last seven to 14 days), remains in consumer meat, says author and well-known veterinarian Michael W. Fox. (See Martha Rosenberg, "Why Has the FDA Allowed a Drug Marked 'Not Safe for Use in Humans' to Be Fed to Livestock Right Before Slaughter?" *AlterNet*, Feb 2, 2010, at <http://www.alternet.org/story/145503/>, accessed May 22, 2018.)

<sup>34</sup> See [http://news.xinhuanet.com/english/2009-12/08/content\\_12612575.htm](http://news.xinhuanet.com/english/2009-12/08/content_12612575.htm), accessed August 1, 2012.

<sup>35</sup> Scott Tips, "The Death Star Arrives, Part 2," *Whole Foods Magazine*, Nov 26, 2012, at <https://wholefoodsmagazine.com/columns/legal-tips/death-star-arrives-part-2/>.

<sup>36</sup> JECFA's risk assessments were undertaken in 2004, 2006, and 2010 and provided its recommended MRLs for Ractopamine (Ractopamine hydrochloride) in the target tissues (muscle, fat, liver, and kidney) for cattle and pigs.

<sup>37</sup> Far too many Codex delegates blindly worship at the false altar of JECFA science, believing that JECFA, like some ancient Greek oracle, infallibly proclaims the truth. This religious adulation of JECFA amongst delegates supposedly trained in science is one of the most incongruent aspects of Codex this writer has ever encountered.

<sup>38</sup> See, e.g., Melody Petersen, "As Beef Cattle Become Behemoths, Who Are Animal Scientists Serving?" *The Chronicle of Higher Education*, April 15, 2012, at <https://www.chronicle.com/article/As-Beef-Cattle-Become/131480>.