By Scott C. Tips, General Counsel, NHF

MANIPULATIVE POLITICS AT CODEX
Where Form Reigns Over Function

The Codex Alimentarius Commission (CAC) opened its 33rd session on Monday, July 5th, at the Centre International de Conferences in Geneva, with a full agenda of food-standard topics to be discussed. Except for those spells during which vice-chairmen ran the meeting for practice, the CAC Chairwoman Karen Hulebak steered the meeting down its bobsled course.

First, though, she made her opening remarks to the assembled 200-plus delegates, admonishing them that they must remember that "we are here to protect the health of consumers and ensure fair trade in food." She then bragged that "We are the most democratic and transparent food-standard setting body in the world." But that was just the starting wind in her sails as she not only went on to quote Mother Theresa, but once again trundled out her theme that "Codex is always about science and about people and helping people." Much to her displeasure, the National Health Federation would remind her of these words later.

In the meantime, many issues were dealt with during that first Monday day; and the discussions often cut the air into jagged slices rather than smoothing it out. Yet, the agenda items were relentlessly blitzed into bureaucratic submission one after another in the cool alpine air of the great meeting hall. Health was nothing more than collateral damage to this blitzkrieg. But one story will illustrate best the inherent bias at Codex meetings to adopt food standards regardless of the health consequences.

Ractopamine

Ractopamine – a beta-agonist drug given to pigs and cattle to promote protein and weight gain in them before slaughter – is our story here. This veterinary drug, developed and owned by Eli Lilly's Elanco Technology,[1] takes nutrients away from fat production and pushes them instead into muscle, creating a leaner and more-valuable animal.[2] The U.S. Food and Drug Administration (FDA) approved this drug for animal use in 2002; but three years later sent Elanco a warning letter accusing the company of withholding critical information that had led to approval.[3]

Others have their doubts too. According to the European Food Safety Authority (EFSA), ractopamine restricts blood vessels and quickens the heart. There are also concerns about its carcinogenic effects as well as its stressing 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.[4] 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.[5]

The proposed standard for ractopamine Acceptable Daily Intake (ADI) and Maximum Residue Limits (MRLs) was just one of the many standards to be considered by the Commission delegates as part of Agenda Item No. 4. Tellingly, though, its handling by the Commission was, and still is, a clear window into the dark soul of the Codex machinery.

Health versus Wealth

The supporters and opponents of this unnatural hog-muscle-growth drug generally fall into three categories, or columns. The opponents (that is, all of the European countries, Turkey, Russia, China, India, Zambia, Malaysia, and the INGO consumer organizations: Consumers International, International Baby Food Action Network, and NHF) want to protect consumers from a synthetic drug that scientific studies have shown to risk the health of humans and animals.

The supporters of the drug – and its MRLs, which would permit it to be sold throughout Codex countries – (Canada, the United States, Mexico, Australia, Brazil, South Africa, Uganda, and the so-called International Federation for Animal Health[6]) consist of two groups: (1) Those acting on behalf of large commercial interests that would definitely increase their revenue through worldwide sales of ractopamine-saturated pig-meat; and (2) Those deluded delegations who ignorantly genuflect at the altar of JECFA[7] scientific supremacy, thinking it to be the last-word, indeed the ***only*** word, in science on any subject.

Both supporters' object of divine worship is the recent JECFA scientific risk assessment of ractopamine.[8] Having conducted its risk assessment, JECFA issued its "expert opinion" on the safety of ractopamine use in meat animals and unsurprisingly – since it has been cherry-picking its experts for a decade now to arrive at pre-determined "expert" conclusions – came to the remarkable conclusion that ractopamine was "safe" at the MRLs sought by Canada and the United States. But NHF rather suspects that the first subcategory of ractopamine supporters finds cynical rather than religious solace in the JECFA findings, knowing that the game was rigged. Indeed, at this most-recent Codex Commission

meeting, and in response to objections raised by China and India, JECFA Secretary Dr. Annika Wennberg petulantly concluded her rambling *non-response* with the announcement that JECFA is "not going to revisit it [the ractopamine safety issue] again." Not surprisingly, Elanco – the Dr. Frankenstein of this drug – announced victory at Codex based in part upon JECFA's findings.[9]

Somewhat of the joker or wild card in the pack, the Chairwoman Dr. Karen Hulebak might be considered her own fourth column. She is an American, 56 years old, spawned from the loins of the U.S. Department of Agriculture, with all of the mindset and prejudices that such an origin entails. Although she professed her neutrality on the ractopamine issue, Ms. Hulebak was anything but neutral. Through her repeated, harping insistence on **process** – in this case "compromise" and "consensus" between the two major sides – she was essentially pushing the ractopamine-drug agenda. After all, if the choice is between adding rat poison to your food or not, how can you find common ground or "consensus"? You either say "no" to the rat poison or else you accept some rat poison in your food. By pushing for compromise, Chairwoman Hulebak discarded the idea that Codex was about health. Better a "result," in her book, than to worry about such niceties as health or protecting the consumer. This came to be a constant theme throughout the ractopamine discussions.

And this theme was very disgustingly parroted by various developing-nations' delegations who wrung their hands over the mere thought that Codex's credibility might be "damaged" if the delegates could not reach an agreement on ractopamine MRLs. Yes, better to have a Codex standard that injures human and animal health than to have Codex's reputation tarnished!!! The thought never entered their minds that a Codex standard that actually harms people and animals would be far more damaging to Codex's credibility than the failure to issue such a monstrosity.

The Push for Consensus No Matter the Cost

So, when the Commission reached that part of Agenda Item No. 4 dealing with ractopamine on Monday, July 5th, the Chairwoman called upon country member delegates for their points of views. The non-governmental organizations, such as the NHF, which had "flagged up" to be recognized, were never called upon to address the full Commission during this one-hour period. Instead, the Chairwoman peremptorily announced that too much time was being taken on the issue but that "given the degree of interest and the level of interest," there should be a special meeting of the interested parties that evening starting at 7:30 p.m. with a report back to the Commission at 4:00 p.m. the following day. With that, the Chairwoman stepped down, a Vice Chairman took her place, and the delegates then began discussing the next item on its Agenda.

Having dutifully waited for one-and-a-half hours after the end of the plenary (regular) session of the Commission, I then attended the truncated "special session" that Dr. Hulebak had called for discussing the ractopamine MRLs. Only 30 or so delegates attended, but these appeared to be the most interested in the subject. Dr. Hulebak acted "informally" – and "not according to FAO/WHO rules," as she put it – as the meeting's facilitator. She was addressed informally as well, often by her first name; and, according to Codex procedure, the country-member delegates spoke first. Their discussions were a replay of what they had already said in the plenary session earlier that day.

Annoyingly, though, the evening session began with another opening harangue by the Chairwoman in her best, schoolmarmish voice. "We are here," she intoned, "to try to reach consensus. Codex is advisory. No one has to adopt these standards." "What would it take to move this matter forward?" Dr. Hulebak preached from the Mount on two main themes: (1) Codex standards are ***voluntary***, so no country would be forced to accept them, hence, how could there be any objections; and (2) The delegates ***must*** reach some consensus (compromise) on this issue.

To be fair to the Chairwoman, the Codex Procedural Manual itself does instruct its chairmen and –women that they "should always try to arrive at consensus."[10] Still, the overarching twin missions stated by Codex are to protect the health of consumers and to facilitate fair trade of foods. Procedure should never trump the Mission. Yet, here was Dr. Hulebak, thumping the drum for compromise, no matter if its rhythm was discordant with Codex's Mission.

The NHF Finally Gets to Speak

When the NHF's turn finally came to speak at this special session, *many* hours after the start of the discussion during the plenary session and literally as the very last speaker to be called upon for the first time on this issue, I was wound up and did not mince words. I said, "This debate is being framed in a rigged way that is dishonest. Our goal here is not compromise and consensus; those are just tools, not an end in themselves. The goal as stated by you [indicating Chairwoman Hulebak] at this morning's opening session is 'to protect the health of consumers.' Unfortunately, there always seems to be a push for adoption no matter what. This Commission has a habit of rubberstamping, rubberstamping, and rubberstamping what has been done below in the committees. Yet sometimes there can be no compromise or consensus reached, and you just have to stand back and say 'no,' 'no more.' That is what has happened here. This product, ractopamine, has been banned in 160 countries and there are delegates here representing 2.5 billion persons who are saying no to ractopamine. This is not a safe product. Others seem to want to push commercial interest over health instead. Some have argued that if we don't approve a standard here than the credibility of the whole Codex system will be called into question. But, what will bring into question the whole system more than anything else would be to crank out a standard that leads to harming thousands of people – that would be far worse than simply failing to adopt a standard! We therefore agree with the comments of the delegates of Norway, the EU, China, and Russia, who are trying to protect the health of their citizens by taking a firm stand here against ractopamine. Thank you."

Taken aback, the Chairwoman then said that while I was entitled to my "opinion" (actually the opinion of many tens

of thousands, if not more), she was "offended." "We don't rubberstamp standards here," she claimed. When I tried to respond (since this was supposed to be an informal session, "not run by FAO/WHO rules," as she had earlier promised), Hulebak refused to let me answer. "But I thought that we were not governed by FAO/WHO rules here?" I retorted. At a loss for a response, she then quickly recognized the U.S. delegate, who proceeded to exclaim in her high and not-so-convincing voice that NHF's comments were a "fairly shocking statement!" Not to be outdone, the Canadian delegate said he, too, must take exception to the NHF's comments. "I would not discuss anything at this session that would compromise the health of the consumer," he sniffed. Right. Just ask all of the innocent victims of recent warrantless, heavily-armed raids by Health Canada that have done nothing but compromise the health and safety of Canadian consumers. We do not even have to wonder what they would say.

The special session ended minutes after the Canadian delegate's interesting disclaimer and after having arranged an early-morning follow-up meeting to draft "compromise wording," but several delegations specifically sought me out afterwards and gratefully acknowledged NHF's strong comments here. One delegation even said that they would vote for me to be chairman of the Codex meeting if they could! That was how strongly they felt on the issue.

The Push Continues

The following day, Tuesday, the ractopamine "group" had two more special sessions where they came up with no fewer than ***nine*** separate options for wording for a possible compromise standard, with the parties far apart in accepting any of the others' versions. At the Tuesday evening session, which I attended more for entertainment than for anything else, the Chinese delegate deservedly received an ovation for his willingness to compromise. But, notwithstanding this fruitless attempt and as I had predicted, these special meetings to hammer out language were either a road to nowhere or else a road to defeat for the anti-ractopamine forces.

On Wednesday, July 7th, and with failure to reach an agreement staring her in the face, the Commission re-opened discussion on the ractopamine MRLs in the general session. She briefly reported on the special session's attempts to reach an agreement and then called for comments. The countries, once again, spoke first. Among them, the U.S. delegate repeated her completely hypocritical point that "countries should not be led by their national interests here." Well, to my mind, if the U.S. was not promoting its own national interests by pushing this drug on the rest of the World, then who was?

After long back-and-forth discussions, the Chairwoman closed "the list" (meaning, no more delegations could ask for the floor other than those who had already "flagged up"). The last two delegations to speak were the INGOs Consumers International and the NHF, with once again the NHF being the last to speak.

Reconstructed from my notes, my final comments for NHF on the ractopamine MRLs were as follows: "Thank you Madame Chairwoman. We appreciate the opportunity to speak. Ractopamine is a drug that has as part of its Warning labeling the following statements: "Not for use in humans. Individuals with cardiovascular disease should exercise special caution to avoid exposure. Use protective clothing, impervious gloves, protective eye wear, and a NIOSH-approved dust mask." How does such a drug become "safe" in human food? And with no washout period? With all due respect to JECFA, and the utmost respect, JECFA puts on its pants one leg at a time just like the rest of us. They are not God. They are not perfect. There is enough other science – certainly the research conducted by China among others – to raise considerable doubts about the safety of ractopamine. There are 160 countries that have banned this drug and it has not been without reason. In fact, this draft standard should not have even reached the Commission level since the Chinese delegates to the Committee meeting were denied visas and could not even attend the meeting that led to its reference at Step 8 to this Commission! We therefore support the comments of the Chinese, EU, Russian, and Norwegian delegates, and urge that this Commission not accept these MRLs. Thank you."

And Continues

With that and the discussion concluded, Dr. Hulebak declared that this ractopamine standard "would be held at Step 8 with a plan to try to work for a solution."[11] She did, however, pull an ace out of her deck by announcing that she was invoking the "Friends of the Chair" procedure that would come up with compromise language within one year. She then shamelessly stacked the deck by weighing it heavily with "friends of ractopamine" members. Out of the thirteen-member "Friends of the Chair" ***only four*** are opposed to ractopamine MRLs: the European Union, China, Norway, and Consumers International. ***Nine*** support the drug MRLs' adoption: Japan, Brazil, Mexico, the United States, Canada, Ghana, South Africa, the International Federation for Animal Health, and the last-minute addition, Tunisia.

In an almost slapstick-comedy routine, tag-along Tunisia only raised its flag and requested being added into the "Friends of" group after the Jordanian delegate dashed over to the Tunisian delegate and whispered something into his ear. Tunisia's hand then quickly shot up to be recognized. Obviously fearing the sufficiency of the already lop-sided odds of 2-to-1 in their favor, the pro-ractopamine forces wanted yet another voice on their side.

When I had a chance to speak again, I pointed out to the Chairwoman and the Commission the very lop-sided nature of this Chairwoman's group. Failing to sense the unfairness of this fact, or more probably because of that fact, the Chairwoman left her "Friends of" group as it was, warts and all. If anyone ever doubted that Dr. Hulebak had a pro-ractopamine agenda before this move, then those doubts were most definitely buried six-feet under after this staged bit of drama.

There can also be little doubt that at the next Commission meeting, to be held in Geneva once again in one year's time, this "Friends of" group will have used everything in its bag of

tricks to coerce the four holdouts into accepting poison into our food supply. Let's support those four in holding firm against those only concerned with "national interests."

In the end, it can be said that the Chinese were the most accommodating, the Americans the least. The Canadians at times offered egg-headed comments that even the Chairwoman could not understand. The EU held firm and the consensus process stalled, like a car stuck in deep mud. Time will tell if enough money exists in this issue to get that car unstuck.

The So-Called Report

At the end of each Codex meeting, whether it is a Committee meeting or a Commission meeting, the Codex Secretariat prepares a draft report for review and correction by the assembled delegates. Many delegates will have already left for home, but it is important to remain for this seemingly-boring task because this is the only official record of what transpired at the meeting. The NHF always stays for the reading of the report.

Unfortunately, over time, these Codex reports have become increasingly useless as a record of events. Originally, Codex taped the meetings and had actual transcripts of what was said by all of the delegates and staff. Later, this practice was discarded and the current system of summarizing discussions and decisions took its place.

What we have observed more recently is that "a policy" has been put in place of not even ***naming*** those delegates who have raised objections or made points during the discussions. To an outsider, attempting to trace what actually happened at a meeting and follow who said what, this can result in frustration and even historical error. Instead of reading, for example, that the delegation of Norway stated its views on a particular standard, the report often will read instead, "One delegation said that it opposed this standard." And at this most-recent Codex meeting, when I politely asked that the NHF be named as the speaker on one particular point (even though I had not asked the same favor in two previous mentions), I was turned down because of "policy."

"We are the most democratic and transparent food-standard setting body in the world," the Chairwoman had said in her opening comments. Clearly, that is a lie.

Endnotes

1 Elanco's two other blockbuster drugs Stilbosol (diethylstilbestrol or DES), now withdrawn, and Posilac or bovine growth hormone (rBST) also became part of the United States' food supply.

2 See ***http://nationalhogfarmer.com/nutrition/ingredients/ractopamine-improves-growth-carcass-value/*** ("typical farms should expect a net return of $2-3/pig sold.")

3 The 14-page letter read in pertinent part: "Our representatives requested a complete and accurate list of all your GLP [Good Laboratory Practices] studies involving Paylean® (Ractopamine hydrochloride), including their current status as well as the names of the respective study monitors. In response, your firm supplied to our representatives multiple lists which differed in the names of the studies and their status. In addition, your firm could not locate or identify documents pertaining to some of the studies. This situation was somewhat confusing and created unneeded delays for our representatives." Moreover, the letter asks: Where was mention of the farmer phone calls to Elanco reporting, "hyperactivity," "dying animals," "downer pigs" and "tying up" and "stress" syndromes. Where was the log of phone calls that included farmers saying, "animals are down and shaking," and "pig vomiting after eating feed with Paylean"?

4 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 ***http://www.alternet.org/story/145503/***)

5 See ***http://news.xinhuanet.com/english/2009-12/08/content_12612575.htm***.

6 IFAH is a Codex-accredited INGO that is animal drug-industry created, sponsored, and controlled. See, e.g., ***http://www.ifahsec.org/Corporate%20Members.aspx?SubMenuId=11&MenuId=6&PageOrder=10&MainPageType=FS&size=***. Its president, Jeffrey Simmons, comes from Elanco. (See ***http://www.ifahsec.org/boardofdirectors.aspx?SubMenuId=10&MenuId=6&PageOrder=10&MainPageType=FS&size=***.) From its website, IFAH appears to equate animal health with drug use.

7 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. Persons in the know say that until 1999, JECFA expert groups were broadly based and of varying opinions. Since then, however, JECFA cherry-picks its experts so that it will receive the outcome that it desires.

8 See Addendum Report at ***http://www.inchem.org/documents/jecfa/jecmono/v53je08.htm***. See also http://www.inchem.org/documents/jecfa/jecmono/v31je09.htm (note that all references used by WHO were submitted to it by Elanco Products Company!).

9 See ***http://www.cattlenetwork.com/Human-Safety-Of-Ractopamine-Reaffirmed-By-Codex-Scientific-Expert-Body/2010-07-09/Article_Latest_News.aspx?oid=1151415&fid=CN-LATEST_NEWS_***.

10 See Codex Alimentarius Commission Procedural Manual (Nineteenth edition, 2010) at page 77, subheading "Consensus."

11 Step 8 is the final step in the 8-step Codex process of approval and adoption.