CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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CODEX ALIMENTARIUS COMMISSION

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(Comments by the National Health Federation (NHF))

Agenda Item 4.12

The National Health Federation (NHF) respectfully submits the following comments noted below for this CAC46's consideration in establishing the Maximum Levels for the specified pesticide residues in food and feed (**REP23/PR54)**.

Introductory Statement

There are 336 scientific articles on PubMed alone showing a correlation between exposure to **endocrine active pesticides (endocrine disruptors)** and illnesses and conditions mediated by pesticide-residue-induced inflammation: congenital anomalies, developmental and cognitive/neurodegenerative disorders, DNA and genetic damage, oxidative stress, carcinogenic effects, reproductive disorders in both man, bees, aquatic, and terrestrial species, soil and much more. Additionally, risk of miscarriage, low birth weight, hypospadias, cryptorchidism, and micropenis were significantly greater in areas with higher use of pesticides in relation to those with lower use. **It is well established that pesticide residues constitute a significant source of contamination of environmental factors such as air, water, and soil, thereby creating a continuous threat to the co-existence of plant and animal communities of the ecosystem, let alone the knock-on effects upon human health.**

A study by Pimentel (1995) showed that only a small percentage (0.3%) of applied pesticides go into the target pest while 99.7% go into the environment. **With losses due to pests leading to one-third of the World's agricultural production being lost annually juxtaposed against the degradation of entire global ecosystems by 99.7% with those pesticide residues, many of which remain in the soils years after the initial exposure, entering the environment, it is clear that this is neither wise nor sustainable,** particularly when building soils would strengthen plants so they wouldn't require the synthetic chemicals or at least not at the current usage rates. Indeed, communities have begun bans on glyphosate and other synthetic chemicals in order to preserve life and avoid the lawsuits currently underway against Bayer (and thousands more are lined up behind the first precedent-setting cases against glyphosate).

A 2015 study titled "Assessment of three approaches for regulatory decision making on pesticides with endocrine disrupting properties," noted that no specific science-based approach for the assessment of substances with endocrine disrupting properties had been agreed upon.[i] It doesn't appear that since that time, a decision has been reached either.

In short, the National Health Federation retains its position stated in the past, that pesticide MRLs are set too high, there have been no studies of ***cumulative*** and ***synergistic*** pesticide, herbicide, and chemical exposures,

and therefore the Codex Alimentarius Commission cannot set with any degree of confidence any safe level of exposure for pesticide residues.

Specific Substances

CHLORPYROFOS-METHYL (254). According to the Pesticide Action Network, Chlorpyrifos is "a neurotoxic organophosphate (OP) insecticide used in the production of fruits and vegetables throughout the U.S. … [and] has been widely studied for its neurodevelopmental effects on children. It was originally derived from a nerve gas developed by Nazi Germany.

Chlorpyrifos has been prohibited for indoor home use since 2001, but it continues to be used in agricultural fields, with an estimated 8 million pounds applied annually. According to Dow, its manufacturer, chlorpyrifos has been registered for use in 100 countries for over 50 crops.

Short-term symptoms of low-dose exposure include headaches, agitation, inability to concentrate, weakness, tiredness, nausea, diarrhea and blurred vision. Higher doses can lead to respiratory paralysis and death. Pregnant women may also be more sensitive to chlorpyrifos toxicity, according to the Agency for Toxic Substances and Disease Registry. In addition to the immediate effects of exposure, chlorpyrifos is linked to a number of serious longer-term health impacts:

- **Adverse effects on neurodevelopment:** There is a body of work around the negative impacts of chlorpyrifos (and other organophosphates) on various aspects of cognitive development. Chlorpyrifos has been well-studied in animal models and has been shown to cause a range of neurodevelopmental effects, such as impacting genes that control essential processes in developing brain cells. Exposure to low levels of chlorpyrifos or organophosphates has been shown to negatively impact various aspects of cognitive development in humans in several studies.
    - In California's Salinas Valley, a UC Berkeley study found that the group exposed to the highest levels of organophosphate during pregnancy was associated with a 7-point drop in IQ scores in 7-year-olds.
    - A Columbia University study found decreases in full-scale IQ and working memory of 7-year-olds associated with tiny increases in prenatal exposure to chlorpyrifos. Another study of the same group found that 3-year-old children with higher prenatal exposures to chlorpyrifos were more likely to experience delays in development, attention problems, ADHD problems and pervasive developmental disorder problems.
    - A UC Davis study found that mothers who live within a mile of fields where chlorpyrifos and other organophosphate pesticides were applied had a 60 percent higher chance of having children with autism spectrum disorder. The link between autism and pesticides may be that gestational exposures tip the balance towards increasing autism risk.
    - In addition, a recent study found associations between exposure to chlorpyrifos and changes to the architecture of the brain in 7-year old children.
- **Reduced birth size:** A study on pregnant women exposed to chlorpyrifos through home insecticide use demonstrated a link between in utero exposure to chlorpyrifos and decreased birth length and decreased birth weight. These effects on size were no longer significant in newborns born after 2001, when indoor residential use of chlorpyrifos was phased out. However, a 2012 study at the University of California at Berkeley found that 87 percent of umbilical-cord blood samples tested from newborn babies contained detectable levels of chlorpyrifos.
- **Endocrine disruption:** Chlorpyrifos is also a suspected endocrine-disrupting compound. Sex-specific behaviors in mice can be altered by chlorpyrifos exposure, with these neuroendocrine-disrupting effects affecting mice differently depending on their sex. Moderate doses have been shown to alter hormone levels in other animal studies. Also, chlorpyrifos has adverse effects on sperm cells and reproductive system of male rats. As shown in a 2017 study.

- **Lung and prostate cancer:** While the U.S. EPA lists chlorpyrifos as providing evidence of no carcinogenicity, recent studies suggest possible links to both lung and prostate cancer."

CHLOROTHALONIL (81) is genotoxic, as noted by the EU delegation. Moreover, (1) dietary exposure to chlorothalonil exceeds levels of concern, especially for children; (2) It has carcinogenic and endocrine-disrupting properties that are not accounted for in current risk assessments; (3) It is toxic when inhaled; (4) Chlorothalonil and its breakdown products, which have not been fully assessed for toxicity, contaminate many drinking-water sources; (5) Chlorothalonil concentration estimates in the environment exceed levels of concern for several terrestrial and aquatic organisms. In 2019, the EU did not reapprove chlorothalonil for registration with all of the uses for it ending in 2020. The main reasons for this decision were the potential for chlorothalonil breakdown products to cause DNA damage, which is linked to increase cancer risk, and the capacity of both the parent and breakdown compounds to contaminate drinking water.

Final Comments

Codex must not disregard the major health dangers posed by a multitude of pesticides, not even to mention the deadly synergistic and cumulative effect of such compounds upon human and animal health. This last concern has ***never*** been reviewed by Codex and is an existential danger to all living things on our Planet, as birth rates plummet.

The endocrine-disruption effects, due to not only massive glyphosate use but to most pesticides, herbicides, and chemicals that are reviewed and approved in CCPR, have impacted aquatic species globally and reduced sperm counts, caused hermaphrodites, and forever damaged the soils around the World. Frogs are threatened with extinction, pollinators such as the bees face the same fate, and song birds have disappeared by the millions.

Now, antibiotic resistance is well-established globally. We have nearly arrived at the point where there are no antibiotics we can turn to in the event of an emergency or crisis. This resistance is attributable, in large part, to the rampant overuse of pesticides in world agriculture. The irresponsible use of antibiotics, which should have been reserved for human and special animal use alone, have been casually and very unwisely allowed to be used universally in animal feed. Pesticides and veterinary drugs for compounds with dual uses as pesticides and veterinary drugs for use have contaminated the food supply and increased antibiotic resistance in man and beast. Coupled with factory farming and heavy antibiotic use in food production animals, now the problem has reached such a crisis that an emergency meeting of the WHO was even held. Chlorpyrifos and chlorothalonil are two of the nastier compounds used around the World. They will be the death of us if we do not get rid of them first.

[i]Marx-Stoelting P, Niemann L, Ritz V, *et al.*, "Assessment of three approaches for regulatory decision making on pesticides with endocrine disrupting properties," *Regul Toxicol Pharmacol*, 2014 Dec;70(3):590-604. doi: 10.1016/j.yrtph.2014.09.001. Epub 2014 Sep 17, at https://www.ncbi.nlm.nih.gov/pubmed/25239592.

Agenda Item 4.15

The National Health Federation (NHF), a global non-profit consumer organization, respectfully submits the following comments on the draft MRLs for Zilpaterol hydrochloride for consideration at CAC46:

Safety Issues for Zilpaterol Still Exist

The reason that there is significant **sustained opposition** to a Zilpaterol MRL is because growth promoters like Zilpaterol do not belong in animal-health husbandry:

- Growth-promoting substances do not belong in animal husbandry and many food companies – including Tyson and Merck itself – have had their own concerns about Zilpaterol causing health and behavioral problems with cattle (with Cargill/Merck even having pulled the product off the market in 2015).
- Countries such as China and Thailand have correctly pointed out that further safety and scientific data are required for Zilpaterol residues in offal tissues (see, e.g., Thailand's excellent CRD4 from CAC44 and last year's CRD7 at CAC45).
- Zilpaterol's **use in horses has already been banned**, so why are we trying to use it in cattle?
- Being a catecholamine, Zilpaterol has been implicated as a contributory cause for increased bacterial problems coming off commercial feedlots.
- No risk assessment of this dangerous chemical compound has been done in connection with other vet drugs and chemicals so there is no data on the cumulative and synergistic effects on humans or animals from the drug residues of Zilpaterol and other drugs and chemicals acting together.
- The residues in food can impact humans even at the levels currently determined by JECFA to be safe, causing tremors, heart palpitations, and other health issues.
- Consumers have the right to know and choose what they are consuming and Zilpaterol residues violate that right since they are not declared on the food.
- Given all of these problems with Zilpaterol, NHF would like to hear from Merck, the sponsor of this drug, how Zilpaterol aligns with its Environmental, Social, and Governance (ESG) goals [especially given Merck's announced commitment to the Precautionary Principle on page 14 of its ESG Progress Report].

No Risk Assessment Has Been Done Per Codex Procedural Manual

The Codex Procedural Manual very clearly states that: **"Risk assessment should be based on realistic exposure scenarios."** (See Section IV, Risk Analysis, 2(e)) This means that one or more risk assessments should have been done on Zilpaterol's synergistic effects with the other drugs, toxins, endocrine disruptors, hormones, and chemicals that animals and humans are directly exposed to in the real world. **This was not done.**

Instead**,** risk assessments were conducted addressing Zilpaterol risk in isolation. That is not a "realistic exposure scenario" in today's world where we are all bombarded not only with numerous chemicals and biological substances but also electromagnetic influences.

So, contrary to all of the claims made at CAC44 and CAC45 that Zilpaterol has been the subject of "robust" risk assessments, CAC46 actually does not have the scientific support for Zilpaterol safety that has been claimed for it.

No Consensus

Whether Codex delegates agree with NHF or not on the safety issue, one other insurmountable obstacle to advancement of the Zilpaterol MRLs is absolutely and irrefutably clear and that is that **there is No Consensus**:

- Consensus is defined as "the absence of sustained opposition."
- There has most definitely been longstanding, sustained opposition to the Zilpaterol MRLs from the European Union, Norway, Switzerland, Russia, China, Kazakhstan, Thailand, Saudi Arabia, Iran, Turkey, Ukraine, and Kyrgyzstan. Codex cannot ignore the strong opposition of a considerable portion of the World's population here!
- Claims of ***"scientific consensus"*** are without legal foundation as there is absolutely nothing in the Codex Procedural Manual to support such a narrowed view of consensus. The CPM simply says "consensus."
- Codex is the sole Risk Manager here, so it is entirely appropriate for it to accept or reject any risk assessment, for any reason whatsoever.
- Not every standard is meant to go forward. It is ***never*** a defeat for Codex to consider a standard and then decide that – upon reflection – this would not be the way to go forward. Real Science is challenge and debate and reconsideration. Real Science is not blindly moving forward "because we have to" or "because otherwise we will look bad." Codex will only project a bad image if we fail to challenge, correct, and even stop a standard when that standard fails to meet our procedural and other requirements.
- Without consensus, not even CCEXEC can advance the MRLs forward, particularly when they were only asked for advice and not action by CCRVDF25.
- It was NHF's understanding from the opinion expressed at CAC44 by Codex Legal Counsel Claudia Nannini to the delegates on November 12, 2021, that CAC may not be able to come to a conclusion on this matter and that it should be postponed. This supports NHF's position that there is no consensus, and her advice should be followed.

It's All About the Money

Regardless, whether you believe that non-therapeutic Zilpaterol is safe or not safe is ***irrelevant*** here. This is not a product that will add to the safety of our food supply. It will not make any one or any animal one tiny bit healthier. What Zilpaterol does is to help increase the profits of a **$260 billion** drug company. They don't need the extra money.

No Voting

There may be some member states that will call for a vote on these MRLs at CAC46, which is ***highly disfavored*** as a procedural move. As everyone here knows, the Codex Procedural Manual calls for guidelines and standards to advance towards adoption based upon the consensus of the members present.

- Do not forget the very destructive fight over Ractopamine at the Rome meeting in July 2012, which led to several influential delegations angrily threatening to leave Codex! We do not want a repeat of that here!
- And if CAC46 shoves this standard down the World's throats, this could happen again, maybe not at CAC46 but certainly when Step 8 adoption is debated.

Conclusion

The MRLs for Zilpaterol cannot be advanced at all for at least two major reasons:

1. No risk assessment based upon ***realistic*** exposure scenarios has been conducted on Zilpaterol residues in accordance with the Codex Procedural Manual, so safety issues for this veterinary drug are still in question; and
2. No consensus exists at CAC46 to advance the MRLs to Step 5.

In the face of such sustained opposition (i.e., "no consensus"), CAC46 only has two choices here – no matter how many of its delegates might wish otherwise – it can either discontinue work on this standard or it can keep it at Step 7.

Moreover, it constantly amazes NHF that Zilpaterol – which is not therapeutic in any way, indeed it harms many animals, and is only intended to increase drug sales – has elicited such fierce support from certain Codex delegates. We remind everyone that the motto of Codex after all is “Safe, Good Food for Everyone” and not “More Sales for Industry.”