EU Opposition to Maximum Residue Levels (MRLs) for Ractopamine in Codex

The EU has consistently opposed the adoption of standards for ractopamine. The EU first tried to block progress in the Codex Committee on the Residues of Veterinary Drugs in Foods (CCRVDF) and then, following the CCRVDF's recommendation that Codex Alimentarius Commission adopt the draft MRLS for ractopamine, the EU has blocked adoption at the Commission level. It is useful to examine the rationale for the EU's position, which runs counter to the independent safety assessments.

The proposed standards, expressed as maximum residue levels (MRLs), were developed by the independent scientific expertise of the Joint Expert Committee on Food Additives (JECFA). JECFA completed thorough analyses of the toxicology, expected residue levels, and estimation of dietary intake of ractopamine for pig and beef meat, liver, kidney and fat and determined ractopamine to be safe.

The EU's opposition to the adoption of ractopamine MRLs was presented in the 2007 CCRVDF meeting:

> "The Delegation of the European Community, making reference to their written comments in CRD13 [conference room document] ,stated that they could not support the advancements of the MRLs to Step 8 in view of the fact that their [EU] legislation did not allow for the use of beta-agonists for growth promotion."[1]

At that meeting, the CCRVDF decided to advance the draft standards to the Commission for adoption, noting that the EU's objection was not based on the Codex principles of scientific evidence. The EU blocked adoption at the Commission level, however, and tried to find a scientific rationale to support the EU position as follows:

> "The Delegation of the European Union declared that they remained opposed to the adoption of the MRLs for ractopamine because the European Union was opposed to the use of drugs intended solely for growth promotion without any therapeutic purposes and was of the opinion that there were still unanswered safety questions and scientific concerns linked to the use of ractopamine"[2].

The "scientific uncertainty" referred to a report[3] commissioned by the EU of its European Food Safety Authority (EFSA) to review the JECFA report for any scientific uncertainties, as well as new data submitted by China that the EU said must be evaluated.

JECFA subsequently examined the data provided by China and concluded that the new data was, in fact, consistent with prior data and that there was no reason to change the previously recommended MRLs. JECFA did observe that if diets in China included a significant amount of lung tissue, which is not accounted for in the JECFA dietary intake assessment, a separate MRL for lung may be needed. JECFA noted, however, that this had no impact on the previously recommended MRLs for cattle or pig meat, liver, kidney and fat.

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[1] Paragraph 46 from the Report of The 17th Session Of The Codex Committee On Residues Of Veterinary Drugs In Foods. A similar rationale was also given at the 31st Session of the Codex Alimentarius Commission.

[2] Paragraph 57 from report of the *Thirty-Third Session* of the Codex Alimentarius Commission

[3] Safety Evaluation of ractopamine:, Scientific Opinion of the Panel on Additives and Products or Substances Used in Animal Feed.The EFSA Journal (2009) 1041, 1-53.

As for the EFSA report, which argued that the study JECFA chose for the establishment of no-effect levels and the MRLs was inadequate, the JECFA secretariat defended the its analysis noting that the JECFA assessment considered multiple mutually supportive studies and did not rely on a single study.[4]

It is useful to examine more closely the EU's initial objection to the use of ractopamine. If the EU were to accept the proposed ractopamine standards and allow the adoption of Codex MRLs, this would create a conflict with an EU law passed in 1996[5] that banned the use of certain classes of compounds covered by that law without any consideration of the possible safe and prudent use of other similar compounds. Ractopamine was first approved for use by the U.S. FDA in 1999, well after the EU established its ban on the entire class of growth promoting compounds. There were earlier EU directives that banned the use of hormones, but this directive also extended the ban to beta agonists.

The specific rationale for the EU's action was given in the preamble:

> "(4) Whereas new substances having an anabolizing action such as beta-agonists are used illegally in livestock-rearing with a view to stimulating the growth and yield of animals;
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> (5) An enquiry … show[s] that beta-agonists are widely available in the livestock rearing sector, leading to their illegal use;
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> (6) Whereas the improper use of beta-agonists can be a serious risk to human health…"

The import of products is covered under Article 11:

> "11.2. Member States shall also prohibit the importation from third countries
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> (a) of farm or aquaculture animals
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> (b) meat or products obtained from animals which could not be imported under point (a)
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> To which substances referred to in point (a) of Article 2 [including beta-agonists] have been administered, unless done for a very limited list of therapeutic treatments."

In short, the EU's rationale for banning all beta-agonists was that "some beta-agonists were being used illegally" and that "*improper use* of beta-agonists can be a serious risk to human health". There are, certainly, beta agonists that are not appropriate for use as routine feed additives. However, there is no scientific analysis that establishes that all beta-agonists cannot be safely used under any conditions. (There are about 40 beta-agonists.)

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[4] Paragraph 18 from the Report of the 18th meeting of the Codex Committee on the Residues of Veterinary Drugs in foods. "18. The WHO JECFA Secretariat noted that EFSA did not perform a risk assessment but reviewed the JECFA assessment, and that no new data were reviewed. In response to concerns related to the ADI, the WHO JECFA Secretariat explained that JECFA, in general, when evaluating compounds applies an overall weight-of-evidence approach and reaches its conclusions considering all relevant studies. In the case of ractopamine, the ADI was established based on a human study, as the most relevant study for human health risk assessment, however the most relevant animal studies (in monkeys) were also considered and these supported this ADI".

[5] Directive 96/22/EC "concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists

It is evident that the EU's domestic legislation makes it difficult for the EU to participate in the Codex process in good faith and to follow accepted Codex norms and procedures for making science-based decisions. The EU delegation clearly would have a very hard time advancing a position in Codex that would create an internal legal conflict.

Further context on the EU's actions is provided in the following excerpts from the report of the 2011 meeting of the Codex Alimentarius Commission, which reflect the views of the large number of Codex member countries that support adoption:

> *95. The delegations which supported the adoption of the draft MRLs emphasized that JECFA had reviewed the MRLs three times and fulfilled its task by considering all available data and noted that these MRLs could be reviewed in the future in the light of new scientific data. It was also pointed out that the draft MRLs were based on JECFA risk assessment, as prescribed in the Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods included in the Procedural Manual, and that the concern of China regarding residues in lung was not within the scope of the draft MRLs currently under discussion. These delegations also underlined the conclusion of JECFA that these MRLs were compliant with the ADI and safe and reiterated their confidence in the science-based work of JECFA, and expressed concern about the precedent that could be set, undermining the work of JECFA and risk assessment.*
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> *96. These delegations further highlighted their concerns on the long delay to adopt the MRLs based on nonscientific factors and stressed the need for Codex to base its decisions on science, in view of the status of Codex standards under the WTO SPS Agreement. They recalled that many countries used Codex standards as the basis for their national legislation and that failure to adopt the MRLs for ractopamine could negatively impact on food security as the establishment of MRLs for ractopamine would allow the safe use of new technologies to meet the increasing demand for food production foreseen by FAO. It was also stated by many delegations that all Codex steps had been followed in the elaboration of the MRL for ractopamine.*
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> *97. The Delegation of the United States of America noted that no government would be required to permit the use of ractopamine but would be able to allow imports, confident that the imported meats are safe for consumers when the exporting country has produced the food according to Codex standards.*