Agenda Item 2 Critical review – Part II

8. MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle)

According to the report of the CCRVDF25 (2021), the conclusion of maximum residue limits for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle) was that the Committee was unable to reach consensus of either advancing the MRLs to Step 5 or 5/8 or to retain them at Step 4. The Chairperson further noted that all efforts had been exhausted in the CCRVDF to reach consensus. Also, the Chairperson reiterated the views of CCRVDF about the safety of the zilpaterol MRLs and the support of the JECFA scientific evaluations while recognizing that some members disagreed.

In CCRVDF24, CAC41, and CCRVDF 25, several countries including Thailand have expressed concerns and reservations in advancement of the proposed draft MRL for zilpaterol in the Step procedure.

Thailand would like to reiterate our concerns on two important issues as follows:

1. Thailand has no objection to the scientific evaluation results of Zilpaterol hydrochloride based on global dietary exposure in liver, kidney and muscle of cattle carried out by JECFA. However, some Codex member countries as well as Thailand have a serious concern on safety of public health due to the fact that their general population highly consume offal, which includes but are not limited to lung, tripe, large stomach, brains, heart, kidney and liver. At the moment, only two types of offal tissues have been assessed by JECFA. If Zilpaterol hydrochloride is administrated to food-producing animals, the residues could be distributed through all animal tissues and thus may be a health concern for consumers. Moreover, additional scientific data and information on the other types of offal are needed and should be considered but this type of toxicological and monitoring information cannot be obtained by the countries at which the use of substance is prohibited and unregistered. In addition, Codex should also take into account other safety concerns that have been raised during the CCRVDF25 such as exposure to multiple chemicals from multiple food sources.

2. Apart from further safety and scientific data required, Codex as the risk manager should carefully and thoroughly take into consideration the other legitimate factors relevant to fair practices in food trade, which is in line with the Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to which Other Factors Are Taken into Account mentioned in the Procedural Manual. Even though Codex standards are voluntary in nature but the implication as reference standards accepted under the WTO’s Agreement on the Application of Sanitary and Phytosanitary Measures, heightens the importance. The adoption of MRLs for Zilpaterol hydrochloride by Codex would signal that the use of this substance is globally accepted. In this case, Codex should also consider different regulations of member countries in order to avoid disputes in the international trade. Countries in different continents, such as European countries as well as Thailand, prohibit the administration of beta-agonists or the use of veterinary drug as growth promoter that also enhance the use of veterinary drug prudently and responsibly.

In summary, Thailand is of the opinion that Codex should carefully and thoroughly consider this issue and identify risk management options in order to find an appropriate path for consensus, based on concerns and other legitimate factors which are related to scientific data affecting consumer health and fair practices in the future food trade. Codex should also consider possible approach from the document CX/EXEC 19/77/10 discussed during CCEXEC77. Furthermore, the discussion should be based on the guidance document about the application of Statements of Principle Concerning the Role of Science which is under development of the sub-committee of the CCEXEC for consistency.