Divergent position on a CVMP opinion on the establishment of maximum residue limits

For extension of fluazuron for fin fish (automatic extrapolation to milk)

Procedure no: EMEA/V/MRL/003471/EXTN/0002

We, the undersigned, have a divergent position to the outcome of the extrapolation and establishment of an MRL for fluazuron for milk.

The Regulation 2017/880, which establishes minimum criteria for derivation of MRLs between species and foodstuffs, does not exclude the need for decisions based on a sufficiently comprehensive and relevant set of data.

Going through the article 7 of this regulation, point (e) states that consideration of the physicochemical characteristics of the active substance and possible accumulation in milk should be given.

Reading summary reports and the assessment report that was prepared for the current procedure, the following can be summarised:

- We do not have accessible any relevant scientific information concerning the behaviour and fate of fluazuron in milk, nor are literature sources of information on residues depletion data in milk available.
- No data concerning the depletion of the substance from milk have ever been submitted over the years and there is no evidence to indicate that there is any intention to submit such data.
- The CVMP has estimated the safe level based on a mathematic calculation only (even if the conclusion is that exposure does not represent a sizable part of the ADI). The approach of establishing an MRL value without any appropriate data and waiting to see what will happen in future is unacceptable for safety of food production.

From our point of view, no appropriate data are available for relevant risk assessment and successful risk management. A full data package needs to be submitted in order to allow establishment of a MRL for milk.

Furthermore, unavailability of fluazuron for the treatment of dairy cattle does not represent an availability problem as there is a range of available medicines for treatment of dairy cattle.

For the purpose of managing possible residues from third countries then we can use the draft Commission implementing regulation on the maximum residue limits to be considered for control purposes for foodstuffs derived from animals which have been treated under Article 11 of Directive 2001/82/EC. In such a case, the value of 200 µg/kg should be applicable and be used.

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London, 5 October 2017