codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel.: +39(06)57051 Telex: 625825-625853 FAO I E-mail: Codex@fao.org Facsimile: +39(06)5705.4593

WORLD HEALTH ORGANIZATION

Agenda Item 4

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS Twelfth Session Washington, D.C., 28 - 31 March 2000

RISK ANALYSIS PRINCIPLES AND METHODOLOGIES OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

ELABORATION OF A RISK ASSESSMENT POLICY BY THE CCRVDF (Prepared by France)

As requested during the 9th meeting of the CCRVDF held in Washington, France prepared a 1. report recommending the integration of a scientific risk analysis approach into the work of the CCRVDF. This text, which was successively presented at the 10th meeting of this committee in San Jose (Costa Rica) and at the 11th meeting in Washington, did not give rise to objections and the French delegation was requested to propose priority actions regarding risk management to be considered by the CCRVDF at its 12th meeting which will be held in Washington in March 2000.

The report presented by France at the 11th meeting of the CCRVDF indicated that the CCRVDF 2. had not yet elaborated a risk assessment policy for public health exposed to drug residues susceptible to contaminate food of animal origin and indicated that it was necessary to do it urgently.

3. The Codex noted this gap and recognised that:

- it was necessary to elaborate a risk assessment policy in order to provide a precise context for _ the risk assessment work carried out by scientific experts
- this risk assessment policy was a component of risk management and thus had to be elaborated by the relevant decision-makers with the technical support of scientific experts in risk assessment.

4. Consequently, the priority actions suggested for managing the risks pertaining to residues of veterinary drugs in food are related with the elaboration of such a risk assessment policy.

The work to be done by the CCRVDF should be facilitated since JECFA had to structure its 5. method for assessing the safety of residues of veterinary drugs in order to

- scientifically justify the MRLs suggested
- ensure the consistency of the assessments and establishments of ADI and MRLs over time
- provide the expected guarantees regarding transparency and equity.

6. To reach all these objectives, JECFA elaborated during its meetings a document which can be used as an appropriate basis by the CCRVDF to define a risk assessment policy.

7. This document is entitled "JECFA guidance and procedure for recommending maximum residue limits for residues of veterinary drugs in food".

8. The following complementary documents, which result from the application of the method described in this general text to particular cases, should also be taken into account by the CCRVDF in order to elaborate this risk assessment policy.

- (a) Assessment of microbiological risks
- (b) Establishment of MRLs for minor species, fish and honey
- (c) Tissues for which MRLs have to be established
- (d) Validation of analytical methods intended to control MRLs
- (e) Harmonisation of MRLs for substances used both as veterinary medicinal products and as pesticides
- (f) Statistical methods to determine MRLs
- (g) Relationships between MRL values and limits of quantification of analytical methods
- (h) Establishment of MRLs for lipophilic substances

9. The close examination of these different texts, which represent more than hundred pages of technical considerations, and the final elaboration of a coherent consolidated text, which will make it possible to express an operational and comprehensible risk assessment policy, will constitute a major workload.

10. France consequently suggests that the CCRVDF adopts a working method adapted to the stake by creating an ad hoc working group similar to the two already existing groups which deal with priority substances and analytical methods. This group would carry out this difficult work and present a report in the plenary session of the CCRVDF which could be commented and then adopted when the time comes.

11. If the CCRVDF considers it appropriate, France, which has been in charge of this report, is available to pursue the task that the committee entrusted it during its 9th meeting by co-ordinating the work to be done by this group with the support of the delegations interested in this project.