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New requirements of safety for the additives

G. Bories
INRA, Laboratoire des Xénobiotiques,
Chemin de Tournefeuille 180, 31300 Toulouse, France

SUMMARY - The scientific context of food safety has not changed dramatically. The perception of the situation is certainly biased by a lack of historical and distortion by the media. Food is one of the most important links between human beings and nature. The overall animal production system (e.g., seeding conditions including feed additives) is questioned. The increase of scientific knowledge in toxicology improves consumer safety, but at the same time sheds new light, and suddenly new dangers appear. A loss of confidence in science and politics is observed. At European level feed additives are undergoing a process based on the determination of $NOEL_s$ (no effect level) from toxicological data, and ADI (acceptable daily intake) derived from the application of safety factors. Moreover, MRL_s (maximum residual limits) for every edible tissue will be fixed. In order to improve the independence and transparency, the EU DG XXIV dealing with Consumer protection has been recently entrusted with risk assessment.

Key words: Additives, animal feeding, risk assessment.

RESUME - *"Nouvelles exigences de sécurité en matière d'additifs". Le contexte scientifique de la sécurité alimentaire n'a pas changé de façon spectaculaire. La perception de la situation est certainement biaisée par le manque de recul historique et la distorsion des médias. Les aliments sont l'un des liens les plus importants entre l'être humain et la nature. Le système global de production animale (c'est-à-dire les conditions d'ensemencement ainsi que les additifs alimentaires) est remis en question. Les connaissances scientifiques grandissantes en toxicologie améliorent la sécurité du consommateur, mais en même temps mettent à jour des éléments qui apparaissent comme de nouveaux dangers. On remarque une perte de confiance dans le domaine de la science et la politique. A l'échelle européenne les additifs alimentaires sont en train de subir cet effet. Ce processus est basée sur la détermination des NOELs (no effect level - niveau sans effet) à partir des données toxicologiques, et des ADI (acceptable daily intake - ingestion journalière acceptable) entraînés par l'application des facteurs de sécurité. De plus, on fixera des MRLs (maximum residual limits - limites maximales de résidus) pour chaque constituant consommable. Afin d'améliorer l'indépendance et la transparence, la DG XXIV, qui s'occupe de la protection du consommateur, a été récemment chargée de l'évaluation des risques.*

Mots-clés : *Additifs, alimentation animale, évaluation des risques.*

The scientific context of food safety has not changed dramatically in recent years when referring to the general increase of life expectancy. The perception of the situation is certainly biased by a lack of historical perspective and a distortion by the medias. Dramatic episodes such as BSE or hemorragic enterocolitis have brought back to memory that we are surrounded by dangers, and must be vigilant and prepared to control risks better. Considerable concern has resulted for the public due to the fact that in a world in deep transformation, food is one of the most important links between the human beings and nature. Moreover, severe criticisms are advanced against the intensive production of animal products and environmental issues, animal welfare and feeding conditions including the use of feed additives. As a consequence, the overall animal production system is questioned, implying important economical consequences, but perhaps even worse an uncertainty for the future.

Legislation is the reflect of the art in science and the society at a given time. The increase of scientific knowledge in all the multidisciplinary areas of toxicology certainly improves consumer safety, but at the same time shed new light on already existing phenomena that where ignored, that suddenly appear as new dangers. The hidden risk, either voluntary or by omission, is stigmatized by the public today. A loss of confidence in science and politics is observed. It is therefore difficult to move from the zero risk concept which has the public's favour, to the realistic and science based toxicological acceptable level of risk.

The international trade agreement under WTO auspices withdraw the barriers to food free exchanges progressively, but food safety concerns, if sufficiently supported, are the only legal barrier left that states may oppose to protect their citizens. If such safeguard clauses are fully justified, they may also be used to exert a pressure and slow down the decision process.

Under the pressure of WTO, a harmonization of the toxicological evaluation of chemical and bio-products used in plant and animal production is taking place. At the European level feed additives are entering this procedure. It is based on the determination of NOELs (no effect level) from toxicological data, and ADI (acceptable daily intake) derived from the application of safety factors. If this approach was already implicit in the toxicological evaluation of feed additives, based on the data required through the Council Directive 87/153 fixing lines for the assessment of additives, it will become mandatory in the near future (Commission Directive amending Council Directive 87/153), in the same way as for veterinary drugs and pesticides. A general re-assessment of additives according to on-coming revised Guide lines will certainly lead to the disappearance of old molecules that will lack sponsors to complete the files according to the up-dated requirements. Moreover, MRLs (maximum residual limits) for every edible tissue will be fixed, based on toxicological and practical (field) considerations. It must be noted that national and independent international bodies (FAO/WHO, Codex alimentarius) proceed separately, but that consensus positions are found progressively. As part of the basic requirements, considerations for the impact of feed additives on the environment will be required. Re-assessment of feed additives on a 10 year basis will be mandatory.

In order to improve the independence of the experts and transparency of the decision process, the EU Direction XXIV dealing with Consumer protection has been recently entrusted with the layout of risk assessment. Therefore a clear separations is made between risk assessment and risk management (Good Manufacturing Practices, control policy, labeling) that remains with the operational Directions like Agriculture or Environment. A Scientific Steering Committee coordinates eight Scientific Committees (the Scientific Committee for Animal Nutrition being one of these) and deals with scientific matters that require a wide horizontal expertise. Similar initiatives are being taken at the country level, for example in the UK and France, to create Food Safety Agencies.