

Beyond zero tolerance: a new approach to food safety and residues of pharmacologically active substances in foodstuffs of animal origin

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Following their article on zero tolerance published in [2003] 6 *Environmental Liability*, the authors here propose a new approach to food safety regulations on residues of pharmacologically active substances in foodstuffs of animal origin. Key aspects of their proposal are a risk-based approach instead of a precautionary approach so as to preclude trade barriers, and a prohibition classification based on proof of toxicity of low-level exposure to food residues. This precludes a probatio diabolica resulting from proof of absence of food residues, such as is now the case with Annex IV of Council Regulation 2377/90.³ Regulation based on these two principles would genuinely address food safety, as its focus is on risk. This is highly desirable in view of an international level playing field for trade, as it would by definition rule out trade barriers masquerading as food safety regulations, and would harness the inevitably advancing analytical field in its proper context, whereby all sources of residue, such as environmental ones, would be taken into account.

Introduction

In our previous paper on chloramphenicol ('CAP') and food safety in Europe we showed that current legislation on banned veterinary substances does not properly address food safety as such.⁴ The opening remark of a Reflection Paper, part of an internet consultation by the EU on veterinary residues, that 'residues of pharmacologically active substances in food of animal origin are essentially a

side-effect of the use of medicines in food-producing animals' has been shown to be false for CAP and has proved false for other veterinary substances as well.⁵ Semicarbazide ('SEM') is the most recent example. This supposed marker molecule for nitrofurans, a banned group of veterinary substances listed in Annex IV of Council Regulation 2377/90⁶ proved to have sources other than the banned substances as a result of which it lost its legal status for demonstrating illicit use of this group of antibiotics.⁷

The response of the European Food Safety Authority ('EFSA') on the issue of SEM in packaged food showed that a risk-based approach to the presence of 'added' carcinogens contributes considerably to reasoned and logical risk assessment, management and communication strategies on food safety.⁸ This response stands in stark contrast to the precautionary legal and political response resulting from the detection of Annex IV substances in food products, which was discussed and critically commented on by Hanekamp *et al.*⁹ That article showed that the human and natural environment is a multiple source of residues, which are frequently, but incorrectly, attributed to veterinary intervention only.¹⁰ In addition, the Reflection Paper comments that:¹¹

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3 Advice of the *ad hoc* expert group set up to advise the European Food Safety Authority (EFSA) on the possible occurrence of semicarbazide in packaged foods: European Food Safety Authority, Brussels, 2003.

4 J.C. Hanekamp, G. Frapport and K. Olieman, 'Chloramphenicol, food safety and precautionary thinking in Europe' [2003] 6 *Env Liability*, 209 to 221.

5 Reflection Paper on Residues in Foodstuffs of Animal Origin: European Commission, DG Enterprise, DG Health and Consumer Protection, 2004, at 4.

6 Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a Community procedure to set up maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, OJ 1990 L224/1-8, 18 August.

7 M. Mandix, letter dated 11 November 2003 from Dr Wiertz, Dipl.Chem. Eggert, Dr Jörissen GmbH, Laboratory for Trade and Environment.

8 See Note 3 above; P. Slovic, *The Perception of Risk* (2001), London: Earthscan Publications Ltd; J. Flynn, P. Slovic and H. Kunreuther (eds), *Risk, Media and Stigma. Understanding Public Challenge to Modern Science and Technology*, London: Earthscan Publications Ltd, 2001.

9 See Note 4 above.

10 See Note 4 above.

11 See Note 5 above at 1.

Existing legislation on pharmacologically active substances used in veterinary medicinal products ... significantly contributed to the decreased availability of medicines for uses in food producing animals in the European Community. Moreover its construction has led to various problems related to the implementation and enforcement of legislation related to the control of residues in foods of animal origin. These have also led to difficulties in the functioning of the Single Market and in international trade.

This section of the Reflection Paper reveals only part of the present problematic state of affairs within the European trade zone concerning residues of pharmacologically active compounds and its impact on other trade relations outside the EU. The zero tolerance issue is not considered in this document, despite the fact that the matter is of overarching concern in the international trade in food. The present article fully addresses the issue of zero tolerance and introduces a number of innovative legislative tools that tackle banned substances rationally. The basis for these tools is as follows:

- they are focused on food safety to measurably guarantee human health;
- they contribute to an international economic and regulatory level playing field;
- they are sensitive to novel advances in the pharmaceutical and food/feed industry.

Food for thought: recapitulating on the zero tolerance issue

The detection in 2001 of CAP in shrimp imported into Europe from Asian countries was presented as yet another food scandal. The initial European response was to close European borders to fish products, mainly shrimp. Some European countries went so far as to have food products containing the antibiotic destroyed.

The legislative background to this response is to be found in Council Regulation EEC No. 2377/90, which was implemented to establish maximum residue limits ('MRLs') of veterinary medicinal products in foodstuffs of animal origin.¹² This so-called 'MRL Regulation' introduced Community procedures to evaluate the safety of residues of pharmacologically active substances according to human food safety requirements. A pharmacologically active substance may be used in food-producing animals only if it

receives a favourable evaluation. If it is considered necessary for the protection of human health, MRLs are established.

Council Regulation EEC No. 2377/90 contains an Annex IV listing pharmacologically active substances for which no maximum toxicological levels can be fixed. From a regulatory point of view, any exposure to these compounds is deemed a hazard to human health. These substances are consequently not allowed in the animal food-production chain; a ban is in force concerning these veterinary substances. Consequently, zero tolerance is in force for Annex IV. The reasons for this are obvious:

- the absence of an acceptable daily intake ('ADI'), and therefore an MRL, was understood to be 'dangerous at any dose' which 'required' zero tolerance regulation;
- with the introduction of zero tolerance, it was believed a veterinary ban on Annex IV compounds (such as CAP) is effective for the listed compounds to disappear from the food chain, as only veterinary use was given as a source;
- earlier analytical equipment was not adequate to perform current tasks of detection (limits of detection ('LODs') developed from parts per million (ppm) to parts per billion (ppb) and parts per trillion (ppt)).

CAP and other Annex IV substances should not be detected in food products at all, regardless of concentrations. The presence of CAP in food products, which can be detected by any type of analytical apparatus, is a violation of European law and moreover deemed to be a threat to public health. Consequently, food containing the smallest amount of these residues is considered unfit for human consumption. To all intents and purposes, zero tolerance is best understood as zero concentration. Only when Annex IV substances are completely absent from food (zero concentration) are the risks deemed to be completely absent.

Although a ban might legally translate logically into a zero tolerance paradigm, in reality this is fraught with complications. As we have shown in our previous article, the presence of CAP in food could be traced to multiple sources not included in current legislation. Both natural and environmental sources of the banned substance could be identified. Other examples of multiple sources emerged during our research on CAP, such as the semicarbazide case.¹³ These examples challenged the effectiveness of MRL legislation, especially when banned substances are considered. Food safety regulation on veterinary residues

¹² See Note 6 above.

¹³ See Note 4 above.

degenerated into fraud prevention and gave rise to trade barriers masquerading as precautionary food safety measures.

The recent 62nd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JEFCA) addressed the CAP issue, implicitly referring to the article by Hanekamp *et al.*¹⁴ The committee drew the following conclusions:¹⁵

There was no evidence supporting the hypothesis that chloramphenicol is synthesized naturally in detectable amounts in soil. Although this possibility is highly unlikely, data generated with modern analytical methods would be required to confirm this; there was evidence that low concentrations of chloramphenicol found in food monitoring programs in the year 2002 could not originate from residues of chloramphenicol persisting in the environment after historical veterinary uses of the drug in food producing animals. However, due to the high variability of the half-life of chloramphenicol under different environmental conditions, such a mechanism might occasionally cause low-level contamination in food; valid analytical methods are available to monitor low levels of chloramphenicol in foods. However confirmatory methods require sophisticated and expensive equipment.

It is remarkable that the committee did not address a number of crucial issues (raised by Hanekamp *et al.*) such as the human use of CAP, which could result in traceable amounts in surface waters, as demonstrated by Hirsch *et al.* for German surface waters.¹⁶ For the United Kingdom, for instance, Webb calculated the predicted environmental concentration (PEC) for human clinical use of CAP. The clinical CAP use in the United Kingdom was estimated to be 377 kg/year. This annual consumption of CAP resulted in a PEC of 0.07 µg/l.¹⁷ It is a gross omission that the JECFA did not address the human medicinal use of CAP and its environmental impact whereby food might potentially be contaminated.

That historical veterinary CAP use would not constitute an overall sustained environmental source for food

contamination is a trivial observation made by the JECFA committee. Astoundingly though, the committee does surmise, in contrast to their initial statement, that historical veterinary CAP use might yet on occasion be an environmental source of food contamination; the multi-source aspect that we introduced above surfaces here unmistakably, albeit selectively. Indeed, if historical veterinary CAP use would on occasion constitute an environmental source for food contamination, then it would be inherently logical to designate present-day human medicinal use as an equally valid source for food contamination, all the more so since present-day human medicinal use of CAP is a much more plausible environmental source for food contamination than past veterinary use. CAP present in the environment as a result of past veterinary use would under environmental conditions vanish over time despite the varying half-life in different environmental circumstances. Human medicinal use conversely is an invariable constant source of contamination of the aquatic environment in particular, unlike past veterinary application. For Asian countries this is all the more pertinent, as human CAP consumption in this region is manifestly higher than in western countries.¹⁸ In its analysis of the CAP issue the JECFA committee acknowledges the multiple source issue we introduced in our previous paper yet for no apparent reason limits the issue to the historical veterinary context and so manifestly fails to take its own argument to its logical conclusion.

In addition the JECFA committee does not address the issue of false positives, which seriously impacts upon global trade. With zero tolerance, compliance and non-compliance are first and foremost dependent on the state of the analytical art. We need not go into detail here, as we addressed this issue quite extensively in our previous article.¹⁹ Finally, the JECFA committee argued that natural production of CAP in soil would not be detectable, so it could not function as a source for food contamination. This is a tenuous statement clearly at odds with our own findings.²⁰ The analysis (presented in our previous article) of numerous foodstuffs for the presence of CAP was also not discussed.

Zero tolerance is contrary to empirical reality and constitutes a *probatio diabolica* for industry; by definition,

14 See Note 4 above.

15 Joint FAO/WHO Expert Committee on Food Additives, 62nd meeting, Rome, 4–12 February 2004.

16 R. Hirsch, T. Ternes, K. Haberer and K.-L. Kratz, 'Occurrence of antibiotics in the aquatic environment', (1999) 225 *The Science of the Total Environment* at 109 to 118.

17 S.F. Webb, 'A data-based perspective on the environmental risk assessment of human pharmaceuticals II – aquatic risk characterisation', in K. Kummerer (ed.), *Pharmaceuticals in the Environment. Sources, Fate, Effect and Risks*, 2001, at 203 to 230.

18 IPCS-INCHEM (Chemical Safety Information from Intergovernmental Organisations), webpage <http://www.inchem.org/documents/jecfa/jecmono/v33je03.htm> (last visited on 15 January 2004).

19 See Note 4 above.

20 Hazardous Substances Data Bank <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB> (last visited 15 January 2004); AINIA, *Presence of chloramphenicol in foods* (2003). (This report can be obtained through the authors; see Note 4 above.)

proof of absence of Annex IV substances (or any other chemical substance for that matter) is unachievable. Legislators clearly did not contemplate the advent of precise analytical machinery, which made zero tolerance legislation an artefact of technological and scientific ingenuity. As the Reflection Paper remarks:²¹

Until the mid-1960s the general idea of food safety meant that food should not contain any potentially harmful residues of veterinary medicinal products. This was a realistic goal because at that time residues could only be determined in concentrations of around 1 mg/kg [ppm]. Since then the availability and sensitivity of methods of analysis has continuously improved and the detection of concentrations as low as 1 ng/kg [ppt] are frequently state of the art today. These improvements mean that ever lower amounts of residues are detected, which would previously have gone undetected.

Annex IV compliance and food safety: a dichotomy

The 'vanishing zero' has become a reality. This has shown that food products compliance, meaning that tested food products did not show, after analysis, any regulated substances to be present, is quite different from 'safe food'. In general the entire toxicological profile of food, which can be regarded as a mixture of numerous chemicals (including natural carcinogens and anti-carcinogens, pesticides, veterinary residues²²), is not changed measurably by the presence of veterinary residues. (We have discussed this issue with the aid of a table depicting various food safety issues in relation to their relative importance.²³) This is particularly true for banned substances as these are usually detected, if at all, at very low concentrations usually in the ppb ($\mu\text{g}/\text{kg}$ product) or even the ppt (ng/kg product) range. Food safety as such is by any standard not determined by the detectable presence of banned substances.²⁴

Moreover, a ban such as in the case with CAP is often the result of risks materialising at therapeutic concentration levels; the (extremely low)²⁵ risk of aplastic anaemia (and possibly leukaemia) resulting from CAP exposure surfaced only as a result of clinical use with an exposure level at least 150 million times higher than food-residue exposure. Extrapolating high exposure risks to low levels found in food-products is fraught with imprecision and usually relies on linear extrapolation models, which are to be regarded as quite conservative.²⁶ It is safe to say that the risks involved are usually grossly overestimated. Therefore it seems logical to modify legislation dealing with banned veterinary substances. Below we will propose innovative legislative tools within the context described above, focusing on food safety, responsiveness to new technology, and the creation of a level playing field.

Innovative legislative tools

Food safety should be the main concern of any future legislation. It should not be a way of tackling fraud (in this case the use of illegal veterinary substances). The chloramphenicol and nitrofurans cases illustrate the regulatory failure to challenge fraud through food safety regulations. SEM, which primarily functions as a marker for nitrofurans (as part of Annex IV) was also found in a number of food products that are packaged in glass jars with metal lids sealed with plastic PVC gaskets. The EFSA review of SEM is an illustration of the cool headedness required to handle contamination from a food safety perspective instead of from a merely legal perspective.²⁷

Semicarbazide is not specifically regulated by EU food packaging directives but if it were present in food packaging materials, for instance as an impurity or a reaction or degradation product, its presence in food would be covered by the Council Directive 89/109/EEC. Under Article 2 of this Directive, it could be present in food contact materials provided it did not

21 Note 5 above at 4.

22 *Carcinogens and Anticarcinogens in the Human Diet. A Comparison of Naturally Occurring and Synthetic Substances*, Committee on Comparative Toxicity of Naturally Occurring Carcinogens, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, Washington DC: National Academy Press, 1996.

23 See Note 4 above at 219.

24 B.N. Ames and L.S. Gold, 'Environmental Pollution, Pesticides, and the Prevention of Cancer: Misconceptions' (1997) 11 *EASEB Journal* at 1041; B.N. Ames and L.S. Gold, 'Paracelsus to parascience: the environmental cancer distraction' (2000) 447 *Mutation Research* at 3 to 13; see the Carcinogenic Potency Project at <http://potency.berkeley.edu/>; see also L.S. Gold, T.H. Slone, N.B.

Manley and B.N. Ames, *Misconceptions about the Causes of Cancer* (Vancouver, The Fraser Institute, 2002); available at http://potency.berkeley.edu/text/Gold_Misconceptions.pdf.

25 See Note 4 above.

26 E.J. Calabrese and L.A. Baldwin, 'Toxicology Rethinks its Central Belief. Hormesis Demands a Reappraisal of the Way Risks are Assessed' (2003) 421 *Nature* at 691 to 692; E.J. Calabrese and L.A. Baldwin, 'Hormesis: the dose-response revolution' (2003) 43 *Annual Review of Pharmacology and Toxicology* at 175 to 197; K.K. Rozman and J. Doull, 'Scientific foundations of hormesis. Part 2. Maturation, strengths, limitations, and possible applications in toxicology, pharmacology, and epidemiology' (2003), 33 (3-4) *Critical Reviews in Toxicology* at 451 to 462.

27 See Note 3 above at 3 to 4.

transfer into foodstuffs in quantities which could endanger human health.

On the other hand, when SEM is viewed as derived from the illicit application of nitrofurans, law demands zero tolerance. This is a flagrant inconsistency, which needs to be remedied. The following regulatory instruments could serve this purpose:

- an 'Annex IV' based on proof of harm from low-level exposure toxicity;
- risk assessment;
- Maximum Tolerable Risk level ('MTR');
- Toxicologically Insignificant Exposure level ('TIE');
- internationally harmonised authorisation and analysis of veterinary products;
- integration of risk assessment, management and communication.

In order to prevent future regulation leading to an unlawful *probatio diabolica*, it is essential that proof of harm of low-dose toxicity supersede the current proof of no harm Annex IV regulation. When *proof of harm* surfaces as a result of exposure to food residue levels, the substance needs to be listed on an amended Annex IV. Lack of data to establish an MRL as such is not sufficient grounds for banning certain veterinary products, particularly when those products are at the same time authorised as human medication and damaging effects surface sporadically only as a result of human therapeutic use. Indeed, with any authorised human and veterinary medication, a balance is struck between toxicity and beneficial effects at the biologically active dosage. Risks materialising at the human therapeutic level are not indicative of exposure to food residue levels.

Risk assessment and management are the tools of choice when dealing with food safety. Through these instruments the legality of food safety regulation is clearly distinguished from the question of toxicological relevance. The RIVM (Rijksinstituut voor Volksgezondheid en Milieu – Dutch National Institute for Public Health and Environment), in their study on CAP in shrimp, estimated the risk of cancer risk in consuming shrimp containing CAP.²⁸ The concentrations in imported shrimp varied roughly between 0.1 and 10 ppb (0.1 and 10 µg/kg product). The estimated

reasonable worst-case risk as a result of eating shrimp containing CAP is lower than the MTR level by at least a factor of 5,000 (being a 1:1,000,000 added cancer risk in the human population). By introducing the MTR as a transparent human health management target, unequivocal answers can be given in relation to low-level exposures through food products. The MTR serves best as a risk assessment and management criterion, as it is internationally recognised and accepted. Moreover, from a risk communication point of view, MTR addresses the relativity of risk much more effectively, as food safety is more dependent on other factors such as those we addressed in our previous article.²⁹ The message of zero tolerance is impossible to communicate in a multi-risk world, especially when food is concerned, as it confuses the issue of risk in food consumption.³⁰

Obviously, acute high-level exposure as is the case with human medication toxicology, differs markedly from chronic low-level exposure, and therefore low-level exposure to food residues requires a prudent approach. Nevertheless, with banned veterinary substances zero tolerance proves to be unachievable and unlawful. We therefore propose a TIE (Toxicologically Insignificant Exposure) level for banned substances in order to rule out analytical progress being the sole defining factor in the determination of regulatory compliance. Research on indirect additives in food, based on the Carcinogenic Potency Project,³¹ suggests a TIE of 0.5 ppb.³² This TIE level is all the more pertinent in view of the current scientific dialogue on hormesis considered in our previous article.³³ On the other hand, based on our propositions on risk assessment and the MTR threshold, the TIE concept leaves open a case-by-case approach to food contamination. The cases of SEM in packaged food, as discussed by the EFSA, and CAP in shrimp, as discussed by the RIVM and Hanekamp *et al.*, are the working examples here.³⁴

Global compliance, which can be measured by a list of universally banned substances, proof of toxicity of low-level food residues exposure, risk assessment methodologies and internationally accepted risk and exposure thresholds, requires an internationally harmonised analytical approach.

28 P.A.H. Janssen, A.J. Baars and M.N. Pieters, 'Advies met betrekking tot chlooramfenicol in garnalen' (2001) RIVM/CSR, Bilthoven, The Netherlands. [Recommendations on chloramphenicol in shrimp.] Kgbw stands for kilogram bodyweight. Toxicological data are usually related to this unit.

29 See Note 4 above.

30 J.B. Wiener, 'Precaution in a Multi-Risk World' (2001), Duke Law School Public Law and Legal Theory Working Paper Series Working Paper No. 23; H. Sapolsky, 'The Politics of Risk', (1990) 119(4) *Daedalus* at 83 to 96.

31 See Note 24 above.

32 A.M. Rulis, 'Threshold of regulation: Options for handling minimal risk situations'. (1992) Food Safety Assessment, ACS Symposium Series 484 at 132–9; see further Note 22 above

33 See Note 4 above.

34 See Notes 3, 4 and 28 above.

This proposed framework for food safety regulation, founded on sound scientific principles, demands a move towards analytical harmonisation. Exporting and importing countries and the various internal markets are in need of universal compliance rules so as to preclude unwarranted trade barriers, or, to put it positively, to generate a truly free and open market for all food-producing countries. To prevent barriers to trade, analytical tools need to be unified horizontally in order to generate global compliance and a level playing field. Trade between nations will benefit from international cross-compliance, in which properly analysed goods will be accepted unreservedly by importing nations. In cases where banned substances are detected, a risk analysis of observed concentrations and potential exposure routes needs to be undertaken with food safety as the leading objective. With the aid of the TIE, endless analytical exercises will thereby become non-operational. This will in our view further add to a renewed pharmaceutical interest in applying for authorisation for innovative veterinary medication. Proof of no harm, as espoused by zero tolerance strategies in particular and the cautious culture in general, generates a chilly climate for innovation which is typical of the cautious culture discussed elsewhere by one of the authors.³⁵

Some thoughts on assessment, management and communication

As argued in our previous article, the case of zero tolerance and its failure to add to food safety demands a reappraisal of the strict separation in Europe of risk assessment and risk management. The assessment of risk, or the lack of it, has by definition policy implications, which need to be addressed in order to avert mishaps. What does it mean for food safety and human health that particular risks of certain veterinary substances have surfaced in human clinical use, or in experimental toxicological research? Is food safety at stake as a result? Does the impossibility of arriving at an acceptable daily intake imply that the substance under scrutiny is dangerous at any dose, so zero tolerance must be mandatory? What are the management and

communication options when these issues surface? What are the regulatory options? What are the regulatory consequences when certain veterinary compounds are banned? Is food impacted by routes other than human intervention when pharmacological substances such as antibiotics or hormones are considered (multi-source issue)?

While there are many other questions that could be raised, these questions show that a scientific assessment raises numerous management, communication and regulatory issues that need to be addressed. We have shown that isolated assessments of veterinary substances and the preferred regulatory choices made on the basis of these assessments do not address food safety as such. Because no acceptable daily intake could be established for CAP, for lack of data, this was translated into zero tolerance by the regulator. The regulatory choice of zero tolerance is, however, not implied by the scientific assessment. It is an expression of the regulatory preference for the precautionary principle and has very little to do with food safety or human health.³⁶ Nonetheless, it is assumed by regulatory bodies that zero tolerance adds measurably to food safety and human health, which, on the other hand, requires scientific inquiry. However, history shows that feedback to the scientific community to assess the regulatory efficacy of zero tolerance has not happened. This gross oversight by both the regulatory and scientific bodies is the result of the strict and ill-fated separation of risk assessment and management.

We therefore propose that strict separation of risk assessment and management is at least in part discarded. Scientific institutes, researchers and advisers on the one hand and regulators and politicians on the other need to recognise that risk assessment, management, communication and regulation are part of one and the same attempt by industry and policy to protect public health when food safety is considered. Feedback to the designated scientific bodies on the implementation of food safety regulations and the contextualisation of the subject of residues within food safety as a whole are matters of science. Regulatory choices in matters of food safety need to add demonstrably to human health so that the social cost-effectiveness can be made transparent.³⁷ This is important in a global market

35 R. Pieterman and J.C. Hanekamp, 'The Cautious Society? An Essay on the Rise of the Precautionary Culture' (2002) Zoetermeer: Heidelberg Appeal Netherlands.

36 Ibid.; I.M. Goklany, *The Precautionary Principle. A Critical Appraisal of Environmental Risk Assessment*, Washington D.C.: Cato Institute, 2001; J. Morris (ed.), *Rethinking Risk and the Precautionary Principle*, Oxford: Butterworth-Heinemann, 2000; A. Wildavsky, *But is it True? A Citizen's Guide to Environmental Health and Safety Issues*, Cambridge, Mass.: Harvard University Press, 1997.

37 R.W. Hahn (ed.), *Risks, Costs and Lives Saved. Getting Better Results from Regulation*, Oxford: Oxford University Press, 1996; J.D. Graham and J.B. Wiener (eds), *Risk vs. Risk. Tradeoffs in Protecting Health and the Environment*, Cambridge: Harvard University Press, 1995; R.L. Keeney, 'Estimating Fatalities Induced by the Economic Costs of Regulation', (1997) 14 *Journal of Risk and Uncertainty* at 5 to 23; T.O. Tengs, M.E. Adams, J.S. Pliskin, D.G. Safran, J.E. Siegel, M.C. Weinstein and J.D. Graham, 'Five-Hundred Life-

that increasingly demands an international level playing field.

In this follow-up article on the issue of zero tolerance we have hopefully added to a discussion, which is in dire need of rationalisation. The fact that the JECFA committee selectively referred to the multi-source issue we introduced – specifically leaving out the present-day human medicinal source – illustrates this need. Obviously, when a contamination source is linked to legitimate human medicinal use of banned veterinary medication such as CAP and nitrofurans, a conflict over the authorisation and application of medication surfaces between the clinical and veterinary fields that has little to do with food safety. To be sure, zero-tolerance in the veterinary field will never result in a ban of useful human medicinal products. Addressing

CAP only within the veterinary context seems to indicate a political choice made to circumvent a conflicting situation with the clinical field whereby the food-safety issue is unduly and unjustly politicised. If a level playing field is to be achieved, international agreement is needed on the issues raised in this article. The scientific approach to food safety is the only viable option. The precautionary zero tolerance episode, which unfortunately has not yet reached a conclusion, has created an unnecessary and damaging chasm between international production of, and trade in food products and regulatory bodies. This gulf also damages communication with the general public and will prove to be unsustainable as globalisation of the food-producing industry (including trade) and of regulation increases.

Saving Interventions and Their Cost-Effectiveness', (1995) 15–3
Risk Analysis at 369 to 389.