Control of residue contaminants in animal products: challenges in meeting evolving 'so-called' consumer demands

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Abstract

European Community (EC) issued Council Directives 96/22/EC and 96/23/EC related to residues. The present paper systematically evaluated the 'risk to human health' of certain substances listed for meat products. Literature on selected growth promoters and veterinary medicinal products was explored using type II and type IV meta-analysis. The latest EC Food and Veterinary Office (FVO) residue control evaluation missions in three countries (United Kingdom- 2005, New Zealand- 2006 and South Africa- 2007) were evaluated to compare in-country risk analytical methods and control measures. Of the 227 scientific papers analysed, results indicate that the available scientific data is not adequate to support the evidence that presence of listed products or presence in excess of the in-country prescribed levels constituted a risk to human health. Although all the three countries had reasonable in-country controls; none of them met the requirements in the directives. The 1995 Sanitary and Phytosanitary agreement of the World Trade Organisation made a provision for the refusal of imports of animal products on the basis of specified risk to human health. It is thus concluded that the directives do not meet this requirement as far as risk to human health is concerned; other drivers of these evolving demands require further explication.

Introduction

Prior to the Agreement on application of Sanitary and Phytosanaitary Measures (the SPS Agreement) coming into operation on the 1st of January 1995, the European Council (EC) had in 1981 adopted Council Directive 81/602EEC prohibiting use of certain hormones to promote growth farm animals on the grounds of 'risk to human health. The Directive was challenged due to the lack of evidence supporting the 'risk factor' and it's was delayed to the 1st of January 1988; and again delayed to the 1st of January 1989 after amendments were proposed. The final implementation spiked trade disputes as it effectively banned the use of the hormones (except for therapeutic reasons) in farm animals intended for consumption in European Union (EU). The ban applied internally and to imports from third countries; any country intending to export to EU needed to implement equivalent legislation for animals intended for EU market. Following the implementation of SPS Agreement on the 1st of January 1995, the EC immediately repealed the Council Directive 81/602EEC under dispute and other associated Directives, and introduced two 'new' Directives, 96/22/EC and 96/23/EC in 1996 under the 'protection of consumers' embedded in SPS Agreement. The two Directives re-affirmed the ban on certain substances with hormonal or thyrostatic action and use of beta-agonists in farm animals, and further established the monitoring of the substances and their residues on animal products, and the levels and frequencies of sampling required, and effectively maintained the status quo which was effected in 1989 when 81/602EEC came into operation.

The implementation of Directives 96/22/EC was found to be inconsistent with the principles of SPS Agreement by the Word Trade Organisation's (WTO) Dispute Settlement Body (DSB) structures in 1997 and 1998 due to 'lack of sound scientific evidence', the EC was instructed to withdraw the implantation or provide evidence within a given time frame. The EC commissioned studies which culminated in the adoption of Directive 2003/74/EC amending Directive 96/22/EC. The implementation of Directive 2003/74/EC was viewed by the EU as 'closing gaps' in previous Directives, thereby 'complying' with the ruling of the Dispute Settlement Body (DSB) and legitimising their application and implementation. The Council Directive 2003/74/EC essentially made use of Article 11a, and placed five of the six hormones banned hormones in provisional ban 'while still looking for the evidence of risk to human health'. The implementation of Directive 2003/74/EC was informed by the three opinions of Standing Committee on Veterinary and Public Health (SCVPH) in 1999, 2000 and 2002. The interest in the think-tank processes leading to adoption of Directive 2003/74/EC and the examination of the evidence that informed the opinions of SCVPH has been ongoing. The present study systematically explored the literature leading to adoption of Directives 96/22/EC, 96/23/EC and 2003/74/EC, and the developments thereafter with the view of finding the evidence-based specified 'risk to human health' and the justification for the continued application of these Directives. The paper outlines general overview of Food and Veterinary Office (FVO) mission reports

evaluating compliance with these Directives. The latest FVO reports in three countries, New Zealand (2006), South Africa (2007) and United Kingdom (2005) were explored in detail.

Study Methods

Literature on six hormones, namely 17ß-oestradiol, testosterone, zeranol, progesterone, trenbolone and Melengestrol Acetate (MGA) was retrieved from various databases including MEDLINE, PUBMED, AGRICOLA, and Chem Abstract. Publications, technical reports, and other publications on various antimicrobials and other pharmacological active substances used for growth promotion, routine husbandry and or therapeutic reasons in farm animals were explored. Data on penicillin, neomycin, erythromycin, gentamicin sulphate, tylosin, tetracyclines, arsenicals, ivermectins, flunixin were also extracted. Publicly accessible literature cited in SCVPH (1999, 2000; 2002), VCM (2006) and FSA (2007) was retrieved. WTO DSB documents relating to EC-Hormone Dispute were scrutinised for references to quantitative values regarding residues, metabolites and MRLs. A total of 227 publications were explored using type II and type IV meta-analysis. Finally, publicly available reports of the EC Food and Veterinary Office (FVO) residue control evaluation missions were evaluated with particular emphasis on latest reports in three countries (United Kingdom- 2005, New Zealand- 2006 and South Africa- 2007) to compare conformity with the FVO prescribed requirements.

Results and discussions

Type II e he majority of the papers analysed seem to concur that hormones and antimicrobials in question are used for three main reasons in farm animals, namely (1) growth promoters, (1) zoothechnical and (3) therapeutic. With regard to hormones, there is also overwhelming agreement among all literature studied that the present evidence is not adequate to provide quantitative information to draw definitive conclusions regarding the risk to human health. A number of studies on *in vitro* and *in vivo* experiments considered the biological effects of the hormones and their residues, and the threshold concentrations associated with consumer average daily intake (ADI) and the maximum residue limits (MRLs) in a product to be consumed. While advanced methods of measurement of hormone residues in tissues, all studies accept that there is no quantitative data indicating the nature and amount residues in edible meat of treated animals, as such, hazard characterisation is not possible. In this regard, two latest major reviews on the subject (1) VPM (2006) strongly concluded that the available evidence indicate likely levels of exposure of humans to hormonally-active substances in meat from treated animals would not be sufficient to induce any measurable biological effect while (2) EFSA (2007) prefers to conclude that the risk of hormone residues in meat is unknown.

Thirty years since the adoption of Council Directive 81/602EEC, and almost 20 years after the ban on hormones came into operation, and 10 years after the implementation of Directives 96/22/EC, 96/23/EC and 2003/74/EC and 10years after the EU was asked to provide evidence or withdraw the ban by the WTO DSB; all studies indicate that the evidence of risk to human health is still not available.

The SPS Agreement was aimed at enabling each country to impose import requirements and necessary measures to protect human, animal and plant health provided that such requirements are not disguised restrictions for international trade. As such, Directives 96/22/EC, 96/23/EC and 2003/74/EC, and other associated rules are still inconsistent with the SPS Agreement. While intensive research for scientific data regarding any evidence, the EU has vigorously implemented Directives 96/22/EC, 96/23/EC and all associated Directives, and has carried various Food and Veterinary Office (FVO) missions to many countries concerning the evaluation of the control of residue contaminants in live animals and animal products, including the control of veterinary medicinal products. In addition, the EU continued to issue more complex Directives related to use, distribution, authorisation and management of pharmacologically active substances used in many veterinary medicinal products, and monitoring of their residues in products of animal origin. For example, Regulation 2377/90 was amended by Directive 2001/82/EC and 2004/28/EC.

A review of FVO reports on missions relating to residue evaluations in Member States (15) and Third Countries (17) indicated many critical deficiencies in many countries, requirements contained in Directives 96/22/EC, 96/23/EC and all associated Directives were not met. This view was heavily pronounced for validation of analytical methods, resources, competences and accreditation in the laboratories area. As a consequence, many countries were de-listed for many commodities previously eligible for export to the EC. For example, South Africa previously exported bovine meat, ovine meat, milk and milk products, wild game meat, ostrich meat, crocodile meat, poultry and pork in 2000 and has deteriorated to the export of ostrich meat only from June 2008. Majority of the losses in exports to EU were on the grounds of non-compliance with residue programmes prescribed in Directives 96/22/EC, 96/23/EC and the related Directives.

An in-depth study of the FVO mission reports evaluating compliance with these Directives in New Zealand (2006), South Africa (2007) and United Kingdom (2005) indicate that although the three countries had reasonable in-country controls; none "offered guarantees equivalent to those required by Community Legislation". Detailed reports indicate a number of discrepancies between the EU expectations and those provided by the countries evaluated. The discrepancies ranged from the test methods, validation, sampling programmes and MRLs. In response to FVO findings, the competent authorities cite procedures from internationally agreed standards such as those of Committee on Veterinary Drugs of the Codex Alimenatrius on MRLs and methods. Sadly, the EC values and or methods differed significantly from those of Codex.

After several debates, legal actions and retaliatory measures by countries able to do so such United States and Canada, the EC's hormone ban, and the application of relevant Directives, was found to be inconsistent with European Union's obligation under SPS Agreement by the Dispute Settlement Body (DSB) of the WTO in 1998. The report of the Appellate Body (AB) concluded that the EU had maintained hormonal ban without credible evidence to indicate that there are health risks from cattle treated with hormones. Instead of complying with the fair trade principles of the WTO, the EU opted to commission series of studies since 1998. These studies culminated on the adoption of Directive 2003/74/EC amending Directive 96/22/EC. The Council Directive 2003/74/EC was informed by the three opinions of Standing Committee on Veterinary and Public Health (SCVPH) in 1999, 2000 and 2002. The scientific reasoning for reaching these opinions has been opposed by major scientific groups within and outside the EU.

Despite the fact that the Directive 96/22/EC and 96/23/EC were ruled to be inconsistent with the WTO Agreements, the direct remain operational, and are implemented in full force by the EU. The above developments within the EU has increased the costs of producers and regulators of the third countries, and effectively hardened the ability to export to the EU. Rich countries such as US and Canada have opted to introduce retaliatory import restrictions of EU products since 1998 and their cases are still with arbitration of the WTO. Unfortunately, other countries have been subjected to compliance audits by the Food and Veterinary Office of the EU.

Conclusions

It is over a quarter of a century since the EU expressed its intention through Council Directive to ban on use of hormones in farm animals due to public heath concerns, the available scientific data is not adequate to support the evidence that presence of listed products or presence in excess of the internationally prescribed levels constituted a risk to human health. The understanding of complex mechanism of action of hormones remains in the infancy stage and a matter of research. There is currently no evidence that hormone residues in meat constitute risk to consumers, exposure risk patterns suggest contrary. In the absence of absolute quantitative information on credible risk assessment and characterisation, the Directives in question, and the amendments thereof, still do not embrace the principles of SPS Agreement requirement as far as risk to human health is concerned. The EU has in-the meantime placed the ban, and continued to make further complex amendments. The thirty year progressive 'goal-shifting' and other drivers of these evolving EU demands require further explication.