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Reports of expert committees and study groups[1]

TOXICOLOGICAL EVALUATION OF CERTAIN RESIDUES OF VETERINARY DRUGS IN FOOD

Seventieth Joint FAO/WHO Expert Committee on Food Additives[2]
Geneva, 21–29 October 2008

Main recommendations

1. The Committee made recommendations on the safety of veterinary drug residues in food. Residues for monitoring purposes were defined where appropriate and maximum residue limits recommended. It also made a number of general recommendations, in particular considerations of an approach based on a hypothesis-driven decision tree for the evaluation of the safety of residues of veterinary drugs.

2. The Committee established acceptable daily intake levels or provided other safety advice for nine veterinary drugs and recommended over 90 maximum residue limits for those drugs in specific food commodities. The Committee considered it inappropriate to establish an acceptable daily intake for malachite green given the health concerns involved and did not support the use of malachite green for food-producing animals.

3. WHO has published summaries of the toxicological and related information upon which the safety assessments of the compounds were made.[3] FAO has also published summaries of the identity and purity of food additives and flavours.[4]

Significance for public health policies

4. The Committee's work identifies and if possible quantifies the public health significance of veterinary drug residues in food through an international consensus scientific risk assessment. Clear recommendations are given if a health concern is identified for action by national governments or through the FAO/WHO Food Standards Programme.

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[1] The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report of expert committees containing observations on the implications of the expert committee reports and recommendations on the follow-up action to be taken.

[2] WHO Technical Report Series No. 954, 2009.

[3] Toxicological evaluation of certain veterinary drug residues in food. WHO Food Additives Series, No. 61, 2009.

[4] Compendium of food additive specifications, FAO Food and Nutrition Paper, 2009.

5. Although all Member States face the problem of assessing the potential risks of chemicals in food, there are only a limited number of scientific institutions, on a national or regional basis, that are able to assess all relevant toxicological and related data. Consequently, it is important for WHO to provide Member States with valid information on both the general aspects of risk assessment and specific evaluations on food additives and flavours evaluated by the Committee. The Committee's work is unique in its complexity and in reaching an international consensus in the evaluation of these compounds and no other organization has a comparable importance and impact on global public health decisions related to food safety.

6. The Committee's recommendations are used by the Codex Alimentarius Commission for setting international food standards. Such standards are established only for substances that have been evaluated by the Committee. That ensures that food commodities in international trade meet strict safety standards.

7. The advice provided by the Committee is also considered by Member States directly when setting national/regional food safety standards.

Implications for the Organization's programmes

8. The evaluation of chemicals in food by the Committee is an ongoing activity. Four Committee meetings, two on food additives, one on contaminants, and one on residues of veterinary drugs in food, were held in 2008–2009.

9. WHO is a partner in the Joint FAO/WHO Food Standards Programme, the principal organ of which is the Codex Alimentarius Commission. The Committee's work is crucial for the Commission.

10. Regional offices and WHO representatives also make use of the Committee's evaluations when advising Member States on food safety regulatory programmes.

TOBACCO PRODUCT REGULATION

Report of the fifth meeting of the WHO Study Group on Tobacco Product Regulation[1] Durban, South Africa, 12–14 November 2008

11. The WHO Study Group on Tobacco Product Regulation has launched a series of reports to provide a scientific foundation of tobacco product regulation. In line with the provisions of Article 9 of the WHO Framework Convention on Tobacco Control, these reports identify approaches for regulation of tobacco products that pose significant public health issues and raise questions for tobacco control policy.

12. This report deals with two types of products that currently concern scientists, given their potential for public health harm and the inadequacy of regulations governing their promotion, sale, and use. The first is electronic nicotine delivery systems which deliver nicotine and other substances directly to the lung unaccompanied by tobacco smoke. They are marketed under a variety of brand names and descriptors around the world, but fall within a regulatory gap in most countries. Few

[1] WHO Technical Report Series No. 955, in press.

studies document their contents and emissions and claims that WHO approves their use for smoking cessation have been circulated. The second is smokeless tobacco products, which also are used in many countries. Scientifically documented differences exist between their contents and formulations, resulting in a variety of adverse health outcomes. Substantive variation in carcinogen levels has been identified for smokeless tobacco products marketed in different regions and across the products marketed within a region. It is desirable and feasible to lower these carcinogen levels through better manufacturing and sales practices.

13. Of the topics discussed at the fifth meeting of the Study Group, electronic nicotine delivery systems and smokeless tobacco were deemed to be most important for issuing recommendations for regulation. This report therefore requests clearance for the main recommendations noted below to be published in the Third Report of the Study Group on the scientific basis of tobacco product regulation.

Electronic nicotine delivery systems: regulatory recommendations and research needs

Main recommendations

14. Electronic nicotine delivery systems that are designed for the purpose of direct nicotine delivery to the respiratory system fall within a regulatory gap in most countries, escaping regulation as drugs and avoiding the controls applicable to tobacco products. There is insufficient evidence currently to assess whether electronic nicotine delivery systems may be used to aid cessation, create or sustain addiction, or deliver constituents other than nicotine to smokers. Clinical trials, behavioural and psychological studies, and post-marketing studies at individual and population levels are needed to answer these questions. Claims for health benefits, reduced harm, or use in smoking cessation should be prohibited until they are scientifically proven. Electronic nicotine delivery systems should be regulated as nicotine delivery devices, and where this regulation is not possible, under tobacco control laws subjecting them to regulation of contents and labelling, prohibitions against public use, and restrictions on advertising, promotion, and sponsorship.

Significance for public health policies

15. Electronic nicotine delivery systems may offer a public health benefit if they promote smoking cessation, but may create public health risks if they sustain nicotine dependence by allowing nicotine intake where smoking is prohibited or if they increase initiation and transition to cigarette smoking among those who would not otherwise have used tobacco. Smokers who attempt to quit may use electronic nicotine delivery systems in place of evidence-based treatments, thereby potentially contributing to delayed smoking cessation and increased risk of smoking-attributable disease if those systems are ultimately ineffective as nicotine replacement therapy devices.

Implications for the Organization’s programmes

16. WHO continues to support pharmacotherapy only where scientific studies demonstrate predicable outcomes under specified conditions and when products have been approved as safe and effective by major drug regulatory authorities. WHO strongly encourages Member States to prohibit manufacturers of electronic nicotine delivery systems from issuing claims that WHO has endorsed their products as legitimate tobacco cessation aids. Member States should ensure that the manufacturers of these products comply with all existing regulatory requirements to preclude unsubstantiated claims that may derail public health efforts in tobacco control.

Smokeless tobacco: setting regulatory limits for carcinogenic components

Main recommendations

17. The regulatory strategy previously advocated by the Study Group for cigarettes should be extended to mandating reductions of toxicant levels in smokeless tobacco. Two groups of toxicants should take priority for the setting of regulatory limits based on their carcinogenic potency and the ability to substantially lower their concentrations in smokeless tobacco with existing technology: tobacco-specific *N*-nitrosamines and polycyclic aromatic hydrocarbons. Upper limits should be set for the combined concentration of N'-nitrosonornicotine (NNN) plus 4-(methylnitrosamino)-1-(3-pyridyl)butanone) (NNK) as tobacco-specific *N*-nitrosamines at 2 µg/g dry weight of tobacco and for benzo[*a*]pyrene as a marker for carcinogenic polycyclic aromatic hydrocarbons at 5 ng/g dry weight of tobacco. Regulators should inform consumers that, like cigarettes, smokeless tobacco products that meet safety standards may be no less hazardous, and they should prohibit product ranking or publicizing test results that are likely to influence user behaviour in ways that will cause harm. Measuring, testing, and reporting should be verified by independent laboratories or governmental agencies and expiration dates and refrigeration requirements must be enforced in order to limit the accumulation of tobacco-specific *N*-nitrosamines.

Significance for public health policies

18. Evidence on the strength of the association of smokeless tobacco with cancer reflects the differences in products available in different markets; therefore, regulators should lower the levels of those carcinogens present in smokeless tobacco by limiting the levels that can be present in products that are marketed. As it becomes technically feasible to have lower detection limits, more aggressive targets for mandated lowering can be set by regulatory authorities.

Implications for the Organization's programmes

19. WHO should begin with regulation of manufactured products even though individuals and a cottage industry that is not easily regulated often dominate the use and production of smokeless tobacco. WHO should recommend the development of companion programmes to educate cottage industry producers and implement improved production approaches for small producers in order to cover the more difficult problem of limiting carcinogen levels in non-manufactured smokeless tobacco. Finally, WHO should reject the concept that higher toxicant levels in manufactured products are acceptable in countries with fewer economic resources.

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