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The regulation and governance of residues of plant protection products.

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Summary

Numerous pesticides or plant protection products (PPP) are registered for use on tobacco around the world and the residues or metabolites of many of them can be detected in tobacco leaf samples. A number of national authorities and industry boards set maximum levels and standards for a wide range of these residues as well as for non-registered or obsolete PPPs on tobacco leaf or products. Residue levels for over 500 different residues exist in various forms of regulation.

To assist CORESTA Members and make them aware of the existence of these regulations the Agrochemical Advisory Committee has collated information from different sources on Maximum Residue Levels of PPPs from around the world. This effort has been supplemented by also gathering information on the global registration status of PPPs for use on tobacco and their application patterns.

This paper outlines the main countries which have specific tobacco regulations for PPP residues, some of the underlying principles used to establish the levels and why in some cases there is little consistency between countries in the levels or residues. The global registration status information is useful for demonstrating the range of products and application rates which may lead to differences in residue levels in different countries.

Script

Good morning, ladies and gentleman. Thank you for providing me with the opportunity of talking about a stimulating jigsaw puzzle for the tobacco industry, which is the control of residues plant protection products in the industry.

I would like to explain where we stand in terms of legislation. As legislation is different from country to country or is lacking I will touch briefly on the problems which come out of a patchy picture. I will also explain what Coresta does to assist in detail later.

25 countries (8 EU countries, the US, 7 Gulf countries in the Middle East, Argentina, Armenia, Belorussia, Croatia, India, Malaysia, Russia, South Africa, Ukraine) have a clear legislation which regulates the levels of residues of agrochemicals in tobacco or finished products.

Another few countries (such as Malawi and Zimbabwe.) regulate residues only by local industry agreements: it means that the bodies which oversee the production of tobacco in a given country take upon themselves to establish the acceptable levels of residues of agrochemicals in tobacco and monitor them.

However it often happens that regulations on the level of residues are unrelated to the authorisation to use the plant protection products.

Some other countries consider tobacco an industrial crop rather than a consumable crop and do not regulate at all the levels of residues of agrochemical.

The same position is taken by the Codex Alimentarius, a branch of the World Health Organisation: the Codex assesses the residues of agrochemicals for human or animal consumption around the world and compiles a list of international MRLs, but tobacco is not included in the list of regulated crops. The Codex also functions as the reference authority in case of international trade: if crops move between countries with different MRLs, in case of dispute the MRL set by the Codex Alimentarius should be respected.

The first requirement of MRLs is that they should reflect the Good Agricultural Practice, which is the approved pattern of use against a certain disease on a given crop in a country. Therefore MRLs should be first of all a way to measure that the application of the agrochemical has occurred correctly.

Secondly, in food crops MRLs are set to protect consumers, in such a way that the consumption of the crop with residues of a certain PPP cannot affect consumers' health. But tobacco is rarely, if ever, considered under this point of view.

Let us start with the official regulations. All seems very clear, but there is confusion on the big picture.

In some countries the law regulates the level of residues of agrochemicals in tobacco. However the situation is not straightforward: in some countries (Italy, Spain), there is an MRL unrespective of the fact that the PPP is registered for use on tobacco or not.

In other countries, such as Germany and the US, there is a much shorter list which does not reflect the local use of the PPPs on tobacco. Often the MRLs are set to avoid the import of undesirable products.

Germany is also in the unique position of having both MRLs on tobacco regulated by law and recommended by the trade association.

A different situation occurs where agrochemical residues are regulated by trade agreements, usually the local tobacco board. It normally affects local production of tobacco and cigarettes. In these countries the agreement normally covers tobacco leaf, therefore we assume there is little control on imported finished product.

If the situation seems rather well defined at national level, the big international picture is very confused.

First of all MRLs are different in most countries, which means that there are often different MRLs in different countries. Furthermore the different countries establish MRLs on different agrochemicals, therefore some agrochemicals are regulated in some countries but not in others. On top of this the definition of the agrochemical varies from country to country, often

disregarding important metabolites or setting the MRL on a chemical substance which is impossible to analyse.

To make things worst, some countries clearly state that MRLs are established on cured leaf, some other countries only occasionally state if the MRL is set on the leaf before or after curing, and some countries set MRLs on specified finished products.

This situation creates a lot of problems, because it is unclear who is responsible for what. Is it the farmer who must respect MRLs? Is it the leaf dealer who buys tobacco from farmers, blends it and sells it to manufacturers? Is it the manufacturer who has the ultimate responsibility of putting tobacco products in the mouth of consumers?

In order to clarify this I would like to make a few examples: if we look across the range of MRLs set by different authorities in different countries we very often notice that for the same PPP there are different MRLs in different countries. This may cause a barrier to trade toward the countries which have set lower MRLs than the country of origin.

Another example: for the fungicide metalaxyl 11 countries have set MRLs, but the level varies from 0.5 to 10 mg/kg, and in some cases it is not clear whether it should apply to metalaxyl or the isomer metalaxyl M. This means that if Malaysian tobacco (where 10 ppm are acceptable) was exported to Spain (where 3 ppm are acceptable) there might be a problem.

Furthermore, local authorities used their best imagination in setting MRLs. There is a great variety, from imported leaf of Burley and Virginia in the US, to finished products in Germany, to "unspecified tobacco" in Spain, to the full glory of 4 different matrices in Italy!

The list of MRLs in the US applies only to imports of Burley and Virginia and covers mainly persistent organic polluters such as DDT that are no longer registered for use as PPPs. The only exception are pyrethroids registered in other countries at higher MRLs. No MRLs are set for domestic production.

This shows that there is a mechanism to allow the import of a crop grown in a different country that contains MRLs of products not registered for use in the country of destination. The import tolerance procedure is also common for food crops. It may be possible that this situation is extended to other countries or other PPPs. The industry is looking at this possibility.

Coresta has two main groups working on the issue: one is ACAC, the Agro-Chemical Advisory Committee, which is actively working on a number of projects, and the other is the Pesticide Residue Sub-group, which is also helping to define another important aspect of the problem. Let us see them in more detail.

ACAC has created two databases of MRLs, one covering the official MRLS by law in 25 countries, and the other one covering the trade agreement and "informal" decision in other 12 countries. Both databases will available to Coresta members in October and will be updated once per year.

ACAC is also working on the Guidance Residue Levels. They are indications of how the industry should behave in case of lacking legislation. The first list of GRLs was published in 2003, but ACAC is planning to update it to include new active ingredients or reflect changes in authorisations. Because the purpose of the GRL list to serve as guidance for the whole

world, it aims to provide guidance residue limits which are acceptable for the whole world in the countries where there is not a specific MRL regulation. The GRLs however do not replace local law where it exists. Furtherore the existence of GRLs does not allow a PPP to be used in a country if it is not registered for use on tobacco in that country.

The third main area of activity of ACAC is the collection of Good Agricultural Practices. These correspond to the registered uses of agrochemicals in the various countries where tobacco is grown. It is a huge task and it still is under development.

The purpose of this database is to allow an assessment of the residue level of agrochemicals in tobacco and also to allow the comparison of MRLs from different countries where tobacco is grown.

The tobacco industry may also be requested to provide prompt information to external bodies on the pattern of use of plant protection products and this database will be of help.

As a conclusion I would like to say that the use of agrochemicals on tobacco raises several challenges for the whole industry. But at the same time it gives us the opportunity to work in a stimulating and proactive way to meet the challenges in the best possible way.

The work goes on well because a great number of people in the industry cooperates well on the different projects and I would like to thank all of them, the members of ACAC and the pesticide residue analysis subgroup, for their good team spirit.