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COMMENTS ON THE DEVELOPMENT AND APPLICATION OF RESIDUE LIMITS TO FOODS IN TRADE UNDER WTO SPS PRINCIPLES

Communication from Argentina

The paper submitted by our Australian colleagues (G/SPS/W/34), in a concise yet detailed summary, is an excellent description of the trade problems connected with chemical residues and Argentina agrees that the matters listed in paragraph 22, "Issues for consideration", are the ones that should be taken into account in setting national residue limits.

With particular reference to the second subparagraph of paragraph 22, we would point out that, in addition to good agricultural practice in the use of agricultural chemicals, account should be taken - by the importing country - of the chemical residues control plan of the country exporting the goods concerned. Such plans should not merely detect cases above the MRLs they have set in each instance, but should especially address the procedures for correcting situations caused by improper use of agricultural chemicals and veterinary drugs. This in particular supports everything clearly stated by Australia in paragraph 21.

An amount above the MRL in some batches should not in itself, or routinely, mean that the food should be seized or destroyed. It is much more effective to report the problem that has been detected to the official department concerned in order to ensure a follow-up to the investigation of the origin of the excess or the violation.

Special plans for special markets may be adopted by exporting countries so as to guarantee the buyer's requirements concerning non-use of certain substances that are prohibited in the buyer's market yet authorized in the country of origin.

In view of the provisions of Article 12:2 of the SPS Agreement, we believe that coordination and integration between international and national systems and approaches should focus not only on the approval of the use of food additives or the establishment of tolerances but also on the surveillance and control plans in member countries.

The National Animal Health Service considers that it is more effective for public health to establish measures to correct the causes of the problem than simply to seize or destroy a food consignment, something that would be appropriate only in exceptional cases.

Having regard to the importance and also the complexity of this topic, we attach the Programme set up as the monitoring and surveillance system under the Argentine Residue and Hygiene Control Plan for Foods of Animal Origin (CREHA).

SENASA - CREHA Plan

Residue and Hygiene Control Plan for Foods of Animal Origin

Types of Sampling - Criteria for Decisions

Unbiased sampling or monitoring

Objective: To provide annually nationwide schematic information on the presence of residues or micro-organisms or toxins in foods or in specific food-producing populations.

Sample size: This depends on two factors:

(a) The level of statistical reliability: generally 95 per cent (internationally accepted value);

(b) the relative frequency or rate of cases of unacceptable values intended to be detected.

The latter depends on the risk to human health of residues of a given substance.

Generally speaking, there are two categories:

When the substance is prohibited or not approved (unknown toxicology):	0.1 per cent
When the substance is permitted with only some restrictions:	1 per cent

Obviously, it is possible to determine intermediate categories, but these are usually the internationally applied and accepted values.

In these terms, for detection purposes the sample size is:

0.1 per cent rate:	3,000 samples a year
1 per cent rate:	300 samples a year

Purposive sampling

Objective: To prevent consumption of contaminated food. This entails a high sampling ratio and, basically, holding back inspected products until a certificate of analysis is obtained with results allowing them to be released.

Points of application and sample size

The ideal sampling ratio is, of course, 100 per cent, inasmuch as it would make for 100 per cent food safety.

If this ratio is applied to all products, the programme is unlikely to be completed because:

- There are difficulties with the capacity to retain goods;

- the warehousing costs would increase significantly, because refrigeration is normally needed;

- the high cost of analysis, if not conducted according to a statistical criterion, could reach the point where, in the breakdown of the cost of the food, the production component would be minimal compared with the control component;

- serious disruption of the marketing chain, owing to inevitable analysis delays.

This does not mean it should not be done, thereby jeopardizing public health. Account should be taken of two matters which mean that, even with a high level of human health protection, these factors do not have a significant impact.

These two matters may be summed up as follows:

(1) To know as accurately as possible the characteristics of the population liable to contamination, so as to select with maximum precision the size of the subpopulation to sample;

(2) to take immediate corrective action with regard to the causes of unacceptable results.

Point (1) is simply done by the taking of samples or requests for analysis designed to produce the greatest amount of information possible.

The greater the information, the greater the number of subpopulations that can be defined, and the fewer the number of components for each subpopulation. Indeed, it is then possible to apply 100 per cent frequency to a sufficiently size-limited subpopulation.

However, although the size of the sampling subpopulation has been reduced, the number of samples for a 100 per cent sampling ratio may still be too high and too difficult to apply, because of the factors mentioned above.

If point (2) is then forcefully and effectively applied and the rate of unacceptable values is recalculated, the proportion of samples to be taken may be reduced to a value which affords the same level of protection as a monitoring programme. It is essential for action to be taken immediately so that the time in which the 100 per cent rate is applied is as short as possible.

Calculations

Where	E	means	Unacceptable cases of amounts exceeding tolerances or positive cases
	N		The number of elements in the population monitored
	M		The number of samples taken of that population
	Ns		The number of elements of the subpopulation which will be the subject of purposive sampling
	Ms		The number of samples taken of the subpopulation
	Tc		The critical rate of unacceptable cases for shifting from monitoring to purposive sampling
	Tu		The rate of unacceptable cases in the population
	Ts		The rate of unacceptable cases in the subpopulation

At the given point, the result will be Tu > Tc, thus shifting to purposive sampling, and it is possible from the data in the samples to define a specific subpopulation.

Obviously, all the unacceptable cases must be contained in the subpopulation and, in so far as further cases emerge in the rest of the population, they must be incorporated in the subpopulation, which, if necessary, will have to be redefined for the purpose.

This means that Tu cannot be estimated by E/M, since a much higher number of samples is taken of the subpopulation with problems, and the result would then by very biased.

It should be estimated by:

$$Tu = Ts \times Ns/N$$

Where Ts can be estimated by:

$$Ts = E/Ms$$

Even when monitoring cannot be used to estimate the population rate, it should be used to detect unacceptable cases that may occur in the rest of the population.

However, the aim is unit retention sampling that will provide the public in general with protection that is not less than the monitoring programme. Accordingly, the proportion of uninspected units must be not more than Tc.

The amount of contaminated units in the subpopulation is:

$$Ns \times Ts$$

If a part of these enter processing or distribution facilities, in a proportion of, say, K ($0 < K < 1$), and

if the proportion held back for analysis at such facilities is P ($0 < P < 1$),

the amount of contaminated units reaching the public is:

$$Ns \times Ts \times K \times (1 - P) \qquad [I]$$

The total amount of units reaching the public from that subpopulation is:

$$Ns \times K \qquad [II]$$

The total amount of units reaching the public from the entire population is:

$$N \times K \qquad [III]$$

Dividing [I] by [III] gives the fraction of contaminated units reaching the public, namely:

$$\Phi = Ts \times (1 - P) \times Ns/N$$

Where Φ is the fraction of contaminated units reaching the public.

If the population is to be afforded the same protection as monitoring, then:

$$\Phi = Tc$$

With this condition, the sampling ratio is:

$$P = 1 - (Tc/Ts) \times (N/Ns)$$

or

$$P = 1 - Tc/Tu$$

It is evident that for the same value of (Tc/Ts), the smaller the size of the subpopulation, the lower the sampling ratio.

This formula should be applied if, and only if, the distribution of the units of the subpopulation affects all of the consumer public, in other words, the units are uniformly mixed with the units of the rest of the statistical population. Otherwise, if the units of that subpopulation are directed towards consumption by a particular group of consumers, the following could be considered:

$$P = 1 - Tc/Ts$$

Which is the result of dividing [I] by [II].