NOTE TO THE COMMISSION

Reflections from France on the issue of residues in foodstuffs of animal origin

Introduction:

The European Commission has published a reflection paper on maximum residue limits and the monitoring of residues of veterinary medicinal products in foodstuffs of animal origin, with a view to overhauling Community legislation in this field.

The main Community texts affected are Regulation 2377/90/EC of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, and Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products.

The goal set by the European Commission is to determine new means to balance consumer protection, animal health, animal welfare and trade requirements concerning residues of pharmacologically active substances resulting from the administration of veterinary medicinal products to food-producing animals.

France agrees with the Commission’s analysis of the problems arising from the legislative instruments at present in force and supports the Commission in this indispensable Community reform exercise. In this present discussion paper we address four main points:

- assessment and establishment of maximum residue limits (MRLs) in foodstuffs of animal origin;
- control plans for residues of veterinary medicinal products in foodstuffs of animal origin;
- the network of control laboratories;
- monitoring of residues of veterinary medicinal products in foodstuffs of animal origin imported from third countries.

Each point begins with an analysis of the problems encountered, followed by proposals for the drafting of the new Community acts.

Preamble:

Scope of these reflections:

The European Commission’s paper addresses the problem of residues of pharmacologically active substances in foodstuffs of animal origin, with a view to the possible amendment of the acts at present in force, including Directive 96/23/EC.

Directive 96/23/EC covers the monitoring not only of pharmacologically active substances but also of other chemical substances (including heavy metals) and certain environmental contaminants (PCBs, dioxins, etc.).

However, the approach concerning these two categories of analytes is very different. In the case of veterinary medicinal products, the substances are administered voluntarily by the veterinarian.
or the keeper of the animals, in accordance with precise rules on the one hand and good practice on the other. Essentially, the detection of residues indicates maladministration of these products. In the case of other chemical substances and environmental contaminants, however, the presence of residues in foodstuffs is involuntary, and the appropriate context for checking for their presence in foodstuffs would be a monitoring plan to assess the risk to consumers. In this paper, our reflections are therefore confined to the problems associated with veterinary medicinal products, or, rather, pharmacologically active substances.

**Proposal:**
Monitoring for residues of chemical substances and other environmental contaminants is a separate issue that needs addressing at Community level in a separate legislative act.

**General observation:**
Veterinary medicinal products play a key role in animal health. This aspect of their contribution to public health (guaranteeing the production of healthy food and preventing zoonoses) should not be overlooked when considering the impact of their residues in foodstuffs of animal origin intended for human consumption. It is therefore important that the ongoing reflections:
- should not put a brake on the development of new medicinal products;
- should not aggravate the problem of the availability of veterinary medicinal products, which is one of the major consequences of the present legislation;
- should not lead to a total reconsideration of the present MRLs.

1. **Evaluation and establishment of MRLs:**

1.1. MRL application dossiers are evaluated by the EMEA, which transmits its opinions to the European Commission for the introduction of amendments to the Annexes to Regulation 2377/90.

The EMEA performs the risk assessment, but it also tends to play a not-insignificant role in risk management via the opinions that it produces. To comply with the risk assessment guidelines set out in the 13th edition of the Codex Alimentarius Commission’s Procedural Manual, risk assessment should be performed by a body that is independent of the body responsible for risk management. The EMEA should stick to the remit conferred on it by the European Community, namely to perform a risk assessment and deliver a clear, documented and reasoned opinion setting out its conclusions (determination of the no-effect dose and the acceptable daily intake (ADI)) and propose various risk management options. The final decision must be left to the risk managers, i.e. the Member States. If a range of options has been proposed and a choice has to be made the Commission should then convene the Member States within a standing committee in order to adopt the necessary management decisions.

In the case of substances which are impossible to assign directly to one of the Annexes, a solution could be to define legitimate factors to circumscribe their use (best practice, legislative restrictions) rather than assigning them to an inappropriate Annex. Residue control would therefore involve not only qualitative and quantitative monitoring by means of physical and chemical analyses, but also monitoring of adherence to the defined legitimate factors.
All these decision-making activities should be fully transparent, in accordance with the principles of risk communication (the opinions should be reasoned and made public).

To give an example of the problems we in France have faced, we could mention the application dossier submitted to the Commission for the establishment of an MRL for two antibiotics (streptomycin and tetracyclines) in honey. The French food safety agency (AFSSA) considered that, based on the results of the analyses performed under the monitoring and surveillance plans, the streptomycin and tetracycline residue levels observed in honeys represented only a very small part of the daily intake and that an MRL could be established based on these considerations. The EMEA rejected France’s argument and considered that no MRL could be established since the studies requested in the dossier had not been provided. It is true that not all the scientific data were present, but risk management measures could nevertheless have been adopted in order to authorise the use of the antibiotics to treat bees. It is preferable to attach conditions to usage rather than not establish an MRL at all and risk seeing illegal usages develop.

**Proposal:**
It is important to separate risk assessment from risk management. When a proposal for inclusion in an Annex cannot be made on a purely scientific basis, the manager responsible for the final decision must make his decision on the basis of a benefit/risk analysis.

The process of assessment and establishment of the MRLs must adhere to the risk assessment guidelines set out in the 13th edition of the Codex Alimentarius Commission’s Procedural Manual (risk assessment, risk management, risk communication).

The Directive must define the risk assessment policy to be followed by the EMEA in its assessment work, taking as a basis the document currently being drafted by the CCRVDF for the JECFA.

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1.2. Certain substances can be the subject of several assessments, according to how they are used (e.g. as a feed additive, as a pesticide, as a veterinary drug). When the EMEA knows of a substance being used as a pesticide, only a portion of the acceptable daily intake (ADI) is used to establish the MRL. However, exchanges of information between the assessment bodies are limited, and differences of approach are possible.

**Proposal:**
Contacts and exchanges need to be developed between the different body responsible for assessing maximum residue limits. Organised cooperation between the European Agencies (EMEA, EFSA), the European Commission’s Directorates-General concerned (DG Enterprise, DG Health and Consumer Protection, DG Agriculture), the Codex Alimentarius and its subsidiary bodies (JECFA, JMPR) would provide a common basis for assessing MRLs and allow all the different uses of a substance (pesticide, additive, veterinary drug) to be taken into consideration when establishing the MRL.

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1.3. In terms of assessing application dossiers for the establishment of MRLs for residues of veterinary medicinal products in foodstuffs of animal origin, the need to establish separate MRLs for each species is not explicitly stated in Regulation 2377/90/EC. An MRL dossier covers pharmacology, toxicology, pharmacokinetics, depletion and analytical methods. As scientific knowledge has advanced, the requirements have changed. Data are now required for each
species. Thus, generally speaking, if several species are being defended, specific data relating to pharmacokinetics, residues and analytical methods must be provided for each of them. At all events, only species and foodstuffs for which data have been provided can have an MRL established.

Restrictions on use (e.g.: age of animals, method of administration) may also be taken into account when establishing the MRL.

As regards the extrapolation of the MRLs, the EMEA has launched a number of discussions, in particular for minor species. Thus, when an MRL already exists for a major species, the only requirements in order to establish the MRLs for a minor species are the identification of the marker residue, evidence that the target tissue is identical to that of the major species, and a minimal validation of the analytical method. When an MRL does not already exist for a major species, an abridged dossier is possible, but the reductions proposed are minor and provide little incentive.

There have been other discussions concerning extrapolation for substances with similar MRLs in at least three categories of species (ruminant, monogastric, poultry). Extrapolations could be envisaged for all species, except fish.

**Proposal:**

With a view to improving the availability of veterinary medicinal products, it is important that all possible and scientifically valid extrapolation measures should be taken into consideration by the EMEA and the European Commission.

In principle, MRLs should be identical from one species to another, unless there are scientific reasons why this should not be the case (marker residue, target tissues, ratio of marker residue to total residues). MRLs should be established purely on the basis of the scientific assessment, from the standpoint of protecting the consumer, irrespective, for example, of the withdrawal period that would arise from the MRLs proposed.

The principle of extrapolation should be included in the MRL Regulation. This proposal is in line with the Communication from the European Commission to the Council and the European Parliament (COM(2000) 806 final) which “accepts the principle that, for any given active substance, MRLs should be established by extrapolation from the MRLs set for other species on a strictly scientific basis”.

1.4. MRLs define the acceptable limits for setting a withdrawal period to ensure that foodstuffs present no risk to public health. They are therefore the reference point for the control.

With regard to controls, we find ourselves faced with situations that are difficult to manage: different MRLs have been established for each species, molecules are included in Annex I even though an MRL has not been established for all tissues, molecules are included in Annex II even though an acceptable daily intake is defined.

For substances included in Annex I or Annex III an MRL has been established and an analytical method validated for measuring the residues. The MRL is the reference point for the control. This category poses no particular problem.

For all substances not included in Annexes I or III, no MRL has been established. A substance which does not have an MRL is therefore:
- a substance included in Annex II, or
- a substance included in Annex IV, or
- a substance which was given a “no recommendation” rating when first assessed by the EMEA, or
- a substance which was abandoned by the applicant while the EMEA assessment was ongoing, or
- a substance which has never been assessed by the EMEA.

The effect of the absence of an MRL on controls differs depending on the situation.

Substances included in Annex II have different profiles: substances of endogenous origin, substances habitually found in food, or other substances. For certain substances included in Annex II, an ADI has been established.

When an ADI has been established, this means there is a potential risk to the consumer. However, when the quantity of residue that it is possible to ingest (estimation based on the housewife’s shopping basket in a usage scenario proposed by the applicant) represents only a small fraction of the ADI, inclusion in Annex II may be proposed, if necessary accompanied by restrictions regarding use. When an ADI has been established and, following the administration of the drug as intended, it is highly unlikely that the animals will be consigned to slaughter, or the administration of the drug is confined to a small number of animals and occurs infrequently, experience shows that the EMEA may also propose inclusion in Annex II even though the quantity of residues ingested represents a not-insignificant portion of the ADI.

In theory, the absence of controls is justified for Annex II substances. However, as the European Commission notes, for substances with an ADI, maladministration of the drug can lead to quantities of residues in excess of the expected amounts, with a concomitant risk to any consumer exposed repeatedly to this situation. A similar scenario can be described for certain injectable formulations containing substances included in Annex II. The “residues at the point of injection” approach for fixing the withdrawal periods for drugs containing Annex I substances can be extrapolated to drugs containing Annex II substances with an ADI. A withdrawal period can be established when the estimation of the quantity ingested by the consumer as a result of consumption of injection sites exceeds the ADI.

With a view to protecting public health, the question of the usefulness of, or need for, controls for Annex II substances with an ADI can therefore be asked in certain cases (injectable, estimated ingested quantity close to the ADI), even though there is no “reference point” for carrying out these controls.

**Proposal:**

Any substance included in Annex II must be a substance that poses no risk. If an ADI has been established for a substance, i.e. a health risk has been identified, that substance should, after the risk has been assessed, be included in Annex I.

**Annex IV** at present contains 10 substances. Pursuant to Regulation 2377/90, the substances included in Annex IV are those for which no no-effect dose (NED) could been determined. For these substances, the mere presence of a residue implies a potential danger. The danger is identified whatever the threshold.

By the end of 2003 there had been forty or so “no-recommendations”, where the EMEA had been unable to come to a conclusion due to lack of data (analytical method, toxicological data, data on residues or combination of shortcomings). We cannot prejudge the outcome (Annex I, II or IV) of these applications, but in certain cases it is probable that an MRL could be established.
Almost 60 MRL applications have been abandoned. In these cases the EMEA has received an initial application dossier but has asked for more information and the applicant has felt unwilling to invest the extra effort needed to continue with the procedure. We cannot prejudge the outcome of the scientific assessment of these applications. Every application must result in a decision published by the risk manager.

It would be advisable to create a subdivision in Annex IV, for substances which have been assessed but for which it has not been possible to reach a classification decision.

**Proposal:**

In the interests of greater transparency, any substance for which an MRL assessment has been requested must be included in an ad hoc Annex to Regulation 2377/90/EC: in Annex I (substance with an ADI and definitive MRL), in Annex III (substance with an ADI and provisional MRL), in Annex II (substance without an ADI), in Annex IVa (substance definitely prohibited), or in Annex IVb (substance prohibited because the application dossier is incomplete or has been abandoned). Every application must culminate in the publication of a decision by the risk manager, in compliance with the principles of risk communication.

**Proposal:**

If it is not possible to establish a residue limit (the risk is suspected but not proven), the precautionary principle should be applied. From a control perspective, the mere presence of the substance concerned should lead to the foodstuffs being withdrawn from the human consumption chain.

These substances should be included in an Annex V, pending the receipt of additional information. Inclusion in Annex V would not be definitive, unlike inclusion in Annex IV, and follow-up controls could be performed.

For **substances for which no MRL application has been made**, the EMEA has no information.

**Proposal:**

In certain situations, notably where data are unavailable, the risk manager should be able to refer the matter to the EMEA, which would then be responsible for reviewing the data available on this substance, identifying the gaps in the data and delivering a relevant scientific opinion to throw light on the establishment of an MRL application dossier. The risk manager should subsequently be capable of taking charge of the research needed for the establishment of an MRL application dossier, providing the research teams with the scientific and financial resources necessary for this task.

In the three latter cases, the problem of controls comes down to preventing a suspected but non-proven risk. As things stand today, in the absence of an MRL no control can be carried out.

**1.5.** In Annex V to Regulation 2377/90/EC (describing the content of an MRL application dossier), it is stated that the method of routine analysis presented in the dossier must be one that can be used by the competent authorities for the detection of residues. However, it is not certain that these methods are actually used in the official control plans (often multiple residues). For all that, certain MRL application dossiers have failed solely because of problems relating to the method of analysis.

In the case of substances not included in Annexes I, II or III, their use is prohibited; no trace of residue is permissible. Analysis methods are not always properly developed and, where methods
do exist, the levels of performance of the various national reference laboratories in Europe differ. This is because certain laboratories are better equipped or have developed more sensitive methods of analysis which allow residues to be detected at levels lower than can be detected by other Member States. As a result, levels of control differ from one Member State to another, which can lead not only to public health problems but also to blocks on trade. For certain substances the Commission has established a “minimum required performance limit” (MRPL), representing the minimum detection threshold that each laboratory must guarantee. This is thus a quality criterion for the laboratories.

The MRPL should not be treated as a trigger for action, which would be tantamount to taking it as the reference point for the controls. As regards substances included in Annex IV, it is not admissible to consider the MRPL as the reference point for the controls.

For all that, an MRPL is necessary for control laboratories (Decision 2002/657) in order to avoid the risks and distortions due to differences in performance between laboratories.

Proposal:
The MRPLs as defined in Decision 2002/657/EC need to be re-assessed regularly in the light of the latest knowledge and or methods available. In every case, the most effective methods should be selected for the performance of these controls.

MRPLs should never take the place of MRLs, in particular in the case of Annexes IV and V. For these substances, they should represent the latest knowledge regarding analytical methods.

Finally, the establishing of MRPLs is inseparable from ensuring the absence of the prohibited substance throughout the production chain.

The establishment of "reference points" would be incompatible with the concept of Annex IV and with the MRL approach. For controls, where an MRL exists, other "reference points" are not possible since they would conflict with the MRL approach.

2. Control plans for residues of veterinary medicinal products in foodstuffs of animal origin:

Directive 96/23/EC sets out the arrangements for monitoring residues of veterinary medicinal products in foodstuffs of animal origin. The sampling strategy is very precise and very restrictive, based on national production figures and without taking any account of consumption data.

Veterinary medicinal products are subject to very precise European legislation at every level, from their inception to their administration to food-producing animals. Thus, there are rules governing:
- the studies to be conducted on the pharmacologically active substance, with establishment of the MRLs,
- the issuing of the marketing authorisation,
- the manufacturing and wholesale distribution of the veterinary medicinal product,
- prescription and administration to animals, with restrictions on use for certain categories (hormones, thyrostatics…),
- checks subsequent to the issuing of the marketing authorisation, such as veterinary pharmacovigilance.

All along this chain, measures concerning traceability and quality are established, implemented and monitored by the Member States. The control plan for residues of pharmacologically active...
substances in foodstuffs is only the last link in this monitoring chain designed to verify observance of the conditions applying to the use of these substances or the medicinal products containing them (observance of the withdrawal period, non-use of certain prohibited substances). The results obtained by these control plans reveal low rates of contamination.

There seems to be no sense, therefore, in setting up a surveillance plan to detect the presence of residues, since such a plan would necessitate a huge number of analyses for, in all probability, very few positive results. Instead, we should stick with a policy of targeted control plans. Nevertheless, it would make sense to change the way the sampling plans are drawn up, in order to create a system which is more flexible, more progressive, more adaptable to the different Member States and more capable of coping with emergency situations and potential deviations in the use of veterinary medicinal products (based on surveys and analysis of practices).

Proposal:
The system for the monitoring of residues of veterinary medicinal products in foodstuffs of animal origin should include:
- a control plan for substances whose use is strictly prohibited (Annex IV);
- a control plan for certain substances specified each year by the Member States on the basis of problems encountered during the year and the dangerousness of the substances. The number of substances specified to be monitored should be limited, but precise targeting criteria should be set.
- The introduction of specific control plans in response to an alert or a danger encountered during the year in a Member State and evidence of a danger to public health.

The general principles of the control plans should be established by a Directive, but the details of the sampling plans and the targeting criteria should be laid down in annual guidelines adopted by committee.

Proposal:
Before a surveillance plan is introduced, the routine analytical methods should be validated and the reference points clearly defined. For analyses requiring it, an MRPL should be established.

Proposal:
The sampling methods should follow the Codex Alimentarius guidelines (CAC/GL 16-1993 on the establishment of a regulatory programme for control of veterinary drug residues in foods) and take into account not only each Member State's national production figures but also levels of consumption by the population, and possibly other parameters such as quantities of veterinary drugs administered per livestock sector.

This mechanism for monitoring residues of veterinary medicinal products in foodstuffs would not be totally effective unless there were controls upstream to verify compliance with the rules governing veterinary medicinal products.

Proposal:
An effective surveillance system for residues of pharmacologically active substances in foodstuffs of animal origin must also include checks on the proper implementation of the rules concerning veterinary medicines by the Member States. Accordingly, the mission of the Food and Veterinary Office (FVO) must be extended to include the field of veterinary medicinal products.
3. Network of control laboratories:

3.1. The present architecture of the Community system of laboratories involved in the official control of residues, as provided for in the present Community legislation (notably Directive 96/23/EC), is apposite and should be maintained. It provides for the creation of a network of laboratories comprising, for each group of substances, a Community reference laboratory (CRL), national reference laboratories (NRLs) and routine laboratories. The main tasks of the CRLs are to provide scientific and technical assistance to the Commission, to promote and coordinate research into new analytical methods, to inform and train the NRLs on routine analytical methods and on technical advances made in the field of analysis, and to verify the competence of NRLs through the organisation of aptitude tests. The NRLs have identical tasks in each Member State, mutatis mutandis.

Proposal:
The proposal for a Regulation on official feed and food controls defines the tasks of each of the types of laboratory and applies them to the entire field of official controls that it covers. The French authorities applaud this. There is no need to repeat these provisions in the new legislative acts to come.

Proposal:
The laboratory selection criteria must be based on the technical competence and independence of the laboratories.

Proposal:
The strategic importance of the role of the CRLs in the Community health control system, and thus of their competence and independence, makes it essential to guarantee continued EU funding of their activities.

3.2. However, the French authorities consider it necessary to ensure this system is applied effectively, all the more so in view of the imminent arrival of the new Member States, in order to guarantee that all control laboratories (CRLs, NRLs and routine laboratories) satisfy the Community requirements in terms of competence, technical expertise, independence and quality organisation. The reason is that the guarantee of this competence guarantees the confidence of the public, the Member States and third countries in the quality of the health checks carried out in the European Union by the competent authorities and the professionals, both for exports and imports.

Proposal:
It would be advisable to build upon the support and expertise provided by the CRLs through the joint exploitation by the Commission and the Member States of the NRL results in the validation tests that they organise. Moreover, the CRLs and even the NRLs should be consulted systematically during the drafting of any Community instruments involving the implementation of analytical methods, in order to help guarantee the suitability and applicability of the provisions.
3.3. Finally, in addition to ensuring the competence of the laboratories performing official controls on residues, it is necessary also to ensure the quality and comparability of the results they produce. As stated in Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results, “As a result of advances in analytical chemistry since the adoption of Directive 96/23/EC the concept of routine methods and reference methods has been superseded by a criteria approach, in which performance criteria and procedures for the validation of screening and confirmatory methods are established”. It is essential that this approach defended by the Commission before the Codex Alimentarius be pursued and applied to the whole field of residues that are subject to official monitoring, notably through the establishing of minimum required performance limits (MRPL). As pointed out in Decision 2002/657/EC, it is necessary also to determine “common criteria for the interpretation of test results of official control laboratories in order to ensure a harmonised implementation of Directive 96/23/EC”. Article 6 of this Decision provides that “The result of an analysis shall be considered non-compliant if the decision limit of the confirmatory method for the analyte is exceeded. (...) If no permitted limit has been established for a substance, the decision limit is the lowest concentration level at which a method can discriminate with a statistical certainty of 1-\(\alpha\) that the particular analyte is present”.

Proposal:
It is essential to ensure that Decision 2002/657/EC is strictly applied, and that there is no confusion between MRPLs and maximum residue limits (MRLs).

4. Monitoring of residues of veterinary medicinal products in foodstuffs of animal origin imported from third countries:

Internally, the European Union has developed a comprehensive range of legislative provisions for residue monitoring. As regards imports from third countries, Directive 97/78/EC\(^1\) provides, in its Article 4, that physical checks be carried out on consignments presented on importation, which may include official analyses, to ascertain their compliance with the relevant legislative provisions. The frequency of physical checks on importation, including laboratory analyses, is laid down in Decision 94/360/EC\(^2\), adopted pursuant to Directive 97/78/EC. The frequencies of the taking of official samples for laboratory analysis should have been laid down at Community level since 1999.

Article 29 of Directive 96/23/EC\(^3\) provides that “Inclusion and retention on the lists of third countries provided for in Community legislation from which Member States are authorized to import animals and animal products covered by this Directive shall be subject to submission by the third country concerned of a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I … Compliance with the requirements of and adherence to the guarantees offered by the plans submitted by third

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countries shall be verified by means of the checks referred to in Article 5 of Directive 72/462/EEC and the checks provided for in Directives 97/78/EC and 91/496/EEC”.

Regulation (EC) n°136/2004⁴, adopted pursuant to Directive 97/78/EC, provides that "Member States must submit consignments of products presented for importation to a monitoring plan, with the objective to monitor conformity with Community legislation or, where applicable, national rules, and in particular to detect residues, pathogenic organisms or other substances dangerous to humans, animals or the environment”.

The implementation of such plans by the Member States should not, however, be regarded a check on the conformity of imported products. Such plans are not in themselves sufficient to guarantee a level of public safety equivalent to that offered for EU products, given the multiplicity of residues that it would be necessary to test for in order to offer such a guarantee and given the Member States’ limited testing capacities. It is therefore up to the authorities of the third countries to guarantee that products comply with safety standards equivalent to those in force in the EU and to demonstrate this.

While such principles are already recognised at Community level, more needs to be done to ensure that account is taken of them. To this end, the resources allocated at Community level need to be increased, so that the guarantees provided by third countries can be evaluated and verified in situ and can be regularly re-evaluated as the Community legislation evolves. To this end, those aspects of third countries’ legislation relating to the use of substances whose use is not authorised in the European Union must be examined.

Since the ability to provide these guarantees depends on the third countries’ testing capacities and on their laboratories’ performance limits, the European Union could provide technical and financial assistance as far as may be necessary.

Proposal:
With regard to importing foodstuffs of animal origin from third countries, we need to:
- make sure that the legislation in force in those countries concerning veterinary medicinal products is equivalent to that in force in the European Union (system for the authorisation and monitoring of veterinary medicinal products, prohibited substances, controls on use, residues monitoring plan);
- conduct import checks on the imported foodstuffs using the same analytical methods as those used for checking foodstuffs produced in the European Union, employing the same reference points for each substance.

Effective checks need to be introduced in the third countries of exportation.

Proposal:
Any legislation adopted in the European Union must be paralleled by “mirror measures” for imported products.

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CONCLUSION:

The European Commission asked the Member States for their comments and proposals on the following questions in particular:

1: Structure for appropriate differentiation of risk assessment and risk management for the assessment and control of residues in food of animal origin

Proposal:
It is important to separate risk assessment from risk management. When a proposal for inclusion in an Annex cannot be made on a purely scientific basis, the manager responsible for the final decision must make his decision on the basis of a benefit/risk analysis.

The process of assessment and establishment of the MRLs must adhere to the risk assessment guidelines set out in the 13th edition of the Codex Alimentarius Commission’s Procedural Manual (risk assessment, risk management, risk communication).

Proposal:
Contacts and exchanges need to be developed between the different body responsible for assessing maximum residue limits. Organised cooperation between the European Agencies (EMEA, EFSA), the European Commission Directorates-General concerned (DG Enterprise, DG Health and Consumer Protection, DG Agriculture), the Codex Alimentarius and its subsidiary bodies (JECFA, JMPR) would provide a common basis for assessing MRLs and allow all the different uses of a substance (pesticide, additive, veterinary drug) to be taken into consideration when establishing the MRL.

Proposal:
In certain situations, notably where data are unavailable, the risk manager should be able to refer the matter to the EMEA, which would then be responsible for reviewing the data available on this substance, identifying the gaps in the data and delivering a relevant scientific opinion to throw light on the establishment of an MRL application dossier. The risk manager should subsequently be capable of taking charge of the research needed for the establishment of an MRL application dossier, providing the research teams with the scientific and financial resources necessary for this task.

2: Procedures for extrapolation of maximum residue limits

Proposal:
With a view to improving the availability of veterinary medicinal products, it is important that all possible and scientifically valid extrapolation measures should be taken into consideration by the EMEA and the European Commission.

In principle, MRLs should be identical from one species to another, unless there are scientific reasons why this should not be the case (marker residue, target tissues, ratio of marker residue to total residues). MRLs should be established purely on the basis of the scientific assessment, from
the standpoint of protecting the consumer, without prejudging, for example, the withdrawal period that would arise from the MRLs proposed. The principle of extrapolation should be included in the MRL Regulation. This proposal is in line with the Communication from the European Commission to the Council and the European Parliament (COM(2000) 806 final) which “accepts the principle that, for any given active substance, MRLs should be established by extrapolation from the MRLs set for other species on a strictly scientific basis”.

3: Procedures for provision of reference points for control purposes

Proposal:
Any substance included in Annex II must be a substance that poses no risk. If an ADI has been established for a substance, i.e. a health risk has been identified, that substance should, after the risk has been assessed, be included in Annex I.

Proposal:
In the interests of greater transparency, any substance for which an MRL assessment has been requested must be included in an ad hoc Annex to Regulation 2377/90/EC: in Annex I (substance with an ADI and definitive MRL), in Annex III (substance with an ADI and provisional MRL), in Annex II (substance without an ADI), in Annex IVa (substance definitely prohibited), or in Annex IVb (substance prohibited because the application dossier is incomplete or has been abandoned). Every application must culminate in the publication of a decision by the risk manager, in compliance with the principles of risk communication.

Proposal:
If it is not possible to establish a residue limit (the risk is suspected but not proven), the precautionary principle should be applied. From a control perspective, the mere presence of the substance concerned should lead to the foodstuffs being withdrawn from the human consumption chain. These substances should be included in an Annex V, pending the receipt of additional information. Inclusion in Annex V would not be definitive, unlike inclusion in Annex IV, and follow-up controls could be performed.

Proposal:
The MRPLs as defined in Decision 2002/657/EC need to be re-assessed regularly in the light of the latest knowledge and or methods available. In every case, the most effective methods should be selected for the performance of these controls. MRPLs should never take the place of MRLs, in particular in the case of Annexes IV and V. For these substances, they should represent the latest knowledge regarding analytical methods. Finally, the establishing of MRPLs is inseparable from ensuring the absence of the prohibited substance throughout the production chain.

The establishment of "reference points" would be incompatible with the concept of Annex IV and with the MRL approach. For controls, where an MRL exists, other "reference points" are not possible since they would conflict with the MRL approach.
4: Procedures for precautionary measures for substances in imported foodstuffs
6: Procedures for the assessment of Third Countries residue control measures

**Proposal:**
With regard to importing foodstuffs of animal origin from third countries, we need to:
- make sure that the legislation in force in those countries concerning veterinary medicinal products is equivalent to that in force in the European Union (system for the authorisation and monitoring of veterinary medicinal products, prohibited substances, controls on use, residues monitoring plan);
- conduct import checks on the imported foodstuffs using the same analytical methods as those used for checking foodstuffs produced in the European Union, employing the same reference points for each substance.

Effective checks need to be introduced in the third countries of exportation.

**Proposal:**
Any legislation adopted in the European Union must be paralleled by “mirror measures” for imported products.

5: Procedure for short-term risk assessments in crisis situations

**Proposal:**
The rapid alert system set up by Regulation (EC) 178/2002 of 28 January 2002 is apposite and effective. The European Agencies (EMEA, EFSA), in collaboration with the national agencies, must be able to make a rapid assessment of the risk to public health in the event of a crisis, and to offer the Member States options regarding the crisis management measures to adopt.

7: Procedures for the nomination of Community reference laboratories

**Proposal:**
The laboratory selection criteria must be based on the technical competence and independence of the laboratories.

**Proposal:**
The proposal for a Regulation on official feed and food controls defines the tasks of each of the types of laboratory and applies them to the entire field of official controls that it covers. The French authorities applaud this. There is no need to repeat these provisions in the new legislative acts to come.

8: Procedures for the establishment of plans for monitoring and targeted controls

**Proposal:**
The system for the monitoring of residues of veterinary medicinal products in foodstuffs of animal origin should include:

- a control plan for substances whose use is strictly prohibited (Annex IV);
- a control plan for certain substances specified each year by the Member States on the basis of problems encountered during the year and the dangerousness of the substances. The number of substances specified to be monitored should be limited, but precise targeting criteria should be set.
- The introduction of specific control plans in response to an alert or a danger encountered during the year in a Member State and evidence of a danger to public health.
- The general principles of the control plans should be established by a Directive, but the details of the sampling plans and the targeting criteria should be laid down in annual guidelines adopted by committee.

Proposal:
Before a surveillance plan is introduced, the routine analytical methods should be validated and the reference points clearly defined. For analyses requiring it, an MRPL should be established.

Proposal:
The sampling methods should follow the Codex Alimentarius guidelines (CAC/GL 16-1993 on the establishment of a regulatory programme for control of veterinary drug residues in foods) and take into account not only each Member State's national production figures but also levels of consumption by the population, and possibly other parameters such as quantities of veterinary drugs administered per livestock sector.

9: Financing of measures of interest to the Community related to food safety

Proposal:
The strategic importance of the role of the CRLs in the Community health control system, and thus of their competence and independence, makes it essential to guarantee continued EU funding of their activities.

10: Residue control specific enforcement measures

Proposal:
An effective surveillance system for residues of pharmacologically active substances in foodstuffs of animal origin must also include checks on the proper implementation of the rules concerning veterinary medicines by the Member States. Accordingly, the mission of the Food and Veterinary Office (FVO) must be extended to include the field of veterinary medicinal products.

Proposal:
It would be advisable to build upon the support and expertise provided by the CRLs through the joint exploitation by the Commission and the Member States of the NRL results in the validation tests that they organise. Moreover, the CRLs and even the NRLs should be consulted systematically during the drafting of any Community instruments involving the implementation of analytical methods, in order to help guarantee the suitability and applicability of the provisions.
**Proposal:**  
It is essential to ensure that Decision 2002/657/EC is strictly applied, and that there is no confusion between MRPLs and maximum residue limits (MRLs).