



The American Chamber of Commerce in Japan  
在日米国商工会議所  
Animal Health Subcommittee



EUROPEAN BUSINESS COMMUNITY  
欧州ビジネス協会  
ANIMAL HEALTH COMMITTEE

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Animal Health Subcommittee  
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**Comments on the Proposal concerning the establishment of Provisional MRLs of Agrochemicals and other Substances in Food (2<sup>nd</sup> draft)**

The joint Animal Health Committee of the American Chamber of Commerce in Japan (ACCJ) and the European Business Community in Japan (EBC) respectfully submit the following comments on the captioned proposal concerning provisional MRLs.

We would appreciate your consideration of the following points.

Comments:

• **Method for establishing provisional MRLs:**

According to the 2<sup>nd</sup> draft for the establishment of provisional MRLs, existing standards will be taking into account in the following order of priority: 1) the CODEX MRL, 2) the domestic standards set at the time of product registration, 3) the MRLs in foreign countries.

However, the draft also mentions that foreign countries' standards may be adopted if it is deemed necessary to consider the production, distribution and usage condition of these agricultural chemicals used for the imported foods.

The domestic standards defined in the 2<sup>nd</sup> draft are 50ppb or less for products regulated by the Pharmaceuticals Affairs Law. However, this value is not necessarily the detection limit determined at the time of product registration (the detection limit applied fore registration before the 1970s was above 100ppb), and some of these standards are not necessarily always justifiable scientifically. Foreign counties usually calculate MRLs based on ADI taking the food basket of that country into consideration. This type of methodology is more justifiable from a scientific point of view.

Other countries do not control the residues of some products with residue standards such as MRLs or tolerance levels but rather with detection limits. However, even in these cases the detection limit is calculated based on the relationship between ADI and the total daily intake calculated from the average food basket.

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Considering the current market share of imported livestock products, i.e., more than 70% for beef, about 50% for pork and about 30% for chicken, residue standards in exporting countries should be taken into consideration, at least for the residue of imported animal products.

For substances for which MRLs have been established in foreign countries through more appropriate, scientific methods or for which the ADI has already been evaluated and detection limit has been validated as appropriate for residue control, we recommend that these standards and methods be fully taken into account.

- **Residue control of organs / tissues without MRLs (usually minor organs / tissues) for animal species with MRLs that have already been determined:**

The 2<sup>nd</sup> draft suggests that the lowest MRL level of the organs for which an MRL has already been established shall be applied to organs/tissues without MRLs.

However, the consumption of organs / tissues without MRLs, i.e. minor organs/tissues, is quite small compared to organs with MRLs, and thus, the daily intake of these tissues calculated as “allowable residue amount” multiplied by “the consumption amount of that organ/tissue”, which is the basic concept for the establishment of an MRL, would be much below the ADI even when adopting the highest MRL among the organs with MRLs.

We understand that Japan’s unique food consumption patterns were taken into consideration in the determination of those final MRLs that have already been established. If that is the case, we think that it is appropriate to adopt the highest MRL (usually the MRL of liver or kidney) for minor organs/tissues. We recommend the MHLW reconsider the residue control over organs/tissues without MRLs.

- **Residue control of minor animal species:**

The way of thinking concerning residue control for minor organs/tissues can also be applied to minor animal species.

In the 2<sup>nd</sup> draft, the default limit (currently 10ppb) or the rules of no residue will be applied to minor animal species without MRLs. However, if MRLs or other residue standards have been established for major animal species, from food basket point of view it would be appropriate to classify these minor animal species into the categories of mammals, poultry and fish, and to adopt the MRLs of major animal species in the same class of animals. Since many of the minor animal species into have been grouped into “other terrestrial mammals”, “other poultry” and “other fish” in the 2<sup>nd</sup> draft, it seems appropriate to refer to the standards of major animal species for minor animal species in these categories.

If the default limit applies to minor animal species as in the current draft, it will largely limit the use of animal drugs and other products for these minor animal species. Even in the current situation, there are few products approved for these minor animal species, and the current proposal would further limit the scope of use of animal drugs in these minor animal species, creating problems from the point of view of animal welfare. We recommend the MHLW consider the application of reference standards for minor animal species from the MRLs of major animal species.

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- **Uniform limit (default limit):**

The 2<sup>nd</sup> draft states that applying 10ppb as a default limit is appropriate, referring to EU regulations and substances with the lowest ADI. However, as far as we understand, no other country applies a uniform default limit of 10ppb on animal drugs or other substances used for food animals. There is considerable difference between the residue in crops and residue in animal bodies, and it is very difficult to adopt the same standards for both crops and animals. Applying the same default limit can be considered a form over-regulation.

Also, even if one applied the default limit of 10ppb to all animal tissues, it would be difficult to conduct accurate quantitative assays with reasonable precision at this very low level using current assay techniques. Furthermore, it would be difficult to conduct the same quality assay in all assay laboratories all over Japan, which may cause false positives as a result of inaccurate assay results.

For those cases in which the default limit will be adopted, it would be better to consider standards, case by case, instead of applying the default limit, especially for substances whose residue is controlled with validated assay limit in other countries and residues of minor animal species for the substances with MRLs for major animal species.

For example, if there is an appropriate explanation based on the ADI, it would be appropriate to adopt the detection limit applied in foreign countries or adopt the standard for major animal species to minor animal species.

- **How to handle “exempted substances” which have no possibility to cause damage to human health:**

With regards to substances in this category, substances that clearly do not have any potential to cause damage to human health are exempted from default limit application. However, not all of the substances that qualify for this category are included in the list of “exempted substances”, and it is unclear how substances included in the list and ones not included in the list will be handled. Also, it may be confusing for consumers if this discrepancy exists. Furthermore, for substances without any residue standards and not listed as “exempted substances”, it is unclear whether a default limit will be applied to these substances or not. This lack of clarity on how to handle these substances will cause further confusion.

Therefore, we recommend handling all these exempted substances in the same way, and to list all the substances if listing is needed, or to differentiate from substances regulated under the default limit by some other way.

- **The principle that antibiotics should not remain in food (zero-residue policy):**

The definition of “food shall not contain antibiotics” is a totally different concept from the positive listing system. The definition of “it shall not remain (zero-residue)” may be confused with substances regulated under the concept of “should not be detected (zero-tolerance)”. The later definition is applied to substances for which ADI cannot be set due to hazards to the human health such as carcinogenic or other safety/toxicity profiles, and there is the possibility for misinterpretation of antibiotics as hazardous substances, which may cause excess concern over antibiotics. Where Antimicrobials for which MRLs have been set for animal species, tissues/organs, etc., at a relatively high residue in food up to ppm level, it seems extreme that for antimicrobials without any standards will not be able to contain any residue even at very low level, which seems to be far from the principle of establishing scientific residue standards.

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For antibiotics other than exceptional ones that have toxicity problems, such as nitrofurans compounds, it is possible to set ADIs (toxicologically and microbiologically), and also possible to establish the MRLs or other residue standards. To avoid confusion in consumers, we recommend MHLW to exclude the provision of “should not be contained” or take some kind of measure to clarify the differences between antibiotics and substances of zero-tolerance, which, based on their toxicity profile, are subject to the “should not be detected” policy.

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