NTMs MAPPING – 2019 (updated 5/4/2019)

Industrial NTMs

1) Medical devices – Lengthy authorisation procedures

Description: Through the reform introduced on November 25, 2014, with the revised Pharmaceutical Affairs Law coming into effect, a new certification system applying for certain categories of medical devices was also introduced. A five year Action Plan was adopted to accelerate the authorization procedures. A significant progress on the reduction of the 'device lag' is recognized.

State of Play: **Partially solved**

Next steps: Current 5 year action plan closed in 2018. However, even after the completion of the action plan, a system should be in place to monitor the approval status. This issue needs to be followed up, to ensure the monitoring of the approval status takes place efficiently.

2) Medical devices - Good Clinical Practices requirements compliance with International standards ISO 14155

Description: In February 2013, Japan issued GCP Guidance indicating that Japan accepts foreign clinical data which conforms to ISO 14155 without duplicative requests for data generated domestically

State of Play: **Not solved**

Next steps: The outcome is not yet acceptable, as Japan has not accepted foreign clinical data from EU companies because it considers their clinical evidence too weak.
In the EU, Medical Device Directive (93/42/EEC) has been replaced by Medical Device Regulation (Regulation (EU) 2017/745). Under the new regulation, more clinical evaluation will be expected but as the regulation is new, one has to collect information about an impact by MDR. If clinical data with stronger clinical evidence can be generated under MDR, Japan may accept more foreign clinical data from the EU.

3) Medical devices - Unique labelling requirements

Description: Through the reform introduced on November 25, 2014, with the revised Pharmaceutical Affairs Law coming into effect, Japan revised the system of unique labelling requirements allowing package insert, or tempu-bunsho, to be omitted under certain conditions, hereby solving the issue satisfactorily. Due to the revision of tempu-bunsho conditions progress was made on this issue as tempu-bunsho can be attached in electronic format. However, because attachment in electronic format is only allowed with advance consent of the product users, in practice, no one introduced electronic format of tempu-bunsho.

State of Play: Not solved

Next steps: In order to make it possible to use electronic format of tempu-bunsho, the condition should be reviewed: the condition of advance consent of the product user under the current regulation should be abolished and electronic format of tempu-bunsho allowed, provided that paper-based tempu-bunsho is available upon request and available online at PMDA website. This proposal has been discussed among industry associations. Since 2018, the Japanese industry associations has been launched a task force to work on a proposal to Japanese government in order to improve the labelling requirements.

4) Pharmaceuticals – Transparency and predictability of pricing, listing and reimbursement rules

Description: EFPIA Japan is disappointed with the outcome and process of MHLW prices revision, which reduces the scheme for innovative products. In practice the business environment risks to go back to the situation that existed before 2010, when the drug lag existed and the pilot pricing scheme for innovative products had not been launched. The Japanese pricing system as such is transparent but the consultation and review procedures lack transparency

State of Play: Not solved – but only the transparency / predictability issue can be followed up at EU level (domestic drug pricing is beyond EU competence)

Next steps: The EPA is not the right forum for discussing the pricing scheme of innovative products due to the taxation /political dimension of the issue. EFPIA Japan is approaching the issue by supporting the relevant Ministerial stakeholder to a more efficient use of resources, so cuts do not necessarily have to go to the detriments of innovative drugs.

5) Pharmaceuticals - 14-day prescription rule

Description: On 16 June, 2015, the Regulatory Reform Council submitted its third report of recommendations “Toward a Japan Full of Diversity and Vitality” to the Prime Minster. In

accordance with the recommendation of the report, the Cabinet has decided that the government would review the 14-day prescription restriction on new drugs in FY 2015, taking into account the assurance of drug safety. The Cabin et instructed MHLW to review the 14-day prescription rule. In November 2015 the MHLW refused to review the rule on basis of safety concerns. Following this the Cabinet re-instructed the MHLW to review the rule but so far there has been no response by MHLW. The 14-day prescription rule is not a priority for the European pharma industry.

State of Play: Not solved

Next steps: EFPIA Japan proposed to prepare data to compare the coverage of 14-day prescription rule and Post Marketing Surveillance (PMS) in order to demonstrate that PMS could cover the 14-day rule.

6) Pharmaceuticals – Specifications and testing methods for biologicals / Data requirements for vaccines

Description: In September 2013, Japan amended "the Minimum Requirements for Biological Products (MRBP)" by the Ministerial Notification to further align them with international practice. The experts from Japan and the EU have acknowledged the need to discuss further harmonization in appropriate bilateral or multilateral fora. EFPIA Japan is not satisfied with the outcome because the amendment of 2013 only provided a minor change in the testing criteria and how to conduct tests. Same quality testing is still required after entry into Japan. EFPIA Japan does not see in which multilateral fora the issue could be discussed as ICH does not cover vaccines (despite the fact that EMA had proposed to have ICH also cover vaccines under its scope) and discussion in the WHO is not active.

State of Play : Not solved

Next steps: EFPIA (Brussels) is actively discussing this issue with DG SANTE. More pressure needs to be applied on Japan to change the testing methods.

7) Cosmetics and quasi drugs: Harmonisation of regulations on ingredients

Description: Regarding threshold of fluoride used in toothpaste, the Japanese government has made good progress so far. However, as a future goal, mouthwash products with fluoride should also be approved as quasi drug. Currently the Japanese government is taking steps towards this direction. For now two Japanese mouthwash products (by Japanese companies Sunstar and Lion) have been approved as drugs requiring instruction by pharmacist. Under the Japanese regulation, the approval as quasi drugs has to pass through the following steps: a) drugs requiring pharmacist's instruction move to Over the Counter (OTC) class I after 1 year; b) OTC class I drugs move to class II or class III after 1 year (low risk products such as

mouthwash usually belong to class III); c) if there are no issues, after 3 years, OTC class III products are approved as quasi drugs.

State of Play: Partially solved

Next steps: Following the steps described above, the fluoride mouthwash products are expected to be approved as quasi drug in 2022. The Japanese government is taking these steps balancing act various stakeholders, whom are either in favour or opposed to the use of fluoride. The expected steps for mouthwash need to be monitored.

8) Standard for cross laminated timber

Description: While the adhesive issue has been delisted, due to a direction shift in the European industry on this topic, the issue with the new CLT standard remains. MAFF and Forestry agency have been collecting data on domestic karamatsu or hinoki wood as a routine review which takes place every five years). These data could now be included in new specific standards for width laminated timber under the Building Act. If the criteria to define the product in the new standards are based on (domestic) wood species rather than on the performance of the product , European timber will be affected.

State of Play: Not solved

Next steps: MAFF is still currently conducting the data review; several expert meetings have already taken place but the timeline for finalising the review is not yet set. The issue needs to be monitored and MAFF and FA should be lobbied to adopt a performance-based criteria rather than a species-based criteria

9) Electronic Equipment and Telecommunications Terminal Equipment (RTTE) - Conformity assessment procedures – use of Supplier's Declaration of Conformity

Description: In June 2013, Japan revised Article 2-2 of the Ordinance concerning Technical Regulations Conformity Certification of Specified Radio Equipment (on the basis of the Article 38-6-1 and Article 38-33-1 of the Radio Law). Specifically, the scope of the 'Supplier's Verification of Conformity (SVC)' scheme managed by the Ministry of Internal Affairs and Communication (MIC) was amended and wireless LAN (Wi-Fi) installed in mobile terminals was included in the scheme. The SVC process allows a manufacturer to take personal responsibility for verifying whether the product meets the relevant technical requirements. This is possible for a number of telecom related products, however not for base stations. MIC rejected to include base stations for mobile networks on the grounds of higher risks for interference. The EBC is disappointed with the outcome as it has requested to cover base stations and has no interest in mobile terminals. The EBC lists this issue as an NTM in its White Paper.

State of Play: Not solved

The "self-verification of conformity" process can be applied to "special specific radio equipment", which is defined in Article 2-2 of the "Ordinance concerning Technical Regulations Conformity Certification etc. of Specified Radio Equipment". Art 2-2 should also refer to radio base station equipment, defined as the "specified radio equipment" in Article 1.

Next steps:
The scope of the "self-verification of conformity" process is extended to cover more type of telecom equipment, including base stations for cellular networks.

10) The periodical testing requirement for AAS base stations.

Description: Article 73 of the Radio Act requires the testing of base stations. Radio Law Enforcement Regulations (Art. 41, 2-6; Art. 41-3) mandate the periodic inspection of radio equipment and explains the points to be checked. The scope of the tests is limited to macro cell base stations above 1W per antenna. Small cell base stations below 1W per antenna do not require testing. The exact items to be tested are listed in Annex 7 of the Radio Law Enforcement Regulations under other types of base station. EBC informed us that how the tests should be conducted is not specified. On completion of these tests a form is to be used to report on the results. The EBC lists this issue as an NTM in its White Paper.

State of play: not solved
This is seen as a major issue for EBC at the moment. They suggest that the periodical requirement to test base station performance is increasingly posing challenges. At the moment tests are being carried out using an antenna port on some types of base stations (typically those at lower frequencies). As base stations are becoming smaller this is becoming more difficult. Furthermore, higher frequency Active Antenna Systems (AAS) (that do not have an antenna port for testing) are being tested using Over The Air (OTA) methods. However, currently in-field tests of AAS using OTA are difficult, with EBC explaining that if an inspection is mandated then the base station needs to be measured in the testing facility, and then set up again in-field. EBC suggest that this testing requirement is cumbersome and outdated. The performance of base stations is constantly being monitored negating the need for periodical tests. Furthermore, OTA methods are also expected to become more widespread following the introduction of 5G.

Next steps:
Japan should review its radio regulation to ensure it avoids imposing undue requirements on radio base stations, especially in respect of AAS (Active Antenna Systems). In particular, the periodical inspection of radio performance at antenna or equivalent monitor ports should be carefully reviewed.

11) IPR (outside the NTM EPA lists)

Description: While Japan has laws and regulations against counterfeits, one peculiarity of the Japanese system is the possibility to import counterfeited copies for personal use. This is unfortunately often abused, to also include commercial-like imports especially via e-commerce. Under Japanese law, the goods infringing IP rights are prohibited to be imported

into Japan. However, since customs has no specific definition of "counterfeit goods", they have to rely on the definition under the Japanese trademark law which as explained above holds that the act of importation for business purposes only constitutes an infringement of trademark rights. Accordingly, the customs cannot stop the counterfeit goods imported for other purposes than commercial. With the introduction of the internet and internet shopping, "personal use" imports have increased rapidly, and the knowledge that Japan Customs will not seize the shipment where "personal use" is claimed is well-spread.

State of Play: Not solved

Next steps: Options to solve this situation would be to request Japan to modify its legislative framework. They could include : a) to remove the requirement of commercial act from the Trademark Act; b) to add a prohibition of possession in the article 37 of the Trademark Act like an indirect infringement; c) to prohibit the possession of counterfeiting goods. The Japanese patent d) to refine the notion of "personal use"; e) to change the definition of "import" in line with the definition given by the Rolex case of the CJEU (Blomqvist vs. Rolex, 6 February 2014); f) to prohibit the import of counterfeiting goods regardless of the personal or commercial use

12) Registration of foreign qualified lawyers (outside the NTM EPA lists)

Description: Article 10 of the Japanese Act on Special Measures concerning the Handling of Legal Services by Foreign Lawyers (the "Foreign Lawyers Law") (Act No. 66 of May 23, 1986) contains several provisions discriminating against foreign lawyers. One of the requirements for a person applying to become a registered foreign lawyer is to have a minimum of three years' experience. A further element of this three-year requirement is that Article 10(2) of the Foreign Lawyers Law requires that any experience gained by the applicant in can only be counted as one year in the calculation of the requisite three years. This effectively means that that the other two years required to make up the three years must be gained by the applicant outside Japan. In addition to the previously mentioned difficulties, the Japanese Attorney Act (act No. 205 of June 10, 1949) requires lawyers to register individually rather than as a firm. Article 8 of the Act states that "To become an attorney, a person must have his/her name registered on the roll of attorneys held by the Japan Federation of Bar Associations." The Ministry of Justice set up a working group to look into this issue and come up with recommendations to amend these requirements. It has done so and is not suggesting that the three-year requirement is amended, so only one year has to be outside of Japan, instead of the current two years. The three-year requirement will however still remain. The proposal was scheduled to be put to a vote in the 2018 session of the Diet, but this never happened.

State of Play: Not solved

Next steps: Japan explained during the EPA negotiations that they consider their legislation to be non-discriminatory since a foreign national is free to choose to become either a *Bengoshi* (laywer certified by the Japanese system) or a *Gaikokuho-Jimo-Bengoshi* (lawyer certified abroad and exerting the profession in Japan) and that the same choice applies to

Japanese nationals. Depending on the category chosen, different rules apply but within the category there is no discriminatory treatment of non-Japanese lawyers. While this may be true that in theory, in practice the requirements to become a *bengoshi* are so high that de facto only Japanese lawyers can get this status. The three-year-requirement should be removed, as it makes no sense that Japan makes additional requirements compared to the country that has certified the lawyer in the first place - especially since the lawyer can only work with that jurisdiction. At the very least, experience in home jurisdiction should be recognised regardless of where it has been practised.

Agri-related NTMs

1) Organic food

Description: Because the 2013 package only covers plant based organic products, its coverage is too narrow to satisfy the EU's interest in particular regarding organic livestock products, organic wine and others. Regarding the quasi-governmental certifying bodies, a list has to be published in the Japanese official gazette and any updates and changes need to be reflected in it in order to be effective. In case of changes in the list, business needs cannot be addressed immediately, as the list has to be updated before certifying bodies can benefit from the system. For publication of the details of certifying bodies the address has to be indicated in a Japanese format, which does not exist in reality. While the package of 2013 has been addressed, the practical implementation regarding quasi-governmental certifying bodies and the limited scope of the arrangement are not satisfactory for the EU. All issues concerning organics should be addressed within the future negotiation between the EU and Japan. Regarding organic livestock and processed organic products, Japan notified to the WTO in January 2018 its intention to expand the scope of mandatory use of JAS organic logo for those products.

State of Play: not solved

Next steps: New EU Regulation on organic farming requires having a bilateral international trade agreement for equivalency within 5 years after entry into force of the new regulation, by replacing the current equivalency arrangement. Therefore, The EU needs to start negotiating such agreement with Japan (on the basis of the currently existing equivalency arrangement). The work will start this year and Japan is one of the priority countries for the EU in this sector. It is expected that the existing issues will be solved at the time of negotiation.

2) Food that needs to be imported using third party (outside the NTM EPA lists)

Description: In preparations for the entry into force of the old TPP, Japan set up a scheme where certain products with high sugar content had to be imported using an organisation called Agriculture & Livestock Industries Cooperation (ALIC). They first informed that 20

products in four different categories had to be imported through them. The categories are cocoa related products (chocolate), milk powder, sweet beans (an), coffee and others. This was later revised to include only four tariff lines for EU products.

- 1806.20-121 Chocolate or other cocoa preparations weighting more than 2kg and having more than 50% sucrose by weight
- 2101.11-110 extracts, essences and concentrates with more than 50% by weight of sucrose
- 2106.10-219 Protein concentrates and textured protein substances with more than 50% by weight of sucrose
- 2106.90-283 Milk powder with added sugar in containers of less than 500 g

While there doesn't appear to be an additional fee as first feared, importation has to go through ALIC which means an additional administrative burden for companies. In practice, it means one additional day for customs clearance.

State of Play: Not solved
Next steps: Japan should immediately abolish this scheme and allow the importer to import without having to use ALIC.

SPS related NTMs

1) Food safety – Insufficient harmonisation of requirements with international recommendations/standards on regionalisation for animal diseases

Description: In practice regionalisation decisions of the EU are not yet recognised by Japan, although the two sides recognise the concepts of zone and compartment as specified in the OIE and in Article 10 of the EPA (the SPS Chapter). The two sides have agreed to move towards mutual recognition of regionalisation decisions through confidence building, including recognition of the EU as an entity in itself. The exercise has started on priority diseases, i.e. FMD for Japan and Avian Influenza diseases for the EU, and it runs in parallel with the export applications of poultry and pig meat from Japan. At the same time, conclusions are limited to products with existing market access without prejudice to potential future applications by either party.

State of Play: Not solved

Next steps: The Commission has raised the matter with Japan in different meetings and fora. Discussions are on- going continuously with a view to find a rapid solution to resume trade. It is important to make sure Japan accepts that each of these discussions is carried out within the framework of the EPA which is already in force, where their main interlocutor is the European Commission, while information exchanges and further clarifications can take place bilaterally between Japan and the concerned Member State.

2) Food safety – Insufficient harmonisation on conditions for import of bovine meat and other bovine products with international standards (OIE) on BSE

Description: Insufficient harmonisation on conditions for imports of bovine meat and other bovine products with international standards (i.e. OIE) on Bovine Spongiform Encephalopathy (BSE) was one of the NTMs under the EU-Japan EPA negotiation. EU Member States which have equal OIE status are not treated in the same manner and Japan's import conditions do not reflect the conditions under OIE for corresponding risk categories. In opposition to OIE standards, Japan applies age limits for cattle. Additional EUMS applications are necessary for processed bovine products (i.e. meatballs for Sweden) as Japan requires the establishment of a protocol and animal health requirements for fresh meat before starting discussions on processed bovine meat products. As of April 2019, nine Member States (France, the Netherlands, Ireland, Poland, Sweden, Austria, Denmark, Italy and UK) can already export bovine fresh meat to Japan. Pending applications are from Belgium, Germany, Spain and Finland. Japanese authorities have been assessing the applications by EU Member States in a steady manner. However, Japan still does not recognise the OIE categorisation of risk assessment as it is: Member States deemed to have a negligible status within the OIE still need to go through risk assessment in Japan. Regarding processed bovine products, on 15 November 2017 MHLW informed quarantine offices about a scope expansion of Italian beef exports to other bovine products, including processed products containing beef products and ingredients of bovine origin (e.g. beef sauce and beef broth). The beef to be processed is limited to Italian beef slaughtered for exports to Japan and additionally, use of already approved fresh beef from other EU Member States or third countries is not allowed. Additional requests on processed bovine meat by other Member States are pending. Concerning ovine meat, only France and UK are eligible to export fresh sheep meat (excluding goat meat). Beyond the fact that the export approvals of the Member States have been advancing, Japan cannot be deemed to be in compliance with international standards (OIE). Most EU Member States have had a negligible BSE status in the OIE for a long time. Additionally, the age limit of cattle is still against the OIE standard. This issue is under discussion in FSC prion expert committee, but other priorities have prevented advancement on the file.

State of Play: **Not solved**

Next steps: Provided that Member States submit the information requested swiftly, Japan committed to continue its efforts to assess the applications without delay. It will be necessary to monitor on a regular basis if these commitments are fulfilled in each case. In addition, Japan should respect the international standards and to be consistent to the OIE standards.

3) Food Additives

Description: Japanese list of accepted food additives is not fully in line with the applicable international standards set up at the CODEX Alimentarius and Japan still does not accept some additives. The definitions of food additives and of food ingredients which could be used as food additives are not clear in the Japanese legislation and often a case by case approach is taken. Regarding food additives and transparency in particular, specific commitments are outlined in the Annex to the SPS Chapter of the EPA. English translations of required documents and Guidelines have been made publicly available by Japan. In 2015 MHLW also set up the Food Additive Designation Consultation Centre (FADCC) in order to assist applicants, and the Japanese government has posted a person in the Japanese mission to the EU in Brussels in order to help companies with the application process. The standard processing time of applications is included in MHLW and FSC documents, publicly available. Therefore, there has been an overall improvement in transparency. Nevertheless, Japan's approach to food additives still continues to pose problems as international guidelines are not fully taken into account. Substances deemed safe elsewhere, including by international standard setting bodies, do not for the moment benefit from an expedited approval in Japan. In particular regarding processing aids, initial data sets required by Japanese authorities for risk assessment differ from those required by EU authorities. This usually entails the need for companies to generate standalone data for risk assessment in Japan.

State of Play: **Not solved**

Next steps: Since several new food additives are approved every year in the EU, the procedural aspect is of critical importance for the future and close follow-up is necessary.

4) **Approval of food additives for wines by the NTA**

Description: The approval process for food additives for wines should be made fully transparent and specific standard processing time for completing the various steps should be included in the relevant legislation. Japan needs to approve a list of priority wine additives for use in Japan in a speedy way. Additives, for which extended use is sought through NTA approval, should be dealt with in an expedited manner. Wine additives and processing aids have been partly addressed within the Trade in goods –chapter, under facilitation of wine exports, which foresees designation of 28 substances used in wine by Japanese authorities. The first phase wine additives are fully designated by 1 Feb, 2019. The second phase is due on 1 Feb 2021. The designation of the substances allows the wine industry to expand the variety of its export products to Japan. However, because Japan is not an OIV member, future harmonisation of oenological practices is not guaranteed. Therefore this issue needs to be followed up carefully.

State of Play: **Not solved**

Next steps: Development along with the wine package of the EPA should be monitored carefully. In addition, the EU should continue to encourage Japan to be a member of OIV for further harmonisation of oenological practices.

5) Food contact material

Description: The Japanese Food Sanitation Act regulates not only food but also products that come in contact with, as well as toys for babies and young children. Examples of products that are covered by the Food Sanitation Act are: plates, pans, cutting boards, plastic containers, utensils, cups and baby toys. If a product is covered by the act it needs to undergo a test usually based on the material of the product, and if imported to Japan a submission of a test report needs to be presented to the quarantine officials at the port of entry. This test report has to be in conformity with the Japanese regulation and there is no recognition of other regions' conformity assessments or approvals. However, it has been difficult for the exporters due to the difference in testing methods between the EU and Japan. Small and medium sized European companies have withdrawn from the Japanese market because they do not have the resources or the ability to negotiate bilaterally with Japanese authorities or deal with all requirements.

State of Play: Not solved

Next steps: Japan should recognise food contact related testing and approvals carried out in accordance with EU regulations. In addition, MHLW's introduction of a positive list system for food contact materials, especially resin based ones, should be monitored. The legislation will be adopted in 2019 with a transitional period and full implementation taking place in 2020. The WTO notification will be redone with a complete positive list, once established.

6) Feed Additives

Description: Even for multinationals based in EU the feed additive approval procedure remains an obstacle. There is a mandatory requirement to perform efficacy trials in Japan. Even if there are valid trials available with the same species, at least two trials out of minimum three trials must be conducted using Japanese strains in Japan. For *enzymes* this requirement has been deleted but for other chemical additives (e.g. *VevoVitall)* it is still a mandatory requirement. From the animal welfare point of view, unnecessary animal tests should not be repeated and there is no scientific reason why the domestic trials are necessary.
Even though regularly new additive applications are accepted, even compared to food additive process, the process is not transparent enough, when it comes to what criteria are in place in order for the authorities to accept a new application of an additive and how many new additives can be accepted for the evaluation stage.
In addition the English translation of "Handbook" has not been revised. Especially in the case of *enzymes* there is no translation (only English translation of the previous version is available and only the chemical additive parts were translated). Also, there is no official English version of the Japanese Feed Additive Specification and Standards available.

State of Play: Not solved

Next steps: MAFF needs to provide guidance regarding approval of feed additives, while close monitoring is necessary to ensure its application by quarantine offices is performed in a consistent and coherent manner, with no room for case by case interpretation.

8) Microbiological standards

Description: Japan should take into account the EU requirements for microbiological criteria as giving guarantees similar to the Japanese regulatory requirements, without imposing additional inspections. This concerns in particular the presence of *coliforms* in dairy products, for which at present there is zero tolerance in Japan. Japan applies zero tolerance on a microbiological criterion of dairy products, in order to detect cases such as insufficient heat treatment during its processing or a poor hygienic practice by producers. There is no international standard on criteria for indicator bacteria, and if Japan were to review the current criteria, it would first need to review available scientific data and conduct a research on how microbiological criteria are set abroad. With this in mind, Japan has started to look into how other countries set their microbiological criteria. MHLW is currently conducting a study on other countries' microbiological standards (including the EU). MHLW's review of the current standard has to be carefully followed up.

State of Play: **Not solved**

Next steps: Once the review is finalised, the results of such assessment need to be followed up closely and checked if based on scientific data.

9) Export of fruits and vegetables

Description: Japan should consider removing requirements to negotiate protocols for each variety of fruit. It should be sufficient to include an explicit mention to the other varieties of fruit in the phytosanitary regulation. Circumstances for diseases and pests on fruits and vegetables vary among member states as well as among varieties of certain products and easing and lifting ban on import from the EU should be considered on a case by case basis. It should be considered on case by case basis by relevant authorities bilaterally. Japan's current processing of applications for exports of fruits and vegetables is lengthy and cumbersome. Japanese authorities need to make public their assessment requirements and standards for quarantine measures, for example cold treatment and addition of new varieties. By providing public information about these, the application process could become smoother.

State of Play: **Not solved**

Next steps: It will be necessary to pressure Japanese authorities to publicise the assessment requirements and the overall guidance.

10) Chemical MRLs (Maximum Residue Limits)

Description: Chemicals accepted safe by international standard setting bodies should be dealt in an expedited manner. On 26th December 2017 MHLW released a notification about timeline for administrative work after receiving risk assessment from Food Safety Commission. Timeline is set as one year, on average. The timeline notification will also be released in English, but no information about when this would happen, is available.

State of Play: **Not solved**

Next steps: one needs to follow up how the new notification will function in practice.