

**XI Meeting of the Special Committee on Standards and
Technical Regulations Mexico – EU FTA
Videoconference
8th November 2012
Minutes**

1. OPENING

1.1. Welcome words and opening remarks

The EU was hosting party of this Special Committee. The EU co-chair welcomed all participants to the meeting. The EU recalled the positive developments achieved throughout the year, regarding for instance whiskey, textiles labelling, recognition of Mexico of certain EU (authorized) pharmaceuticals. The EU also thanked the Mexican Ministry of Economy and Mexican mission in Brussels for the good collaboration with DG TRADE and the EU Delegation in Mexico. The EU further wished to carry on a fruitful and smooth discussion of all the issues in the agenda. The list of participants at the meeting is contained in annex 1 to these minutes.

1.2. Approval of the agenda and minutes of the previous meeting

The Parties approved the agenda of the meeting, which is contained in annex 2. The minutes of the previous meeting had already been approved and signed by the parties.

2. ISSUES OF INTEREST TO MEXICO

**2.1. Honey containing pollen from genetically modified maize MON810,
Ruling from ECJ**

The Commission representative informed that in September 2012 the Commission adopted a proposal for a new Directive amending Directive 2001/110/EC relating to honey (COM(2012) 530), which will now follow the co-decision procedure. The new proposal clarifies that pollen is a natural constituent and not an ingredient of honey. Accordingly the new Directive will have impacts on two main issues. Firstly, there will be no longer the need to put on the label of honey a list of ingredients. This will apply for honey containing GM (Genetically Modified) pollen or non-GM pollen. Secondly, according to Regulation (EC) 1829/2003 on GM food/feed, foods containing or produced from GMO should be labelled GM if the proportion of GM material (by ingredient or of the food in case of one ingredient) is higher than 0.9%. As pollen will no longer be considered as an ingredient but as a natural constituent, the amount of GM pollen will be calculated to honey and not to total pollen. The Council has not yet decided when this proposed Directive will be discussed among Member States. This is up to the Presidency to decide. Mexico will be kept updated about the issue by communicating when the draft proposal will be put on the Council agenda.

2.2. Environmental Foot printing

Mexico expressed its interest to be debriefed about the on-going process for the definition of a methodology to calculate the product and organization of environmental

footprints, as well as the next steps in the application of the methodology. The Commission explained the on-going work on the development of the EU harmonised methodology for the calculation of the environmental footprint for products and services. This work has been undertaken following a request from the Council. The methodologies, which were developed through an open and transparent consultation process, are basically completed and are online on the public website of DG Environment. The possible policies for the use of these methodologies are currently being impact assessed. It is likely that the favoured approach will be that the Commission will recommend to Member States and to private actors to use these methodologies whenever they decide to communicate the environmental footprint of products and organisations or decide on a scheme with such purposes. The recommendation is likely to be announced in the first quarter of 2013. This would not make neither the use of these specific EU methodologies nor the communication of environmental footprint mandatory in the EU. As a next step, in the first quarter of 2013, the Commission will decide on the development of Product Environmental Footprint Category Rules (PEFCRs) for priority products. PEFCRs are complimentary to the general methodology and contain a set of tailored specifications and instructions to be applied for a specific product group. The Commission believes that a high uptake of the EU methodologies would reduce the fragmentation of approaches in the Single Market, and help providing reliable and comparable information on environmental performance. Imported products would also benefit from the harmonisation of methodologies across the EU as this would reduce the need to comply with multiple requirements. The Commission is mindful about the potential trade impacts and develops its policies in this area in a way that the principles of non-discrimination, proportionality and least trade restrictiveness are fully taken into consideration.

2.3. Updates for Mexico

2.3.1. Draft proposal COM (2010) 542 for a regulation for the future EU type approval for L-category vehicle (2 and 3 wheeled vehicles as well as quadricycles)

With reference to several discussions between the EU and Mexico, Mexico wanted to be informed about any further development concerning the decision-making process. EU explained that the process of co-decision is still on-going. Between March and September 2012 there has been an intense 'trialogue' among the EU institutions. The Council will soon take a pre-final step, while the Parliament will vote on its plenary session on November 19, 2012 (we will need to report on outcome). It is expected that the Regulation is adopted by the end of 2012. As regards Mexican industries concerns about side-by-side vehicles, the EU reassured that the regulation's provisions will be fully operational only after January 1, 2016.

2.3.2. Indication of the country of origin of certain products imported from third countries "Made In"

Mexico wanted to be informed about any further development concerning the decision-making process. EU stated that since the last EU-Mexico bilateral discussions in September 2011, no progress has been taken place in the Council. Given the fact that EU Member States positions remain far apart and no clear majority has emerged, the political deadlock has influenced the Commission to propose the withdrawal of the proposal. The withdrawal is in the official Commission Work Programme for 2013 (which is still subject to Council and EP scrutiny) and the Commission has currently no intention to put forward a new proposal. Mexico took note and did not add any further comment.

2.3.3. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Mexico expressed its interest in receiving an update on this issue. Commission highlighted five main points:

1) Further to the 2010 deadline where almost 25.000 dossiers were registered covering 4300 chemical substances: 86% were made by large companies, 19% by only representatives, 94% were joint registrations;

2) A new deadline has been set up at the end of May 2013 for substances over 100 tonnes threshold;

3) As regards authorisation, there are currently 84 substances on the Candidate List of Substances of Very High Concern (SVHCs); with ECHA launching recently a public consultation for a further 54 substances. It is expected that by the end of 2012 there will be 136 substances on this list;

4) As regards Restrictions, there are the following additions since last year's meeting: Commission Regulation (EU) No 412/2012 of 15 May 2012 amending Annex XVII REACH by restricting the use of dimethylfumarate in articles in concentrations greater than 0.1mg/kg and the placing on the market of articles containing that substance (OJ L128 of 16.5.2012, p.1); Commission Regulation (EU) No 836/2012 of 18 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead, prohibits the use of lead in jewellery articles at a concentration level of 0.05% or above and the placing on the market of articles containing that substance (OJ L 252 of 19.9.2012, p.4); Commission Regulation (EU) No 847/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards mercury extends the scope of entry 18a to mercury measuring devices used in industrial and professional applications (OJ L 253 of 20.9.2012, p.1); Commission Regulation (EU) No 848/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards phenyl mercury compounds as regards the prohibition of the manufacture, placing on the market and use of 5 phenyl mercury compounds as well as placing on the market of articles containing those 5 substances at a concentration level of 0.01% or more (OJ L 253 of 20.9.2012, p.5); Commission Regulation (EU) No 109/2012 of 9 February 2012 amending Annex XVII REACH adding a number of newly classified CMR substances (boron compounds) in the list of substances which may not be sold to the general public, on their own or in mixtures (OJ L 37 of 10.2.2012, p.1); Commission Regulation (EU) No 835/2012 of 18 September 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) in particular the use in a list of plastic materials (OJ L 252 of 19.9.2012, p.1). There is also one new draft measure to prohibit the sale to the general public of substances newly classified as CMR category 1A or 1B and of mixtures containing those substances has been recently proposed. The draft proposes a time limited derogation (of 30 months) for the use of boron compounds in detergents.

5) In 2012 the Commission is obliged to carry out a review of the REACH Regulation, in particular as regards any overlap with other relevant legislation. The Commission decided to broaden the Review to include other aspects such as the implementation. The Review will be completed by the end of 2012 and will be made public. Finally, some of the studies that were launched to provide input to the review are available on the Commission website.

2.3.4. Electromagnetic Compatibility and Repealing (EMC), 2004/108/EC

The Commission informed Mexico about the status of the revision of this Directive, which has in fact been notified to WTO on 27 February 2012 (G/TBT/N/EU/20) with 90 days for comment. There were no comments received from third countries. The proposal is part of a package of 9 European Directives to be aligned to the New Legislative Framework. The essential requirements were maintained as well as the conformity assessment procedures. The proposal is expected to be adopted by the end of 2012 and will be applicable 2 years after adoption.

2.3.5. Waste electrical and electronic equipment (WEEE), 2002/96/CE

The Commission informed Mexico that the new Directive on waste of electrical and electronic equipment WEEE Directive (2012/19/EU) has been published on 24 July 2012 after second reading and its transitional period will go from 2012 to 2018. The Directive sets new collection targets at 85% of WEEE generated and will ensure a substantial increase of the quantity of waste collected (from 2 to 10 million tons per year). The new WEEE Directive will also give EU Member States the tools to fight illegal export of waste more effectively. A further improvement is a harmonised format to be used for the supply of information.

3. ISSUES OF INTEREST TO THE EU

3.1. EU request for equivalence on electric products and electrical appliances

The EU thanked Mexico for the letter from the Sub-Secretaria de Comercio Exterior dated 8 October 2012 and signed by Dr. Francisco de Rosenzweig Mendialdua stating that this issue that has been discussed in the meetings of this Special Committee in 2010 and 2011 would be addressed in this meeting. The EU recalled the background of the EU request and highlighted the importance of the issue. In 2010, Mexico recognised the equivalence of three Canadian and US standards with their Mexican equivalent NOMs and the recognition of conformity assessment results. This was followed by a formal request by the EU to get similar treatment for the equivalent EN/IEC standards. The EU noted the dossier recently sent to Mexico (letter dated 27 September 2012 of TRADE Deputy Director General J. Aguiar Machado) with a very detailed analysis of equivalence (article by article) following the Mexican request during the 2011 Special Committee. The three main conclusions drawn from this exercise can be summarized as follows: (1) Canadian and US standards are based on IEC standards and therefore are practically similar to the EN/IEC ones; (2) the requirements of the EN/IEC standards are more comprehensive than those of the Mexican NOMs and therefore guarantee, at least, the same degree of product safety; (3) the IEC standards have a list of national deviations that can be used for Mexico.

Mexico explained that the recognition of equivalence of the Canadian and US standards and conformity assessment procedures had been challenged before the Mexican Supreme Court on the grounds of lack of legal basis of the Government to undergo such recognition. Mexico noted that the case is still on-going and therefore it would not be appropriate to engage in similar exercise with the EU at this stage. Mexico agreed, however to analyse the information provided by the EU (in view of advancing the technical work) while attending the result of the Court case. Mexico has also agreed to inform the Commission as soon as the court case is finalised

3.2. Revision of NOM-001-SEDE-2005 - "Electrical installations (use)" (G/TBT/N/MEX/241)

The EU thanked Mexico for having notified this draft standard on electrical installations to the TBT enquiry point. On substance the EU shared the Mexican concerns on the safety of electrical installations. However, the EU referred to its written comments and noted that several of the Articles of the notified standard establish product specifications instead of product performance characteristics, which is the usual method in international standards and which leaves the choice to the manufacturer on how to attain the safety requirements. Therefore the EU requested Mexico to substitute these product specifications by product performances characteristics as defined in the relevant international standards.

Mexico welcomed the comments of the EU and informed that they would be analysed together with other input received from stakeholders. Mexico explained the internal procedure of treatment of third party comments. Answer to comments is published in the official gazette and only then a written reply can be sent to the Commission. The Technical Regulation will be adopted once it has been published in the National Gazette.

3.3. Revision of Mexico's labelling requirements for Textile products (G/TBT/N/MEX/84/Add.3)

After having provided written comments on 8 May 2012 as regards Mexico's notification to TBT of NOM-004-SCFI-2006 "Commercial information – Labelling of textile products, articles of apparel, clothing accessories and household linen", the EU thanked Mexico for the answer received on 6 November 2012. The EU informed the Mexican counterparties that that due to the fact that the reply of the Mexican authorities to the EU comments was received very recently, the assessment is just a preliminary one. Overall the Mexican reply seems positive. The EU welcomes the fact that the equivalence of the Mexican standards referred in the text with the relevant ISO standards was pointed out in the Mexican reply. It is also considered positively that the labels can be modified before the products are placed on the Mexican market. Furthermore, the EU understands from the Mexican reply that the control checks will be done on a systematic way (whereas they should be random). Nevertheless, the EU still considers that the indication of size, trademark and name of the manufacturer on the label is excessive. The Commission will further analyse Mexican answer and it will come back to Mexico if necessary.

3.4. System for measuring and dispensing Petrol and other Liquid Fuels PROY-NOM-005-SCFI-2011 notified under (G/TBT/N/MEX/219)

The EU informed that it is still seeking an answer to its comments (December 2011) and requests for clarification on the consistency of the Mexican standards with the relevant international standards. The main EU comments are:

- The draft law is only partially based on the relevant international standard in the area concerned: recommendation R117 of OIML. In particular, the EU observes that the requirements for Maximum Permitted Errors (MPE) and E-max are more stringent than the international standard and, as a consequence, instruments conforming to the international standard might not be able to enter the Mexican market.
- Definition 3.4 of the Mexican draft law promotes 128 bit checksum which does not appear in the OIML recommendation R117-1
- It is unclear whether definition 3.33 ("extraordinary verification") should be interpreted as a "subsequent verification" as mentioned in the OIML recommendation R117-1
- Definition 3.34.1.1 concerns "encapsulated circuits" and the technique is explicit, which is not the case in OIML recommendation R117-1

The EU further inquired about the possible timeline but Mexico was unable to give a clear deadline for adoption given the complexity of the regulation at stake. Mexico ensured that an answer to EU comments will soon be sent.

3.5. Registration of medicines and medical devices by COFEPRIS

The EU requested a follow up on the delays with registration of medicines and medical devices by COFEPRIS that have been a serious concern for EU business in Mexico for years. The information gathered by the EU Delegation is that the situation has been improving since a year (shorter delays, backlog reduced, better transparency), but a lot remains to be done before the situation can be deemed as normalized. Equivalence recently granted to EU and others for certain medicines (new molecules) is a step in the right direction, beneficial for EU business and for the Mexican medical system. EU expects that it will serve as a model for other sectors, including non-medical, where equivalence has so far been granted only to NAFTA partners. In this regard, the EU requested information about how to accelerate the registration procedures for pharmaceutical products; it inquired on the possibility to accelerate procedure for the registration of medical devices through the so-called 'fast-track analysis'. The Commission further enlightened Mexico on the new EU regulatory framework on medical devices notified recently to WTO (G/TBT/N/EU/71 and G/TBT/N/EU/72) and offered the availability to provide further information, upon Mexico's request. Adoption of the new Regulations is foreseen during the first semester of 2014.

Mexico explained that unfortunately COFEPRIS could not be present at the meeting but would be willing to receive Commission written questions and would answer them. Mexico stated that it is already in the process of addressing registration issues through bilateral cooperation between embassies.

3.6. Updates for EU

3.6.1. Rules concerning the Good Manufacturing Practice of medical devices (G/TBT/N/MEX/221)

The EU asked Mexico whether the GMP rules apply only to Mexican manufacturing sites or also to foreign manufacturing sites and in case they apply to foreign manufacturing

sites if there will be recognition of foreign GMP certificates. The answer to this question was not found amongst the answers Mexico provided during the public consultation.

Mexico informed that the competent Mexican authorities are still analysing these questions and will provide a written answer as soon as possible.

3.6.2. Revision of Mexico's labelling requirements for ceramic tiles

The EU repeated its interest in the possibility to make labelling less cumbersome, in particular that Mexico allows the name of importers and product characteristics would be put on a separate accompanying document and not on the individual ceramic tiles boxes. Mexico affirmed that it is not possible to review the relevant legislation.

3.6.3. Revision of the cadmium and lead content in ceramic products (NOM-231-SSA-2002)

Mexico informed about the measures taken in the standardization process. On 31 June 2012 the proposal to amend the legislation has been notified as G/TBT/MEX/237.

4. OTHER

4.1. Exchange of information on a proposed technical regulation by the Colombian government to phase-out HCFC gases

Following Mexico's warning about a technical regulation to be issued by the Government of Colombia with the objective of phasing-out HCFC-containing appliances, the Commission states that it is not aware of any industry complaints, maybe because it has not yet been notified to TBT. The Commission thanked Mexico for sharing its concerns and further ensure that it will analyse it as soon as possible and in particular in view of a recent EU proposal for a regulation on fluorinated greenhouse gases that will be notified to TBT in the next days.

4.2. Exchange of views on the current work programme of the TBT Committee including TBT Triennial Review 2012

EU informed Mexico about some of the issues to be raised by the EU at the next TBT Committee meeting (end November 2012). Two offensive cases (n° BRA 440 and BRA 328) involve Brazil as regards requirements for health products. Another offensive case concerns alcoholic drinks in Russia.

Mexico informed that it had previously raised the Russia point as regards two typical Mexican alcoholic products, notably Tequila and Mescal. Meanwhile Mexico obtained protection of the Geographical Indications (GIs), therefore it would have to verify if the Russian Regulation would be continued to be raised by Mexico. Mexico proposed to hold a bilateral meeting just before the TBT Committee and the EU agreed.

As regards the TBT Triennial Review the EU stressed the importance of taking an active role in Good Regulatory Practices and Conformity Assessment Procedures working groups. The Commission further stressed that the EU and Mexico are very much in line on topics such as transparency and regulatory impact assessment. Mexico informed that it had submitted a detailed contribution to WTO and put forward its ideas on a number of areas.

4.3. Exchange of information on regulations and standards (Sept.2011 – Sept.2012)

The Commission handed over to the representative of the Delegation of Mexico attending the meeting, the hard copy listing eighty-eight EU notifications to the WTO between September 2011 and September 2012. Mexico stated that it will hand over its list as soon as possible.

4.4. Next steps – minutes and next meeting

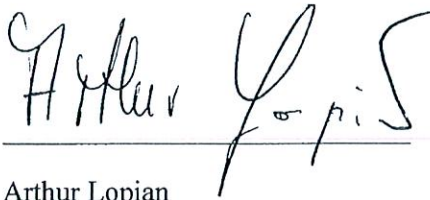
Mexico thanked the EU for hosting the meeting and stressed the importance of the Special Joint Committee on Technical Regulations.

The parties agreed that the EU would prepare the first draft of the minutes and would send it to Mexico for comments.

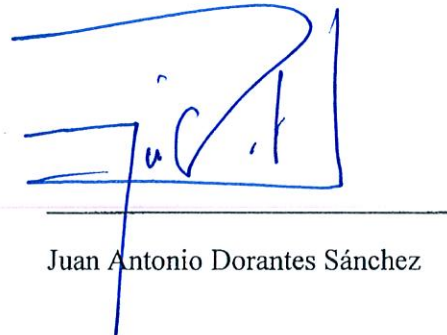
The parties agreed to have the next meeting during the last quarter of 2013.

From the EU

From Mexico



Arthur Lopian



Juan Antonio Dorantes Sánchez

Deputy Head of Unit
Directorate General for Trade
Tariff and Non-Tariff Negotiations

General Director of International
Trade Rules
Undersecretariat for International
Trade Negotiations
Ministry of the Economy

Annex 1 – List of Participants

Delegation of the European Commission of the European Union (EU)

Arthur Lopian – Chair, Deputy Head of Unit, DG Trade, Tariff and Non-Tariff Negotiations.

Ivone Kaizeler – Policy Officer, DG TRADE, Tariff and Non-Tariff Negotiations, TBT.

Paul Bonnefoy – EU Delegation in Mexico.

Miriam Frisch – EU Delegation in Mexico

Pablo Neira – Policy Officer, DG TRADE, Tariff and Non-Tariff Negotiations, TBT.

Gabriele Lo Monaco – Former Desk Officer for Mexico, DG TRADE, Bilateral Trade Coordinator.

Sabine Pelsser – Policy Officer, DG SANCO, Biotechnology.

Peter Czaga – Policy Officer, DG ENV, Sustainable Production and Consumption.

Sean McLaughlin – Policy Officer, DG ENTR, REACH.

Laszlo Kojnok – Legal Officer, DG ENTR, Prevention of Technical Barriers to Trade.

Joanna Kaczanowska – Policy Officer, DG ENTR, Prevention of Technical Barriers to Trade.

Daniel Hanekuyk - Desk officer Metrology, Measuring Instruments and Prepackaging, DG ENTR.

Martin Pilser – Policy Officer, DG TRADE, Market Access, Industry, Energy and Raw Materials

Delegation of Mexico

Juan Antonio Dorantes Sánchez - Chair, General Director for International Trade Rules, Ministry of the Economy.

Monica Lugo Aranda – Deputy Director for Technical Barriers to Trade, Ministry of the Economy.

Roberto Reyes Barrera – Minister, Representative Office of the Ministry of the Economy, Mission of Mexico to the EU.

Miguel Ángel Narváez – Economic Counsellor, Representative Office of the Ministry of the Economy, Mission of Mexico to the EU.

Paloma Vertiz Robleda - Representative Office of the Ministry of the Economy, Mission of Mexico to the EU.

Jesus Figueroa – Deputy Director for International Standardization (DGN), Ministry of Economy.

Edgardo Arenas Gasca – Analyst, Federal Commission for the Protection against Sanitary Risks (COFEPRIS).

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Annex 2 - Agenda

1. OPENING

- 1.1. Welcome words and opening remarks**
- 1.2. Approval of the agenda and minutes of the previous meeting**

2. ISSUES OF INTEREST TO MEXICO

2.1. Honey containing pollen from genetically modified maize MON810, Ruling from ECJ

Mexico supported the Argentinian concern expressed before the TBT Committee on November 2011 regarding the ruling of the European Court of Justice of 6 September 2011 (Case C-442/09) on honey containing pollen with traces of DNA from genetically modified maize MON 810. According to the ruling, the honey containing pollen derived from Genetically Modified Organisms (GMOs) authorized by the EU was a food product produced from GMO, and therefore came under Article 3, paragraph 1C of the Regulation (EC) 1829/2003. This ruling adopted a new interpretation regarding the scope of Regulation 1829/2003 without appropriate scientific justification. At the same time, the ruling interpreted that pollen was an ingredient of honey, not a natural component, conflicting with the standard for honey in Codex and the European Regulations (Annex II of Directive 2001/110/CE and Article 6, paragraph 2C of the Directive 2000/13).

2.2. Environmental Footprinting

Mexico would like to have a briefing on the on-going process for the definition of a methodology to calculate the product and organization environmental footprints, as well as the next steps in the application of the methodologies.

Mexico would like to have a briefing on the environmental footprinting measures that the EU intends to adopt, besides the ones referred above. There is a particular interest to know if these measures may be taking as a reference the work under the IEC TC 111 and which are the sectors where the EU may be considering applying this kind of measures.

2.3. Updates for Mexico

2.3.1. Draft proposal COM (2010) 542 for a regulation for the future EU type approval for L-category vehicle (2 and 3 wheeled vehicles as well as quadricycles)

At the last meeting EU informed that the proposal was still in the decision making process. Mexico would like to know if there has been a decision regarding this.

2.3.2. Indication of the country of origin of certain products imported from third countries "Made in".

Mexico would like to have information on the technical discussions related to this measure, and would also like to know the dates of its adoption and publication.

2.3.3. Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Mexico would like an update in this issue.

2.3.4. Electro Magnetic Compatibility and Repealing (EMC), 2004/108/EC

Mexico would like to know the results of the revision of this Directive and if it has already been notified to the WTO.

2.3.5. Waste electrical and Electronic Equipment (WEEE), 2002/96/CE

Mexico would like to know the outcome of the discussions towards the definition of this Directive and it has already been adopted.

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3. ISSUES OF INTEREST TO THE EU

3.1. EU request for equivalence on electric products and electrical appliances

In December 2010, the EU has formally requested Mexico similar treatment as the one granted to Canada and US, i.e. to recognize the equivalence of EU technical regulations with the Mexican technical regulations and the acceptance by Mexico of EU conformity assessment results for electronic products and electric appliances. In September 2011, Mexico requested additional information from the EU, notably a detailed table comparing the EU standards with the Mexican ones (article by article). The EU sent to Mexico a detailed analysis at the end of September 2012 and would be interested to discuss next possible cooperation steps in this area.

3.2. Revision of NOM-001-SEDE-2005 – "Electrical installations (use) (G/TBT/N/MEX/241)"

The EU has issued written comments on NOM 001 notified recently under G/TBT/N/MEX/241. The EU would be interested to communicate some preliminary comments and to know the timeline for adoption and entry into force.

3.3. Revision of Mexico's labelling requirements for Textile products (G/TBT/N/MEX/84/Add.3)

On February 2012, Mexico notified to TBT a revision of NOM-004-SCFI-2006 "Commercial information Labelling of textile products, articles of apparel, clothing accessories and household linen" (G/TBT/N/MEX/84/Add.3). The EU has provided written comments on 8 May 2012. The EU is seeking an answer to its comments and requests for clarification.

3.4. System for Measuring and dispensing Petrol and other Liquid Fuels PROY-NOM-005-SCFI-2011 notified under (G/TBT/N/MEX/219)

The EU has provided written comments on the Mexican System for Measuring and dispensing Petrol and other Liquid Fuels on 5 December 2011. The EU is seeking an answer to its comments and requests for clarification, notably on the consistency of the Mexican standard with the relevant international standard: recommendation R117 of the International Organisation of Legal Metrology (OIML).

3.5. Registration of medicines and medical devices by COFEPRIS

The EU would like a follow up on the registration of pharmaceuticals and medical devices by COFEPRIS (actions taken and impact in the backlog)

For pharmaceutical products: COFEPRIS-EMA cooperation (new molecules)

For medical devices: Discussion on possibilities for certain EU products to be granted "fast track analysis"

3.6. Updates for EU

3.6.1. Rules concerning the Good Manufacturing Practice of medical devices (G/TBT/N/MEX/221)

EU sent an inquiry last year on Mexican GMP rules for medical devices notified under G/TBT/N/MEX/221 to which Mexico replied. However, it remains unclear whether the proposed rules only apply to the national Mexican manufacturing sites or also affect manufacturing sites situated outside the Mexican territory. In case the draft rules apply to manufacturing sites outside the Mexican territory, the EU would like a clarification as to how these rules will apply and whether there will be recognition of foreign GMP certificates or GMP approvals.

3.6.2. Revision of Mexico's labeling requirements for Ceramic tiles

The EU would like to know if there is the possibility to allow labeling of the name of importer being placed in commercial documents and not on each individual tile box i.e. provide for an exemption for this type of products.

3.6.3. Revision of the cadmium and lead content in ceramic products (NOM-231-SSA-2002)

At the last meeting MEX informed that the revision of NOM-231 (notably in view of an alignment to ISO 6486-2) would be included in the 2012 national standardization program. The EU would like to receive an update on whether this revision has been initiated and timeline for TBT notification.

4. OTHER

4.1. Exchange of information on a proposed technical regulation by the Colombian Government to phase-out HCFC gases.

Mexico would like to know if the European industry (particularly the refrigeration industry) has expressed concerns on the proposed technical regulation to be issued by the Government of Colombia with the objective of phasing-out HCFC-containing appliances.

4.2. Exchange of views on the current work programme of the TBT Committee including TBT Triennial Review 2012

4.3. Exchange of information on regulations and standards (Sept. 2011-Sept. 2012)

4.4. Next steps - minutes and next meeting

The EU side will produce the first draft of the minutes

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