## **Summary of Discussion**

# The 1st Free Trade Commission on Chile – Malaysia Free Trade Agreement (CMFTA)

November 12, 2018. Santiago, Chile

Working Group on: Chile-Malaysia TBT Committee

Lead Negotiator of Chile: Mr. Fernando Catalán (DIRECON)

Lead Negotiator of Malaysia: Mr. Syahril Syazli Ghazali

**Summary of Discussion** 

 Adoption of international standard ISO 13485 for the process of sanitary registration in medical devices.

Chile requested information regarding the adoption of international standard ISO 13485 for medical devices by Malaysian regulation. The interest of Chile to know the situation on the adoption this Standard in the regulation of Malaysia, is because Chile considers that the adoption of this international standard, it is essential on the harmonization of the medical devices control.

Malaysia informed that ISO 13485 is adopted into MS ISO 13485, as a mandatory standard. It is currently regulated by Malaysian Medical Device Authority (MDA) as in page 215 and 217 of Medical Device Regulation 2012. Malaysia also provided the web page address for further details regarding this regulation.

Chile appreciated the information and commented that will send it to the relevant agencies in Chile for their consideration and review.

#### Beef and Sub-Products of Cattle.

Chile informed that there are some Chilean establishments are exclusively dedicated to produce Halal bovine meat and bovine products. Chile also mentioned that the interest is not only for beef, but also for ovine meat and ovine products. In this respect, Chile would like to know if





there are any changes in Malaysian's regulations regarding the Halal requirement for these products, given there is interest on the initiation of the process for the authorization of the exports of meat and meat products (bovine and ovine) to Malaysia.

Malaysia informed that there is no changes in the regulation and the existing requirement related to Halal are still valid and the information in the website are up to date. Malaysia shared the link for Chile's perusal.

Chile appreciated the information and commented that it will review the information and will send comments or further enquiries in case it is necessary.

### 3. Update Contact Points.

TBT Agreement contact points were updated and annexed to these minutes (Annex)





# Annex Contact points

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