

Statistical Report for Conformity Assessment Bodies Inspections

2023



Introduction:

As part of Roles, Saudi Food and Drug Authority conducts regulatory inspections/audits on conformity assessment bodies. The main objective of these inspections is to ensure compliance with Designation Regulation of Conformity Assessment Bodies (CAB)" issued by Board Resolution No. (5-20-1440) dated 07/09/1440 AH, amended by the SFDA Board Resolution No. (1-33-1443) dated 16/09/1443 AH , Guidance on the Requirements of Designation of Conformity Assessment Bodies (CAB) .This report will provide statistical information about inspections that were conducted on conformity assessment bodies during the period 1 January 2023 to 31 December 2023. The aim of analyzing CABs inspection deficiency data trends is to promote a culture of continuous improvement and ensure that CABs consistently adhere to high-quality standards. By understanding the underlying causes of nonconformities and addressing them proactively, the industry can enhance its reputation, and ensure the availability of safe and effective products.



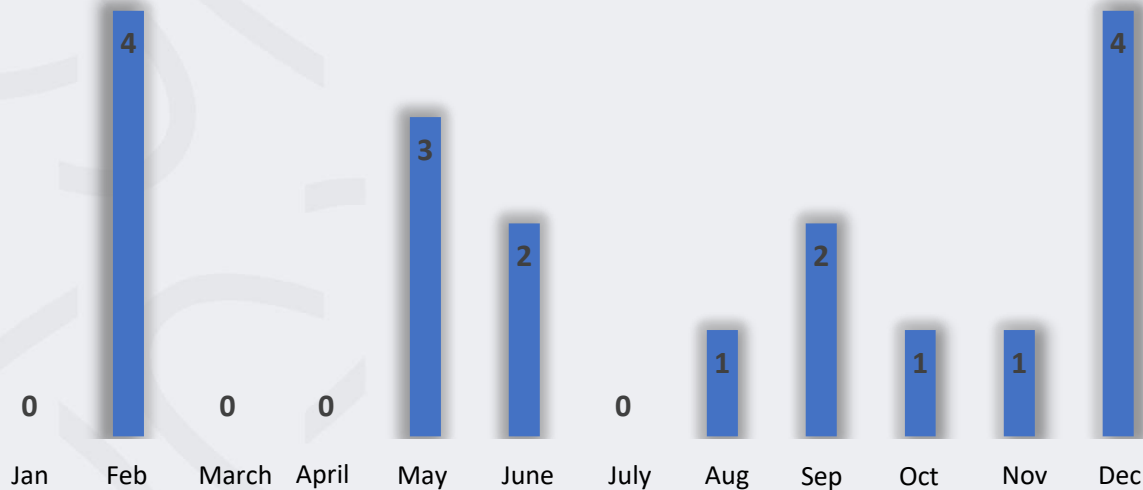
Executive Summary

During the year 2023, Saudi Food and Drug Authority conducted a number of 18 regulatory inspections/audits on conformity assessment bodies. These inspections were at different regions (for example: 14 inspection on CABs located at the central region). These inspections included CABs which are designated in different scopes such as quality management system and conformity certificates consignments. **47** Nonconformities were detected and enforcement actions were taken against **three** CABs.



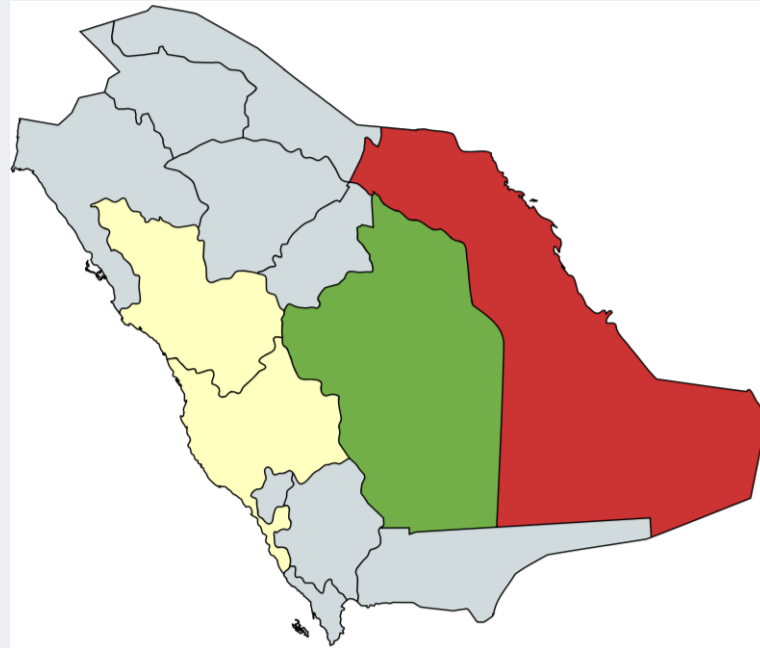
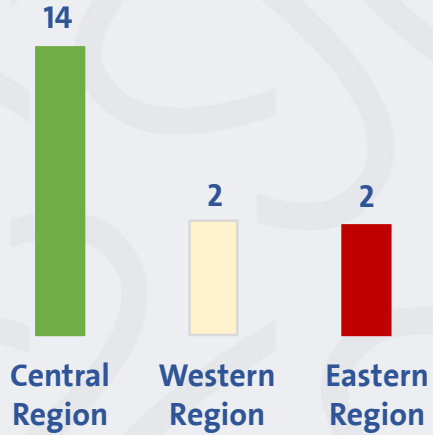
Number of Inspections:

In 2023, a total number of **18** inspections were conducted on Conformity Assessment Bodies. On a monthly basis, the maximum number of inspections was conducted on February. The average of the inspection was about 2 inspections per month.



Location of Conformity assessment bodies :

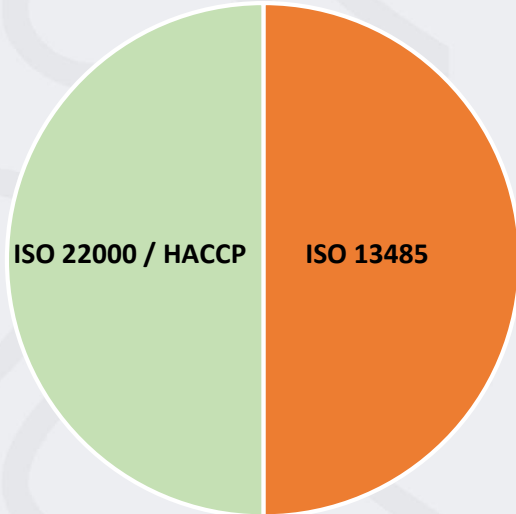
77% of the inspections were for conformity assessment bodies located in Riyadh



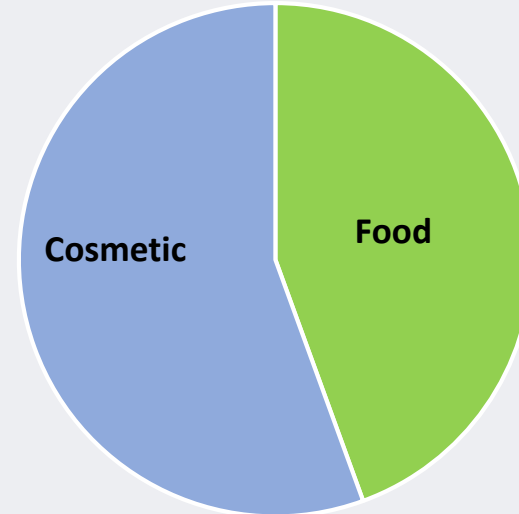


Scope of designation:

Similar number of the inspections (2 inspections) were conducted on conformity assessment bodies which are designated in Quality Management System (ISO 22000 / HACCP and ISO 13485). On the other hand , 10 inspections were conducted on conformity assessment bodies designated for conformity certificates for cosmetics products consignments and 8 inspections for those designated for conformity certificates for food products consignments .



Quality Management System

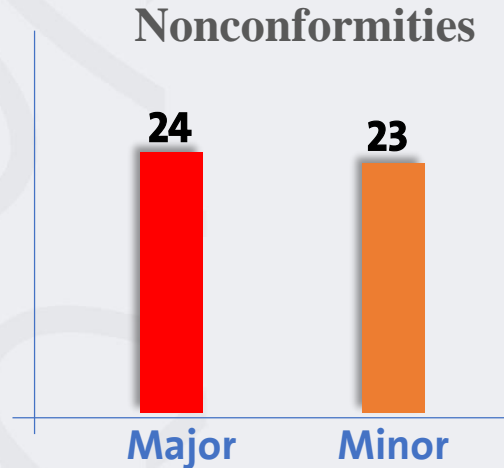


Consignment Conformity Certificates



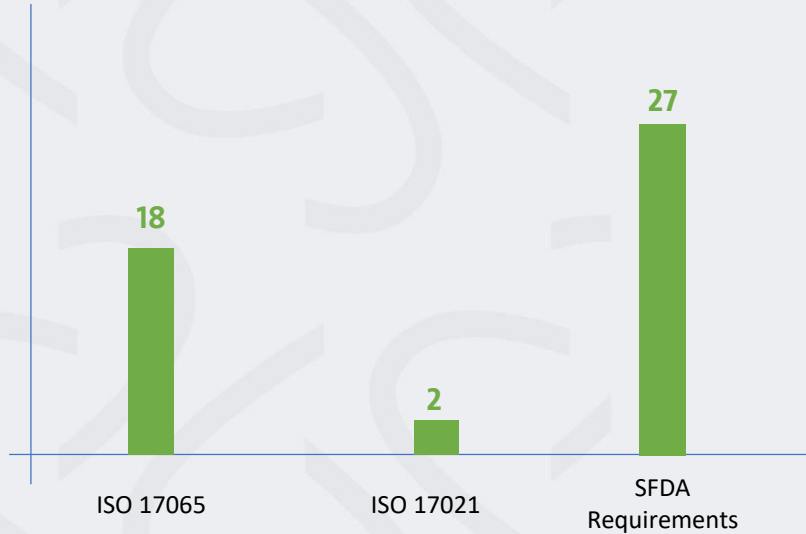
Number of Nonconformities:

In total, Almost **47** Non conformities were detected during the inspections during the year 2023. the major NC is 51% of the total NC.





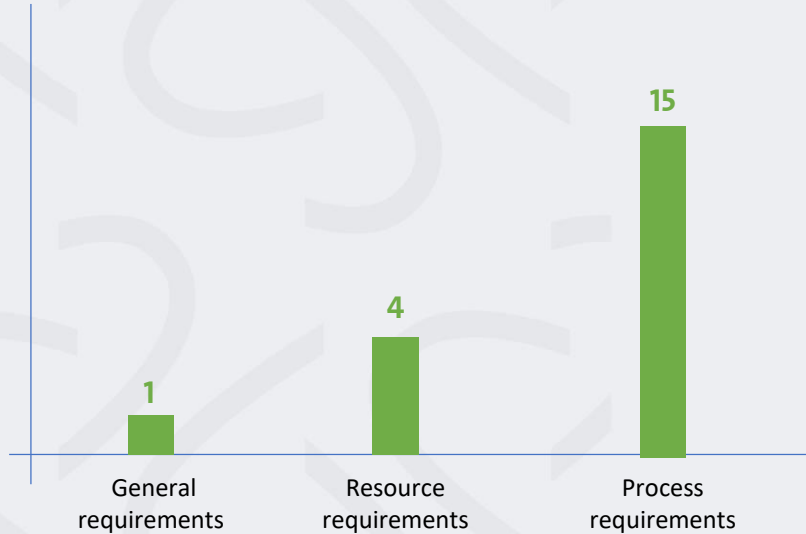
Nonconformities types based on the Standards:



57% of the nonconformities were detected against compliance to SFDA requirements while 38 % were for not complying with the requirements of ISO 17065 and 0.5 % for ISO 17021



Nonconformities types based on Area:



With regards to the requirements of ISO standards (17065 , 17021), 75% of nonconformities were detected against compliance to Process requirements while 20 % were for not complying with resource requirements and 0.5 % for general requirements.

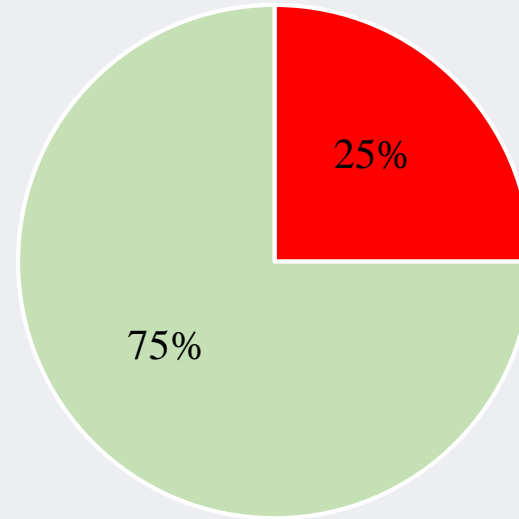


Enforcement actions:

Enforcement actions were taken against (3) of the inspected conformity assessment bodies as a result of the major nonconformities detected which represents 25% of inspected conformity assessment bodies.

Enforcement Actions

Suspension of designated scope 3





Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Thank You