

**VOLUNTARY CERTIFICATION
SCHEME
FOR
AYUSH PRODUCTS
*AN OVERVIEW***



ANIL JAUHRI
***NATIONAL ACCREDITATION BOARD FOR
CERTIFICATION BODIES***
QUALITY COUNCIL OF INDIA

INTERNATIONAL SCENE



- Increasing use of standards for products, services, processes and systems – either by regulation – or voluntary regimes
- Regulation on grounds of health, safety, environment mandated under WTO Agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS) – latter applies to food trade
- Drugs and Food typical examples of heavily regulated sectors
- No of voluntary initiatives in food – retailer driven – none in drugs
- Indian initiative – a unique step



BACKGROUND

- ✘ Meeting taken by Secretary, AYUSH in Dec, 2008 for consultation with QCI and BIS
- ✘ QCI offer to develop Scheme
- ✘ Concept Paper submitted - discussions
- ✘ Formal MoU signed in July 2009 – one time grant by AYUSH
- ✘ Department of AYUSH and QCI to be Joint Scheme Owners – QCI to provide secretariat and manage the Scheme
- ✘ Draft Scheme designed – Aug 2009 – public consultation – approved Oct 2009

ELEMENTS OF SCHEME



- ✘ Governing Structure – Multistakeholder steering committee in line with international practice – set up by Deptt of AYUSH - Secretary (AYUSH) Chair
- ✘ Technical and Certification Committees set up by QCI – Dr GN Qazi, VC, Hamdard Univ and SG, QCI as chairs
- ✘ Meetings of TC & CC to consider comments – 25 Sept 2009
- ✘ MSC meeting – 14 Oct 2009



ELEMENTS OF SCHEME *(CONTD)*

- ✘ Certification Criteria or Standards
- ✘ Certification Process
- ✘ Internal Quality Assurance Protocol for units to follow – self certification
- ✘ Requirements for Certification Bodies (CBs)
- ✘ Approval of CBs
- ✘ Rules for use of Certification Mark



CERTIFICATION CRITERIA

- ✘ Domestic regulation - regulatory requirements prescribed under the Drugs and Cosmetics Act, 1940 for AYUSH products
- ✘ GMP Requirements based on WHO Guidelines for Ayush Products
- ✘ Permissible levels of contaminants
- ✘ Regulations of importing countries – to be identified by the organization seeking certification and provided to the Certification Body



LEVELS OF CERTIFICATION

- × Certification at two levels
 - + **Ayush Standard Mark** compliance to the domestic regulatory requirements
 - + **Ayush Premium Mark**
 - + **Option A:** Compliance to the GMP Requirements based on WHO Guidelines and Levels of contaminants as given in Certification Criteria document .
 - + **Option B:** Compliance to regulatory requirements of any importing country provided these are more stringent than Option A above.

CERTIFICATION PROCESS

- ✘ Registration of Application – separate certification for each premises – any number of products
- ✘ Initial Evaluation
 - + Single stage evaluation for Std Mark - two stage evaluation for Premium mark
 - + Testing of samples
 - + Factory and independent testing
 - + Use of NABL accredited laboratories
- ✘ Internal quality assurance protocol – to be followed by each certified unit – self certification
- ✘ Grant of certificate valid for 3 years
 - + NABCB accredited certification body
- ✘ Surveillance
 - + Evaluation every 6 months – flexibility to increase or decrease based on performance in each certification cycle
 - + Market samples



CERTIFICATION BODIES

- ✘ Accredited as per international standards – ISO Guide 65 - by NABCB
- ✘ Requirements under the Scheme — beyond international standards
- ✘ E.g. publicly available information, mandays to be spent, competence of evaluators
- ✘ Approval under the scheme – simple process
- ✘ 2 CBs approved – Foodcert India, Bureau Veritas

INTERNATIONAL ACCEPTABILITY

- ✘ Design of Scheme to promote international acceptability
- ✘ Multistakeholder oversight
- ✘ Certification criteria – development process follows international best practice – public comment period – multistakeholder – requirements aligned with international norms
- ✘ Certification bodies – to meet applicable international standard – ISO Guide 65
- ✘ Labs – to meet ISO 17025
- ✘ National accreditation bodies – NABCB and NABL



GOAL

- ✘ Enhance consumer confidence – quality mark on products
- ✘ Improve compliance to regulations – considered low currently especially to Schedule T GMP
- ✘ Product differentiation – claim world class – choice to consumer
- ✘ International acceptance – Premium mark – G-2-G dialogue and agreements



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THANK YOU