



Q/C & Standardization of Herbal Drugs

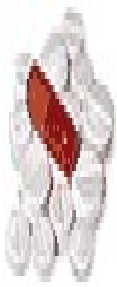
The World Health Organization (WHO) estimates?

4 billion people use herbal medicine.

Herbal medicine is a major component
of all traditional medicine

- ◆ Ayurvedic
- ◆ Naturopathic
- ◆ Homeopathic
- ◆ Native American Indian Medicine

WHAT IS A STANDARDIZED HERBAL DRUG?



A standardized extract means that the manufacturer has verified that the active ingredient believed to be present in the herb is present in the preparation and that the potency and the amount of the active ingredient is assured in the preparation.

The action of the herb may be from a number of constituents and not from just one or two ingredients.

WHO note that

119 plant-derived
medicines are used in
modern medicine.

Major pharmaceutical
companies are

now on research on
plant materials for
their potential
medicinal value.



Q/C & Standardization of Herbal Drugs



Today in USA

- Herbal products could be marketed only as **Food Supplements**.
- A herb manufacture could make no **Health Claims** without FDA approvals.



Q/C & Standardization of Herbal Drugs



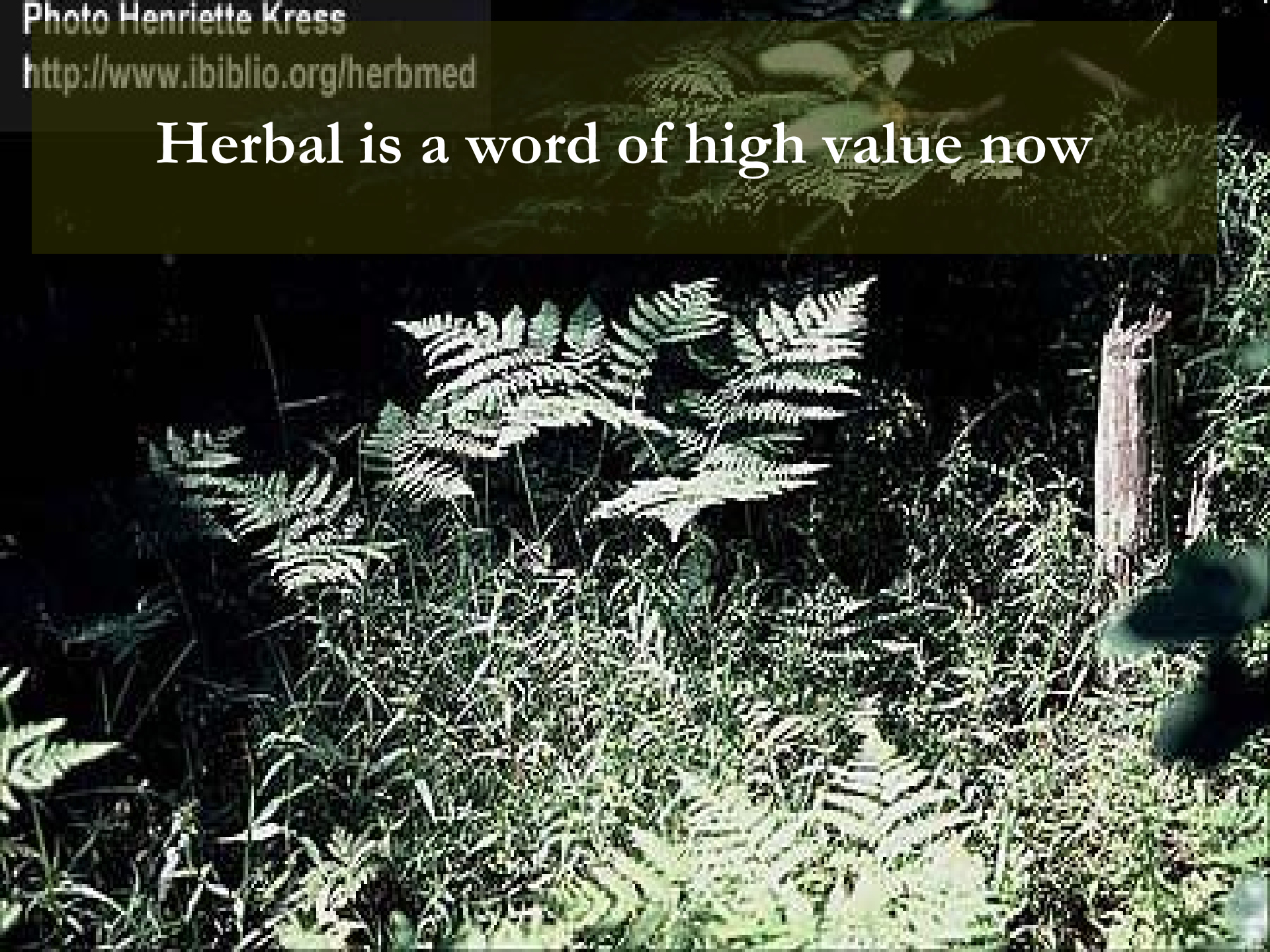
Role of EU

- The drug Regulation is very hospitable to market natural remedies.
- Less time to approve medicine as safe & effective-particularly for substances with a long use history.
- Follows WHO Guidelines which states that a substance's historical use is a valid way to document safety and efficacy in the absence of scientific evidence to the contrary.

Photo Henriette Kress

<http://www.ibiblio.org/herbmed>

Herbal is a word of high value now





HERBAL DRUG/NATURAL FOODS

A BIG BUSINESS



Q/C & Standardization of Herbal Drugs



**Ayurvedic or Herbal
Food Supplement
trade is on an increase
nationally as well as
internationally**



Q/C & Standardization of Herbal Drugs



Drugs & Foods are under the control of MOH.



**The GMP application in Drug is fully in place in
India**

Q/C & Standardization of Herbal Drugs



Corrective Actions are taken under the 'Act'
when any batch of drug fails during
inspection



Q/C & Standardization of Herbal Drugs

For Herbal Food Supplements



All laws & Regulations in respect of Foods are applicable



PFA, FD & C Act, Japanese Quarantine etc.

REGULATIONS

- EU DIRECTIVES
- US FDA 21 CFR 19 VOLUMES
- HACCP –21 CFR –1240
- FPLA
- NLEA

IN ALL THESE AN INCREASE IN DEMAND FOR

Agreed inspection & examination procedures &
certification by governments of exporting countries
for product & process compliance with their
REGULATIONS

Herbal Food Supplements

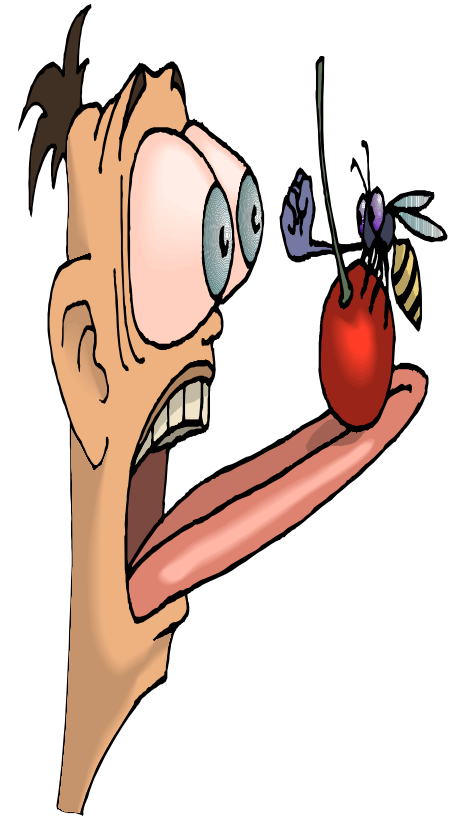
What is the basis of these Rules?

Foods shall not be adulterated



What is Adulteration?

Adulteration is mixing up of a food supplement with a harmful /objectionable /disease producing chemical or product or micro organism.



Q: Is the Product Safe Today?



Poisoning Outbreaks are on the Increase ...



April 1997

APRIL - 1997

Icecream poisoning: 125 hospitalised

ALUVA, April 7: Some 125 people, several of them children, were admitted to hospitals in and around Angamaly yesterday and today following suspected food poisoning.

According to Angamaly SI T.K. Thomas, the patients had eaten ice-cream from a vendor, who distributed the local-made ice-cream on April 5. Those who ate it developed abdominal pain, fever, vomiting, diarrhoea and excessive tiredness, forcing them to approach hospitals.

Most of them belonged to the Mookkannur area.

According to Dr Tomy of Mar Augustine Golden Jubilee Memorial Hospital, Mookkannur, the first case was brought in last forenoon. About 25 persons were admitted later with the same complaints.

He suspected bacterial toxin reaction, most probably infec-

tion caused by *Staphylococcus* toxin. Samples were collected and sent for culturing. Results would be available in two days.

The patients were administered antibiotic coverage, IV fluids and symptomatic treatment, Dr Tomy said.

Many persons with the same complaint were also admitted to the Little Flower Hospital, and the Angamaly Government Hospital, Stella Maria Hospital, Edakkunnu, and Alphonsa Hospital, Karukutty.

Ernakulam rural SP T.M. Somarajan, Perumbavoor Deputy SP S. Gopinath visited the patients. A team of doctors from Ernakulam were sent to Angamaly to assist the local doctors.

The police are in search of a Joseph Madassery Thacker, who allegedly distributed the ice-cream. • FAC

1993 ഡിസംബർ 23 വ്യാഴം CC1 3

സദ്യയുണ്ട്

30 പേർ

ആശുപത്രിയിൽ

അങ്കമാലി: വിവാഹനിശ്ചയത്തിന്റെ സദ്യയുണ്ട് മുപ്പതു പേർ അങ്കമാലി-കാലടി മേഖലകളിലെ സ്വകാര്യ ആശുപത്രികളിലായി.

വയറിളക്കം, ഛർദ്ദി, പനി എന്നിവയാണു രോഗലക്ഷണങ്ങൾ. സസ്യഭക്ഷണം കഴിച്ചവർക്കു രോഗമൊന്നുമില്ല.

പാലാരിവട്ടത്തായിരുന്നു വിവാഹനിശ്ചയം.

1993 December
Marriage Party – Near Cochin
Food poisoning for those consumed Non Veg food
Veg food – No Problem

Veg-food - no problems

കല്യാണ വിട്ടിൽ നിന്നു ഭക്ഷണം കഴിച്ച നൂറോളം പേർക്കു വിഷബാധ

വടകര: കുറിഞ്ഞാലിയോട്ടുള്ള കല്യാണ വിട്ടിൽ നിന്നു ഭക്ഷണം കഴിച്ച നൂറോളം പേർക്കു ഭക്ഷ്യ വിഷബാധയേറ്റു. ചികിത്സ ആവശ്യമായ എൺപതോളം പേരെ വടകര ഗവ. ആശുപത്രിയിൽ പ്രവേശിപ്പിച്ചു.

കുറിഞ്ഞാലിയോട്ടുള്ള കൊളുക്കോട്ടു കുഞ്ഞിക്കണ്ണന്റെ മകൻ മനോജിന്റെ കല്യാണത്തലവന്നു നടത്തിയ അത്താഴ വിരുന്നിൽ ഭക്ഷണം കഴിച്ചവർക്കാണ് വിഷബാധ. മിൻകരിയിൽ നിന്നായിരിക്കാം വിഷബാധയെന്നു സംശയിക്കുന്നു. മത്സ്യക്കറി കഴിക്കാത്തവർക്കു വിഷബാധയുണ്ടായിട്ടില്ല.

അത്താഴ വിരുന്നിൽ ആരും അത്താഴം പേർ പങ്കെടുത്തിരുന്നു. ഞായറാഴ്ച ഉച്ചയ്ക്കു ശേഷമാണു വയറിലുക്കവും ഛർദ്ദിയും അനുഭവപ്പെട്ടു തുടങ്ങിയത്. അർധരാത്രിയോടെ അൻപതോളം പേർ ആശുപത്രിയിലെത്തിയിരുന്നു. ബാക്കിയുള്ളവർ ഇന്നലെ ഉച്ചയോടെയും ആശുപത്രിയിലായി. ചിലർക്കു ശക്തിയായ തലവേദനയും പനിയുമുണ്ട്. വൈകി ആശുപത്രിയിലെത്തിയ പലരും അവശനിലയിലായിരുന്നു. എല്ലാവരും സൂഖം പ്രാപിച്ചു വരുന്നു. നാലു പേർ ഓർക്കാട്ടേരി കമ്മ്യൂണിറ്റി ഹെൽത്ത് സെന്ററിലും മറ്റൊരാൾ സ്വകാര്യ ആശുപത്രിയിലും ഉണ്ട്. ഭക്ഷ്യ വിഷബാധ മൂലം വലിയ പ്രശ്നങ്ങളില്ലാത്ത പലരും പ്രഥമ ശുശ്രൂഷയ്ക്കു ശേഷം ആശുപത്രി വിട്ടു.

100 people who participated in a marriage feast near
Calicut had food poisoning

Responsible item - Fish Curry

Fish curry responsible

21-7-99

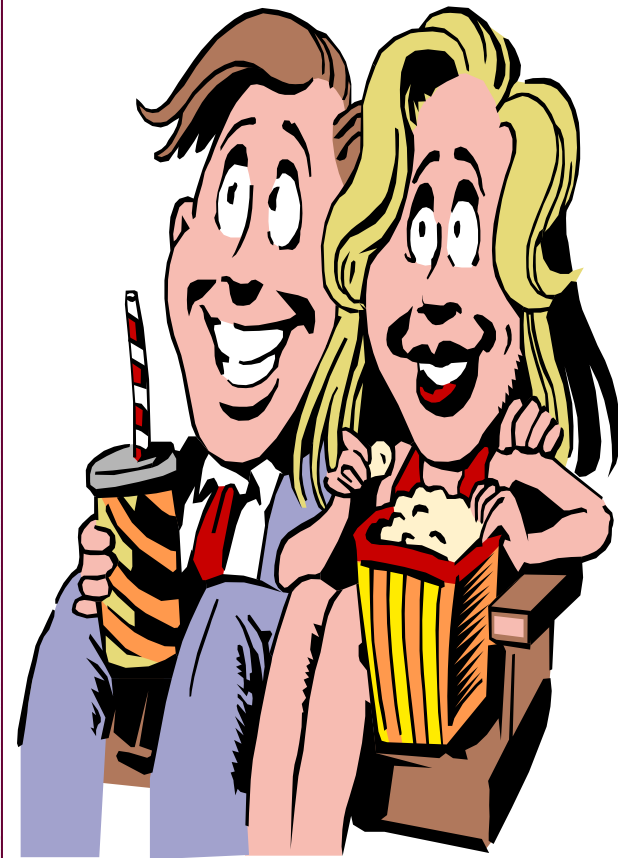
INDIA DIGEST

Bhujbal appointed Maharashtra NCP chief

MUMBAI, July 20. — Leader of the Opposition in the Maharashtra Legislative Council, Mr Chhagan Bhujbal, was today appointed president of the Nationalist Congress's state unit. — SNS

Food poison

MIDNAPORE, July 20. — Two persons died and hundred were taken ill after eating a wedding feast at Mechagram village in Midnapore last night, police said today. — PTI

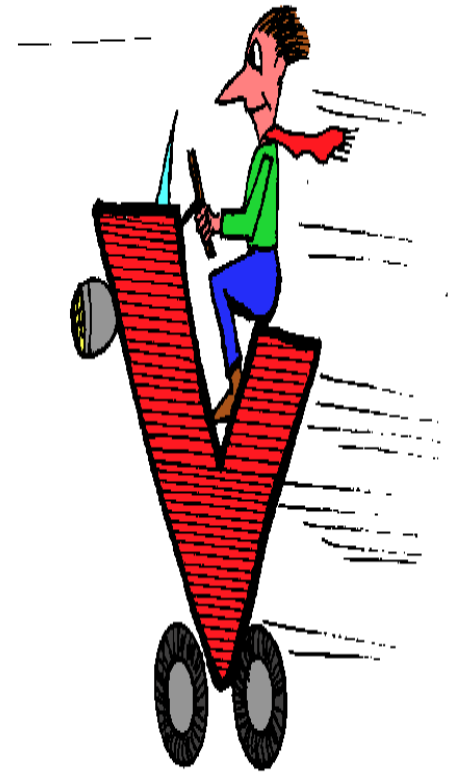


W. Bengal

July 1999

WHAT ARE THE LEARNING EXPERIENCES FROM THESE INCIDENTS?

- Product Safety has to be our priority in an overall quality assurance system in the industry and regulatory bodies.
- Most of these incidences are controllable if we apply rigorously principles of Hygiene including HACCP



WHAT IS THE SOLUTION



HAZARD ANALYSIS CRITICAL CONTROL POINT



HACCP

HACCP is now recognized as a benchmark in the International Inspection system under **Codex Alimentarius Commission (CAC)** the Global Standard making body.

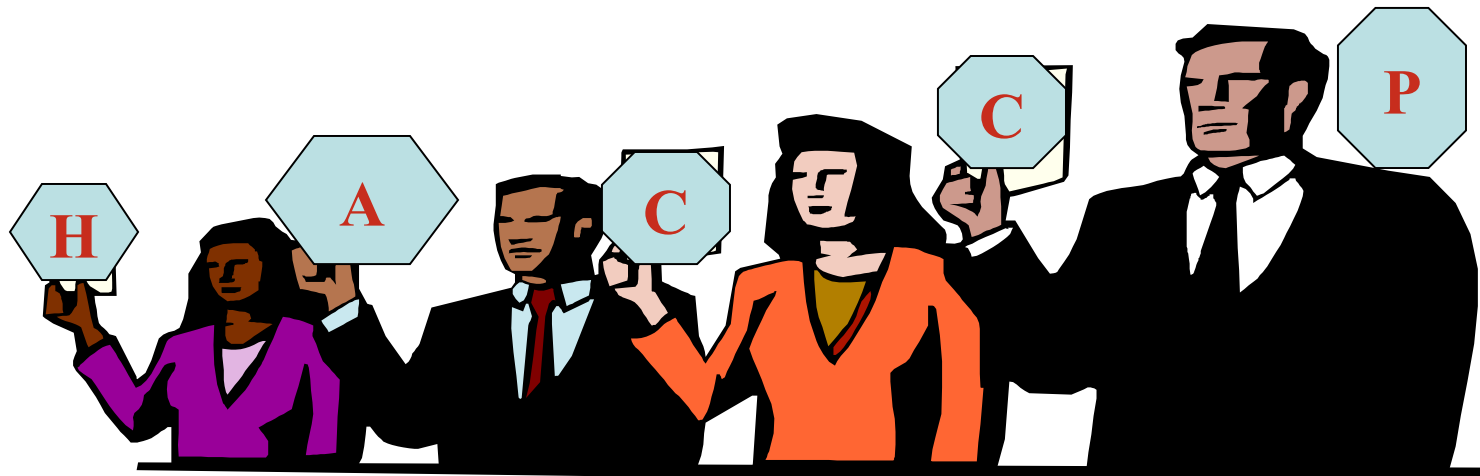


HACCP IS

- PREVENTIVE AND PROACTIVE
- SCIENCE BASED
- SYSTEMATIC
- FLEXIBLE
- COST EFFECTIVE
- MULTI-DISCIPLINARY
- INDUSTRIES LEAD ROLE
- GOVERNMENT FACILITATES

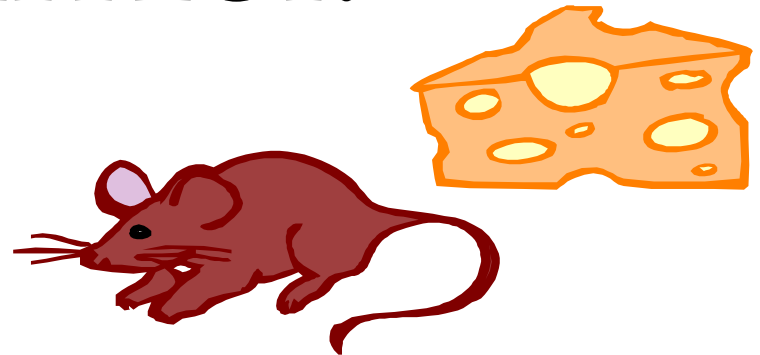
HACCP IS

- PRODUCT SPECIFIC
- PROCESS SPECIFIC
- LOCATION SPECIFIC
- COUNTRY SPECIFIC



HAZARD

• A BIOLOGICAL, CHEMICAL OR PHYSICAL AGENT IN, OR CONDITION OF, FOOD SUPPLEMENT WITH THE POTENTIAL TO CAUSE AN ADVERSE HEALTH EFFECT.

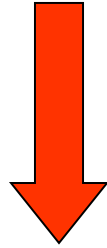


HAZARD ANALYSIS

THE PROCESS OF COLLECTING AND EVALUATING INFORMATION ON HAZARDS AND CONDITIONS LEADING TO THEIR PRESENCE TO DECIDE WHICH ARE SIGNIFICANT FOR SAFETY AND THEREFORE SHOULD BE ADDRESSED IN THE HACCP PLAN.



HACCP PLAN



A DOCUMENT SHOWING THE CONTROL
OF IDENTIFIED SIGNIFICANT HAZARD
TO AN ACCEPTABLE LEVEL



HACCP IS NOT A ZERO-
RISK SYSTEM

IT MINIMIZES

THE RISK OF FOOD-SAFETY
HAZARDS

UNDERSTANDING HACCP



**IN IT'S
TRUE SENSE IS
FUNDAMENTAL
TO IT'S
APPLICATION AND
IT IS A
LEARNING PROCESS**

BASE OF HACCP (PRE-REQUISITES)



- PRODUCT IDENTIFICATION(CODING)
COMPLY WITH AND MONITOR
GMPs

21 CFR PART 110
SANITATION, CLEANING
&
MAINTENANCE

AIMED AT SAFE FOODS
ALL ARE PRPs & NOT CCPs

BASE OF HACCP (PRE-REQUISITES)

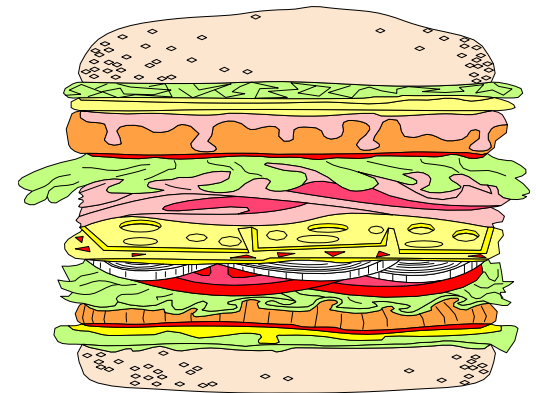
- **SSOPs**-SANITATION STANDARDS OPERATING PROCEDURES
- **PROCESSOR**-SHOULD HAVE & IMPLEMENT A WRITTEN SSOP PLAN
- **PROCESSOR**-SHALL MONITOR THE SANITATION CONDITIONS & PLANS
- **PROCESSOR**-SHALL CORRECT INSANITARY CONDITIONS
- **PROCESSOR** SHALL MAINTAIN RECORDS

FOOD SAFETY CONTROL

HACCP

SSOP

G.M.P

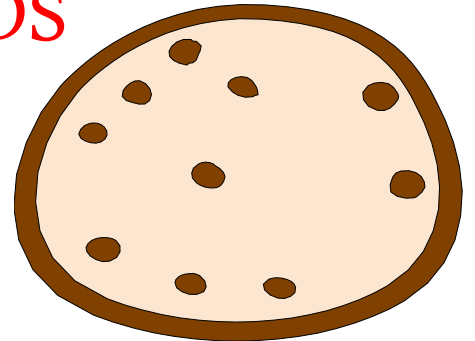
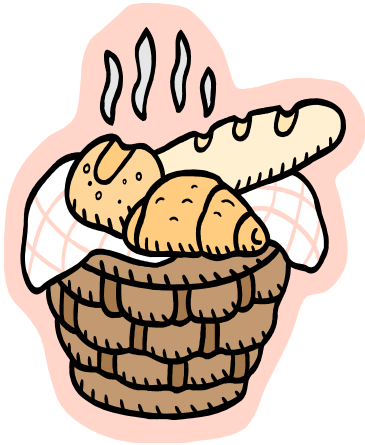




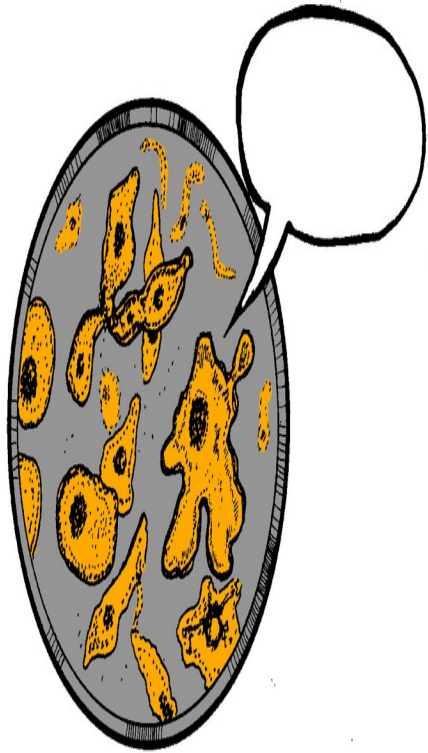
ANTICIPATING
HAZARDS
IS THE KEY
TO PREVENT THEM

WHAT ARE THESE HAZARDS?

- BIOLOGICAL HAZARDS
- CHEMICAL HAZARDS
- PHYSICAL HAZARDS



BIOLOGICAL HAZARDS



- SALMONELLA
 - CLOSTRIDIUM BOTULINUM
 - VIBRIO CHOLERA
- OR
- THEIR TOXINS

CHEMICAL HAZARDS

- ENVIRONMENTAL
- CONTAMINANTS
- ADDITIVES
- PRESERVATIVES



PHYSICAL HAZARDS

- GLASS
- METAL
- PLASTIC



12 STEPS OF HACCP

Assemble the HACCP Team



Describe the product



Identify intended use



Construct flow diagram



On-site verification of flow diagram



List all potential hazards conduct a hazard analysis. Determine control measures



Determine CCPs and describe the measures to control the hazards



Establish critical limit for the control measure at each C C P



Establish a monitoring system for each C C P



Establish corrective action for deviations that may occur



Establish verification procedures



Establish record keeping and documentation

WHO SHALL BE RESPONSIBLE?

THE PROCESSOR

- THE PROCESSOR SHALL
UPGRADE THE FACILITY
- DESIGN HACCP SYSTEM
- IMPLEMENTATION
&
- DOCUMENTATION



ROLE OF GOVERNMENT

- CHANGE FROM TRADITIONAL INSPECTION
- FACILITATE HACCP APPLICATION
- PROVIDE GUARANTEE TO REGULATORS & CONSUMERS

“PRODUCT SAFE “& “PRODUCT SMART”



PROBLEMS IN HACCP APPROACH IN OUR COUNTRY



Product Description wrongly written



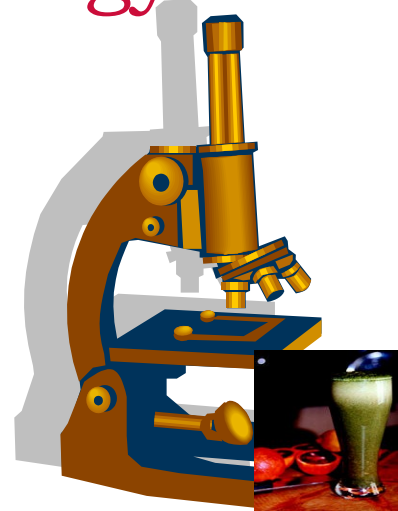
PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

Un-Scientific Hazard Identification



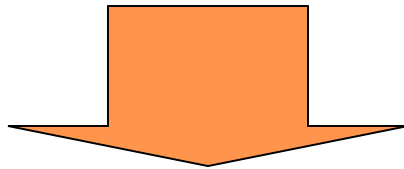
Lack of knowledge on **hazards**-Filtration

Lack of knowledge on **Microbiology**



PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

Improper CCP Determination



which leads to poor application of
Verification & Unreliable records

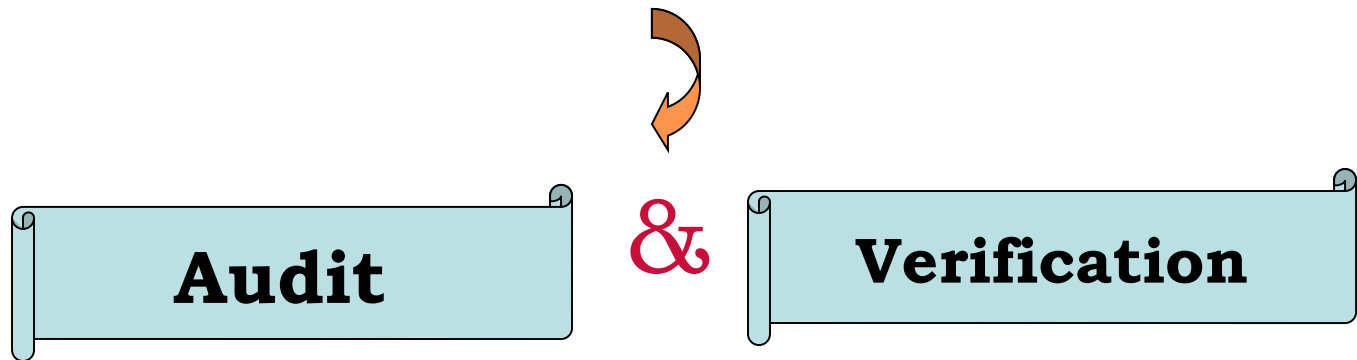
PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

Improper & Inadequate



PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

Confusion between



PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

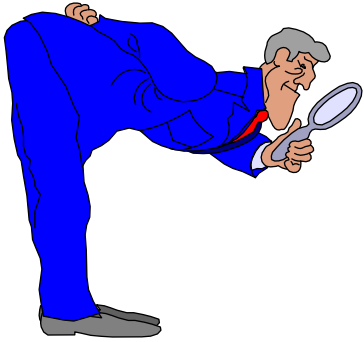
HACCP CERTIFICATE

HACCP Certification



Many ISO - No Accreditation

PROBLEMS IN HACCP APPROACH IN OUR COUNTRY



Improper Monitoring

Metal Detector

once in 2 hours

PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

Inadequate & untimely
Corrective Actions



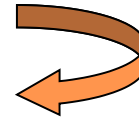
PROBLEMS IN HACCP APPROACH IN OUR COUNTRY



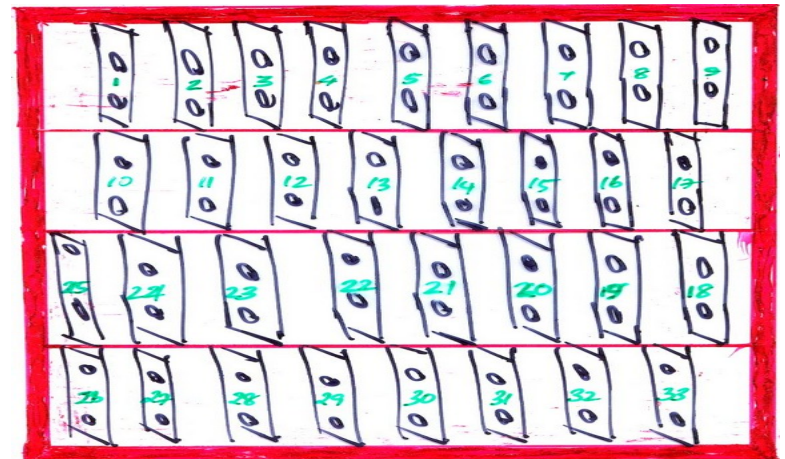
No Verification procedures in place

PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

In adequate/In accurate



Record keeping/Documentation



PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

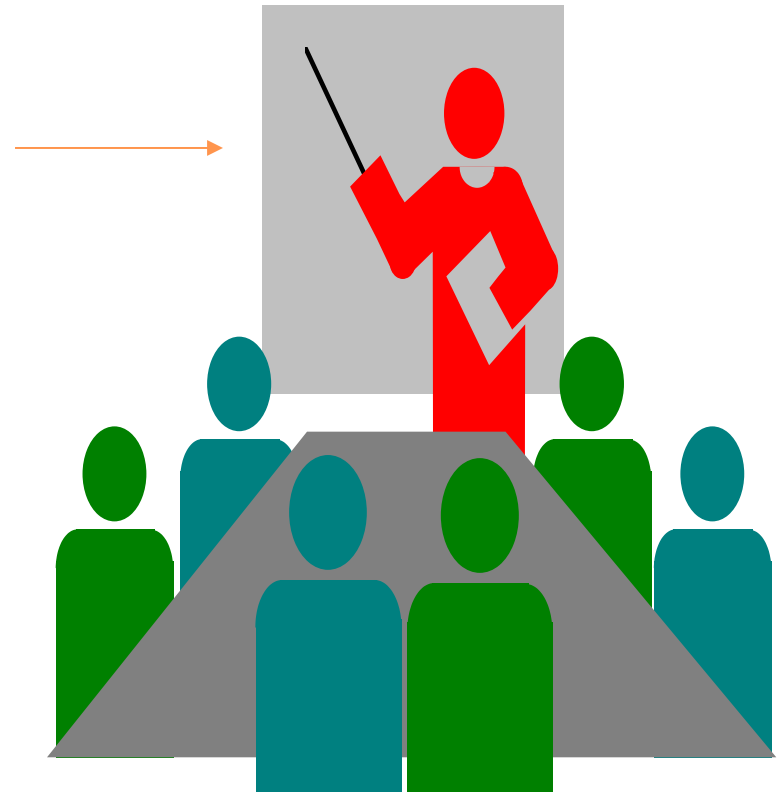


Lack of Unbiased
Auditors



PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

Lack of Training

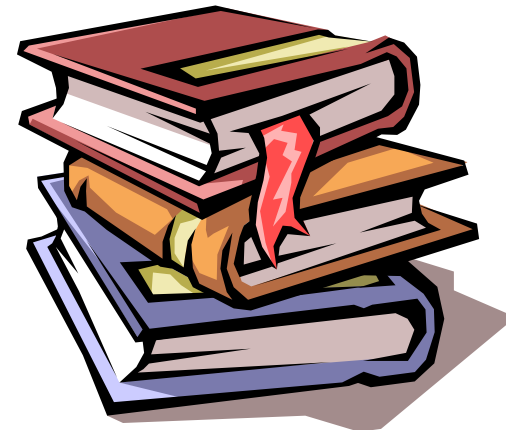


PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

Lack of ➡ Verification Schedule &
Procedures/Agenda & Records

PROBLEMS IN HACCP APPROACH IN OUR COUNTRY

Lack of Records-No Name on
records & Location



HACCP STUDY TIPS

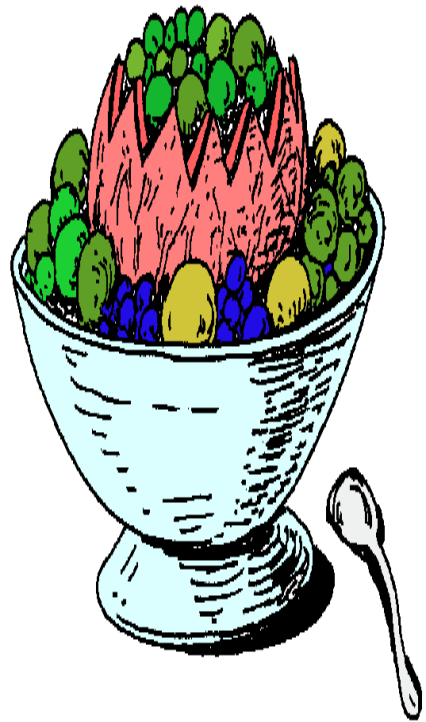
- Use disciplined approach
- Don't make assumptions
- Challenge beliefs
- Discuss Non-hierarchical
- Don't rush
- Set deadlines for comments
- Team leader should moderate not dominate

REQUIREMENTS FOR A SUCCESSFUL HACCP SYSTEM

- **MANAGEMENT COMMITMENT**
- **PLANT DESIGN AS PER GMP**
- **INSECT AND PEST CONTROL**
- **HYGIENE AND SANITATION**
- **TRAINED PERSONNEL**

FUTURE CHALLENGES

PRESSURE FROM CODEX / WTO



- ON HACCP APPLICATION
- HACCP BASED ON RISK ASSESSMENT
- EMERGING HAZARDS
- HACCP SYSTEM DESIGNED SHALL BE

DYNAMIC & LIVING

NOT A PAPER PROGRAMME



**HACCP COULD BE
INTEGRATED TO ANY
QUALITY SYSTEM
APPLIED FROM**

“FARM TO FORK”

FACING REALITY



- HACCP IS AN ESSENTIAL STRATEGY AIMING AT CONTROL FOOD HANDLING, PROCESSING AND MARKETING BOTH, FOR EXPORT AND DOMESTIC MARKETS
- **TRAINING** IS THE BACKBONE IN THE LEARNING PROCESS

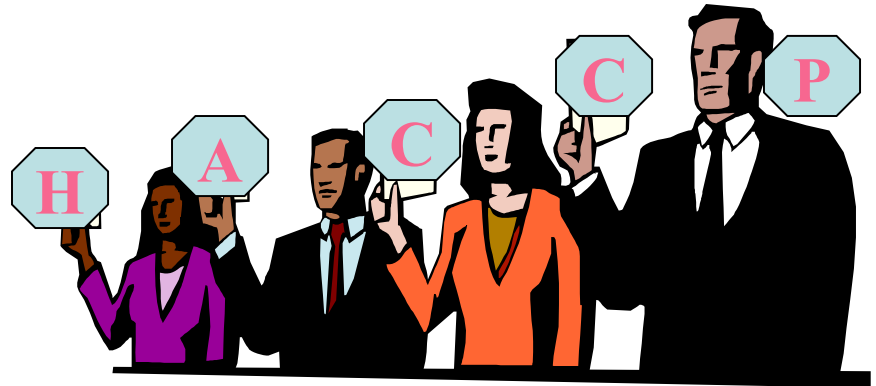
THE NEW CHALLENGE



- **SHIFTED RESPONSIBILITY TO PROCESSOR**
- **DOCUMENTATION TO DEMONSTRATE EFFECTIVE IMPLEMENTATION OF FOOD SAFETY PROGRAMMES TO AUDIT INSPECTORS OF FOOD CONTROL AGENCIES**

EFFECTIVE WAY TO MEET CHALLENGES

- COLLABORATIVE EFFORTS
- COMMITTMENT FROM BOTH INDUSTRY AND REGULATORS
- TRAINING



BENEFITS

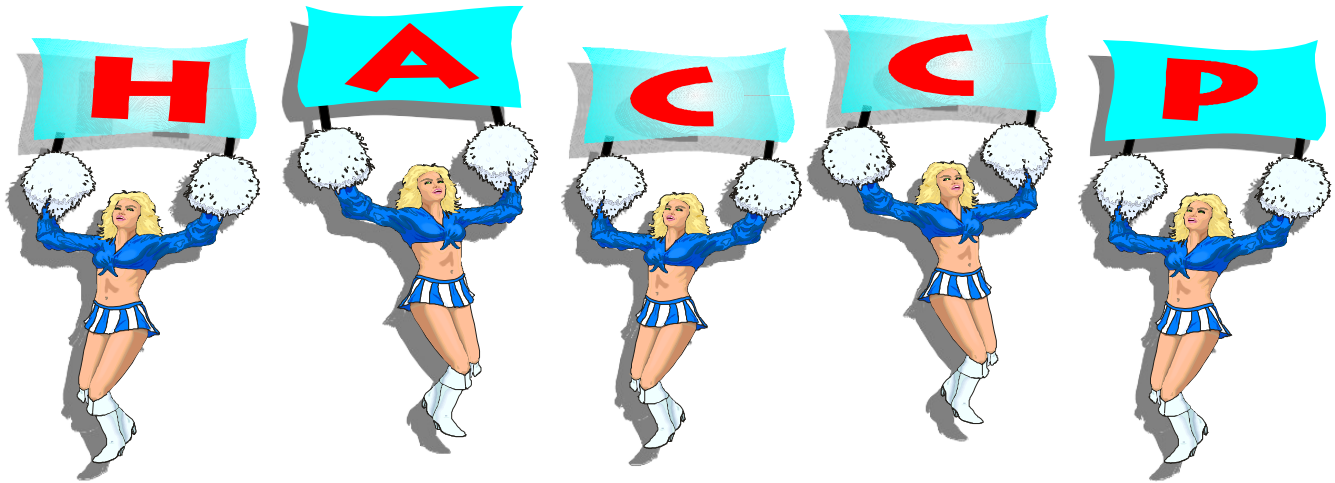
- COST EFFECTIVE
- BETTER UNDERSTANDING BETWEEN BUYER, SELLER, GOVERNMENT & R&D
- REDUCE END PRODUCT INSPECTION
- BETTER PRICE FOR BETTER QUALITY AND SAFE PRODUCT
- IMAGE-ENHANCEMENT OF INDUSTRY & COUNTRY
- LANGUAGE OF SAFETY





**“TO RAISE NEW QUESTIONS
NEW POSSIBILITIES
TO REGARD OLD PROBLEMS FROM A
NEW ANGLE
REQUIRES CREATIVE IMAGINATION
AND ADVANCEMENT IN SCIENCE”.**

ALBERT EINSTEIN



**WE MUST DO THIS
OTHERWISE**

“HAVE A CUP OF COFFEE & PRAY”

HACCP

**T
h
a
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Y
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