


ITC FOODS DIVISIONAL POLICY			
	Hygienic Zoning	POLICY NO.	ITC/FBD/PLC 6.6-09 Ver:00
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Consumer inspired Quality in BUILDING WORLD CLASS BRANDS FOR INDIA			

Objective, Purpose and Scope of this policy

As committed via our “Quality & Food Safety Policy” to craft and deliver superior, delightful and safe products to our consumers and to safeguard our products from cross contact and cross contamination, we at ITC are committed to our “**Hygienic Zoning Principles and Requirements**”. The requirements apply to all ICML facilities which manufactures and handles ITC Food products.

Principle

As a general principle, manufacturing, storage/ warehousing, maintenance and other plant operation shall follow hygienic Zoning principles, practices, procedure and requirements to prevent the risk of environmental cross contamination in the manufactured products.

Hygienic zoning basics:

Hygienic Zoning refers to the division of manufacturing areas based on the physical barriers, cleaning procedures, employee practices and people movement, equipment and materials necessary to protect products from potential physical, chemical and microbiological hazards (as applicable) originating from the manufacturing environment and its surroundings.

Hygienic Zoning programs shall focus on appropriate controls to protect product, raw materials, packaging during their movement from one area to another area in the manufacturing facility and from the processing environment risks.

Entire manufacturing plant can be classified as:

Raw /limited process zone:

- Raw over here refers to, the materials which is not followed with heat kill step or which is being agriculturally harvested and taken to the manufacturing process without any microbiological kill step.
- This includes but not limited to receiving areas, storing or handling of raw agricultural products (e.g. raw milk, raw cocoa beans, flour, wheat, raw vegetables, raw spices, raw meat, raw meal, raw nuts, raw potatoes etc..), including areas of product preparation that will be thermally or otherwise processed and that are known to or have the potential to be contaminated by pathogens.
- These zones are often requiring physical separation from controlled zone or high control zone.
- Follow-up of basic GMP practices will be on the basis of the risk assessment and transition layering (intercepting areas where two zones meet) of this zone with other zones, so as to prevent the risk of cross contamination to the material

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- Raw zones shall always have separate air handling units with prevention of cross contamination to the nearby zones. The area of raw zone shall always be in negative pressure than the surrounding areas.

Non-manufacturing zone:

- Areas where there is no open product.
- Non-production areas such as utility rooms, maintenance workshops, offices, cafeteria, locker room, laboratories, warehouse (including PM/FG) and raw materials where there is no direct product exposure, power supply areas, water treatment/ processing area, canteens and redundant buildings/rooms.
- Specific requirements related to the temperature control shall also be maintained in the area as per the storage norms of material to prevent growth and contamination from spoilage microbes.
- Specifically, for warehouse area appropriate control shall be maintained to reduce hazards created by birds and pests.
- The appropriate required basic GMP's needs to be fulfilled for this zone
- Waste/ scrap (wet / dry) shall be part of non - manufacturing zone. Wherever on-line discharge of waste in drains happens, the same zone shall be considered

Manufacturing/ Controlled zone:

- Manufacturing/ Controlled zones are the zones where products are not highly sensitive and which can be exposed to the environment and the operators.
- GMP practices shall be maintained stringently, as per the ITC design the air exchange and the required temperature and flow shall be maintained.
- Example includes the product post kill step, such as Primary packaging area, rework handling area, semi-finished products and intermediate products areas such as Premix preparation rooms, minor ingredient storage areas, Seasoning areas etc.

High control zone:

- Highly sensitive products include products where:
 - Potential for spoilage organisms is a significant issue
 - Final product is susceptible to the growth of pathogen if the controls are compromised
- High control zones are the zone where the product susceptible to the microbial contamination exposed to the environment post kill step. Such product categories areas include areas of RTE, cake, dairy or juice beverage product post kill step (retorting/ pasteurization) wherever exposed to environment.
- The highest level of hygiene must be maintained in such areas. A “High Hygiene” room, which in food processing is the equivalent of a cleanroom.
- Any add-on or process equipment interior to the processing equipment shall be maintained in high controlled zone
- Environmental air shall be filtered with high grades of filters such as HEPA or equivalent.

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- Additional GMP practices, such as captive footwear/clothing, shall be required and more stringent equipment/building sanitary design requirements shall be followed.
- In such zones material/ tools with high contamination such as maintenance tools, packaging materials, people hygiene, used product/ old product, material stored inside cardboard boxes shall be prohibited or it is recommended to use visually distinctive colours maintenance tools for risk management.
- In High control zone, all maintenance tools shall be maintained at high hygiene conditions, used tools shall be removed instantly.
- In High control zone, used maintenance tools, packaging materials, used/trial products, packed product / rework / cardboard boxes shall be prohibited.

To achieve our goals for this policy, we shall ensure:

- A documented risk assessment of the facility, implementation of necessary controls, evaluation and verification of hygienic zoning for the site

1. Risk Assessment of the facility:

- A documented risk assessment shall be conducted for susceptible cross contamination of product to establish the level of hygienic Zoning requirement.
- Site's risk assessment shall consider for all the cross-contamination risks related to storage, traffic movement (people/ material movement), infrastructure, utility controls, product type and GMP measures.
- Facility Map shall be used for the assessment and marking the different zones, as applicable post risk assessment.
- **Frequency of Assessment:** Risk assessment review and updation shall occur in following circumstances:
 - The hygienic zoning program shall undergo review and validation along with HACCP review and updation.
 - Whenever a change occurs to the factors affecting risk assessment of hygienic zoning
 - New product, New line, extension of line, new packaging line etc

2. Implementation of control measures:

- For each identified risk from above risk assessment, specific control measures shall be drawn. These specific control measures shall be classified under below sub headings.
- **Storage**
 - Physical separation shall be created between raw products receiving / storage and other manufacturing areas.
 - In case of non-vegetarian products/ Identified allergen, materials or products are procured that needs to be placed separately in an identified physically separated location.
 - Waste collection areas inside plant is identified and physically separated from production areas (e.g. Scrap room)
 - Individual separate cold stores/ freezers shall be used to store Veg and Non-veg products, Allergen shall also be separately stored.

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- Warehouse for storing raw ingredients and finished products/ packaging supplies shall be stored physically separated.

- **Traffic control**

- Plant traffic movement for people, material and waste as appropriate for plant situation shall be drawn in such a way that shall not pose any risk of cross contamination. The defined movement of people, material and wastes shall be drawn on separate hygienic zoning layout for the plant.
- Common elevators, hallways, staging areas etc between different parts of plant shall be prevented or adequately controlled for cross contamination
- As a best practice, site shall follow the PRP controlled apertures for transfer of material at loading and unloading bays. Wherever not possible, adequate controls shall be made available to prevent criss-cross of people to different ones of the plant.
- Material movement trollies carrying material from one area to another area also needs to be considered for separation of hygienic zoning principles. Necessary cleaning (including hard to reach area) and segregation strategies such as color coding or nomenclature of such equipment shall also be some.
- Traffic pattern of the plant shall be maintained in such a way that it should not pose any risk for cross contamination. Intent is to adhere to principle of separation with respect to raw Vs. processed, allergen Vs. Non – allergen, Higher contamination Vs lower contamination zones

- **Infrastructure**

- Infrastructural barrier for segregation of the different zones is the prime most important strategy for prevention of cross contamination. In any case, none of the zones shall be diluted for ease of operation.
- Effluent and wastewater drains from production areas shall be separated. Inter-connection between drains in raw processing area and other areas shall not be promoted as the effluent pose high level of contamination risk. Back flow prevention shall be installed to avoid cross contamination
- Drains from lower contamination zones shall run towards higher contamination zone for prevention of cross contamination. As an example, drain should flow from high controlled to controlled zone and from controlled zones to raw zones.
- All overhead drains shall be protected and constructed to prevent product or area contamination to below production lines / equipment
- The building design shall prevent seepages from ceilings, in between rooms / doors.
- Doors, strip curtain and shutters shall be provided at specific locations for prevention of cross contamination and demarcation of zones.
- All windows for provision of the natural light shall be constructed such that the same shall not pose any risk of cross contamination from external environment.
- Necessary changeover areas/ transition zones shall be provided, wherever required.

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- For promoting the basic hygiene and employee personal hygiene, site shall have appropriate changeroom facility with changeover benches, locker and other necessary requirements.
- Floor shall be maintained without any cracks/ crevices and maintained with sufficient slope to drain.
- Warehouses and plant building shall be constructed/ protected in such a manner so that cross contamination from natural wind/ rainfall (e.g. canopy)/ Pest (including pigeons and rodent) shall be prevented.
- Specific controls for allergen Vs. non-allergen separation via infrastructure shall be provided in the plant for prevention of cross contamination. If not possible then specific controls related to the cleaning and maintenance needs to be adhered.

• Utility Controls

- Under utility, air flow plays a vital role in cross contamination, hence areas of higher contamination risk to lower contamination risk zones shall be designed to prevent risk of cross contamination.
- The high hygiene zones shall always be maintained under positive air pressures from the adjacent zones
- Raw zones being the high susceptibility/ risk zones shall be maintained under negative pressure to adjacent areas.
- High control zones shall be maintained under positive air pressure, relative humidity levels and levels of air changes/ per hour shall be maintained as per the product design
- External environment air shall not directly enter inside the manufacturing zones without appropriate filtration
- Condensation shall be adequately controlled in processing and storage areas to prevent product contamination.

• GMP measures

- All ITC employees shall report in company approved uniforms only. All contractors, trainees, SPP staffs shall be in approved garments while entering production /process/primary packaging areas. Wherever required secondary garments shall be provided to prevent risk of cross contamination.
- All employees working in production, processing or packaging area shall wear caps/ hair restrains to avoid cross contamination.
- Clothing restrictions and GMP rules shall be enforced for visitors/ outside contractors (OEMs).
- Necessary hand wash and sanitizer station shall be provided wherever process or product type demands.
- Maintenance tools, operator's utensils / tools shall be cleaned & sanitized after usage to avoid cross contamination or location wise dedicated tools/ color coded shall be used.
- Common pipe connections for receiving or unloading of different liquid ingredients shall be avoided.

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- Peoples shall be trained and made aware for hygienic zoning related requirements on regular basis. Site shall train workmen specially for issues of hygienic zoning violation at transition zones (such as at bay section).
- Controls with respect to the GMP such as dedicated job processes for employees handling allergen, changeovers, cleaning & sanitation, dedicated tools/ color coded tools etc, shall be maintained for allergen Vs non-allergen products

3. Hygienic Zoning Evaluation and Verification Programs Shall be carried out periodically to assure effectiveness and compliance to the requirements. Program shall be verified and evaluated from start to end of the manufacturing process including incoming, storage, processing, dispatch etc.

All employees, visitors, contractors, OEM's shall follow this policy and shall not pose any risk of cross contamination to the manufactured product.

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