- ETO Sterilization
- Buhler Cleaning And Grading
- Buhler Sortex – Z3+ Series
- 24000 Gauss Magnetic Separator
- All Metal Separators
- Microbiological Analysis Test Lab

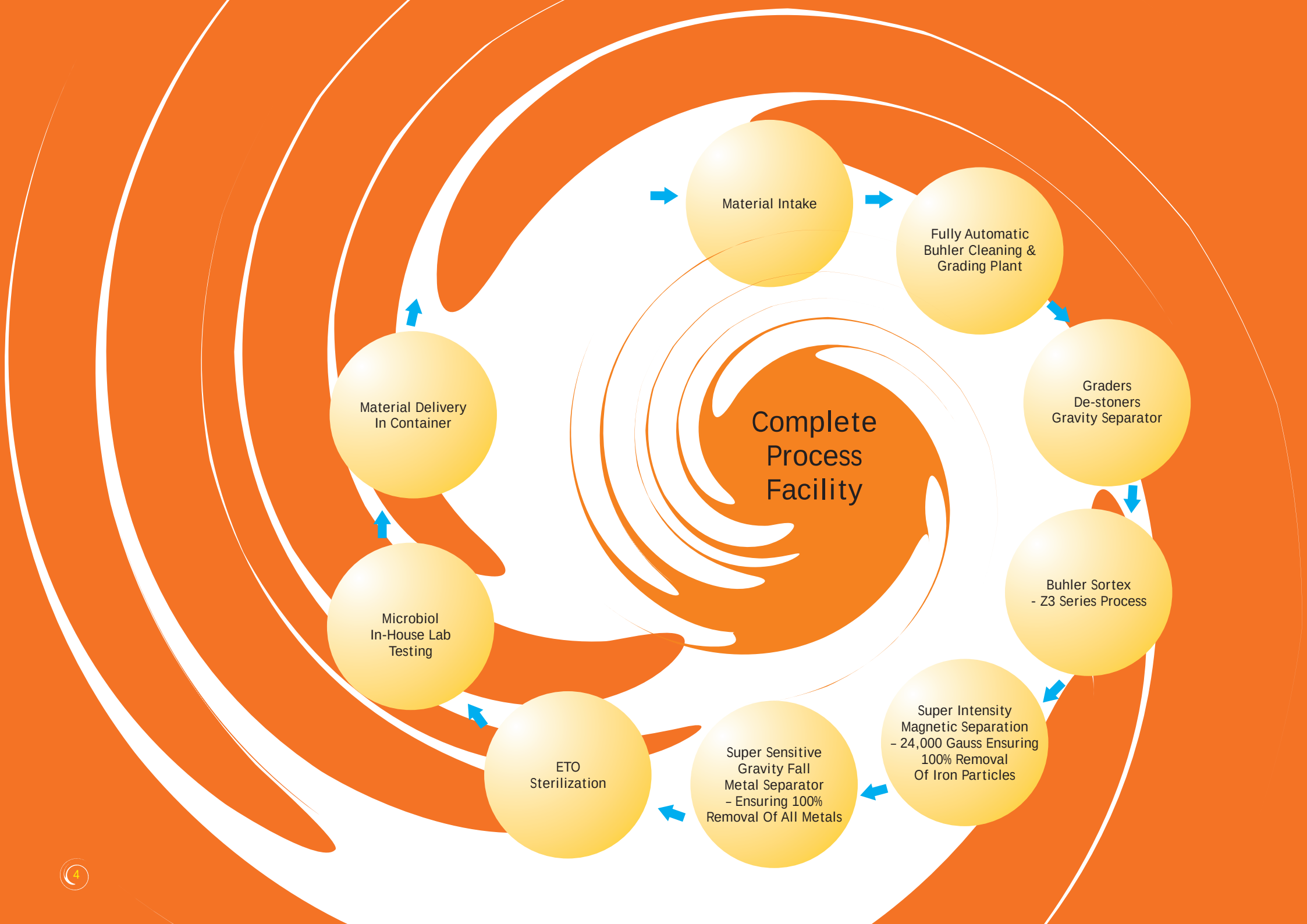
ETO Sterilization

For Spices/Herbs/Medical Equipments

Namah
ETO sterilization

Head Office

The Factory


Material Intake
Fully Automatic Buhler Cleaning & Grading Plant
Graders De-stoners Gravity Separator
Buhler Sortex - Z3 Series Process
Super Intensity Magnetic Separation – 24,000 Gauss Ensuring 100% Removal Of Iron Particles
Super Sensitive Gravity Fall Metal Separator – Ensuring 100% Removal Of All Metals
ETO Sterilization
Microbiol In-House Lab Testing
Material Delivery In Container
Complete Process Facility

BUHLER PLANT
Cleaning/Grading Plant with Sortex – Z3 Series

• Herbs and botanicals contamination is often an issue, and they need to be decontaminated. Depending on harvesting, drying and processing methods, contamination level can go up to 10 billion/gram. The main solution which was used to reduce TPC was ETO, but it is now banned by many countries and forbidden in the USA since 2007. NAFI Steam Sterilization is a natural process which replaces ETO treatment.

ETO Sterilization

- Mission :

To promote the safe use and handling of ethylene oxide for sterilization purposes.

- Ethylene Oxide (ETO) sterilization is mainly used to sterilize medical and pharmaceutical products that cannot support conventional high temperature steam sterilization

- Such as devices that incorporate electronic components, plastic packaging or plastic containers.

ETO gas infiltrates packages as well as products themselves to kill micro organisms that are left during production or packaging processes. This gas, mixed with air at a ratio of at least 3% ETO gas, forms an explosive mixture. Pure ETO gas boiling point is 10.73 ºC at atmospheric pressure. Most of the time, it is mixed with Nitrogen or CO_2 . This explosive condition requires Intrinsic Safe material (ATEX) zoning, for security of people as well as security of the process itself.

Ethylene Oxide - Advantages

Well characterized process:

Appropriate for a wide variety of materials and products.

Good for kits:

EO does not penetrate ampules of drug products, a common kit component.

Parametric Release:

Improving EO equipment control technology is facilitating parametric release validation for some products (no end process microbiological testing and product quarantine pending results).

ETO Sterilization process:

Most ETO sterilization lines involve three different stages. These can be separated into three different cells depending on the size or amount of devices to treat:

- PRE CONDITIONING
- STERILIZER
- DEGASSER

The EO Enhanced Process

During the past several years Cosmed Group has worked with other members of the spice industry to develop a new technology for pasteurization of spices and herbs using gaseous ethylene oxide (EO). The technology was developed in response to a mandate from the US Environmental Protection Agency to reregister all pesticides registered prior to 1989. The aim of the preregistration mandate was to insure that these pesticides meet the same safety criteria as pesticides registered more recently under much stricter regulatory requirements.

Analysis of a 1996 ASTA study of EO residual levels in spices treated by conventional EO pasteurization indicated that in order to meet the current EPA safety requirements it would be necessary to devise a new method providing significantly lower EO residuals.

Lower Residuals

The ASTA studies, conducted over a 3-year period, were guided by technologies originally developed by Cosmed Group to rapidly reduce residual levels in medical devices sterilized with EO. The ASTA studies demonstrated that it is possible to utilize subatmospheric vacuum and humidity pulses to effectively reduce EO residuals to levels which support the registration of EO as a safe treatment for spices, herbs and seasonings.

Enhanced Microbial Reduction

Although the EO Enhanced process was designed solely to provide lower EO residuals, it was found that the process also yields an approximately 10-fold greater microbial reduction than conventional EO treatment.

This additional benefit has proven to be of particular importance in view of current efforts to enhance food safety and to guarantee the security of the nation's food supply.

Excellent Organoleptics - No Weight Loss

Additional studies conducted during development of the new technology suggest that organoleptic qualities including taste, color and aroma are indistinguishable from those of spices treated with conventional EO pasteurization.

In fact, the only difference which has been regularly observed using the new process is that moisture levels remain at or near pretreatment levels. This is a significant advantage over the conventional EO treatment process which often results in a 1% to 2% reduction in product weight through moisture loss.

Improved Equipment

Most equipment currently being used for EO treatment of spices will not support the EO Enhanced process without significant modification. To achieve optimal results with the new process the treatment chamber must be uniformly heated on all surfaces including the door and must be equipped with a high performance vacuum system, food grade high pressure steam supply and a source of chilled water to supply the condensation and recovery system for the large quantities of steam used in the process. A sophisticated control system is needed to ensure that the process parameters do not vary significantly from the conditions required for optimal microbial inactivation and residual reduction. The EO Enhanced process requires approximately 24 hours for completion of each treatment cycle, a significant increase over typical cycle times for conventional EO treatment.

A Better Product

The EO Enhanced process for treatment of spices provides a number of benefits over conventional EO pasteurization including lower residuals, enhanced microbial reduction and little moisture loss without affecting the organoleptic qualities of the treated spice.

Ethylene Oxide Sterilization

Ethylene Oxide (EO or ETO) is a simple chemical compound that is commonly used for gaseous sterilization of disposable healthcare products. A wide variety of materials and components commonly used in the manufacture of these products may be sterilized with ethylene oxide in their final breathable packaging configuration.

History of ethylene oxide

1859 – Ethylene oxide is discovered
1920s/1930s – EO is used for fumigation
1940s – EO is developed as a sterilant by the U.S. military
Late 1950s – The McDonald process is patented for medical devices
1998 –technology introduced

How does ethylene oxide work?

EO sterilization is a chemical process consisting of four primary variables: gas concentration, humidity, temperature and time. Ethylene oxide is an alkylating agent that disrupts the DNA of microorganisms, which prevents them from reproducing. EO sterilization assures that a safe and sterile product will be delivered to the market each and every time.

What is ethylene oxide used for?

The EO process is ideal for:
Custom procedure kits

Cellulose and plastic products that may exhibit discoloration with irradiation devices manufactured from materials whose physical properties degrade with heat or irradiation various materials not compatible with other methods of sterilization, such as tissue and collagen.

What is a typical ethylene oxide processing cycle?

The EO sterilization process may take place within a traditional cycle or through our exclusive expedited processing cycle. Both options consist of three processing phases.

Pre-conditioning:

Used to preheat and humidify product loads to predefined conditions. This will assure a repeatable sterilization process regardless of pre-processing load storage conditions.

Sterilization:

Performed using process phases specifically designed to provide the required level of ethylene oxide exposure to assure sterility for a device or family of devices

Aeration:

Used to accelerate out gassing of exposed product loads and to contain and eliminate residual ethylene oxide emissions. Traditional Ethylene Oxide Processing Biological indicators are placed into the sterilization load, and the load is placed into a preconditioning room. The product is then moved into the sterilization chamber where it is treated with EO gas Following exposure, the product is transferred into an aeration cell for dissipation of the EO Biological indicators are removed from the product and tested Product is shipped to the Customer while still in quarantine. Product is released once the biological indicators have completed testing and the EO residual levels are acceptable Expedited Processing Product is loaded into the sterilization chamber, where it is exposed to all three phases of the sterilization process. (pre-conditioning, sterilization and aeration) This process uses parametric release, which eliminates the labor and time of post-process sterility testing, In-chamber aeration prevents products from having to be held for EO residual dissipation, Products can be processed and released to market within one day.

EO Cycle Validation

Designed for process validation of industrial-sized vessels, this TIP option is for Customers who lack in-house validation resources, or prefer to use outside validation services. We also have the capability to perform small-volume validations for limited production or small lots on our premises or at your location of choice. Periodic revalidation (a single half-cycle) is available.

BI Incubation Time Reduction

This TIP option uses an FDA approved guideline to reduce the incubation period for post-exposed biological indicators. Appropriate for routine processes only, it is an acceptable way to decrease unreleased inventory time

Note:

To benefit from this program, your residual hold time must be shorter than your indicated incubation period.

EO Residual Reduction (Hold Time Reduction)

Through state-of-the-art equipment that removes residues during the sterilization process, this TIP option reduces the time required for dissipation (off-gassing) of residuals that remain after sterilization. Reducing residual hold time (when it is longer that the biological indicator incubation time) results in reduced "in-process" inventory and a faster release of products to market.

EO Cycle Optimization

This TIP option improves the EO process for routine sterilization of existing devices. Through manipulation of temperature and gas concentration, EO cycle optimization can also help achieve further cycle improvements, such as reduced residual hold times, shorter total cycle times and lower temperatures for temperature-sensitive products.

Product/Package Functionality Evaluation

This TIP option gauges post-sterilization material compatibility and function. It is appropriate if you do not have in-house sterilization or small-volume capabilities.

NAFI Services EO Technology center

The NAFI Services EO Technology Center is an organization designed for and committed to the assistance of NAFI Services Customers in all facets of the ethylene oxide sterilization validation process. The Center develops and optimizes your ethylene oxide sterilization processes. It assures that you receive the most complete, cost-effective, and high quality ethylene oxide contract sterilization services available.

The EO Technology Center can help you:

Determine if your product can be sterilized with ethylene oxide. Determine if ethylene oxide is the best sterilization method for your product. Determine which ethylene oxide sterilization process is best for your product Validate a reduced incubation time for biological indicators. Reduce EO residue dissipation time. Save money by using equipment that is specifically designed for either small-volume applications or large-scale production

Equipment

Our equipment delivers industrial EO sterilization processes, both 100% ethylene oxide (deep vacuum) and nitrogen "soft" cycles (shallow vacuum). It ranges in size from 30 cubic feet (24" x 36" x 60") to 2100 cubic feet (60" x 112" x 540").

Our Services

- Validation Support
- Same Day Service
- New Product Qualification
- Dose Mapping
- Laboratory Coordination
- Protocol Generation
- Materials Selection
- Engineering Studies
- Technical Support and Analysis
- Sterility Validation
- Dose Validation/Setting
- Education and Consultative Services

In-House Laboratories & Professional Research Equipment

All spices and herbs cultivated/harvested in different areas of the world and dried in different conditions need thorough and specialized research work (investigation). We have our own laboratories on site and the most modern specialized equipment. All raw materials & semi-finished products go through very strict quality control processes and testing.

We deliver proven products of the highest quality with the guarantee of their health safety.

Namah
ETO sterilization

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