

September 24, 2018

To whom it may concern

Food Hygiene and related topics standards INEOS Olefins and Polymers Europe Policy

In response to the legitimate public concerns on health issues linked to food, feed and chemicals subject to ingestion in general and in contact with food or drugs in particular, several professional standards have been published: BRC-IoP, HACCP, EN 15593:2008, ...

The Authorities are logically an active actor in this trend: in EU, the so-called Good Manufacturing Practice (GMP) Regulation (EC) 2023/2006 has been issued ruling the succession of processes that finally end-up into materials intended for food packaging, as a natural complement of former Directives ruling the products themselves.

INEOS is willing to also be an active actor in this field; more precisely, its Polyolefins business considers that GMP not only include the legal requirements as defined by 2023/2006 on food-contact materials but includes as well the requirements coming from some very demanding applications like organoleptic packaging or pharmacy.

1. Scope

This position paper is intended to clarify most of the questions related to hygiene and public health protection measures taken by INEOS O&P in the matter of materials – namely LDPE, LLDPE, m-PE, HDPE and PP - intended to come into contact with food and drugs. This should help its customers to ensure compliance with their own rules or standards.

2. Description of actions taken to certify the compliance with GMP (as defined above)

These actions can be divided into two series: transversal actions valid at any place in the value chain and step-by-step actions, specific to one given step in the value chain.

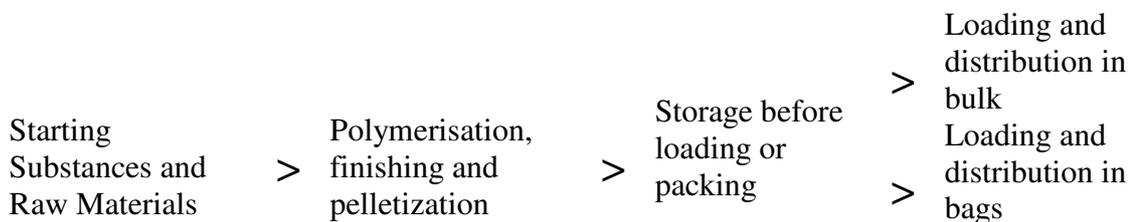
2.1. Transversal actions

- Sensitization, information and training: all the people involved in the production, storage or transportation of food-contact materials have been informed and trained, accordingly to their position and activity in the chain.
- Regular reviewing of GMP is performed in order to maintain the level of awareness and, when necessary, take corrective actions to restore the performance level required by GMP. Changes of any kind are adequately managed and critically reviewed in front of GMP requirements
- Supporting documents, eg supplier certificates and testing results - are kept, in order for the authorities to review them

- The GMP assessment is backed by the ISO 9001 certification of all our plants; this certification is regularly renewed; full traceability is one important item of this certification. In complement of traceability, recall or confinement processes are in place in case of necessity
- All our suppliers are certified ISO 9001 resulting in guaranteed traceability
- One part of our activities is sub-contracted: INEOS requires that its contractors apply the same standards as itself, including GMP; our full attention is given to that point.
- Auditing and reviewing actions are carried out on a regular basis, based on the FCA-PlasticsEurope-EuPC GMP guidelines, built as a practical adaptation of the above-mentioned Regulation 2023/2006; intermediate reviews are performed on an ad-hoc base.

2.2. Step-by-step actions

This review is based on HACCP-like process: taking into account our position in the food-chain, we have applied the process consisting in appraising the resulting potential exposure of public generated by every step of the production, storage, ..., process:



2.2.1. SARMA (Starting and Raw MAterials) management

- Every raw material is reviewed not only from a technical perspective but also from the regulatory point-of-view; they are always assessed for compliance with applicable laws and regulations when they exist or, if there is no legal reference, with recognized toxicological assessment process before being introduced on the production lines, in case of new RM.
- The quality of any incoming material is reviewed in front of the corresponding Quality Agreement between INEOS and the supplier
- SARMA are stored and handled in convenient conditions, in order not to degrade or contaminate them

2.2.2. Polymerisation, finishing and pelletization

- As soon as the production of one given product is decided, a lot number is generated that will follow the product all along its life.
- Every produced grade has its own Technical Specifications: these latter govern the nature and amount of SARMA by means of proven procedures; they also appeal for specific control set. The control set includes formulation control.
- Production parameters and incoming ingredients are recorded along time, as well as the places where the product transits inside the plant.
- Transitions, cleaning operations, purges are designed to bring the risk of contamination to an acceptable level in regards to the foreseen application. By default, the requirement level is aligned on food-contact applications.

- The polymerization reactors and finishing lines are closed machines: the only contact points at the end of reactors and finishing lines with air or water have been designed and controlled in such a way that no alteration is possible.

2.2.3. Storage before loading or packing

- The quality of the air used for transfers is appropriate in regards to foreseen applications.
- A special care is given to the prevention of contamination of any kind, regarding as well the processes as the various materials coming into contact with the plastic pellets.
- Degradation or adulteration of goods is prevented by means of an appropriate storage and pest control policy.

2.2.4. Loading and distribution in bulk (cisterns and containers)

- A specially studied check-list is used to control the cleanliness and absence of contamination of cisterns. There are restrictions on previous loadings and prescriptions on various items, including safety but also documentation or behavior
- Containers are inspected for integrity and cleanliness before acceptance for use
- Ancillary equipments are systematically submitted to cleaning and inspection before loading; air blowers are controlled to prevent any contamination by oil, water or dust.
- Reference to GMP and practical advices are included in the Service Level Agreement, that is clearly part of the contract between INEOS and the haulier.

2.2.5. Loading and distribution in bags

- Bagging lines are cleaned between changes of grade; first bags are systematically down-graded
- Bags are made of food-contact approved materials
- Warehouses are kept in the appropriate conditions of cleanliness

3. Statement

Based on the previous items, INEOS Olefins and Polymers Europe states that its processes are designed and controlled in such a way that the products can effectively be involved in the applications for which they are intended.

The status of our products in regards of these applications, food-contact, pharma-medical, organoleptic is detailed in our certificate, available on the INEOS website at <http://www.ineos.com/products>

Yours faithfully,

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Regulatory and External Affairs Manager
INEOS Olefins and Polymers Europe

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