

To whom it may concern

Regarding: Genetically modified organisms in cell culture products

Regulations concerning genetically modified organisms (GMOs) are aimed at protecting human health, animal health and the environment. To allow for appropriate risk assessment, several guidelines and directives are in place to ensure clear labeling and traceability of GMOs in marketed products:

- Directive 2001/18/EC covers the deliberate release of GMOs into the environment.
- Regulation (EC) 1829/2003 on genetically modified food and feed and Regulation (EC) 1830/2003
 concerning the traceability and labelling of genetically modified organisms and the traceability of food and
 feed products produced from genetically modified organisms.
- The US Food and Drug Administration Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants (March 2019).

It is hereby stated that Cytiva's cell culture products are not intended to be used as food or feed, as ingredients in food or feed, or as direct components/constituents of ingredients used in food or feed. Therefore, these products do not fall under US, EU or international GMO food or feed legislation.

In addition, article 2 of Directive 2001/18/EC defines an "organism" as "any biological entity capable of replication or of transferring genetic material." As such, Cytiva cell culture products do not contain any genetically modified organisms.

Signature:	Date:
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