

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: 10 July 2020
Name: Alaine Smith	Title: Regulatory Support Manager

The information herein is provided to the best of our knowledge and belief, based on the information we have been given and the information available to us at the time that this document was issued. The information may change as additional facts come to light, or as the circumstances warrant. Your use hereof is hence at your own risk and does not relieve you of your own responsibility for checking the suitability of our products for your intended use.