

IMPLEMENTATION OF REACH REGULATION

GRI Standards :

416-1 : Customer Health and Safety

EXECUTIVE SUMMARY

Registration, Evaluation, Authorization, and restriction of Chemicals (REACH) is a European Union's regulation created to protect human health and the environment through improved identification and handling of the hazardous properties of chemical substances.

Because of its integrated upstream chemical production in Europe, Sanofi is highly concerned and has implemented a proper governance, policy and action plan to comply with this regulation and anticipate the future.

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1. BACKGROUND

The European Union's REACH (Registration, Evaluation, Authorization and restriction of Chemicals) regulation came into force on June 1, 2007. The objective of this regulation is to protect human health and the environment through improved identification and handling of the hazardous properties of chemical substances. Sanofi has organized its activities to comply with the regulation and ensure its implementation.

Sanofi is by far the pharmaceutical company most impacted by the REACH regulation. There are reasons for this: Sanofi has a strong presence in chemicals in Europe, with highly integrated upstream chemical production. Consequently, Sanofi is the most highly-monitored pharmaceutical company in Europe. For the last two years the Company underwent seven inspections, bringing to 31 the number of inspections carried out since 2009 at Sanofi sites in various countries including France, Germany, Italy and the United Kingdom.

2. POLICY AND ACTIONS

2.1. Internal organization

To ensure application of the REACH and CLP (Classification, Labelling and Packaging) regulations, Product Stewardship provides technical and scientific support. It defines the classification and labeling of substances according to the CLP and hazardous substances regulations. It also creates, updates and edits the Safety Data Sheets (SDS) requested by the sites.

A REACH coordinator from the Global HSE Department acts as the point of contact for several other functions. In addition, since 2008 there has been a REACH coordinator for every Sanofi site. The coordinator is responsible for the implementation of REACH at the site level, with the responsibility to :

- Develop procedures defining the roles and responsibilities of the various participants.
- Ensure that the product portfolio is updated in compliance with the regulation.
- Centralize collection of operational information.

A Health Safety and Environment Regulated Substances Council is set as a coordination platform and a forum for the exchange of information to organize the Group's REACH-related activities. The Council, which defines Sanofi policy and ensures compliance with the REACH regulation, is overseen by the Global Health Safety and Environment (HSE) Department. Committee members include representatives of impacted activities and functions (Legal, Procurement/Outsourcing, Quality, etc.).

2.2. Registrations & authorization

Sanofi successfully met the three regulatory milestones (December 1, 2010 / June 1, 2013 / June 1, 2018) with the submission of 39 / 58 / 247 dossiers, respectively, to the European Chemicals Agency (ECHA). Since the last milestone 17 additional submissions have been performed linked to new activities.

Sanofi submitted an authorization dossier which is currently under examination by the European Chemicals Agency.

2.3. Training

Training on the extended Safety Data Sheets (eSDS) has been implemented in both French and English at our European sites in order to verify that, at site level, we are using substances according to the exposure scenarios described by suppliers.

2.4. Newsletter

An internal newsletter is sent out periodically to report on progress in REACH implementation, to exchange best practices and experiences at different Sanofi sites, and to comment on action plans.

3. IN THE FUTURE

Sanofi is following up the developments of the restriction and authorization processes of ECHA, and preparing proactively to comply with any new future requirement.

To be compliant, Sanofi is preparing an authorization dossier for continuing the use of a substance which sunset date will be 2021 January 4th.

Sanofi is also following its portfolio of products to register any chemical which would fall under the criteria.

Sanofi is seriously following up the progress of the actions regarding Brexit, and does every effort to secure its business and the supply continuity from/ into the UK.

