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Implementation of REACH Regulation

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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 the 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. The Company underwent 33 inspections by the Authorities 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 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; and
- 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 Company'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 (Corporate Social Responsibility, Emerging Risks, R&D, Legal, Procurement/Outsourcing, Quality, etc.).

2.2. REGISTRATIONS & AUTHORIZATION

Since the regulation in place, Sanofi has submitted 344 dossiers respectively, to the European Chemicals Agency (ECHA).

Because of recent organizational changes (creation of EuroAPI) our actual portfolio in 2023 consists of ~160 registrations.

Sanofi seriously followed up the Brexit negotiations and took every effort to secure its business and the supply continuity from/ into the UK.

Sanofi submitted an authorization dossier which was approved by the European Commission.

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

Companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1% weight by weight (w/w) on the EU market must submit information on these articles to ECHA, as from January 5, 2021. Sanofi is building a robust system to track the new SCIP notification obligations of our suppliers. Sanofi has reached out to more than 200 suppliers to ensure compliance with this new obligation, and continuously works with partners on checking if any SCIP notification is necessary to perform by the Company.

Sanofi is actively following up the regulatory development of the future EU restrictions of Bisphenols and Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) and working together with Its suppliers to ensure conformity and business continuity.