FRANCESCO GREGORINI*, FRANCESCA ROMAGNOLI, GIULIA FRABBONI
*Corresponding author
CEPRA srl, Casalecchio di Reno (BO), Italy

REACH and CLP Role in the Cosmetics Regulation

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ABSTRACT

REACH and CLP regulations entered into force more than 10 years ago and it is high time to make some considerations. The article gives information on the interface between REACH/ CLP and the Cosmetic world. The article would focuses on the main interactions between REACH – CLP and the Cosmetics Sector.
In conclusion the article gives an overview on the future considerations and challenges of REACH and their effects for the Cosmetic Supply Chain and potential opportunities.

INTRODUCTION

Reach is the European Regulation (1907/2006) on the Registration, Evaluation, Authorisation and Restriction of chemicals.
The main goals of REACH:
- collect data on properties and uses of the substances;
- safe management in the whole life cycle of the substance;
- communicate safe uses along the supply chain;
- find alternatives for high concern substances.

CLP is the European Regulation (1272/2008) on the Classification, Labelling and Packaging and it is based on the United Nations' Globally Harmonised System (GHS). Its purpose is to ensure a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles. It requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market.

MAIN INTERACTION BETWEEN REACH –CLP AND THE COSMETICS SECTOR

Registration

Registration is required for substances manufactured or imported exceeding 1t/y. Substances used as cosmetic ingredients are not out of the scope of REACH regulation. So, in the case of production of raw materials or importation of substances on their own or in mixtures (including end-products), a registration could be necessary. Some specific exemption could be applied for substances listed in Annex IV (e.g. glycerine) or if the criteria described in annex V (e.g. substances which occur in nature) are met. In table 1 and 2 are just a few numbers and some information on the registration to describe the current situation (1).

REGISTRATION
>15.000 companies
>22.000 subtances
>97.000 dossiers

Table 1.

Most of the dossiers have been submitted by importers or OR (only representative). It means that we had many registrations of imported substances on their own or in mixtures.

ROLE IN THE SUPPLY CHAIN
31% Manufacturer
34% Importer
9% Manufacturer & importer
26% Only representative

Table 2.

The REACH registration mainly requires a proper identification of the substance and a submission of a dossier which includes physical-chemical, toxicological and eco-toxicological data of the substance. All the data collected and submitted are improving the knowledge concerning impurities, proprieties, risk management also for many cosmetics ingredients. In the registration process, the SIP (substance identification profile) is a crucial point. Identify correctly the substance and its potential impurities, have an impact on the proper use of (eco) toxicological data and any other propriety of the substance used for the registration and also for further regulatory activity, like the CLP classification or the cosmetic safety assessment. One of the action planned by the REACH Review (2) is to improve the quality of the registration dossiers, including the identification of the substance.

The role of OR

The Only Representative is a key role, especially in the case of importation of raw materials and end products, such us cosmetics. Companies based outside the EEA can appoint a

European-based only representative to take over the tasks and responsibilities of importers for complying with REACH. This can simplify access to the EEA market for their products, secure the supply and reduce the responsibilities for importers. The skills and the know-how of the OR are very important for the compliance of the all supply chain. The Report concerning Forum REACH-EN Force 3 (3) in 2014 concluded that "Only representatives have the highest non-compliance rate, which is twice the average rate for non-compliant companies. Only representatives are often non-compliant not only due to missing registrations, but also due to the breach of Article 8 of REACH regarding the duties of only representatives".

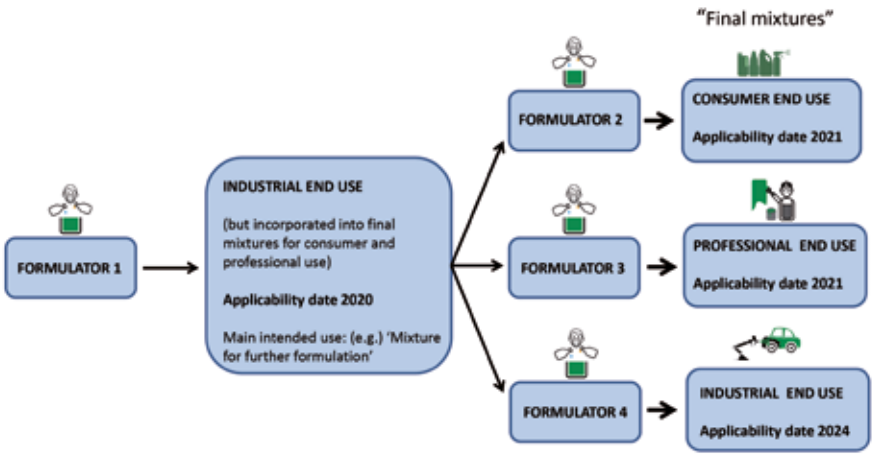

Table 3.

Authorization and Restriction

According to REACH, the authorization and restriction processes do not affect the cosmetic sector regarding health concerns. Annexes of the cosmetic regulation already list prohibited substances and specific restriction on use. However, restriction provided by REACH could impact on cosmetics if there are any environmental concerns. An example concerns D4 and D5 silicones. The use in wash-off cosmetic product will be restricted starting from January 2020 (4). Currently, the restriction proposal for micro plastic particles that are intentionally added to mixtures is a very hot topic which will also impact on the cosmetic sector (5)

eSafety Data Sheets, Classification&Labelling

SDS and Labelling of cosmetics are not mandatory when the product is in the finished state, intended for the final user. They are required for raw materials or cosmetics (if they are not in the finished state) which are dangerous according to CLP. SDS are necessary also when chemicals which do not meet the classification criteria of CLP, when they contain a substance posing human health or environmental hazards or a substance for which there are Community workplace exposure limits. Exposure scenarios are one of the most critical point of REACH, in particular exposure scenarios of mixtures. ECHA, the Commission and other stakeholders are working on the workability and quality of extended Safety Data Sheets. Cosmetics sector is partially involved in this issues because the health assessment of the consumer stage is out of the scope of CSA/CSR process. In any case, the assessment of industrial uses (e.g. cosmetics production) and the environmental exposure also of the consumer stage are required. This is very important because also in the cosmetic sector it's necessary to assess environmental impact of a substance.

Poison Centers Notification

A new Annex VIII was added to the CLP Regulation in 2017(6), implementing harmonised information requirements for notifications under Article 45. This information is submitted to the appointed bodies in the Member State and is used for emergency health response (the Poison Centres). Annex VIII defines a unique formula identifier (UFI), which will be required on the label of the mixture, creating an unambiguous link between a mixture placed on the market and the information made available to emergency health response. Different deadlines are foreseen based on the end use of the mixture, as shown in the table 3. For the cosmetic supply chain the deadline is 2024.

REACH REVIEW

Some 10 years after its entry into force, REACH is fully operational and delivering results towards achieving its objectives. It has steadily improved as experience was gained. However, further improvements are needed to make the legislation more efficient. The European Commission is working on a number of **concrete actions** to improve the implementation of REACH (2). The issues requiring most urgent action affecting the cosmetic sector are:

- non-compliance of registration dossiers
- enhance enforcement and ensure a level playing field with non-EU companies
- improve the workability and quality of extended Safety Data Sheets
- tracking substances of concern in the supply chain

Non-compliance of registration dossiers

According to Article 22 of REACH, registrants are responsible for updating their registrations with relevant new information on their own initiative and without undue delay and submitting them to ECHA. The most frequent cases for which it is necessary to update the dossier are:

- change in the composition
- changes in the quantities manufactured or imported
- change in the classification and labelling
- new information on the risk management measures

The Commission and ECHA wish to identify why registration dossiers are not being updated and aim to improve the situation.

Enhance enforcement and ensure a level playing field with non-EU companies

Compliance of importers is vital to work towards a level playing field, and therefore enforcement will be directed at these actors through coordinated projects, preferably in close cooperation with customs authorities. REF-7 project should be carried on with the cooperation of customs. Concerning this issue, the Commission is aware that is necessary to clarify and enhance the role of REACH enforcement authorities as well as customs authorities in the enforcement of REACH. The European Commission has suggested regulatory measures, as well as recommendations and guidelines, to clarify the role of the customs authorities in enforcing REACH, and to promote a harmonised approach to goods entering the trade bloc. An example of suggested implementing measures (8):

- to ensure uniform application of customs controls, including common risk criteria and standards on the basis of Article 50 UCC (Union Custom Code);
- on the roles of the customs authorities for REACH enforcement on the basis of Article 132 of REACH; and
- adopted in the framework of the future Market Surveillance Regulation.

THE TOLL MANUFACTURER

"Toll manufacturer" is one of the most frequently used terms for describing a second company carrying out an activity on behalf of a first in cases where the activity is manufacturing. The activity is correspondingly described as toll manufacturing and is a common practice in the chemicals industry. REACh and the Cosmetics Regulation do not
have specific provisions on toll manufacturing. Nevertheless, toll manufacturers may have obligations, specially under REACh.
In the cosmetic supply chain, it is possible basically to identify two types of toll manufacturers:
- manufacturer of substances
- manufacturer of mixtures (raw materials or end products)

In both cases, the toll manufacturer could have specific obligation under REACH-CLP, even the registration.
It's strongly recommended that toll manufacturing agreements explicitly address the REACH obligations related to manufacturing activities in the EU - as a minimum the registration obligation, ownership of data, future updates, responsibility for compiling and providing Safety Data Sheets (SDSs).

ON LINE SALES

The last Forum enforcement project (REF-8) (7) will concentrate on online sales of substances, mixtures and articles. One reason for this focus is the high rate of non-compliance detected in the Forum's pilot project on internet sales and which is a hot topic also for the cosmetic sector. The detailed scope to be checked under REF-8 is yet to be defined. The project will be prepared in 2019 and carried out in 2020, with the report expected to be published by the end of 2021

CONCLUSION

In conclusion cosmetics are not out of the scope of REACH and subjects involved in cosmetics need to understand well their roles and responsibilities. Also in the case of importation of cosmetics, the REACH compliance of the raw materials is necessary. ECHA and the European are increasing the Evaluation and the Compliance Check (The Evaluation Joint Action Plan (9) set that ECHA's aim is to screen all registration dossiers submitted by 2023 for substances registered over 100 tonnes per year and by 2027 for substances in the tonnage band 1-100 tonnes per year) and the cooperation of the customs for non-European products. Be compliant to REACH it's a work in progress challenge and be up to date on REACH evolution is necessary also for the cosmetic industry. Actually we can say that now REACH has completely started.

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ABOUT THE AUTHOR

Francesco Gregorini *- manager of "chemicals compliance" area at CEPRA - CONSULTING and TESTING – Italy (www.ceprasrl.it) - and founding member of "REACH360" (www.reach360.it).*
Francesco Gregorini has expertise in product stewardship, regulatory affairs and chemicals safety assessment.
Graduated at University of Bologna (Italy) in Chemistry and Pharmaceutical Technologies, now he is REACH – CLP contact person for local Chemist Society, member of EurChem – European Chemist, vice president of SICC (Società Italiana di Chimica e Scienze Cosmetologiche), member of ERPA (European Responsible Person Association).