

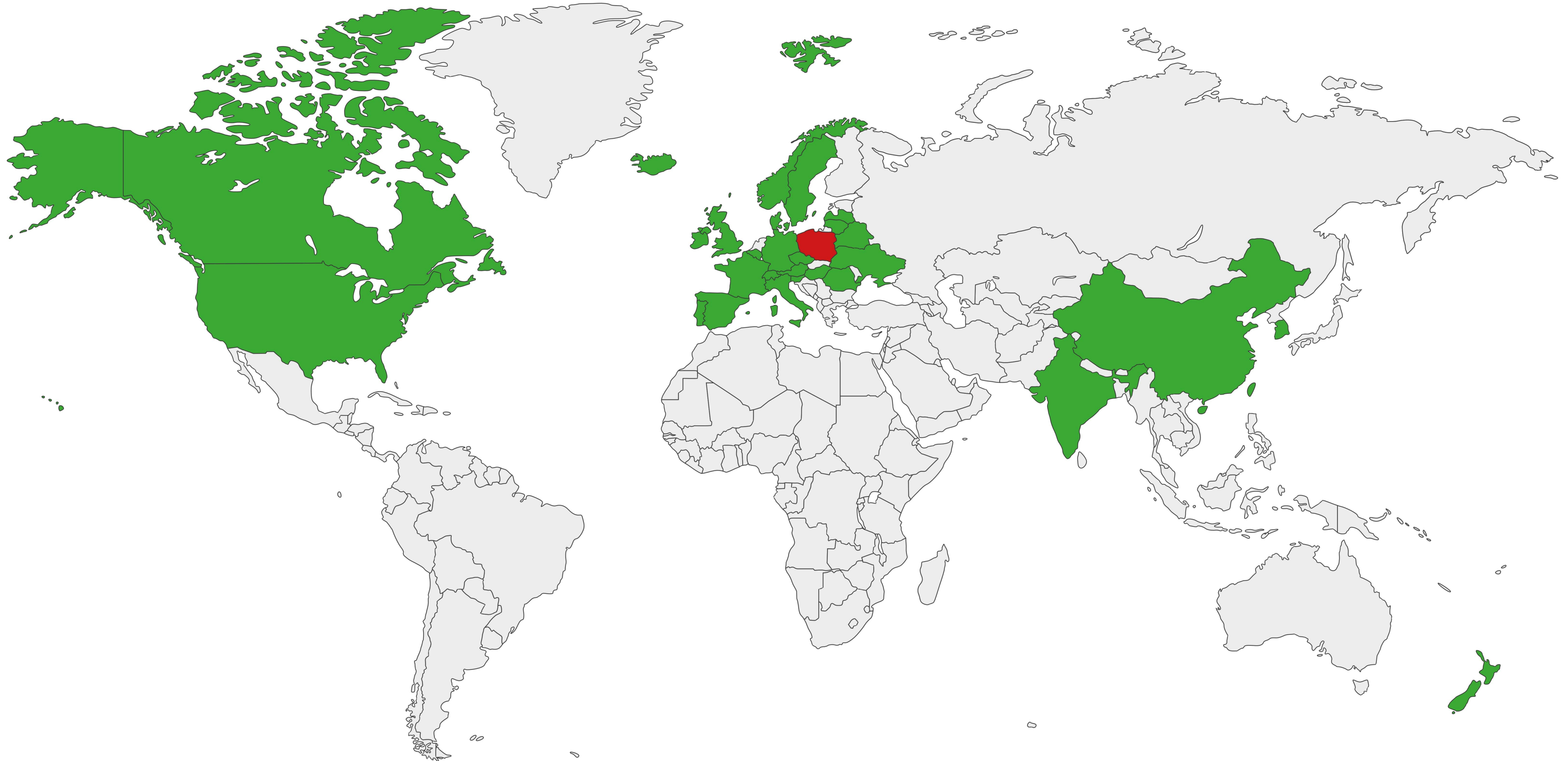
THETA[®]

our knowledge, your success

OFFER



THETA Worldwide



MORE THAN **20 YEARS** ON THE MARKET

The infographic features a central title 'MORE THAN 20 YEARS ON THE MARKET' in a large, dark grey font. A green line descends from the end of this title, then turns left and then down to a green dot. From this dot, a horizontal green line extends to the left, with four vertical green lines descending to four green dots. From each of these dots, a vertical green line leads to a text block. The first text block on the left contains 'over 500 registrations and notifications'. The second text block contains 'over 6500 MSDSs annually', with a vertical green line leading to 'in more than 18 languages'. The third text block contains 'over 300 authorisations for marketing annually'. The fourth text block contains 'over 1500 trained companies', with a vertical green line leading to 'more than 6000 trained people'. The fifth text block on the right contains 'over 550 safety assessments'. All numbers are in a bold green font, while the descriptive text is in a dark grey font.

over **600** customers
in 35 countries worldwide

over **500**
registrations and notifications

over **6500**
MSDSs annually

in more than **18**
languages

over **300**
authorisations for
marketing annually

over **1500**
trained companies

more than **6000**
trained people

over **550**
safety assessments

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ABOUT US

In the times of constantly changing regulations and legislative requirements, the most important matters are represented by the state-of-the-art knowledge and prompt assistance provided to companies in the field of the key safety issues. You can receive professional and reliable support from THETA, the most thriving consulting company in the technical and legal consulting line of business in Poland.

THETA operates on Polish market since 2001. Perfectly reacts to new, more and more difficult requirements and fast-changing regulations. We assist our customers, providing them with expert consulting services in scope of placing on the EU markets chemical substances, mixtures and products from almost all areas – intended for both, consumers and professional users.

We built a dynamic team of experts with relevant knowledge and extensive experience in the field of company assessment, preparation of documentation, classification of substances and mixtures, registration and certification of products – auditors, lawyers, chemists, engineers, safety assessors, toxicologists, environmental protection, REACH and SDS experts, as well as ADR/RID, IMDG & IATA transport advisors.

Our aim is to create a comprehensive safety system based on the EU regulations. System, that shall enable your company to legally market, transport, sale and dispose of chemical substances, mixtures and articles.

Thanks to the continuously expanded knowledge, adjustment to the requirements and needs of clients and daily intense efforts of the whole team, THETA is present on most of the EU markets and also outside the Community.

We are always two steps ahead of changes, and each day we pursue our motto:

Our knowledge, Your success



01

SAFETY DATA SHEETS AND LABELLING

THETA Consulting is a major company in Poland dealing for more than 15 years with compilation, updating and translations of the safety data sheets, as well as preparation of safety information for the labels of chemical products in all European languages. Our team of experts: chemists, toxicologists, translators and experts in environmental protection, is able to help you in any situation – in a professional and reliable way.



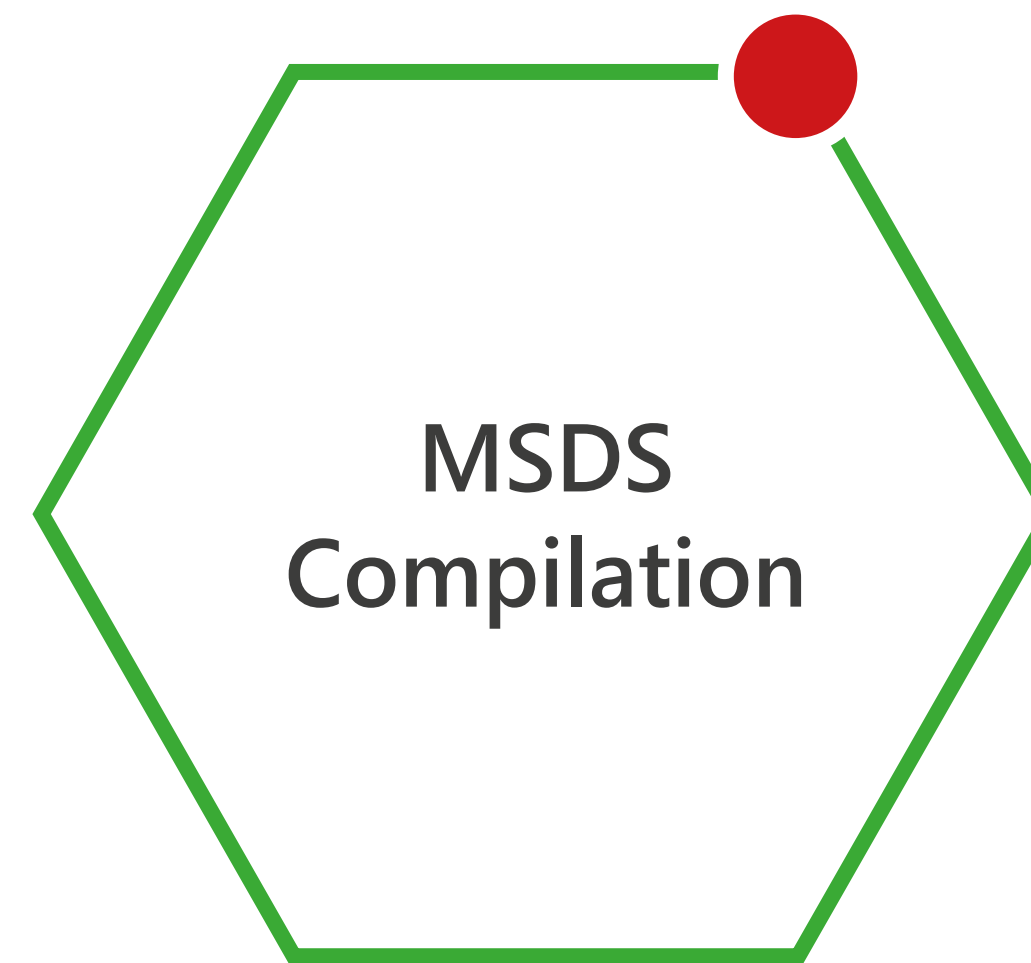
Safety Data Sheets

- with us, you can do it right

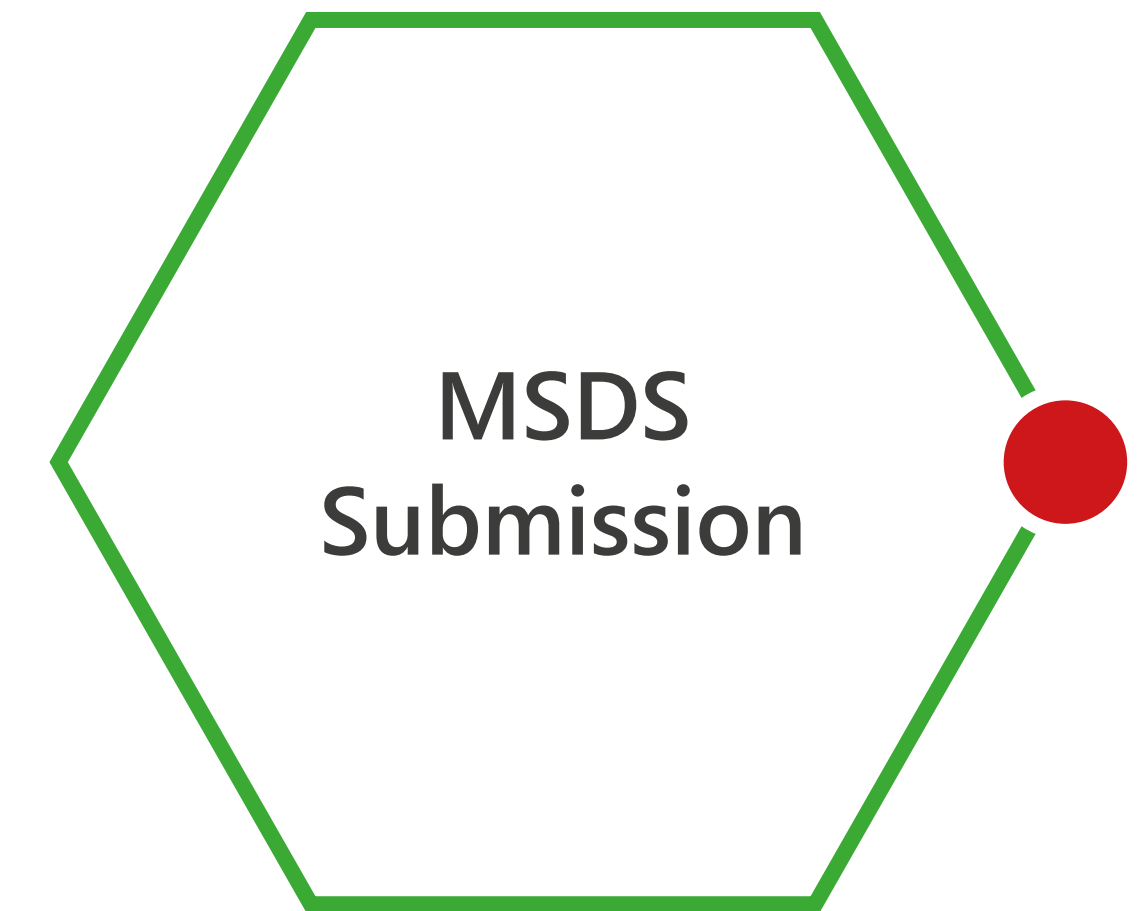
In accordance with the **Regulation No 1907/2006/EC (REACH)**, a basic communication tool regarding information on hazards and risk management within the supply chain between the manufacturer, supplier and downstream user is the safety data sheet (SDS/MSDS). Its task is to enable every user conducting their business to undertake at their workplace all necessary actions aimed at ensuring human and environmental safety.

It is prohibited to use within the framework of the business activity, any dangerous substances or mixtures, without safety data sheet required for them.

Manufacturers, their representatives, importers or suppliers of a given chemical product are responsible for correct preparation and placing on the market a properly, substantially and formally, compiled safety data sheet.



- SDS preparation/update;
- Compilation in any EU language;
- Compilation in non-EU languages;
- Translation to and from Polish language together with adjustment to the current EU regulations;
- Audit and assessment of owned documentation;
- Preparation and implementation of schedule for compilation/ update of multiple safety data sheets.



- Complete registration in ELDIOM system in Poland and obtaining the authorisation;
- Monitoring and update of submissions;
- Notification to information systems of individual member states;
- Registration and meeting relevant requirements in individual Member States



Labelling

- label/ classification and CLP requirements

Safety data sheet is a document, which should be provided to entities conducting their business. On the other hand, for an individual consumer, the only source of information on risks caused by a product is the label. Therefore, it is very important, that the label is compiled in a reliable way, compliant with all the regulations.

Provisions concerning the classification of mixtures and requirements for the product label are set out in the Regulation No 1272/2008/EC [CLP].

- Chemical product classification compilation;
- Product label assessment;
- Compilation/update of safety information on labels;
- Notification in C&L database;
- Job instructions;
- Restrictions and prohibitions while placing products on the market (Annex XVII to REACH);
- Company audit for meeting CLP regulations and provisions related to labelling, classification and marketing of chemical products;
- Monitoring and notifying changes in regulations;
- Help in scope of interpretation of regulations, preparation of letters and interpretations for clients, suppliers and control bodies and support during inspections;
- Consultancy on a current basis and support provided in scope of contact with control bodies.



Label
Compilation

Consulting
Services

02

REACH

The idea of the REACH Regulation is based on the assumption, that it is the responsibility of the manufacturer, importer and downstream user to ensure, that substances they manufacture, place on the market or use, have no negative impact on human life or the environment.

Due to the numerous requirements for manufacturers, importers and downstream users, meeting all the REACH-imposed obligations is not an easy task. It requires broad legal and chemical knowledge, and practical experience resulting from long-term work covering various cases is very useful.



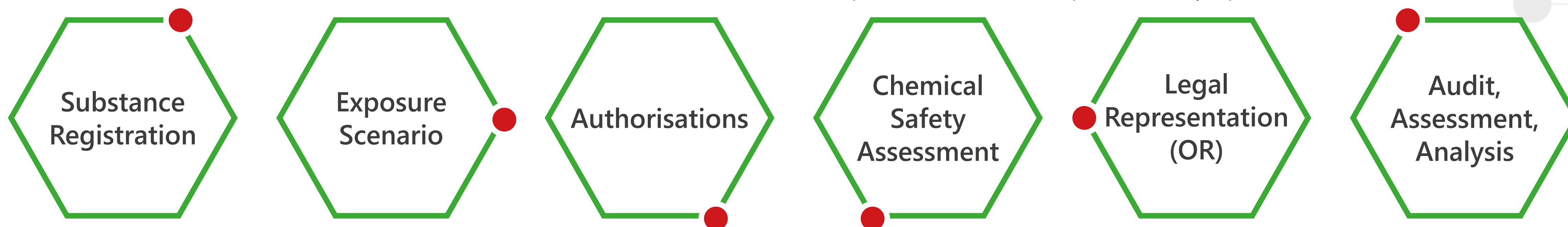
REACH

– the most important chemical law in EU

THETA offers comprehensive legal support for manufacturers, importers and downstream users, accompanied with knowledge and extensive experience of our team of experts and lawyers. We have registered tens of substances and intermediates from various industries in every tonnage band. We are the Only Representative for non-Community companies and we also provide consulting services on a current basis for more than one hundred companies – from Poland and from both European Union and non-EU countries.

We prepared a comprehensive offer for support in a wide range related to meeting the requirements of the REACH Regulations.

- Determination of company responsibilities;
- Legal support;
- Information on identified uses;
- Submission of articles;
- Declaration of SVHC substance content;
- MSDS compilation;
- Chemical Safety Assessment and Exposure Scenario;
- Application for issuing the authorisation for substances (Annex XIV to REACH);
- Support when selecting the most economic registration method;
- Conducting the full registration;
- Update of registration dossier;
- Declaration of meeting the requirements of CLP and REACH Regulations;
- Notification of classification and labelling in accordance with CLP;
- Representation of non-EU companies – the Only Representative.



REACH

– the only such certificate

The certificate of REACH compliance for company and products*

Unique and only in EU certificates confirming the compliance of the company and product with the requirements of the REACH Regulation.

REACH compliance confirmed by THETA

Product compliant with REACH confirmed by THETA

Validation made by an independent company in scope of meeting the obligations imposed on your enterprise in relation to the REACH Regulation or compliance with the requirements of the REACH Regulation of the supplied products themselves.

- Independent assessment;
- Compliance with law;
- Official confirmation;
- Customers' trust;
- Suppliers' trust;
- Competitive advantage;

REACH
Certificate



for manufacturing companies, importers and downstream users who are subject to the provisions of the REACH Regulation.



for specific products placed on the EU markets: substances, mixtures or articles subject to the requirements of the REACH Regulation.

* "REACH compliance confirmed by THETA" and "Product compliant with REACH confirmed by THETA" are proprietary registered word and figurative trademarks.



03

BIOCIDES

THETA has an extensive experience in registration of biocidal products. Our specialists shall conduct the process of obtaining the authorisation for you – from the help with selection of active substances and tests necessary for preparation of the registration dossier, through the comprehensive evaluation, compilation of documentation and supervision of registration procedure. Acting on behalf of a client, our consultants represent them also before the URPLW MiPB (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products), supervising the registration procedures until the authorisation is obtained.

Biocides

– registration? Let the experts take care of it

All the biocidal products (biocides) placed on the market or used within the territory of Poland are subject to the obligation of registration and obtaining the authorisation in the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLW MiPB).

They can be registered in transitional procedures (so called national ones) or in European procedures. The type of registration procedure does not depend on the registrant's will, but, inter alia, on active substances contained in the product and its use. The most important stage of the registration of a biocidal product is establishing the right registration strategy, enabling the optimisation of time and costs.

Registration in transitional procedures covers products containing at least one active substance, which evaluation (performed within the framework of the active substance review programme) has not ended yet.



Within the framework of the registration in national procedure, we offer:

- Analysis of owned documentation;
- Selection and performance of tests;
- Compilation of complete registration dossier;
- Conducting complete product registration in URPLW MiPB;
- Representing the entity before URPLW MiPB;
- Consulting services on a current basis;
- Support in case of inspection;
- Translation of documents;
- Certification of documents by a notary public.

Biocides

– the most important thing is the strategy

Registration in European Procedure

As the work on the review programme progresses, the list of approved active substances becomes longer and longer. As a consequence, more and more biocidal products are subject to registration in European procedures.

The requirements in the European procedure, regarding the scope of the biocidal product documentation, differ depending on the product, active substances contained in it, type of procedure and many other factors. The procedure itself is much more complicated, time and effort-consuming, than it is in case of the transitional procedures.

The essential issue is to select the right registration method, scope of tests and documentation, that should be submitted, in order to receive the authorisation.

Within the framework of the registration in European procedure, we offer:

- Analysis of owned documentation;
- Help with selection of registration procedure;
- Selection and performance of tests;
- Compilation of complete registration dossier for registration in IUCLID6 programme;
- Preparation of short product characteristics (SPC);
- Conducting complete product registration;
- Representing the entity before URPLW MiPB;
- Consulting services on a current basis;
- Support in case of inspection;
- Translation of documents;
- Preparation of document certification by a notary public.



04

COSMETICS

Cosmetic products, besides undoubtedly beneficial influence on the human body, can also show some harmful effects. Cosmetic is most of all a chemical product, which may contain substances dangerous for the health.

THETA, with its team of experienced safety assessors, and also thanks to the cooperation with the best laboratories, is able to provide safety assessment compliant with legal requirements, for any cosmetic product.

We support our clients, by conducting European notifications CPNP, compiling label contents and verifying documentation.



Cosmetics

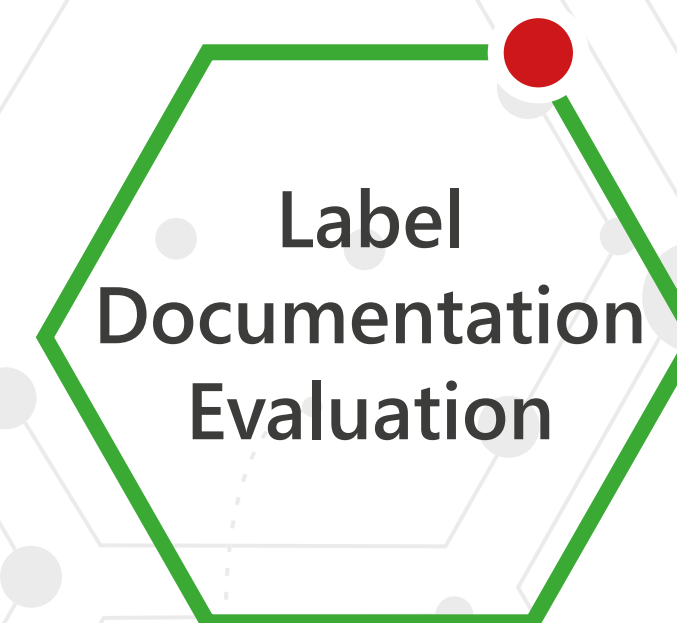
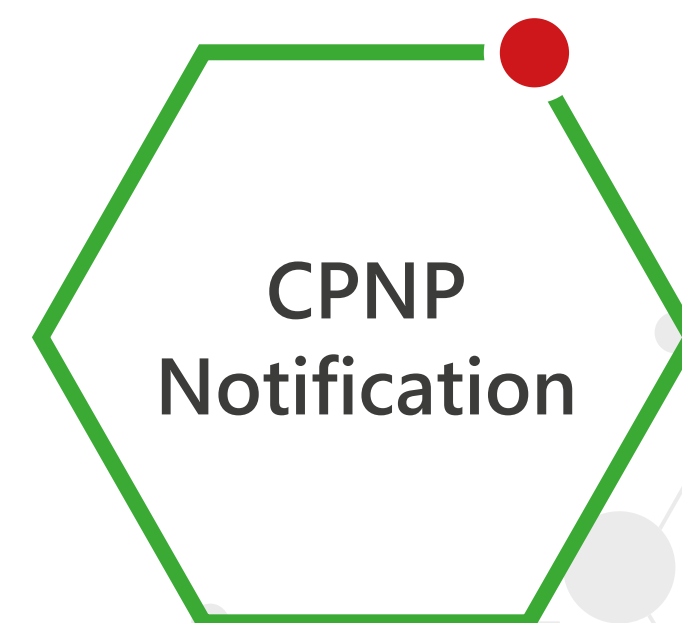
– they are chemical products too

Cosmetics, due to their manner of use, are specific chemical mixtures, and as such are subject to very strict regulations, related to their way of manufacture, permitted composition, type of tests they have to undergo before they reach the consumer, documentation confirming their safety, as well as labelling and information on the packaging, that should be presented to the user.

The core role of the responsible person is to ensure the safety of a cosmetic product for the human health in normal or reasonably foreseeable conditions of use.

Within the framework of consulting services regarding placing cosmetics on the market, we offer among others:

- Preparation of documentation together with the Chemical Safety Report for a cosmetic product;
- Verification of the cosmetic product ingredients for presence of prohibited substances or substances authorised with restrictions;
- Determination of cosmetic product composition in accordance with INCI nomenclature;
- Determination of scope, performance and final assessment of tests;
- Preparation of labelling content for the cosmetic product packaging;
- Verification of marketing texts for compliance with regulations;
- Notification of cosmetic product via CPNP portal;
- Verification/update of owned documentation;
- Consulting services and legal support;
- Preparation of safety data sheets for cosmetic raw materials.



05

CONSULTING IN TRANSPORT

Materials and goods, that present risk or can be potentially hazardous in transport, must be safely delivered to the distributors and recipients. Each type of transport (road, rail, maritime or air) is subject to detailed international and national regulations. These provisions control carriage of such products, and the purpose is to eliminate or limit the risk related to transportation.

THETA has a team of authorised advisors with extensive experience in scope of the land transport (by road ADR, by rail RID), maritime transport (IMDG) and air transport (IATA/ICAO).

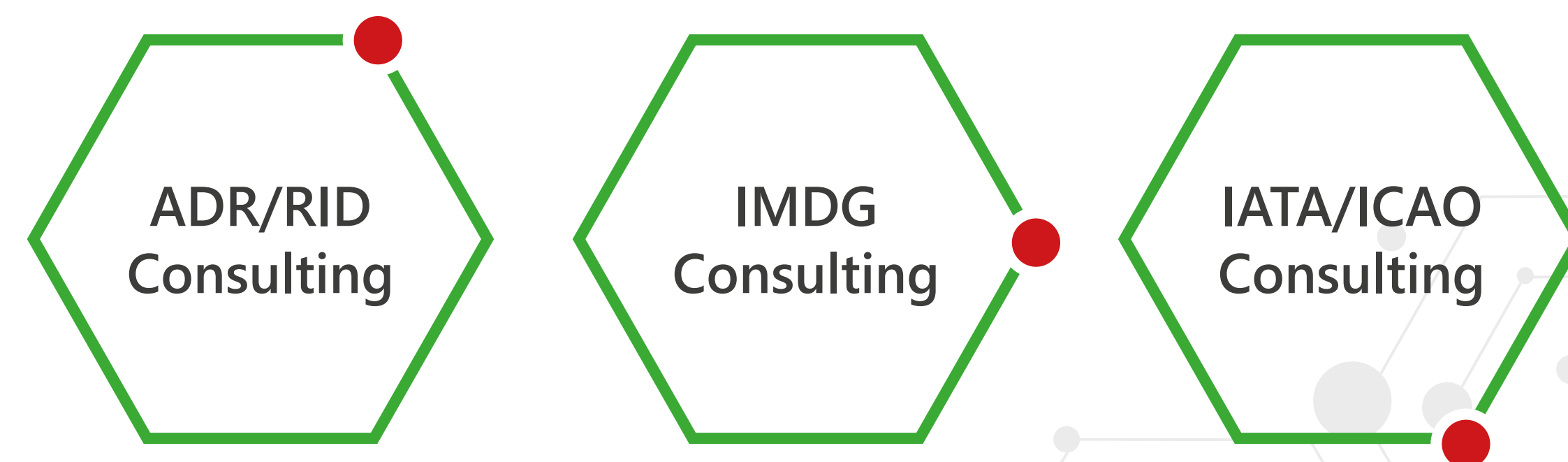


ADR/RID/IMDG/IATA

– safe transport by each route

A common base for all the transport types is represented by the Model Regulations issued by UN, and on that basis, regulations concerning individual types of transportation (ADR, RID, IMDG, IATA) were developed. Under the regulations of the European ADR Agreement, RID Regulation and on the basis of the Act on dangerous goods transportation, any entrepreneur involved in the transport of dangerous goods or related loading or unloading, is obliged to appoint a certified dangerous goods safety adviser (DGSA), submit annual reports regarding their activities in this scope and train the employees performing actions related to transport of dangerous goods.

Within the framework of our services, we offer support related to fulfilment of legal obligations in scope of the transport of dangerous materials



Within the framework of consulting services in transport, we offer:

- Appointment of the dangerous goods safety adviser RID/ADR;
- Classification of dangerous materials;
- Determination of transport method and conditions;
- Selection of packaging, packages and warning labels;
- Compilation of templates of relevant documentation;
- Help in application of exemptions and reduction of transport costs;
- Conducting employee training sessions;
- Compilation of documentation for transportation of dangerous wastes (ADR/RID);
- Preparation of annual reports regarding the activity in scope of ADR/RID;
- Checking additional restrictions for ports (departures/arrivals); so called limitations;
- Support on a current basis for advisors, resulting from the provisions of ADR/RID, IMDG and IATA/ICAO.

06

CERTIFICATION

Over recent years, a significant growth of consumer awareness in scope of quality and safety of all the daily use articles was observed, and personal care products or household products can directly influence human health. Therefore, the quality became the most important issue. In order to meet the growing requirements of both, consumers and trade networks, particular emphasis is laid on the implementation of GMP or IFS HPC standards – proved by relevant certificates.



IFS HPC standard

– it is right for you

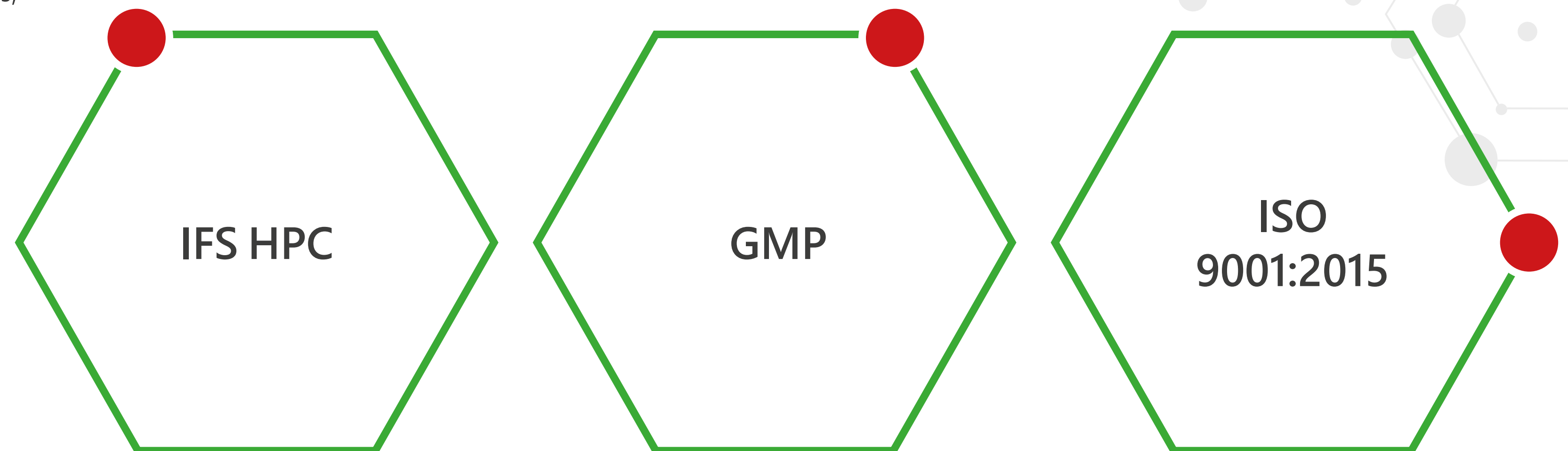
The new IFS HPC standard is a complementation of key aspects of the Quality and Safety Management System implemented in companies (among others GMP, ISO 9001, etc.). IFS HPC standard covers a range of consumer products, such as cosmetics, household chemicals, daily use consumer goods, personal care products. It is applicable for both, branded products, and articles manufactured under own brands of the recipient.

What are the benefits of the IFS HPC standard implementation?

- Independent and objective confirmation of high quality and safety of products and meeting of legal requirements;
- Improvement of competitiveness and getting advantage in negotiations with clients;
- Increase of trust of customers and contracting parties;
- Opening the possibilities for cooperation with trade networks;
- Improvement of company's performance;
- Opportunity for obtaining the international IFS HPC certificate, reflecting the highest standard in the industry.

How can we help?

- Preparation of company for the IFS HPC/ GMP/ ISO 9001:2015 certification – “turnkey” execution;
- Initial audit, support in implementation of requirements, training, verification audit and support during certification audit;
- Providing the required legislative compliance – preparation of necessary documents, including cosmetic product safety reports, safety data sheets for hazardous chemical mixtures, conducting necessary notifications (CPNP, ELDIOM), compilation and verification of label content etc.;
- Development of procedures and guidelines;
- Cooperation with leading certification bodies.



07

PROFESSIONAL TRANSLATIONS

An indispensable element while working with chemical products, both at production and import or distribution, is correct translation of documentation. It is required not only by the regulations, but most of all, by the consumers.

THETA offers you the opportunity to execute regular and certified translations of: documents and technical texts related to chemical products, laboratory test results, product information, technical leaflets, safety data sheets, labels and other texts in many European and non-European languages.



Professional translations

– core factor for the quality of communication

Safety of work with chemical substances depends on many factors, and the dully prepared documentation takes the lead. It is of great importance, that the documents are correct in terms of both, law and language.

A crucial issue is the precision and substantial correctness of translations, which should be understandable for all the users.

All translations are prepared by experts familiar with not just the language itself, but also with the specificity of industry-related vocabulary within the area in question.

We offer regular and certified translations in most European languages, and in particular in:

- English language
- German language
- Russian language
- Greek language
- Ukrainian language
- Czech language
- Slovak language
- Hungarian language
- Italian language
- Spanish language
- French language
- Swedish language
- Norwegian language

Preparation of documentation in this languages, including among others:

- Safety data sheets;
- Labelling;
- Texts of information and technical leaflets;
- Laboratory test results;
- Documentation for biocidal products and cosmetics.



Professional
Translations

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our knowledge, your success

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