

You focus on improving your Turkish market, and we do the rest for your compliance...



Services

- Regulatory compliance Check-Up
- Acting as Registrant
- Detergent Notification
- Legal Representative Services
- Notification to Turkish C&L inventory
- Biocidal Product Registration
- Outsourced regulatory services
- Notification for C.I.C. Regulation
- Turkish compliant SDS authoring

Your window for compliance.. Your key for the Turkish Market



Your one stop solution center for compliance in Turkey: CRAD

CRAD was founded in 2008 with the aim of supporting the chemical and allied industries for compliance with Turkish and global chemical regulations.

With its team of dynamic, experienced and knowledgeable experts, with good interpersonal skills, CRAD provides you with excellent communication and understanding. Our result oriented team provides you comprehensive and sophisticated regulatory compliance solutions. As wide as you wish: From a single SDS to full regulatory compliance support. We believe and trust in our principle: Work once with CRAD and we will become a loyal solution partner for you.

Thanks to our global consultant network we can easily interpret the international regulatory language and find solutions to the most challenging compliance issues. This allows us to compress many years of experience into our company history.

We thank our clients for training us as well. With every case that our client bring to us to solve, we gain permanent experience. This means our clients share in our success.

With high level of satisfaction, our clients always request us to enlarge our portfolio of services. However, we have a philosophy "Only do something, if you can do it at its best". Thus we enlarge our service portfolio with a new scope only if we believe that we had reached the perfect level.

Our mission...

Is to provide global expertise and knowledge through our dynamic and experienced staff who work in a team spirit and who create added value for the wellbeing of society and our stakeholders.

Our Vision...

Is to support the chemical and allied industries to be regulatory compliant and socially responsible for humanity and the environment.



Notification of Detergents under the scope of (OG-28807 - 31.10.2013)

The products covered by the scope of "Communiqué on Detergents and Surfactants used in Detergents" are required to be notified to the MoCT before being placed on the market.

This Communiqué also aims to implement the provisions set out for detergents by the EU Regulation on detergents (648/2004 EC). The Communiqué which was initially enforced by MoH moved to MoCT for enforcement by the corrigendum published on 31.10.2013.

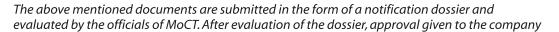
Products under the scope of this Communiqué can be identified as; Detergents, Laundry softeners, Auxiliary washing mixtures, Cleaning mixtures, other washing mixtures, industrial detergents.

MoCT has a specific department with in the "General Management of Consumer Protection and Market surveillance for Product Safety" who reviews and approves the notifications.

The procedure is identified in 2 phase: Phase 1 Submission of notification dossier:

The notification dossier including the below needs to be submitted;

- · Sample of the TR Compliant Label
- TR Compliant SDS
- Certificate of SDS author
- Notification form



Phase 2

- ·Publishing the ingredient sheet on web
- ·Compiling the Technical dossier

The regulation also requires a technical dossier to be kept ready for inspection of competent authorities at the registered address of the applicant company.

Our Services for Compliance to Communiqué on Detergents;

- · Regulatory Compliance Support and Consultancy
- · Acting as representative/applicant
- · Preparation of notification dossiers
- · Preparing Sample TR Compliant Label
- · TR Compliant SDS
- · Compilation & maintenance of the technical dossier.
- · Publication of ingredient sheet on the web (via our specific web site e-deterjan.net)
- · Data gap assessment
- · Consultancy Services on packaging of detergents.





Notification For Cleaning Products, Containing Strong Acid & Base (OG-28807-31.10.2013)

Products under the scope of "The Communique on Production, Import, Market Surveillance and Notification Procedures of Cleaning Products containing Strong Acid&Base" needs to be notified to MoCT (Ministry of Customs & Trade) before being placed on the market.

The purpose of the Communique is to reduce the risks that might be posed to human health and the environment by the products which contains strong acid&base. Household or industrial cleaning products such as drain cleaners, limescale removers or other cleaners which contains strong acid and basis are covered by the scope of this communique.

Our services for notification of Cleaning Products, Containing Strong Acid & Base:

- Act as notifier/representative
- Compiling the notification dossier
- Label Compliance

- SDS Compliance
- Specific packaging provisions.
- Compiling and keeping the technical dossier.

Notification For Chemicals Used in Pools (OG-28807-31.10.2013)

Products under the scope of "Communique on Production, Import, Market Surveillance and Notification Procedures of Chemicals Used in Pools" needs to be notified to MoCT (Ministry of Customs & Trade) before being placed on the market.

It is important to consider that products used in pools that has a sanitary or disinfection claim are to be considered as Biocidal Products. The products covered by the scope of this communique are the ones that does not have a biocidal claim but used for other purposses such as optical brightners, pH adjustment, physial oxidisers etc. The Communique is carried out by the Ministry of Customs and Trade.



Our services for notification of Chemicals Used in Pools:

- Act as notifier/representative
- Compiling the notification dossier
- Label Compliance

- SDS Compliance
- Specific packaging provisions.
- Compiling and keeping the technical dossier.

Notification For air Aromatizers (OG-28807-31.10.2013)

The Communique on Production, Import, Market Surveillance and Notification Procedures of air aromatizers covers the products which diffuse aroma to the ambiance and that are not covered by the cosmetics regulations due to there area of use (such as products giving pleasant odor to the ambient such as room air fresheners or auto air fresheners). Such products are required to be notified to the MoCT.

Like the ones for pool chemicals and acid & base products, this regulation is a one of the unique regulations specific for the Turkish market.

Our services for notification of air aromatizers:

- •Act as notifier/representative
- •Compiling the notification dossier
- Label Compliance
- SDS Compliance
- •Specific packaging provisions.
- •Compiling and keeping the technical dossier.





Registration of Biocidal Products under the scope of Biocidal Products Regulation (OG, 27449, 31.12.2009)

Biocidal Products Regulation has been published in the Official Gazette and came into force on December 31st 2009. It aims to implement the BPD (98/8/EC) of the European Union and enforced by the Ministry of Health. The scope is identical with the scope of 98/8 EC. However the new concepts and approach brought by the new EU BPR (528/2012 EC) such as treated article, in situ generation and Product family is not yet adopted to the Turkish BPR.

Active substances that are under EU review program are also listed as applicable active substances under the Turkish BPR. Thus any Active substance listed in EU supported list or the ones agreed for inclusion can be used with in the same way for the products under the TR BPR.

Turkish BPR also has correlations with other regulations such as;

- Regulation on Classification, Packaging and Labelling of the Dangerous Substances and Mixtures
- Regulation on Preparation and Distribution of SDS's of Dangerous Substances and preparations
- Regulation on Biological Risks
- Regulation on Restriction for Manufacture, use and Placing on the Market of Certain Substances and Articles
- Regulation on Principles on Good Laboratory Practices and accreditation of Test Laboratories

Procedures and General Principles:

A Biocidal product can be placed on the market either after approval of inventory notification or full registrations depending on the PT.

Procedures for several PT's:



Such products were regulated by several authorities prior to enforcement of TR-BPR. Thus those PT's are subject to full registration and can not benefit from inventory notification to be placed on the market.

A corrigendum to Turkish Biocidal Product Regulation was published on 12 March 2014 O.G.28939 and came into force on the date of publication. Transition period for some PT's is extended. Key points brought by the corrigendum can be summarized as below:

Biocidal Products that fall under Product Types 6 and 13,

Needs to be notified to the Inventory before 1.1.2015, can be placed on the market after the approval of this notification till 1.1.2017. A registration dossier for these products needs to be submitted before 1.1.2016.

Within this period the producers, importers or registrants identified on the label are responsible for compliance of the products to that regulation (in brief as per labelling, SDS and other provisions of the Turkish Biocidal Product Regulation)

Biocidal Products that fall under Product Types 7,8,9,10,11,12,21,22,23

Needs to be notified to the Inventory before 1.1.2018, can be placed on the market after the approval of this notification till 1.1.2020. A registration dossier for these products needs to be submitted before 1.1.2019.

Biocidal Products that fall under Product Type 20;

No new application for Biocidal Products PT20 will be accepted. If there are products that are registered for PT20 before 1.9.2013 can be placed on the market till 1.7.2015. After 1.7.2015 no products under PT20 are allowed to be on the market.

- * For the claims for which the efficacy testing is not available in Turkey, products can be tested at a GLP accredited laboratory or at a Lab that is accredited in related testing parameters
- * In can preservatives used in the cosmetic industry are included in the list of products that are out of scope.

Our services under the scope of TR BPR are:

- · Regulatory Compliance Support and Consultancy
- · Acting as representative/registrant
- · Label compliance in accordance with TR BPR
- $\cdot \ \textit{Compilation of Inventory notification}$
- · Compilation of Provisional application dossier
- Generation of compliant SDS according to Turkish SDS regulation with our certified team of experts
- · Data gap assessment
- $\cdot \ \textit{Compilation of Registration dossier}$
- · Consultancy on frame formulation structure



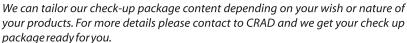


Regulatory Check-Up

Our experiences showed us that a successful and healthy business in a new market for your chemical products should start by regulatory compliance. This is why we named our initial service package as Regulatory check-up. As per the term Check-up covers, we first start with understanding the composition of your chemical products and the fields they are used. Screening your chemical products within the context of HS codes, and chemical identifiers of the substances with in.

At the end of the check-up procedure you have a robust report to share with your colleagues for ensuring full compliance of your products and predicted budget for the compliance procedure.

Our check-up team collaborates with CA as well as the other consultants in the field of customs regulations. This provides you not only chemical regulatory compliance but also demonstrates what will be experienced from the custom to the shelf by you or your commercial experts. Everyone would prefer to distribute hassle free products on the market for which all issues are identified and solved prior to negative experiences being exercised.





Registration of Plant Protection Products and Consulting Services (OG- 27885 - 25.03.2011)

The regulation on Registration of Plant Protection Products covers PPP, Plant Activators placed on Turkish market under its scope. It is enforced by MoFAL (Ministry of Food, Agriculture and Livestock).

There are specific conditions to be met by the registrant for registering a PPP. We can briefly list these as;

- √ To have 3 regional offices in Turkey and have at least one responsible manager who has the qualifications identified in the regulation,
- ✓ To compile a provisional application dossier
- \checkmark TR Compliant SDS
- √ TR Compliant Label (with specific provisions of PPP labelling)
- ✓ Getting the approval for controlled trials at approved institutes.
- ✓ Providing required information & data about ingredients and the product



Our services for Registration of Plant Protection Products under the scope of this regulation:

- · Preparing product labels (with specific provisions of PPP labelling)
- · Authoring Turkish compliant SDS
- · Communication with authorities and institutions
- · Data gap analysis
- · General consultancy



Safety Data Sheet Compliance Services

We as CRAD team are providing SDS Compliance Services to the all chemical industry in and abroad. A Safety Data Sheet (SDS) is a document that provides health and safety information to the recipient of a dangerous chemical. It is designed to provide the employer with sufficient information to be able to assess the risks of using the product and to put appropriate safety measures and procedures in place. Also it targets to provide sufficient information to the employee or the user of the chemical products, about the hazard properties of the product and the precautions to be taken.

There are some differences between Turkish and European format of the SDS as the related regulations on preparation of SDS differ from one another. In the EU the required content and format of the SDS is set out in Annex II of the REACH Regulation (as amended by 453/2010 EC), and SDSs should now contain information under 16 obligatory headings and 48 associated subheadings.

In Turkey and as of today, the provisions on SDS is set out in Turkish Regulation published by MoEU, OG 27092 published on 26.12.2008. We can define the format as per the initial Annex II of 1907/2006 EC as its first published version.



A Turkish compliant SDS needs to be authored by a certified expert. The same conditions are expected to be met by the CA for the imported chemical products too. Thus exporters to Turkey mostly collaborates with a person or a company to ensure SDS compliance for their products. For sure, it would be a great advantage for them if they ensure the trustworthiness and competence of the expert that they collaborate for SDS as well as ease of communication with them. This is due to their protection of CBI as well as ensuring the compliance.

CRAD team of certified experts had authored more than 12000 SDS till today and had gained great experience, on the top of the regulatory and scientific knowledge, with every product and case. We are as well capable of global SDS provisions thus we can easily talk and interpret what we call "the Chemical Regulatory Language".

The authorities have published a draft regulation on SDS Provisions which aims to implement the format of 453/2010 EC as well as define the use of the new classifications identified by SEA Regulation (CLP). The expected new regulation on SDS continues the same principle for certified people for authoring SDS to. CRAD team is ready for compliance to that future regulation even from today. We also keep track and records of every SDS authored by us so that we can easily track back per the regulatory requirements for at least a past 10 year period.

Besides that, we are capable of authoring e-SDS which includes exposure scenarios related to the uses of your chemical products per the legal obliqation set out by REACH Regulation EC 1907/2006.

We do provide tailor made services as an one-stop solution partner with respect to SDS and label generation.

We can also author SDS's in 33 languages which includes all official EU MS languages and some other languages such as Japanese, Arabic, Chinese and Azerbaijan etc. Such SDS are as well compliant with the country specific legislations such as OEL's applied at that member state.

 ${\it Please contact CRAD for further information}.$

Label Compliance Services

The "Regulation on Classification, Labelling and Packaging (SEA) T.C. No. 28848/2013" is published on the date 11.12.2013 which is the latest regulation setting out the Classification, Labelling and Packaging provisions in Turkey. All chemical products placed on the market in Turkey needs to be labelled according to the provisions of Turkish SAE and SEA regulations according to the transition periods given with in the "Regulation on Classification, Labelling and Packaging (SEA) T.C. No. 28848/2013".

CRAD provides label compliance services to the chemical industry with not only translating them but also being in compliance with regulatory obligations such as label and symbol/pictogram size and phrases to be used.

We offer classification, labelling and packaging solutions for your dangerous chemicals manufactured for both industrial and end user needs with the professional contribution of our experienced team which received relevant local and foreign based trainings. Besides, we are able to provide such solutions through faster, reliable and up to date information by means of technological investments made.

CRAD team is also capable of preparing multilingual labels of your products with in 33 Languages, with the support of the IT systems as well as the global network of consultants that we are a part of.





Expert Translation Services

Neither the splendiferous booths nor the trendy architecture of your site is seen by all of your clients. But your documentations such as labels, TDS, Instructions for Use are seen by all your clients and your products end users including consumers. Taking this into consideration we see such documents as the most important instruments of company prestige as well as the media for communicating with clients.

Under the light of the above mentioned approach we think that no one should trust on neither the automated translations nor the plain translations made by the translators that are not specialized in the field of Chemical products.

For IT and Consultancy companies that are providing phrase libraries and chemical management databases, we do provide translations and continuous update service related to the regulations in the field of Chemical products so that they can easily update their software and databases for top quality and full client satisfaction.

We also have a network of Chemical regulatory consultants for your translations requirements other than Turkish such as Arabic, Uzbek, Azerbaijan we cooperate with them who are native speakers of the relevant languages.

Please ask CRAD team for further information.



Bespoke Consultancy Services

Chemical industry is an endless field with its potential for technological improvements and range of product portfolio. Due to that reason sometimes our clients asks us a service which is not on our standard menu or a mix of services that we already have. We are flexible in providing the options tailored for our clients as far as we believe that we can meet our principles on quality of service.

We do thank all our client for expanding our portfolio of services with their demands. It is hard to define our bespoke services here as it is shaped by your order and tailored for your company.

For further information on our tailored services please contact our consultants.





Notification Services under the scope of Chemical Inventory and Control Regulation (C.I.C.R.) (OG- 27092 – 26.12.2008)

The Turkish Chemical Inventory and Control Regulation (C.I.C.R.) was mostly called as Turkish REACH. We need to note that it is not. It is indeed the implementation of the 793/93 EC of the EU. It is the first obligatory intention of authority to form a National inventory of chemicals manufactured or imported into Turkey. The C.I.C. Regulation was published on 26.12.2008 and had several amendments afterwards.

Under scope of the regulation, companies are required to notify the requested data to the notification portal set up by the Competent Authority, for chemical substances manufactured in Turkey or imported to Turkey either itself or in mixtures. There are two tonnage thresholds which identifies the content of the data to be notified. These are 1-1000 tonnes and equal to or above 1000 tonnes per annum. Substances below 1 mta are out of the scope of the regulation.



Due to the CBI concerns of the industry related to data required under the scope of several Chemical regulations Turkish C.I.C. Regulation also provides an option to appoint a Legal Representative almost with the same principles as O.R. under REACH 1907/2006 EC

Under scope of C.I.C. Regulation CRAD provides you Legal Representative Services and notifications to the IT system of Competent Authority.

We do thank our some hundred global clients who trusted CRAD for confidentiality and compliance.

Our support services under the scope of C.I.C.R.:

- · Consultancy support for determination of obligations
- · Supply chain mapping
- \cdot Process planning and organization associated with the purpose of legislative compliance in full coordination with the respective staff of the client.
- $\cdot \ Consultancy \, support \, for \, the \, purpose \, of \, collecting \, and \, compiling \, required \, data.$
- $\cdot \, Supplying \, the \, required \, data \, from \, third \, party \, legal \, entities \, covered \, by \, a \, NDA \, (if \, required)$
- $\cdot \ Submitting \ notification \ within \ the \ framework \ of \ methods \ and \ dead lines \ set \ out \ by \ the \ regulation$
- $\cdot \textit{Regulatory follow-up and maintenance of the notifications submitted}$



Compliance to Turkish SEA Regulation (O.G. - 28848 - 11 December 2013)

Turkish implementation of CLP has been published on the date 11th December 2013 on the Official Gazette with the number 28848 and comes into force on the date of publication. Turkish CLP which we can call with its Turkish abbreviation as SEA also has transition periods for its obligations to come in to force, as it was in the EU-CLP for the new classification principles to be applied for substances and mixtures. Also, it will be fully repealing the former Turkish classification regulation as of date 1st of June 2016.

Classification & Labelling according to the new regulation for substances will be obligatory as of 1st of June 2015 and for mixtures the CLP Classification & Labelling criteria obligation will apply as of 1st of June 2016. As a general principle and similar to EU CLP, a two-year transition period for the products that were placed on the market prior to that date, will apply to prevent a re-labelling.

The Turkish SEA will not directly apply to the SDS as the existing SDS regulation is not amended according to the new classification regulation yet. Thus till the SDS regulation is amended according to the Turkish SEA (CLP) Reg. No: 28848 the former format of SDS's with old classification system will remain the same.



Notification to Turkish C&L Inventory

Notification to the Turkish C&L inventory is another obligation to meet for which the notification period will start by 1st of June 2014 and will be ending as of 1st of June 2015 for the substances that have been placed on the market, either on their own or in a mixture, before 1st of June 2015. For the substances placed on the market, either on their own or in a mixture

One of the unique point in the Turkish CLP implementation is, as defined in article 41 of the regulation, without any prejudice to the primary obligation belonging to the importer, chemical exporters to Turkey may cover the C&L notification obligation of their importers through their appointed Legal Representatives who are appointed by to Turkey can make their notifications through the appointed legal representative on behalf of their importers in Turkey. Thus this was intentionally added to the legal text after the first draft to prevent the CBI issues of Chemical industry who exports to Turkey



Our services for compliance to Turkish SEA Regulation (O.G. 28848/11 December 2013):

- $\cdot \textit{Consultancy support for determination of obligations and their timing}$
- $\cdot \textit{ Process planning and organization associated with the purpose of legislative compliance in full coordination with the clients regulatory team$
- $\cdot \textit{Consultancy support for the purpose of collecting and compiling required data}\\$
- · Supplying the required data from third party legal entities covered by a NDA (if required)
- · Submitting notification within the framework of methods and deadlines set out by the regulation
- · Regulatory follow-up and maintenance of the notifications submitted
- $\cdot \textit{Classification support under the provisions of Turk is hSEA \textit{Regulation}}$

For further information please contact CRAD Team

The devil is in the details.







CRAD ÇEVRE RİSK ANALİZ DENETİM VE EĞİTİM HİZ.LTD.ŞTİ.

Atakent Mah. Türkler Cad. Göktürk Sk. No: 8/A Ümraniye - İstanbul Tel.: +90 216 335 46 00 - +90 216 443 07 63 Fax: +90 216 335 46 06 www.crad.com.tr info@crad.com.tr