Introduction
Ethyl alcohol (ethanol), CAS No:\(^1\) 64-17-5, EC No:\(^2\) 200-578-6, is a chemical substance applied first of all in the food industry for the vodka and liquor brands manufacturing in the spirituous branch, and also as an additive for making some selected sweetmeats, cakes, layer cakes and food fragrances. This way of use prevails in Poland.

It should be not forgotten that ethanol belongs simultaneously to the most important basic solvents for both organic and inorganic substances used in the chemical, cosmetic and pharmaceutical industries, in this latter as a raw material for production of numerical medicaments. As an additive to the gasoline is used as an engine fuel.

Main suppliers of this feedstock for spirituous branch in Poland are distilleries making raw ethyl alcohol in the process of alcoholic fermentation of agri- and fruit culture products containing carbohydrates. To such natural feedstock used by distilleries belong: fruits, potatoes and cereals grains, in the case of these latter – first of all rye.

Basic legal problem which directly or indirectly concerns spirituous branch in the last years relies on fact that ethanol similarly like other chemical substances is subject of registration duty resulted from the provisions of REACH\(^4\) regulation. Main burden of this substance registration lies exactly on distillers as its producers provided that they manufacture it in quantities of 1 tonne or more per year in terms of given manufacturer and this alcohol is not intended for the consumption purposes. Usually each distillery exceeds mentioned above minimum tonnage output and very often, if not whole, significant part of this production is intended for the purposes lying beyond consumption. Management of distilleries often does not understand legal conditions being in force at the EU since several years or trivialize them, insisting that the REACH regulation is not of their concern, because they produce “agricultural spirit”. Legal basis of meeting mentioned above conditions or not and final decision, whether ethanol is a subject of registration duty or not – will be wider discussed in the further part of this article.

REACH and its legal basis in the spirituous branch
REACH regulation has been published in the EU Official Journal on 30 December 2006 and entered into force on 1 June 2007. Assurance of safe management of chemical substances on their own, in mixtures or in some selected cases in articles\(^5\) in regard to practically every field of the economy is the primary aim of this regulation. This legal act having acronym REACH (derived from Registration, Evaluation and Authorization of Chemicals), definitely makes stricter requirements for the enterprises in the area of chemicals’ management and control. These requirements result in the necessity of significant costs to be incurred associated with preparation of relevant registration dossier, preceded by pre-registration, participation in the consortium created with the purpose of common submission of certain data required in the technical dossier as well as making some supplementary experiments or purchasing already made tests’ results for the chemical substances manufactured or imported outside the customs territory of the Community\(^6\) in quantities of 1 tonne or more per year in terms of given manufacturer or importer. REACH regulation lays also certain duties on Downstream Users (DU) and also to a lesser extent on chemicals’ distributors\(^7\), particularly in case of communication in the supply chain, first of all with use of the SDSs\(^8\).

Every manufacturer or importer of ethyl alcohol in quantities of 1 tonne or more per year in terms of such manufacturer / importer is obliged to register it according to the REACH provisions provided that the final use is not subject of any exemptions described in detail by article 2 of the REACH regulation entitled “Application”. Similarly the downstream users (DU) of ethyl alcohol have their own obligations described in title IV and title V, unless in the mentioned above article 2 they find provisions allowing them to be exempted from these duties.

Regarding ethyl alcohol provision of the article 2, item 5, letter b) is particularly important. It reads as follows:
5. The provisions of Titles II\(^9\), VI\(^10\) and VII\(^11\) shall not apply to the extent that a substance is used:
   a) [...];
   b) in food or feeding stuffs in accordance with Regulation (EC) No 178/2002 including use:

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\(^1\) CAS Number – numerical denomination assigned to the chemical substance by the US organization Chemical Abstracts Service (CAS), allowing legible substance identification.

\(^2\) EC Number – means number assigned to the chemical substance in the European Inventory of Existing Chemical Substances - EINECS, or number assigned to the substance in the European List of Notified Chemical Substances - ELINCS, or number of chemical substance listed in the European inventory of substances recognized as so called “No longer polymers”. This number next to CAS is basic number for substance identification applied in the European chemicals legislation


\(^4\) See article 3 entitled Definitions in the REACH regulation, points (1), (2) and (3)

\(^5\) Community – this term used also in further part of the article in regard to customs territory of REACH implementation means: 27 EU Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Great Britain, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain and Sweden as well as selected 3 countries of so called EEA (European Economic Area): Iceland, Liechtenstein and Norway. Switzerland belongs as one more country to the EEA, but it has not yet declared implementation of REACH regulation provisions, although fitting to this venture is currently on quite significant stage of development. Three EEA countries mentioned earlier are treated as the states, where REACH regulation is in force equivalently to all 27 EU Member States. Thus, chemicals’ purchasing from every mentioned above countries except Switzerland by Polish company is perceived as placing on the market within the customs territory of the Community and such company is regarded as a downstream user (DU). In case of substance purchasing from Switzerland (and also from other countries worldwide, except mentioned above thirty states) in the tonnage 1 ton or more annually – such transaction is regarded as classical import (see article 3 Definitions, point 10) of the REACH regulation) and such company bringing substance from abroad is regarded as importer (see article 3 Definitions, point 11) of the REACH regulation) with registration obligations on its shoulders.

\(^6\) See article 3 entitled Definitions in the REACH regulation, point 14.

\(^7\) SDSs – Abbreviation derived from the English term: Safety Data Sheets, in Poland: „artykul chemiczny”.

\(^8\) Title IV (“information in the supply chain”) concerns obligation of communication up and down the supply chain (on the way supplier – receiver and vice versa).

\(^9\) Title V (“Downstream users”) is related to the obligations of downstream users.

\(^10\) Title VI (“Registration of substances”) is related to the obligation of registration.

\(^11\) Title VII (“Authorisation”) is related to the authorisation requirement.
This provision means that manufacturers or importers of ethyl alcohol outside the Community in quantities of 1 tonne or more per year in terms of relevant producer / importer do not need to register this substance, if it is used solely for the consumption purposes. Similar legal approach accompanies downstream users – they are exempted from the provisions included in title V if the substance is solely used for the consumption purposes.

It is worth to mention another provision significant for all actors in the supply chain of ethyl alcohol – article 2, item 6, letters b) and d):

6. The provisions of Title IV shall not apply to the following preparations in the finished state, intended for the final user:

a) [...].
b) cosmetic products as defined in Directive 76/768/EEC;
c) [...].
d) food or feeding stuffs in accordance with Regulation (EC) No 178/2002 including use:
   (i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC.
   (ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EEC.
   (iii) as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003.
   (iv) in animal nutrition within the scope of Directive 82/471/EEC.

Mentioned above provision means that if ethyl alcohol in given supply chain is used solely for the consumption purposes [letter d)] or for cosmetic products [letter b)] then every legal entity, participant of such supply chain is exempted from the obligations written in this title and reflecting first of all the duty of SDS preparation and making it available to the trade partners down the supply chain.

Every other use of ethyl alcohol (like in case of any other substances) results in obligation of registration according to the REACH provisions.

**Full registration deadlines**

REACH regulation precisely determines in the article 23, when and what range the substances shall be registered in.

Meanwhile, article 5, title II of the regulation ("Registration of substances") introduces the following principle: "No data, no market". This means that "substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required".

Obviously this provision did not mean that since 1 June 2007 when REACH regulation in the majority of its articles has been entered into force – every legal entity had to stop its operation until the moment of registration of substance manufactured / imported in quantities of 1 tonne or more per year. Legislators have foreseen transition periods, mainly conditional on tonnage band provided that legal entity who has the registration duty will make pre-registration to the European Chemicals Agency (ECHA) located in Helsinki, Finalnd. Information about Agency and main obligations resulting from REACH regulation can be found on the ECHA website: http://echa.europa.eu.

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14 R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

13 CMR substances – abbreviation from English term Carcinogenic, Mutagenic and Reprotoxic Substances.
Pre-registration

Basic condition for the transition periods described in the article 23 was participation in the pre-registration procedure. This procedure is in detail described in the article 28, particularly in items: 1, 2, and 3. Pre-registration has been made free of charge on the portal REACH-IT of the European Chemicals Agency (ECHA): https://reach-it.echa.europa.eu/.

According to the item 1 in pre-registration the following information had to be communicated:

a) the name of the substance, including its EINECS and CAS number or, if not available, any other identity codes.
b) name of the legal person and address and the name of the contact person and, where appropriate, the name and address of the person representing legal person.
c) the envisaged deadline for the registration and the tonnage band.

According to the provision of article 28, item 2, pre-registration had to be made within half a year in the period from 1 June until 1 December 2008 (Fig. 1).

Obviously this period intended for pre-registration was assigned for all manufacturers or importers of so called phase-in substances operating on the market before these dates.

Thus, both all distilleries producing ethyl alcohol for industrial purposes (not for consumption) and vodka producers, manufacturing also spirit for industrial purposes (not for consumption) have registration obligations in relation to this tonnage band, which is assigned for out of consumption purposes. All mentioned above legal entities fulfilling above described conditions had to participate in the pre-registration procedure both of ethyl alcohol and also other substances in the production amounts of 1 tonne or more per year, like for example so called fusel oils – tails formed as by-products of the fermentation process, where they are not perceived as waste by the law. Ethyl alcohol in resolute majority of cases will be registered as mono-constituent substance, if it contains 80% by weight or more of the main component (i.e. ethanol). Problems concerning the way of manufactured substances’ registration depending on their composition have been discussed in further part of this publication.

Late pre-registration

There are lot of cases, when production or import of substances outside the Community have been launched for the first time after the period assigned for pre-registration, that is after 1 December 2008. Companies depending on market conditions and operations are developed or being subject of transformation. Many times change of company’s legal owner takes place resulting in establishment of new entity or declaring insolvency of a company so far existing on the market or some companies’ merge. Very often such transformations are associated with commissioning of new production or starting of new imports.

In such cases the enterprise starting with new production or new import after 1 December 2008 could take advantage of the transition periods (deadlines for full registration) using late pre-registration procedure (under certain conditions) according to the provision of article 28, item 6 of the REACH regulation. This provision reads as follows:

6. POTENTIAL REGISTRANTS WHO MANUFACTURE OR IMPORT FOR THE FIRST TIME A PHASE-IN SUBSTANCE IN QUANTITIES OF 1 TONNE OR MORE PER YEAR OR USE FOR THE FIRST TIME A PHASE-IN SUBSTANCE IN THE CONTEXT OF PRODUCTION OF ARTICLES OR IMPORT FOR THE FIRST TIME AN ARTICLE CONTAINING A PHASE-IN SUBSTANCE THAT WOULD REQUIRE REGISTRATION, AFTER 1 DECEMBER 2008,

shall be entitled to rely on Article 23 provided that they submit the information referred to in paragraph 1 of this Article to the Agency WITHIN SIX MONTHS OF FIRST MANUFACTURING, IMPORTING OR USING THE SUBSTANCE IN QUANTITIES OF 1 TONNE OR MORE PER YEAR AND NO LATER THAN 12 MONTHS BEFORE THE RELEVANT DEADLINE IN ARTICLE 23.

This provision for today means that:

• Companies starting manufacturing or import for the first time in the tonnage above 1000 tons or 1 tonne or more of the CMR substances of category 1 or 2 or 100 tons or more of the substances classified as R50/53 for a long time were not able to take advantage of the late pre-registration, because the first full registration deadline for these substances has been already expired on 1 December 2010. In other words they cannot start with such production or import until they fully register their substance

• Companies starting manufacturing or import for the first time in the tonnage band 100 – 1000 tons per year also are not able to take advantage of the article, because the deadline intended for the late pre-registration for this tonnage band has been already expired on 1 June 2012 (the provision communicates that no later than 12 months before the relevant deadline in Article 23 – for this tonnage band deadline for full registration has been determined for 1 June 2013, the date 12 months earlier occurs therefore on 1 June 2012). In other words similarly like in first indent they cannot start with such production or import in the tonnage band 100 – 1000 tons per year, until they fully register their substance

• Only companies starting manufacturing or import for the first time in the tonnage band 1 – 100 tons per year have certain freedom to take advantage of the provision concerning late pre-registration – they only have to remember to comply with half-year period since the date of first start with production or import. Second time limiter (12 months before the third registration deadline) is still enough long – it occurs therefore on 1 June 2017.

Full registration, registration fees paid for ECHA

As mentioned already above the companies operating in the spirituous branch in the resolute majority of cases will register their products (including first of all ethyl alcohol) as monoconstituent substances if they contain 80% by weight or more of the main component that is ethanol. The remaining ingredients are treated as impurities, whereby those present in the concentration of 1% by weight or more shall be also identified and indicated in the prepared registration dossier (name of the ingredient, CAS No, EC No, molecular formula).

In case of substance obtained in the production process containing main component (ethanol) in the concentration range from respectively 10% till below 80% by weight, such substance would be registered as multi-constituent substance. Name of this substance would be determined as the reaction mass of the main components (i.e. ethanol and remaining ingredients being present at the concentration equal or exceeding 10% by weight). In such case main ingredients should be described with the aid of all relevant identification parameters and the sum of typical concentrations of the main components (equal or being above 10% by weight) and impurities being contained below 10% by weight must amount to 100%.

In case of the substances with unknown or variable composition or complex reaction products – such substance would be registered as so called UVCB substance.

Presumably the last two cases will rather not appear in the spirituous branch and remarkable majority of products, if not exempted from registration duties – will be registered as monoconstituent substances.

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16 See definition in article 3 Definitions, point 20).

17 See article 2, item 2 of the REACH regulation.

2. Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council is not a substance, preparation [mixture] or article within the meaning of Article 3 of this Regulation.

18 UVCB – abbreviation from the English term: Unknown or Variable Composition, Complex Reaction Products and Biological Materials.
Full registration procedure is carried out with help of sophisticated computer application IUCLID\textsuperscript{19} 5. This software is \textit{free of charge} and can be downloaded from the website \url{http://iuclid.eu}. Currently since the end of October 2012 version 5.4.1.1. is available, whereby since first half of March 2013 ECHA receives applications from the potential representative of companies interested in testing of IUCLID 6 version.

In order to download IUCLID software potential user have to register on the mentioned above website to generate \textit{Username} and \textit{Password}. Username and password enable to logon on the portal and downloading the software application necessary for registration dossier preparation. In case of lack or poor computer experience downloading with help or directly in presence of experienced computer scientist is recommended. It is also worth to download from this website an instruction service manual for this software, because application does not belong to easy in use and by intuition “friendly” in operation. With help of this application data are collected and loaded in appropriate fields concerning registered substance (ethanol), required by relevant Annexes of REACH regulation, dependent on tonnage band of production or import. In majority cases full range of data required by those Annexes is not at the companies’ disposal (it refers particularly to the toxicological and eco-toxicological information). Therefore, company wishing to possess this information – should try at the stage of preparation to full registration to join consortium going to register (or which already has been registered at the first deadline – 1 December 2010) the same substance and repurchase the test results needed for successful submission of registration dossier. Such activity is unfortunately associated with costs to be incurred for the data purchase or obtaining so called \textit{Letter of Access} (LoA)\textsuperscript{20}.

For that purpose potential registrant should logon on the REACH-IT portal of the European Chemicals Agency (ECHA) and review his so called pre-SIEF just after the pre-registration procedure (that is the list from pre-registration containing contact details to all companies, which in the framework of this procedure notified ECHA the same substance. Among those companies potential partners in future consortium should be identified, as well as so called \textit{Lead Registrant – LR}, who as a first company in given consortium will register or rather has already registered the substance being the subject of interest. Basic task is to find such LR, to get in contact with him in order to agree formal financial and legal conditions of joining the consortium, obtaining necessary data or purchasing \textit{Letter of Access} (LoA), obtaining a token that is special access code authorizing to use the data from LR, which consortium has used or is going to use for joint submission of the registration dossier. Simultaneously, potential registrant should prepare this part of registration dossier which every potential registrant has to submit individually (first of all the data referred to the company itself and detailed identification data of the substance being subject of registration).

After preparation and completing full registration dossier using IUCLID application (with use also those data which are required under the joint submission in the framework of relevant consortium) – potential registrant will submit registration dossier in electronic format (exported file in XML format with help of REACH-IT portal of the European Chemicals Agency) before the second deadline 31 May 2013 (for the substances manufactured / imported in the tonnage band 100–1000 tons per year) or before the third deadline 31 May 2018 (in case of substances manufactured / imported in the tonnage band 1–100 tons per year). It is worth to make this work in adequate advance to the relevant deadline in order to dispose earlier the substance registration number, because the potential registrant’s clients will sooner or later demand this number, for example in the extended SDS. If the registration dossier will be formally approved by ECHA, potential registrant receives electronically an invoice for payment of the registration fee to the ECHA. Fees are defined by the Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) – Official Journal of the EU OJ L 107 of 17 April 2008\textsuperscript{21}. It is worth to emphasize that on 21 March 2013 in the Official Journal of the EU No OJ L 79 a new Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013 amending the fees and charges payable to the European Chemicals Agency\textsuperscript{22} has been published. The main changes consist in:

- Decreasing the registration fees for SMEs (35 95% depending on the company size)\textsuperscript{23}
- Increasing the standard registration fees and charges for non-SME companies by 4%\textsuperscript{24}
- Increasing the standard authorisation fees by 3.5%\textsuperscript{25}
- Adjustment of all fees for the first time to the inflation that was recorded in the EU in 2011 on the level of 3.1%\textsuperscript{26}
- Possibility of application by companies for an extension to the payment deadlines in two specific cases: invoices concerning confidentiality claims in updated dossiers and invoices concerning legal entity changes
- Clarification of provisions on reduced fees for confidentiality claims in Joint Submissions or submitted by the \textit{Lead Registrant – LR}
- Next review of the Fee Regulation scheduled on 31 January 2015. It is worth to visit the website of the European Chemicals Agency (ECHA): \url{http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation} and download first of all the most up-to-date Guidance on registration (version of May 2012) available so far in English. Older version 1.6 of the same guidance of January 2011, but in Polish is also available. This guidance contains information, when and how to register substance under REACH system. It consists of two parts: first concerning tasks and obligations in the framework of registration and second concerning technical dossier preparation. We also recommend to study the \textit{Frequently Asked Questions (FAQs)} published on the ECHA website as well as to use so called practical guides: \url{http://echa.europa.eu/pl/web/guest/practical-guides}, particularly practical guide No 9 discussing details of registration under joint submission (in consortium). REACH & CLP Centre of the Industrial Chemistry Research Institute, Warsaw, POLAND has also at its disposal the Polish version of handbook concerning joint data submission (part 07).

\textbf{Consortia}

According to the made discrimination – currently two consortia are active in the area of REACH ethanol registration:

- \textit{European REACH Joint Submission of Ethanol}\textsuperscript{24}
- \textit{Ethanol REACH Association}\textsuperscript{25}

\footnotesize
\textsuperscript{19} IUCLID - abbreviation from the English term: \textit{International Uniform Chemical Information Database}.
\textsuperscript{20} Letter of Access (LoA): Document signed by the potential registrant enabling purchase of access right and to make reference to the data being in possession of given consortium without possibility of looking into the purchased data and their further use (in purposes other than substance registration in REACH itself) or their relevant assessment.
\textsuperscript{21} Full text of this regulation can be found on the website of REACH and CLP Consulting Point operating on behalf of the Polish Ministry of Economy: \url{http://www.reach-info.pl} or through the official Internet portal of the European Union: \url{http://europa.eu} and then with use the legal acts data base EUR-Lex: \url{http://eur-lex.europa.eu/RECH_legislation.do?ihmlang=en}. Direct link enabling downloading the English version of this regulation is available under the following Internet address: \url{http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:107:0006:0025:EN:PDF}
\textsuperscript{23} The size of the company is defined on the grounds of Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, where principal criteria for determining the size of the enterprises are following: number of employees, annual turnover or annual balance sheet. No-one should forget, that relevant size category of enterprises are strictly dependent on ownership structure. If 20% or more shares belong to the public sector – such company cannot benefit from reductions in fees intended for SMEs.
\textsuperscript{24} Website link: \url{http://ethanol-reach.vze.com}
\textsuperscript{25} Website link: \url{http://www.eoh-ethanol.eu}
European REACH Joint Submission of Ethanol

First one does not contain lot of information on the existing website. All circumstances indicate that this consortium has been launched and came out from several companies, existing as part of the Substance Information Exchange Forum (SIEF)\(^{16}\). This consortium spontaneously has been created just after substance pre-registration by the interested entities. Consortium is located in Barcelona (Spain) and consists of the European companies, manufacturers and importers of ethanol. It has been proposed as an alternative for other consortia, not only regarding the cost involved, but especially the way of developing the steps to complete the registration dossier assuming all the work to be done and all actions to complete the dossier.

It assumes also all the work and perform all actions to complete the dossier in a simple way and with minimal investment of time and resources, ensuring the strictest confidentiality, and developing the whole registration dossier for all companies – consortium members without the availability of the IUCLID 5 as a tool for data submission (?).

Moreover the consortium ensures an exchange of information and a proper distribution of costs among all participants and a return in case of new participants acceding.

On the website the contact address\(^{27}\) has been inserted as well as an active link in case of searching for more information on costs and methodology. Any trial of this link activating unfortunately finishes with failure and communicate about lack of possibility of finding this document on server. Mentioned above information of very general character and statement of substance registration possibility without access to the IUCLID 5 application – make credibility of this consortium under very big question mark.

Ethanol REACH Association (EtOH-REACH)

REACH Ethanol Association has been launched on 9 May 2008 by the leading producers of ethanol in Europe. More information about it can be found on the website under the following address: http://www.ethanol-reach.com. It has been established on the association rules of operation by the following companies: Abengoa Bioenergy, Bauche Energy, CropEnergies, INEOS, Royal Nedalco and Tereos. The three European ethanol interest associations, eBIO, IEA and UEPA, are also active participants. It is worth to highlight that this consortium has been formulated one month before official start of pre-registration procedure scheduled for 1 June 2008 by the provision of article 28, item 2. Thus it did not wait for pre-SIEF and then SIEF formation in the framework of pre-registration but it decided, in anticipation to the just created legal provisions, to start its activity with vigour making an assumption: the sooner it begins the easier and calmly without pressure of forthcoming deadlines it will register its substance. The REACH Ethanol Association, so called EtOH-REACH consortium enables its members to jointly submit a consistent and high-quality dossier that meets the requirement of the legislation. Members may participate in a joint submission and they need not to produce the full dossiers themselves. Consortium has an intention and aims to have amongst its membership all the members of the Ethanol Substance Information Exchange Forum (Ethanol SIEF).

During the production process of ethanol – intermediates and by-products with need to register occur. In case of such need appearance, cooperation between ethanol manufacturers that need to register these substances will be facilitated by the existence of this association. Currently the association facilitates the registration of mentioned earlier fusel oil as well as vinasses.

EtOH-REACH is governed by the Executive Committee. It has general supervision, control and direction of the affairs of the Association and will adopt any appropriate rules and regulations for the conduct of the Association, and have the authority to do everything necessary and desirable for the conduct of the business of the Association in accordance with the bylaws. The Executive Committee is responsible for determining new strategies, policies, positions, actions and representations of the Association.

The General Assembly brings together all the EtOH-REACH Members once a year to decide on nominations and budget. At the meeting of the General Assembly all issues relating to the registration requirements of the REACH regulation are discussed that are important for ethanol and associated with associated substances.

The Executive Committee is advised by a Steering Group and several Taskforces. Members of the Steering Group are appointed by the Executive Committee. All members of the association except anonymous members can be appointed.

The Executive Committee may install and dissolve Taskforces. Taskforces are installed to address specific subjects such as the toxicological dossier, risk assessment, exposure scenarios, registration of associated substances, etc. Similarly like in case of Steering Group – members of the Task Forces are appointed by the Executive Committee. All members of the association except anonymous members can be appointed.

EtOH-REACH in the daily activity is managed by the President, Vice-President, Treasurer, Project Manager, Secretary-General. These activities are supported by group of experts or other competent third parties or consultants for advice and consultation.

The Association has in its structure Ordinary Members and Associate Members.

Ordinary Members

Ordinary Members are EU-based manufacturers and importers of ethanol, Non-EU-based manufacturers of ethanol and formulators of preparations (mixtures) containing ethanol and Third Party Representatives and Only Representatives\(^{28}\) intending to register ethanol under REACH. The association requires all individual manufacturers and/or importers that wish to register ethanol to be separately become a member of the association either directly or indirectly through a Third Party Representative or an Only Representative.

Within the category of Ordinary Members a distinction is made between:

- **Large Ordinary Members** intending to register ethanol in the tonnage band greater than 1000 tones annually
- **Small Ordinary Members** intending to register ethanol in the tonnage band above 100 and up to 1000 tons annually
- **Micro Ordinary Members** intending to register ethanol in the tonnage up to 100 tons annually.

Only Representatives and Third Party Representatives provide the association with a yearly up-to-date list of all the manufacturers and/or importers that they represent for the purposes of REACH registration. Third Party Representatives and Only Representatives pay also a membership fee for each manufacturer and/or importer that they represent in accordance with their respective tonnage band.

The Executive Committee requires proof of the correctness of the number of manufacturers and/or importers that the Third Party Representatives and Only Representatives represent and whether they are Large, Small or Micro Ordinary Members, to be updated annually.

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16 SIEF – Substance Information Exchange Forum.
17 Contact: Rosa Beaus, European REACH Joint Submission of Ethanol Coordinator, C/Ganduxer 5-15, Local 5, 08021. Barcelona (Spain), Tel./ Fax: (+34) 932414118, E-mail: ethanol-reach@tbaassores.com
18 Only Representatives – OR: From the provision of article 8 of the REACH regulation entitled: Only representative of a non-Community manufacturer:
- A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to SIEF, as its only representative, the obligations on importers under the Title.
- The representative shall also comply with all other obligations of importers under this Regulation. In this regard, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
- If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

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**Associate Members**

Associate Members are those members who are not Ordinary Members. Within the category of Associate Members a distinction is made between:

- **Non Registration Members:** Manufacturers and importers of ethanol who are not subject to a registration requirement for ethanol (for example they produce ethanol solely for consumption purposes and on the grounds of article 2, item 5, letter b) are exempted from registration duty.
- **SIEF Members:** Any natural or legal person not falling into one of the membership categories above who is entitled to be a member of the SIEF for ethanol.
- **Trade Federation Members:** Trade Associations or Federations of companies or natural persons engaged in a professional way with ethanol market.
- **Other Associate Members:** Natural or legal persons engaged in a professional way with Ethanol and REACH not falling into the categories mentioned under 4.4 of the association charter on admission.

**Participation costs in consortium EtOH-REACH**

Every entity, which wish to become a member of the association (consortium), shall pay an entrance fee according to the table below.

**Entrance fee table for potential members of Ethanol REACH Association (EtOH-REACH)**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Category</th>
<th>Entrance fee in €</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordinary member</td>
<td>Large</td>
<td>12 800</td>
</tr>
<tr>
<td></td>
<td>Small</td>
<td>1 280</td>
</tr>
<tr>
<td></td>
<td>Micro</td>
<td>128</td>
</tr>
<tr>
<td>Associate member</td>
<td></td>
<td>750</td>
</tr>
</tbody>
</table>

On the REACH Et-OH website there is an information that these fees are valid until 31 March 2012. However, in this case for today any drastic changes are rather not expected.

In addition to this entrance fee, the association has the right to charge members additional contributions, depending on project developments, actual costs and number of members joining EtOH-REACH. Before the end of each calendar year the Executive Committee approves a draft annual budget for the following year. After it has been approved by the Executive Committee it is submitted to the General Assembly for its approval.

Any valid and outstanding invoices not settled with the association will mean that the partners will not receive their authorisation number.

Currently according to the information available on the Internet website of the EtOH-REACH among 393 entities being present on the members’ list (company name and country of origin without any further details) 53 entities have Polish origin. In majority cases Polish distilleries are represented on this list.

**Letter of Access (LoA)**

The Ethanol REACH Association [EtOH-REACH] will make the Letter of Access (LoA) for purchase for non-members of EtOH-REACH who intend to register ethanol. The LoA grants the legal entity the right to refer to the technical parts of the registration of the Lead Registrant as a co-Registrant for the purposes of Joint Submission. The LoA does not involve granting of ownership of any data or studies produced or obtained by the association, and it does not allow the requesting company access to view or to use these data/studies.

In case of LoA purchase – a company receives from EtOH-REACH:

- **A LoA document confirming that the legal entity has the ‘right to refer’ to the Lead Registrant dossier for the sole purpose of making its REACH-registration for that substance. The lead registrant will submit jointly the IUCLID dossier chapters 2, 4, 5, 6 and 7 plus the guidance on safe use**
- **The ‘token’ that enables the legal entity to ‘join the Joint-Submission’ in REACH-IT portal of the European Chemicals Agency (ECHA) located in Helsinki, Finland**
- **A Chemical Safety Report (CSR) including details of the agreed classification and labeling and all identified uses for the substance according to what is known by the association.**

Requesting legal entity remains responsible for completing aspects of its registration not covered by the Letter of Access.

In order to LoA purchase a requesting company should download from the Et-OH REACH website the LoA document itself and to fulfill LoA order form worked out by Et-OH REACH. Then it should send a completed and signed Letter of Access agreement and a completed Letter of Access order form by e-mail and post. After a signed copy of the Letter of Access agreement and the completed Letter of Access order form have been received by EtOH-REACH, EtOH-REACH sends the requesting company an invoice by e-mail and post. After the requesting legal entity has made full payment (registered by the bank of EtOH-REACH), EtOH-REACH will send the requesting company the Letter of Access and the Chemical Safety Report by E-mail, and originally mutually signed copies by post. Then EtOH-REACH will provide the requesting legal entity with the ‘token’ to ‘join the joint-submission’ for ethanol in the ECHA REACH-IT system as soon as the token has become available for the specific tonnage band of the requesting company. In the event that the token has expired prior to requesting legal entity submitting its co-registration, EtOH-REACH will provide a new ‘token’.

**Procedure of the requesting legal entity within framework of LoA purchase**

In the document of LoA consortium EtOH-REACH informs requesting legal entity by e-mail when the Lead Registrant – LR has submitted its registration to ECHA. Legal entity interested in procedure finalises its registration using IUCLID 5 by completing sections 1 and 3 and any other relevant sections and attaching received Chemical Safety Report (CSR). Then the requesting legal entity confirms its membership of the joint submission for ethanol in REACH-IT using the ‘token’ after which it can submit its registration.

**LoA purchase costs**

Information about purchase costs of the Letter of Access (LoA) is available on the website with the following address: http://www.etohreach.com/templates/mercury.asp?page_id=1857.

EtOH-REACH considers that all the costs incurred to date in preparing these technical elements of the registration for ethanol and a provision for future costs associated with this work by the association should be considered in calculating the costs of the Letter of Access. This includes all technical costs relating to the data/studies, exposure assessments, and dossier preparation as well as the management costs relating to the preparation of data-sharing agreements and managing communications (e.g., questionnaires to the members of the Substance Information Exchange Fora – SIEFs).

On the mentioned above consideration, the association has been decided to set the price for a Letter of Access as the same as membership of EtOH-REACH.

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*See footnote 20.*
It is also important that Letter of Access will be available and must be purchased on a “per legal entity” basis. An Only Representative – OR or a Third Party Representative will need to purchase a Letter of Access for each legal entity that represents that wishes to register ethanol.

A general conclusion is visible that these prices, in opposition to the consortia’ prices operating for registration of other substances, fortunately are anticipated, quite stable and are not subjects of considerable increases within the recent years.

When approaching either the membership in association in order to submit REACH registration dossier under ‘joint submission’ or benefitting the Letter of Access (LoA) purchase option – potential company has to meet five conditions related to the so called sameness of substance to be registered. These conditions are following:

1. Above 80% ethanol by weight (excluding any water present).
2. Commonly agreed classification of the substance as F++, R11 (Highly flammable) according to the „old” classification criteria described in DSD (Dangerous Substances Directive)39, and currently in Table 3.1 of the regulation No 1272/2008 – CLP33.
3. Product contains no impurities classified as category 1 or 2 carcinogens, mutagens or reprotoxic substances under the EC DSD (Dangerous Substances Directive38) (equivalent to category 1A or 1B carcinogens, mutagens or reprotoxic substances under CLP33 regulation) totally exceeding level of 0.1% by weight.
4. Product contains less than 3% methanol by weight (equivalent to 2368 g per hectoliter) (exclude any water present in the calculation).
5. Product contains less than 1% acetaldehyde by weight (equivalent to 789 g per hectoliter) (exclude any water present in the calculation).

Minimum total costs to be incurred during ethanol registration by medium sized company: tonnage band 100 – 1000 tons annually – registration deadline 31 May 2013

Making an assumption that the company interested in registration in 2013 belongs to the medium sized category (Number of employees in the range of 50 – 250 people and annual turnover not exceeding 50 millions € or annual balance sheet not exceeding 43 millions € – from the provisions of mentioned already above Commission Regulation (EC) No 340/2008 the registration fee paid to ECHA has been until recently amounted to 6038 €. Thus totally costs to be incurred by the medium sized company (assuming that it has already made pre-registration) until 31 May 2013 (not taking into account labour costs of employees responsible for coordination and technical dossier preparation) would amount to 1280 € (LoA purchase) + 6038 € (registration fee for ECHA valid until 21 March 2013) = 7318 €.

In connection with publication on 21 March 2013 newest Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013 amending the fees and charges payable to the European Chemicals Agency – registration fee paid to ECHA in case of medium sized company currently amounts to 6004 €. Thus the total costs to be incurred by the medium sized company (assuming that it has already made pre-registration) until 31 May 2013 will decrease to: 1280 € (LoA purchase) + 6004 € (new registration fee being in force since 22 March 2013) = 7284 €.

Thus, loudly announced „considerable reduction of fees paid by SMEs to ECHA“ in case of medium sized companies amounts to hardly 34 € (!!!). There is nothing strange in fact that numerous representatives of companies perceive introduction of the new regulation amending the fees and charges (seemingly decreasing them considerably) as camouflaged form of budget increase of the European Chemicals Agency (ECHA).

Other sources of information

In order to benefit from use other documents and guidance available in Polish – potential user may visit the website of mentioned earlier REACH & CLP Consulting Point operating on behalf of the Polish Ministry of Economy: http://www.reach-info.pl, and particularly to explore hyperlink entitled AKTUALNOŚCI44 (RECENT EVENTS), as well as hyperlink Akty prawne45 (Legal acts). With help of this link potential user can reach text of discussed above REACH regulation and relevant legislation (both European and Polish ones).

It is worth to take advantage of the active data base of legal acts in the chemical line of activity on the website of the REACH & CLP Centre of the Industrial Chemistry Research Institute: http://www.ichp.pl/centrum-reach-clp, hyperlink: Akty prawne46 (Legal acts).

Summing up

In the spirituous branch distilleries are the main producers of ethyl alcohol (raw ethanol) and they directly have registration duties on their shoulders in the framework of REACH system, if they manufacture alcohol in the quantities of 1 ton or more per year in terms of given distillery. Only one option to avoid this costly procedure is to be exempted from the registration duty, if whole production is intended solely for the consumption purposes (article 2, item 5 of the REACH regulation). Even if part of this production finds its application for industrial purposes “out of consumption” – production in this tonnage band is subject of registration duty and the scope of information required for submission corresponds with tonnage band contained in this direction of use.

Companies processing alcohol (vodka, liquors and tincture producers) generally belong to ethanol downstream users category. In general they have no registration duties, because most often whole production is intended for the consumption purposes and beyond the fact that they are classic downstream users – they can additionally take advantage of the exemption described already in the mentioned earlier article 2, item 5. In case their product is intended for “out of consumption” purposes – they need not register this substance as downstream users, if they are able to prove that in their production process chemical transformation is excluded and their product is the same substance (ethyl alcohol) being input raw material. For the “out of consumption” production stream they are obliged to comply with the provisions resulted from Title IV “Information in the supply chain” (articles 31 ÷ 36) and Title V “Downstream users” (articles 37 ÷ 39).

In the remaining cases, i.e. if chemical transformation appears in the production process and given production stream of substance is intended for the “out of consumption” purposes – companies generally have to register and they can only avoid this procedure when they treat this production stream as waste with all legal consequences resulted from waste legislation (possessing relevant permissions for waste
generation, waste transfer to the relevant authorized entity further processing this waste by the special obligatory document “waste transfer card” and similar waste requirements). Mentioned above fusel oils can be included to this category. However, it should be taken into account that a new Polish Waste Act17 – introduces a concept of waste, which as an object or substance have been acknowledged as by-products or have been lost the waste status. Thus, according to the provisions of this act – if any of the waste streams in the enterprise will obtain such status, then immediately obligation to register such substance resulting from REACH regulation will appear and only one provision allowing to avoid registration is point 5 of the Annex II to the Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V (OJ L 268 of 9.10.2008)18. According to this point the following substances are exempted from Titles II, V and VI [article 2, item 7 letter b]):

5. By-products, unless they are imported or placed on the market themselves.

The following fact have to be highlighted here that mentioned above exemption is only in force when considered product will be acknowledged as by-product according to the Polish waste legislation being currently in force and additionally will be not placed on the market, but at the very most used for the purposes of the relevant company itself.

It has to be remembered that companies having opportunity to exempt from the ethanol registration, for example vodka, liquors and tincture producers or classic downstream users of ethyl alcohol assigned for the “out of consumption” purposes – unnecessarily are able to avoid this obligation as a whole. Distilleries as suppliers of the raw material for these companies often have poor financial condition and have not sufficient resources (both financial and human) to cope with registration duty. Ethyl alcohol buyers wishing to maintain their supply sources – shall assist the distilleries to comply with this legal obligations, and even to make registration in their name in exchange for beneficial supply conditions in order to keep their raw material resources secured in the future.

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