



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

REACHing out to the bio-based economy
Perspectives and challenges of EU chemicals legislation

RIVM Letter report 2016-0178
R.J. Luit | S.L. Waaijers-van der Loop | E.H.W. Heugens



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Colophon

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R.J. Luit (author), RIVM
S.L. Waaijers-van der Loop (author), RIVM
E.h.W. Heugens (author), RIVM

Contact:
Richard Luit
RIVM-VSP / ICH
richard.luit@rivm.nl

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P.O. Box 1 | 3720 BA Bilthoven
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www.rivm.nl/en

Synopsis

REACHing out to the bio-based economy

Perspectives and challenges of EU chemicals legislation

The Dutch National Institute for Public Health and the Environment (hereafter: RIVM) recently investigated how the bio-based economy, more specifically the bio-based chemistry sector, relates to the EU REACH Regulation on chemicals. From this investigation, RIVM learnt that REACH may actually be an opportunity rather than the administrative hurdle that it is often perceived to be.

To conduct their analysis, RIVM provided an overview of the daily practice issues encountered by bio-based companies with respect to their roles and obligations under REACH. The analysis was performed on the bio-based economy-related queries received by the Dutch REACH helpdesk between 2013 and 2015. The issues were grouped and discussed under the REACH process categories that they pertain to, namely: registration, authorisation and restriction. The majority of questions submitted focussed on registration and exemption opportunities.

It is well known that smaller companies, in particular, perceive REACH as a hurdle and often do not have enough knowledge about the consequences that this legislation can have on their own business situation. For aspects like the scope and applicability of REACH exemptions, what is most important is that better clarifications are provided which give companies insight into their duties and show what possibilities there are for them to use exemption clauses. The more complex issues, such as those concerning substance identity and resource recovery from waste, require attention from policy makers. Details about the borderlines between waste, which is covered by specific legislation, and the substances and products which fall under the remit of REACH, need to be more clearly elaborated.

From a legal and safety perspective it is useful, and understandable, that 'a chemical is a chemical' under the REACH regulation, irrespective of the source feedstock. However, from a practical point of view, it is noted that some registration exemptions may be specifically applicable to bio-based manufacturers. This means that if certain conditions are met, the REACH registration obligations will be less of a burden to some of the bio-based manufacturers. REACH also offers all bio-based manufacturers the opportunity to develop safe bio-based alternatives to substances which are currently of very high concern.

Keywords: REACH, bio-based economy, perspectives, opportunities, chemicals, obligations, manufacture, exemptions, registration, sustainability

Publiekssamenvatting

REACH voor de bio-based economie

Mogelijkheden en uitdagingen van Europese chemische stoffen wetgeving

Het RIVM is nagegaan hoe de zogeheten bio-based economie, of specifieker de bio-based chemische sector, zich verhoudt tot de Europese chemische stoffenwetgeving REACH. Daaruit blijkt dat, meer dan tot nu toe vaak gedacht, REACH een kans kan zijn in plaats van een administratief obstakel.

Er is een overzicht gemaakt van de vragen waar bio-based bedrijven in de dagelijkse praktijk tegenaan lopen als zij hun rollen en verplichtingen voor REACH waar willen maken. De analyse is gedaan op basis van vragen over bio-based economie die tussen 2013 en 2015 zijn gesteld aan de Nederlandse REACH-helppes. De vragen worden besproken aan de hand van de processen die deze wetgeving voorschrijft: registratie, autorisatie en restrictie. Het overgrote deel van de vragen gaat over registratie en de mogelijkheden om hiervan uitgezonderd te zijn.

Bekend is dat vooral kleinere bedrijven REACH als een belemmering beschouwen en vaak onvoldoende kennis hebben van de gevolgen van deze wet voor hun eigen situatie. Over een aantal zaken, zoals de reikwijdte en toepasselijkheid van uitzonderingen, is vooral betere uitleg nodig zodat bedrijven zien wat vereist is en waar mogelijkheden liggen om gebruik te maken van uitzonderingsclausules. Voor ingewikkelde vragen, zoals over naamgeving en terugwinning van stoffen uit afval, is aandacht van beleidsmakers gewenst. Het onderscheid tussen afval, waarvoor specifieke wetgeving geldt, en stoffen en producten die onder REACH vallen, dient duidelijker te worden uitgewerkt.

Vanuit wettelijk perspectief en vanuit het oogpunt van chemische veiligheid is het nuttig en begrijpelijk dat onder REACH een chemische stof wordt beoordeeld ongeacht zijn herkomst. Er bestaan evenwel specifieke registratie-uitzonderingen die van toepassing kunnen zijn op bio-based producenten. Dat betekent dat onder bepaalde voorwaarden de REACH-registratieplicht voor een deel van de bio-based producenten minder belastend zal zijn. Verder biedt REACH kansen voor producenten om veilige bio-based alternatieven aan te reiken voor zeer zorgwekkende stoffen.

Kernwoorden: REACH, bio-based economie, perspectief, kansen, chemische stoffen, verplichtingen, productie, uitzonderingen, registratie, duurzaamheid

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Summary

We investigated how the bio-based economy, more specifically the bio-based chemistry sector, is related to the EU REACH chemicals Regulation. An overview was given of daily practice issues encountered by bio-based companies with respect to their roles and REACH obligations. We discussed these points along the lines of the different processes of REACH: registration, authorization and restriction. We note that 4% of questions handled by the Dutch REACH helpdesk between 2013 and 2015 were BBE-related. By far most BBE queries were on registration obligations and its exemption possibilities. Authorization and restriction queries were sparsely received which is remarkable as these REACH processes -we conclude- offer a window of opportunity for (BBE) companies allowing them to come forward with information on bio-based alternatives to highly regulated hazardous substances.

The REACH registration phase gave rise to most questions from bio-based companies. We tried to analyse and structure these issues in a broader context. For aspects like the scope of REACH exemptions and supply chain roles of companies it proves to be mainly a matter of clarification and proper communication. But for other issues, such as chemical identity and sameness of recovered substances with already registered or exempted ones, or on the borderlines between waste legislation and REACH (i.e. end-of-waste queries), there is definitely a need for serious attention by policy makers. Issues with substance identification and end-of-waste hamper straightforward understanding of legal obligations. The term 'recovery' as used in REACH is related to end-of-waste as at the borderline where waste ceases to be waste, it becomes a product (substance, mixture or article) and hence is covered by the scope of REACH. Since European harmonised and even nationally established end-of-waste criteria for most waste streams are lacking, there is no sharp borderline between waste and chemicals or products. For bio-based companies manufacturing bio-based chemicals from waste streams it is therefore hard to establish and accomplish their legal obligations.

We also demonstrated, however, that REACH opens up several specific opportunities for bio-based industries. For example, a range of favourable exemptions may apply to bio-based chemicals at the registration phase of which companies are not always aware. As bio-based manufacture originates from natural (non-fossil) materials, EU manufacturers should carefully study their possibilities for exemptions under Article 2 of REACH for substances occurring in nature or retrieved from a natural source (laid down in Annex V). Furthermore, in specific cases recovery exemptions from registration may be applicable.

Authorization and restriction are REACH mechanisms put in place to regulate chemicals that are of highest concern, either because of the intrinsic hazardous properties or because of unacceptable risks at EU level. The so-called substitution principle is strongest for the authorization of Substances of Very High Concern (SVHCs). The mechanism of public consultation is designed allowing third parties (e.g.

competitors) to come forward with information on alternative substances or technologies. However, we note that this window of opportunity has to date only scarcely been used by alternative manufacturers (BBE or non-BBE). We conclude that drop-in substitution replacing chemical uses that are regulated through authorization and restriction is not an easy process. Most knowledge on substitution possibilities will in general be available from companies directly involved. Specific information on uses is often claimed proprietary. Therefore, it is extremely difficult for other companies to know the exact use and generate relevant information. For bio-based companies it may be more favourable to strive for an integrated approach towards material design rather than reacting on drop-in substitution queries following regulatory management measures initiated by authorities.

From a legal and safety perspective it is necessary that 'a chemical is a chemical' under REACH, irrespective of its origin. The underpinning REACH principles therefore also apply to bio-based chemicals. From a practical point of view, companies may however find out that REACH does offer specific exemptions for bio-based chemicals. Hence, especially for smaller bio-based manufacturers the hurdle they perceive may turn out to be smaller than expected as a result of specific exemptions. It is a task for authorities to better explain these opportunities. From a sustainability perspective, we conclude that REACH is targeted at meeting its sustainability goals by focussing on chemical safety rather than on a broader set of sustainability aspects. Here we identify a possibility for policy development targeted towards BBE and opening for integrated assessment of alternative chemicals and technologies. The potential sustainability benefits of bio-based chemicals are evident: e.g. less greenhouse gas emissions and less depletion of and dependence on fossil and mineral resources. Safe and proven sustainable bio-based alternatives to any SVHC should thus be embraced by REACH. In our opinion, innovative bio-based companies could take more advantage of this window of opportunity. For this the European Chemicals Agency (ECHA) and Member States should create a better platform for more prominently weighing safety and sustainability aspects in the authorization and restriction processes.

Summarizing, we state that a responsible bio-based chemistry could significantly contribute to reaching both the sustainable development goals and the objectives of a non-toxic environment. The REACH regulation could be seen here as a chance for bio-based companies rather than an administrative hurdle.

1 Introduction

Building on the global Sustainable Development Goals, the circular economy has become a top priority for sustainable national and international policies [1-3]. The Dutch House of Representatives recently stated that in 2030 the use of primary raw materials (minerals, fossil resources and metals) has to be reduced with 50% [4]. Partly, this should be achieved by increasing the current efficiency of using resources and further optimizing recycling, reducing waste and the use of raw materials. The other part should be achieved by increasing the contribution of biomass, not only for renewable energy production, but also for products and the chemical industry, cascading or optimizing the use of this resource [5]. This is in line with the national and international government programs striving to replace fossil for renewable resources and increase the contribution of biomass. Inevitably, due to the scarcity of fossil resources, the bio-based economy (BBE), including the (re)use of waste streams, is likely to significantly increase. Bio-based industries will gradually gain market share in chemicals and products supply chains and compete with traditional industry. Several bio-based manufacturing processes may be identified and are likely to evolve the coming years. From a 2013 survey among 50 selected Dutch chemical companies out of a total of 120 members of the chemical association, CE Delft concluded that a majority (76%) are involved in bio-based economy (production or R&D), taking into consideration all their activities at a global level [26]. First we can distinguish the manufacture of pure or essentially pure chemicals directly from biological feedstock. Examples are the manufacture of methanol through fermenting of sugars in plant material, the production of glutaraldehyde based on glycerol derived by methanolysis of vegetable oil and the manufacture of fatty acid methyl ester (FAME) biodiesel through transesterification of fats with methanol. A second category is the manufacture of substances with a complex or variable composition from such biological feedstock. Examples are lavender oil extracted from plant material and wood oil or lignin fraction derived by pyrolysis of wood feedstock. A third category that is of importance is the manufacture of chemicals through biochemical processing or by applying synthetic biology. Examples of this category are the production of lactic acid by genetically modified microalgae or bio succinic acid through fermentation by genetically modified yeasts.

Companies producing or using bio-based chemicals operate at the interface between agriculture, forestry, waste treatment, and chemical production. At this interface, it is not always easy to understand which EU and national laws apply to the various steps in the supply chain, and what are the obligations and responsibilities of the actors involved. In particular, it may be challenging to know which safety regulations are applicable for bio-based compounds. In the European Union, manufacture, supply and use of chemicals is governed by the REACH Regulation [6], which aims to achieve a high level of protection for man and the environment. Where traditional chemical companies are generally aware that they should comply to REACH, other companies (especially new players on the market and the smaller ones) are not

always well accustomed to REACH since they may not consider themselves as part of a chemicals supply chain, while in fact they are.

With this report, commissioned by the Dutch Ministry of Infrastructure and the Environment, we investigate how REACH relates to using biomass and its waste streams for the production of chemicals. The goal is to analyse if REACH poses different challenges for bio-based companies compared to fossil-based chemical industry. We do so, by discussing questions on REACH obligations and responsibilities relevant for stakeholders in bio-based supply chains, but also we show perspectives for action and opportunities that REACH provides. In the end, aligning the BBE and REACH will bring a safe, sustainable and circular bio-based economy closer together.

From interviews and discussions with bio-based companies we are aware of signals from within the bio-based industries that there is both a generic lack of awareness about REACH obligations as well as a tendency to perceive REACH as a hurdle reducing the innovation capacity of companies [7]. Such signals were also communicated by companies attending the workshop 'Safe with Bio-based' hosted by the Dutch Ministry of Economic Affairs, the Ministry of Infrastructure and the Environment, and the National Institute for Public Health and the Environment (RIVM) in January 2015 [8].

Triggered by these signals we searched all questions received by the Dutch REACH-helpdesk between 2013 and 2015 for BBE relevant queries and categorized these by subject (for more information see Annex I. REACH-helpdesk questions, RIVM, 2013-2015). This confirmed that bio-based companies have questions on various REACH-related subjects, as can be seen in Figure 1.

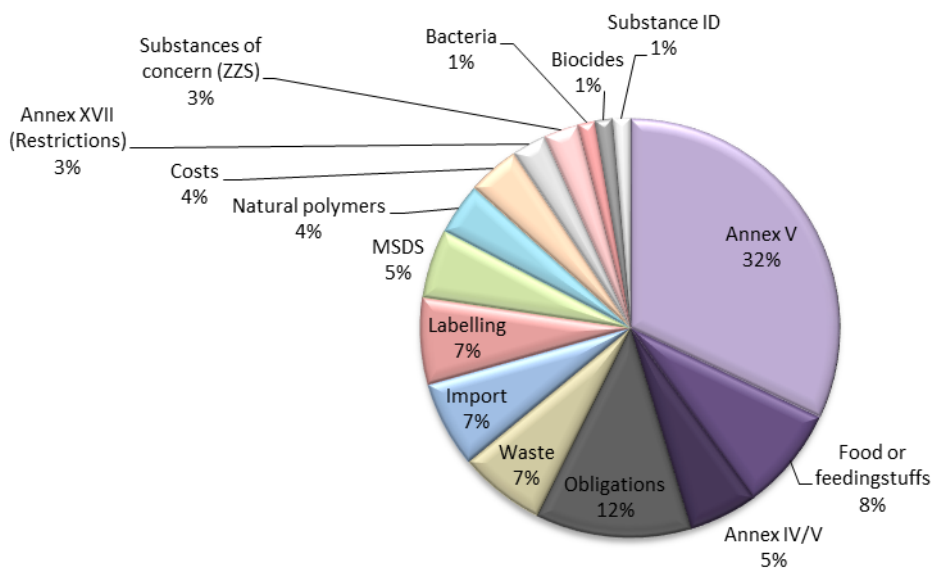


Figure 1: BBE related REACH-helpdesk questions 2013-2015 the Netherlands (n=52).

Almost half of all questions are about REACH article 2 exemptions (Annex IV, V and for food or feeding stuffs), in fact meaning that companies mostly wonder if they have to register their (perceived) 'natural' substances. Other frequently asked questions are on general obligations under REACH, followed by BBE-related questions on waste, import, labelling and (M)SDS (Safety Data Sheet) in similar percentages. These signals indicate a need for clear guidance for these companies, to structure the debate and clarify the relationship between REACH and bio-based chemistry for all relevant stakeholders.

While biomass feedstock becomes increasingly important for the chemical industry, questions remain on how to handle REACH within the bio-based supply chain. In the current paper, we investigate how the bio-based economy, more specifically bio-based chemistry as a whole is affected by the REACH Regulation. The main purpose is to provide an overview of issues encountered by bio-based companies with respect to their REACH obligations and to assess these along the lines of the regulatory context. We discuss the different processes of REACH being registration, evaluation, authorization and restriction respectively. Especially the REACH legal requirements regarding registration are analysed since this is an important pre-marketing obligation for companies and explanation is needed on applicability of exemptions to bio-based products. The study will provide insight into how bio-based chemicals fit within the REACH Regulation and which corresponding roles and responsibilities are relevant. The goal is also to increase the awareness of opportunities offered by REACH. A development towards a bio-based economy may open opportunities to increase safe and sustainable import, manufacturing and use of chemicals. As the REACH Regulation aims to achieve sustainable development (recitals 3, 4 and 131), the bio-based production of chemicals may help to achieve this goal.

For each subject, we will elaborate on:

- a) **The process:** what does a particular REACH topic mean, how it is relevant for the BBE and to whom in the supply chain it is applicable (roles).
- b) **Examples:** each REACH process is illustrated by examples of relevant current questions and issues from companies. We inventoried signals from literature studies, online sources (platforms), the Dutch REACH-helpdesk and several bio-based companies were briefly interviewed.
- c) **Opportunities and perspective for action** for bio-based industry: The examples from Chapter 3-5 not only show which (perceived) hurdles bio-based companies experience, but in many cases they also provide answers to the questions these companies have based on their roles in the bio-based supply chain. In the final discussion of this report (Chapter 6) we elaborate on the opportunities and perspectives for action that REACH holds.

To illustrate

Each chapter is illustrated by examples of current questions and issues from bio-based companies. These are addressed in a separate text box. The examples of questions and issues are from several different sources between 2013 and 2016 .

Perspective for action

Each chapter finishes with possible opportunities that REACH provides for bio-based companies and perspectives for action for the specific REACH process shown. Chances, which REACH may hold for the BBE, are singled out and discussed.

2 REACH and bio-based chemistry

European Union manufacture, supply and use of chemicals is covered by REACH. The REACH Regulation entered into force in the EU in 2007 and compared to previous EU chemicals legislation it introduced a paradigm change reversing the burden of proof from authorities to the chemical industry. The REACH acronym stands for Registration, Evaluation, Authorization and restriction of Chemicals. REACH lays down legal obligations for companies importing, manufacturing, placing on the market and using chemicals. The main purpose of the REACH Regulation is to achieve a high level of protection for man and the environment, including the stimulation of the use of alternative (non-animal) testing methods for assessing chemical hazards. Furthermore, REACH aims to ascertain the free movement of substances on the EU internal market while increasing the competitiveness and innovative capacity of EU companies. Companies may have differing duties depending on their role in the supply chain, the properties of the chemical substance and the type of use. Other obligations apply to authorities such as the coordinating body the European Chemicals Agency (ECHA), national member state competent authorities, the European Commission and national enforcement agencies.

In general, REACH obligations apply to chemical supply chains as a whole and no distinction is made between supply chains of chemicals produced in a conventional way using fossil feedstock, and supply chains of chemicals produced in an alternative way using bio-based and renewable feedstock. However, because of the nature of bio-based production, some REACH exemptions will be typically relevant for bio-based manufacturers.

Approaching 'the bio-based industry' as a separate industry is challenging as several large companies produce and develop both fossil-based and bio-based chemicals. Hence, in such companies both industrial sectors are combined. Since the tendency towards bio-based production is a relatively new development, in general, bio-based companies will have a focus on innovation, investments, process optimization and marketing. Sectors that were not connected before are now connected, e.g. agriculture and chemistry or forestry and chemistry. Legal requirements will need additional explanation or guidance when approached from a bio-based industries' viewpoint.

Where the large chemical industries are aware of legal obligations following from REACH, typically new players and innovative startups will have limited attention or limited financial means for REACH. Moreover, specifically for bio-based companies the attention for REACH obligations may be even lowered due to the perceived or expected level of safety (green equals' safe paradigm) or if companies inappropriately do not consider themselves as manufacturers of chemicals.

2.1 Sustainability and REACH

The REACH regulation was developed with the aim to regulate safe use of industrial chemicals in the EU. In its nature the REACH regulation therefore contributes to the goal of a non-toxic environment, in line with the European Commission's Environment Action Programme, but also in line with the sustainable development goals, striving for minimal toxic exposure [1, 9].

In principle, REACH includes in its scope all chemical substances¹. Hence, in its nature REACH applies equally to bio-based chemicals as it does to conventionally produced chemicals based on fossil feedstock. Except for the generic aim of contributing to sustainable development, REACH includes no specific reference to bio-based, renewable, green or sustainable chemistry. In its recitals 3, 4 and 131 REACH refers to 'sustainability' by stating the Regulation should ensure a high level of human health and environmental protection, with the goal of achieving sustainable development [6]. Chemicals should be produced and used in a way that leads to the minimization of significant adverse effects on human health and the environment. These principles form the foundation for the REACH processes, such as registration and evaluation, where chemical safety is assessed from the perspective of human toxicological risks, environmental risks and human risks following physical hazards. Therefore, REACH contributes to sustainable development by increasing chemical safety and providing guidance for adequate control of risks during use and production of substances. Other aspects of sustainable development such as the use of energy resources or carbon dioxide emissions, are not included in the REACH principles, but could be considered implicitly in minimizing adverse effects on the environment.

2.2 Roles within the supply chain and REACH

The roles that companies have in chemical supply chains determine their legal obligations in the scope of REACH. The REACH Regulation covers all life cycle stages of a chemical, including manufacture, placing on the market and use in the supply chain. Although waste is not in the scope of REACH (See paragraph 3.1), risks resulting from releases and exposures during the waste stage following supply and use of chemicals have to be assessed.

Within the supply chain, several roles can be identified relevant to REACH, see Figure 2. For the purpose of this paper the roles are defined as follows:

- importers of substances or mixtures
- importers of articles, and article manufacturers
- manufacturers of substances
- (industrial or professional) downstream users (including distributors and formulators of mixtures)
- consumers

¹ Some exemptions of legal obligations are applicable to specific uses or chemical groups, this is further explained in chapter 3 and 4.

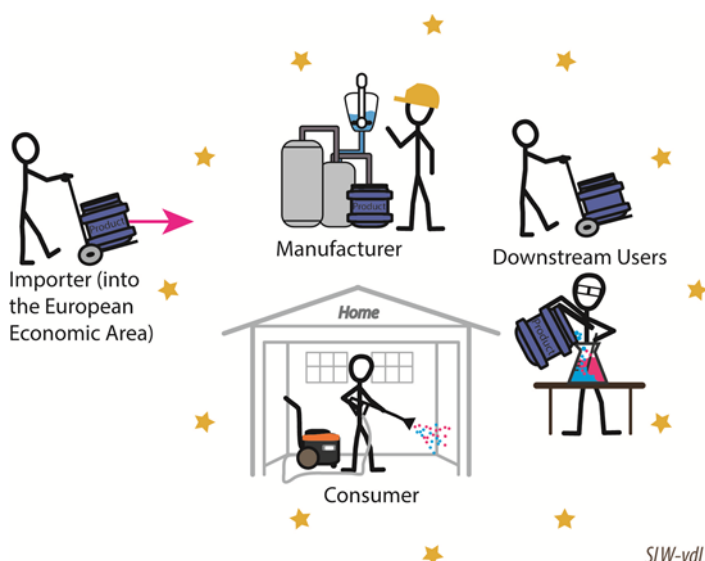


Figure 2: Roles in the supply chain for REACH.

Importers of substances and mixtures in general are companies that have a position high in the supply chain and have duties such as the registration of their chemicals, their classification, packaging and labelling in accordance with the CLP Regulation [11] and communication to their downstream recipients (e.g. through the safety data sheet). For registration purposes these companies will need to know their supply chain as in their REACH registration they will have to claim responsibility for adequate control of risks of all uses in their supply chain. Manufacturers of substances have similar duties for their whole supply chain and in addition will have to cover the production step in their assessment.

Importers of articles may also have registration obligations if the articles they import are in fact a combination of an article (being a carrier or container) and a mixture or substance (e.g. a printer cartridge or a can of paint). In such cases the registration rules would apply to the substance or mixture contained in the article. For other articles, where chemical substances are an integral part of the article matrix, registration obligations do not apply, unless the exceptional case applies where a chemical contained in such article is intended to be released (e.g. a fragrance compound). Importers of articles have the obligation to know whether their articles contain substances of very high concern (SVHC) that are on the candidate list² and depending on the concentration and tonnage they have to notify this to ECHA. Furthermore, they have to inform their recipients and consumers upon request on the presence of the SVHC chemical in the article. Similar obligations apply to article manufacturers.

Downstream users form a substantial part of the supply chain. For the purpose of this report we distinguish four types of downstream users: formulators, distributors and other industrial and professional downstream users. Whilst it is obvious that consumers themselves have

² See also section 5.1 on authorization.

no specific duties under REACH, they play an important role as actors in the supply chain using chemicals in many forms and ways. Many chemicals are used by the public at large in household product formulations (e.g. cleaning products or paints) or are incorporated in articles and materials. REACH aims to protect consumers against risks caused by exposure to these chemicals through duties that apply to companies responsible for the supply and use. Consumers are protected from exposure to substances causing unacceptable risks through restrictions or use instructions. One important restriction applies to carcinogenic, mutagenic and reprotoxic substances (Category 1A and 1B) that may not be used in products (substances and mixtures) sold to the general public. Furthermore, for the SVHCs that are placed on the candidate list for inclusion in REACH Annex XIV, consumers have the right to be informed if such a chemical is incorporated in an article (cf. REACH article 33(2)). Classification, packaging and labeling as laid down in the CLP Regulation assures that consumers are informed on hazards of products (substances and mixtures) containing hazardous substances and are able to take precautionary measures in order to avoid chemical risks [11].

In principle, REACH applies to all importers, manufacturers, downstream users, distributors of substances in the EU. Companies will have differing duties depending on their role in the supply chain and may have multiple roles for a range of chemicals they use. For example, a downstream user of chemical A uses this chemical in the synthesis of chemical B, for which he has the role of manufacturer. Another example is that of an article manufacturer having obligations for the article but also being a downstream user of a range of chemicals or mixtures he uses in the process of making the article. As REACH applies similarly to bio-based supply chains as it does to fossil-based supply chains, the roles as defined above also apply to both as well. At the manufacturing stage, bio-based industry uses feedstock of natural origin, which can be virgin material, a by-product or a particular bio-waste stream.

It should be noted that the production of the feedstock itself (i.e. exploitation of mineral resources or production of organic material (crops)) is outside the scope of REACH. Bio-based chemical manufacture starts with the further processing of any bio-based feedstock after initial harvest.

Legal requirements following product specific legislation (e.g. following the RoHS Directive (2002/95/EC) restricting the use of hazardous substances in electrical and electronic equipment, etc.), and their specific applicability to bio-based chemical industry are not included in the scope of this report.

3 REACH registration for bio-based companies

3.1 General obligation to register and tonnage

At the onset of REACH, the chemical industry was made responsible for safe use of its chemicals throughout the supply chain. In order to achieve this, REACH introduced a general obligation to register, requiring manufacturers and importers to submit information and provide evidence for adequate control of risks for all uses in the supply chain covered by the registration. Registration covers all life cycle stages of a substance being production, formulation of mixtures, distribution, uses in industrial settings or by professionals and consumer uses. In addition, the registrant is responsible for the waste stage³ of the registered chemical which means that he has the duty to assess emissions, release and exposure and prove adequate control of risks of waste treatments following use of the chemical (see further section 3.2.2).

Registration is the sole responsibility of manufacturers and importers or to so-called only representatives appointed by non-EU manufacturers taking up the registration duties for one or a group of importers. Downstream users and distributors have the role to provide and receive information and have other obligations such as the duty to work within the boundaries set in the exposure scenarios provided to them by their suppliers⁴.

REACH requires registration of every chemical produced or imported into the EU above an annual volume of 1 tonne. This obligation applies to manufacturers of substances and importers of substances and mixtures. Below 1 tonne annually per manufacturer or importer there are no registration obligations but other obligations such as the need to communicate in the supply chain still apply. In addition obligations following authorization or restriction could also apply to uses for which the company places the substance on the market or uses it himself, albeit at low volume.

In addition to REACH, the legal requirements apply of the EU Regulation on classification, labeling and packaging (CLP Regulation)[11]. Manufacturers, importers and downstream users placing on the market substances and mixtures have an obligation to classify, label and package their chemicals and mixtures. In addition, the hazard classification should be notified to the so-called classification and labeling inventory. These CLP requirements apply irrespective of the tonnage. The legal requirements apply to bio-based companies in the same way as to any other company.

³ According to Article 2.2 waste is not a substance, mixture or article, as such waste is exempt from REACH. Nevertheless, the waste stage as a final life cycle step at the end of the supply chain of a chemical is covered by the registration. The registrant is responsible for adequate control of risks also in the waste stage (as explained in section 3.2.2).

⁴ More specific information on roles in the supply chain and registration can be found on the website of the REACH helpdesk: <https://www.chemischestoffengoedgeregeld.nl/>.

Above 1 tonne per year (import or manufacturing), REACH distinguishes between new (non phase-in) chemicals that have an immediate pre-marketing obligation to register, and existing (phase-in) chemicals. Phase-in chemicals were already on the market before entry into force of REACH or listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). For phase-in substances, REACH offered companies the possibility to make use of delayed registration using tonnage-based deadlines, see Figure 3.

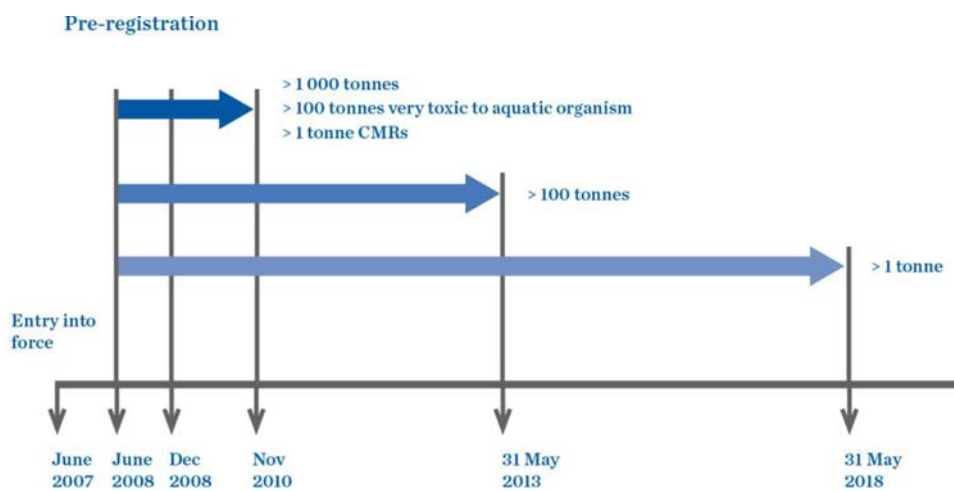


Figure 3: REACH registration deadlines per tonnage. The pre-registration period (for non-phase in chemicals ended in December 2010. For phase-in substances produced or imported between 1 and 100 tonnes annually, the registration deadline is due 1 June 2018.

Registration entails that the importer or manufacturer of a substance provides information to ECHA such as the substance identity, information on use and on the intrinsic properties of the chemical compound by means of a technical data file. Information requirements are tonnage dependent and REACH requires companies to cooperate through data sharing in order to prevent unnecessary animal testing and expenditures. These properties are for example physical chemical specifications, *in vitro* toxicity, ecotoxicity, biodegradability and *in vivo* toxicity of the substance. Exact information requirements depend on the tonnage of the substance and are specified in the Annexes VI to X of REACH. In addition to the technical registration data file, at annual production or import volumes exceeding 10 tonnes, the registrant should provide a so-called chemical safety assessment in the form of a chemical safety report. The chemical safety assessment includes a hazard assessment and if the substance or mixture is classified as hazardous or concluded to have persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties, an exposure assessment and risk characterization is required. Exposure scenarios have to be defined for all identified uses. The exposure scenarios describe the operational conditions and risk management measures for proper use of the chemical under adequate control of risks.

3.2 Exemptions possibly applicable for bio-based chemicals

While the REACH registration obligation applies to all chemicals, a number of exemptions exist. First, the scope of REACH is limited to the manufacture, supply and use of chemicals. Uses and processes such as radioactive materials, the transport of dangerous goods, non-isolated intermediates, substances that are under customs supervision and substances that are used under national exemptions in the interest of defense are exempted from the scope of REACH. In addition, other partial exemptions apply, the following of which are mainly relevant for bio-based chemicals and are discussed below:

- Exemptions from registration for:
 - Substances used in medicinal products (article 2.2(a));
 - Substances used in food and feeding stuffs (article 2.5(b));
 - Substances which have been registered and which are recovered in the EU (article 2.7(d));
 - Substances included in Annex IV (article 2.7(a));
 - (groups of) substances included in Annex V (article 2.7(b));
 - Isolated intermediates (article 2.8);
 - Polymers (article 2.9);
 - Substances meeting criteria in Annex III (limited information requirements following article 12.1 (a) or (b)).
- Article 9 exemptions from registration for:
 - Substances used in scientific research and development (R&D) and in product and process orientated R&D (PPORD).

Uses of substances in biocides or plant protection products are covered by the authorization schemes of the Biocidal Products Regulation ((EC) No 528/2012) and the Plant Protection Products Regulation ((EC) No 1107/2009). REACH considers substances authorized for use in the scope of these regulations as being registered (article 15 and 16).

To illustrate – Registration issues

- Two interviewed downstream users (small and medium enterprises (SME's, said to avoid REACH registration willfully by using substances that are already registered and thus not importing or producing un-registered substances. In this way they avoid extra administration and costs [7].
- Registration costs are often mentioned as a hurdle for (bio-based) companies, especially as holding back innovation for start-ups and small businesses [7 and this report - Helpdesk Questions Annex I, 12-14, 23].
- About 50 questions of the 1200 received by the REACH helpdesk (between 2013-2015) were concerning BBE and the general obligation to register. These questions are essentially whether or not a company importing or manufacturing a specific substance needs to register. Most questions can be divided in several subcategories, such as: waste, import and article 2 or article 9 exemptions. Chapter 3 elaborates on these exemptions as well as other exemptions relevant for bio-based substances.

Perspective – Registration

- Bio-based companies operating at the interface between agriculture, forestry, waste treatment, and chemical production, may not always be accustomed with REACH. It can be difficult to understand which exemptions apply for natural substances. Therefore, REACH helpdesks at the national (and EU) level can be consulted to give guidance and clarify specific exemptions or obligations [20, 21].

3.2.1 *Exemption from registration for substances used in medicinal products and food and feeding stuffs*

Uses of substances in human or animal nutrition are covered by the provisions of European food and feed safety legislation (Regulation (EC) No 178/2002 and others). REACH exempts chemical substances used in human or animal nutrition from the registration obligations. This means that manufacturers and importers do not have the obligation to register for the tonnage placed on the market for the purpose of use in food- or feeding stuffs. If they place on the market the same substance for other uses, these will require registration, unless exempted due to other reasons.

Uses of chemicals in human or animal nutrition are highly relevant in the scope of bio-based economy as many bio-based production processes typically are focused towards these market sectors. Traditionally and historically in the food sector, food production includes processing steps that in fact use or produce bio-based chemistry. Examples of these are biochemical processing of sugars with yeast in the production of alcoholic beverages or the use of palm oil or its derivatives in the manufacture of food products. Another example is the used of modified starches by the food industry to increase food quality. Similar modified starches may also be used by the pulp and paper industry in order to increase the quality of paper (requiring REACH registration). In such cases the industrial manufacture of these modified starches has to take

account of a split tonnage, one requiring REACH registration and another exempted from this duty.

Similarly to uses in food and feed, also uses of chemicals in medicinal products are exempted from registration. Importantly, these substances are exempted only to the extent that they are used in medicinal products in accordance with Regulation 726/2004, Directive 2001/82 and Directive 2001/83. Quantities of the same substance used for other purposes, such as manufacturing precursors of medicinal products, are not exempted. The exemption applies also to EU manufacture of medicinal products or active substances that are exported out of the EU and to imported medicinal products or active pharmaceutical ingredients (APIs).

Synthetic pharmaceuticals are manufactured using chemical or biochemical synthesis routes. The starting material may either be of fossil origin or of biological nature. Typically, some medicinal products that have been on the market for a long time have a biological origin. In the future, the use of biological starting materials may be expected to increase as a consequence to increased focus of the market on renewable production. The term bio-based pharmaceutical is different from what is generally understood by biopharmaceuticals. These are drugs that are different from chemically synthesized pharmaceuticals and include vaccines, blood, blood components, allergens, somatic cells etc.

Perspective – Registration exemptions for medicinal products and food and feeding stuffs

- Manufactured or imported volumes marketed for uses as food or feeding stuff or in medicinal products are out of the scope of REACH registration.

3.2.2 *Exemption from registration for substances which have been registered and which are recovered from waste in the EU*

The interlink between waste, falling under the scope of the European Waste Framework Directive (2008/98/EC) and supply and use of chemicals covered by REACH has been triggering debate in the policy arena ever since the REACH Regulation was published. The discussion initially focused on registration obligations and at a later stage on the substances of very high concern that may typically be found in certain waste streams possibly necessitating authorization at the recovery phase. A major factor of importance in these discussions has been the uncertainty around the so-called end-of-waste criteria for specific waste streams. As regards REACH and waste and the relevance for bio-based industry, the following aspects need to be addressed further:

1. Waste is not a substance, mixture or article as defined in REACH;
2. According to REACH, chemicals supply chains include the waste stage following industrial or professional use of chemicals. The registrant is therefore responsible for safe use also in the waste treatment step;
3. REACH provisions may also apply were substances, mixtures or articles are recovered from waste streams.

In accordance with article 2.2 of REACH, waste as defined in the waste framework Directive is not a substance, mixture or article. The waste

framework Directive defines 'waste' as any substance or object which the holder discards or intends or is required to discard. Hence, waste is not excluded from the full scope of REACH-as is often perceived- but rather none of the REACH provisions that apply to substances, mixtures or articles, apply to waste. This is different compared to e.g. radioactive substances that are fully outside of the scope of the REACH regulation (article 2.1(a)). The reason for not excluding waste totally from the scope of REACH lies in the fact that the waste treatment step as part of the life cycle of the chemical supply chain falls under the responsibility of the registrant. As such, REACH addresses the waste stage at the end of each chemical supply chain. Waste treatment may result in exposure of man and the environment that is not otherwise assessed as part of a life cycle stage such as:

- Emissions to workers and the environment as a consequence of waste processing of a contaminated solvent used in the chemical industry;
- Emissions to the environment as a consequence of landfilling of discarded articles at the end of their article service life.

The registrant needs to include the waste stage in his chemical safety assessment and provide a justification that the risks are adequately controlled. This applies to any registrant (where relevant) independent on the feedstock used at the start of the supply chain. Because of its generic nature, we will not further analyze these obligations in this report.

Waste operators, have no obligations in accordance with REACH as far as they are handling waste. REACH however becomes relevant for recovery operators where their substance or product acquires the end-of-waste status. An end-of-waste status in the scope of the waste framework Directive means that recovery is taking place and the resulting product is covered by the scope of the REACH Regulation. In REACH terminology substances, mixtures⁵ or articles are in such case recovered from waste and as a consequence a recovery operator (in the role of manufacturer) initiates a new chemicals or product supply chain. The waste framework Directive in article 6 lies down conditions for end-of-waste criteria to be set at Community level for certain waste streams such as glass, metal, aggregates and tires. For other waste streams member states may decide on a case by case basis whether certain waste has ceased to be waste taking into account the applicable case law. Hence, recovery operators willing to claim end-of-waste status for their recovered materials should contact responsible authorities in the member state where the recovery takes place.

Under REACH in such cases, the recovery operator has a role of manufacturer and he has registration obligations. Through article 2.7(d) he may be exempted, however, from such registration obligations if the substance he recovers is identical to a substance already registered. He then needs to be in the possession of a safety data sheet and provide proper information, describing his use and recommended risk

⁵ According to the REACH guidance on waste and recovered substances, besides substances also mixtures and in some circumstances articles (as defined by REACH article 3.3) may be recovered from waste.

management measures in order to control risks adequately. In practice, this means that a recovery operator should check in the REACH databases for any registration of the chemical that he recovers and obtain a safety data sheet if the substance or mixture is hazardous. If the material recovered is a pure chemical substance (e.g. methane from fermented biological waste), such check in the REACH registration database will be relatively easy. However, if the recovered material contains impurities, is a multi-constituent substance or a complex material with variable composition (so-called UVCB), it may become challenging for the recovery operator to check whether the recovered material is identical to one or more chemicals that have already been registered. A sameness check with the substance already registered is needed and if substance identity differs because of other constituents, additives or impurities or differing concentration ranges, sameness may not be confirmed. In such cases the recovery operator would need to register separately. If the recovered material is a mixture, the company will need to identify each individual component and for each of these consider whether registration is deemed necessary taking into account the annual tonnage of the component recovered and the possibility of exemption through art 2.7(d).

In order to make use of the recovery exemption, the recovery operator should refer to an existing registration of the recovered chemical(s). The registration he refers to may be from his own or any other supply chain and it does not need to be of the same tonnage band (article 2.7(d) simply refers to a substance already registered without specifying an appropriate tonnage band). Also, the exemption applies regardless of whether the subsequent (downstream) uses taking place after recovery (e.g. making of new plastic articles from recycled PVC) are included in the registration he refers to. However, in case these 'recovery uses' are not described in the registration referred to, it would be appropriate for the recovery operator to assess the relevance and adequacy of the information he has available from the original substance and act accordingly. This means that if the information that is available in the referral registration does not cover the recovery uses of his substance, he could conclude that it would be inappropriate to use the recovered substance for these purposes without prior registration by himself, including assessment of conditions under which his uses are carried out safely.

REACH does not provide a clear definition of the term 'recovery' that is only used in article 2.7(d). The waste framework Directive (article 3.15) defines recovery as *'any operation the principal result of which is waste serving a useful purpose by replacing other materials which would otherwise have been used to fulfil a particular function, or waste being prepared to fulfil that function, in the plant or in the wider economy'*. Annex II of the Directive sets out a non-exhaustive list of recovery operations. Discussions between European Member States, the Commission and the European Chemicals Agency have led to the prevailing interpretation that recovery referred to in REACH article 2.7(d) covers waste and processed waste. This means it includes processes through which substances are recovered from waste without chemically changing the waste (e.g. recovery of metal from scrap metal waste or a solvent from a liquid waste stream) and processes where

chemical or biochemical processing of the waste takes place (substance or mixture). The latter is highly relevant from the perspective of bio-based manufacturers since these are typically the type of processes they use. Where waste organic feedstock is processed by mechanical means and subsequently digested by means of any type of aerobic or anaerobic treatment with microorganisms, the resulting chemicals, which are in fact the result of biochemical transition, are considered as 'recovered from waste'. Hence, these chemicals are exempted from REACH registration through article 2.7(d) if the conditions described above are met.

Identification of recovered materials

As can be deduced from the analyses above, identification of the waste stream and the substances recovered from it is an issue of high importance for recovery operators. To be able to register under REACH or to make use of an exemption, information on the processes applied and the chemical identity is needed. REACH's guidance on waste and recovered substances [17] prescribes that recovery from waste streams may apply to substances and mixtures but also to articles. In the latter case, a recovery operator would make new articles directly from waste feedstock (e.g. recycled plastic outdoor furniture). In this case, there would be no registration obligations as no chemical production takes place. Instead, the company would need to check their obligations being an article manufacturer (article 7 and 33 of REACH). For meeting these obligations he would need to have detailed knowledge on the chemicals in the newly manufactured articles and especially on the presence of SVHC substances as these would trigger obligations. This reinstates the need for the recovery operator to have knowledge on the chemical content of the waste material supplied to him. Such information should normally be provided by his suppliers though it should be recognised as a challenge for waste streams that have a variable source and material composition.

Recovery from waste streams and especially the applicability of the definitions of substances, mixtures and articles has been subject of extensive EU policy debate and to date these discussions are ongoing. Where recovery takes place from scrap of waste articles that are made of a solid matrix in which a range of chemical components are typically present and where separation of the individual chemicals from the matrix is technically and practically impossible or economically infeasible, the prevailing interpretation among member states is that recovery concerns the mixture as a whole. This is based on the argument that the material the original article was made of also constituted a mixture. Examples of such cases are plastics containing additives such as pigments, stabilisers, plasticisers or flame retardants or rubber infill granulates made from recycled tires. The recovery operator will need to know the chemical identity of the substances present in the mixture and their concentration ranges and typical concentrations. For each of the chemicals in the mixture they would have to determine the annual tonnage recovered and hence, the need to register. Again, information on the presence of SVHC candidate list substances is of high importance as this would trigger additional obligations.

Waste recovery could also result in chemical substances that are pure or relatively pure (e.g. a relatively pure solvent recovered from contaminated solvent waste). The REACH guidance on substance identification ([18], p. 29, distinguishes mono-constituent substances ($\geq 80\%$ concentration of main component), multi-constituent substances ($< 80\%$ concentration of main component) and UVCB substances. The latter category concerns a group of products that is identified primarily on the basis of a description of the process applied, rather than on chemical identifiers (e.g. an extracted vegetable oil with variable composition or a thermo-cracked petrochemical stream). Because of the partly unknown or variable nature of some recovered materials and their standardized processing applied, this UVCB identification may prove highly relevant for certain recovery processes as well (e.g. for fly ashes). All of these means to chemically identify and characterize the recovered materials in the scope of REACH may be applicable to recovery operations. We expect that especially recovery of mixtures and of UVCB substances may be most appropriate from the perspective of bio-based companies. REACH obliges recovery operators to know what they are recovering and to 'translate' this process and chemical information into the REACH terminology of substance typology, mixture or article. Based on this starting information, companies need to go ahead and check whether any of the other REACH obligations or exemptions applies.

To illustrate – substances recycled from waste (questions considering registration; Article 2.7d)

Does company X need to register if it recycles a substance from the waste supplied by company Y, and directly (and only) supplies the recycled substance back to company Y?

Answer: The company X recovers a substance from waste and hence is regarded as a manufacturer with registration obligations (> 1 tonne/year). Hence, unless company X can apply for an exemption in accordance with article 2.7(d) (substance already registered) or for any other reason (i.e. exempted uses), he has to register. If he wants to make use of the exemption through article 2.7(d) he needs to be in possession of a valid safety datasheet. The fact that company Y in this theoretical case is as well the waste supplier as the recipient of the recovered material is of no influence on the registration obligations of company X.

A company treats wood through pyrolysis and hence manufactures wood oils and other related substances. Would the company need to register the wood oil and would this be depending on the source of the wood being either a natural resource or waste?

Answer: The company applying the pyrolysis should be regarded as a manufacturer and in this respect has duties in the scope of the REACH Regulation. Chemicals manufactured by pyrolysis should be registered above 1 tonne per year. The source of the starting material (wood) determines whether exemptions could apply. If waste wood is used, article 2.7(d) exemption may be applicable if the wood oil has already been registered. If wood as a natural resource (crop) is used, registration obligations apply.

Perspective – Registration exemptions for substances recovered from waste

- Bio-based production companies have the possibility to be exempt from REACH registration. Exemption from registration through REACH article 2.7(d), substances recycled from waste, may apply to many processes in the bio-based economy where they are regarded as manufacturers of the recovered material.
- Whenever bio-based production starts from (biological) waste feedstock, REACH comes into play but exempts these recovery operators from their registration obligations if the recovered substances are already registered. In such cases they can refer to existing registrations of the recovered chemical(s) and ensure that they are in possession of a valid safety datasheet.
- Through offering registration exemptions for recovered substances REACH in effect stimulates resource efficiency and re-use as compared to production based on virgin feedstock.

3.2.3

Exemption from registration for substances included in Annex IV

According to article 2.7(a), substances included in Annex IV are unconditionally exempted from registration because sufficient information is known about these substances. They are considered to cause minimum risk because of their intrinsic properties. Annex IV is a list of 40 substances or chemical groups, 7 of which are substances that are inorganic and hence not of relevance for bio-based companies. All 33 substances (or groups) that are of organic nature (e.g. D-glucitol, ascorbic acid, glucose, maltodextrin, glycerides (C10-C18), etc.) may be relevant from the perspective of bio-based manufacturers. Many of these chemicals will have a production process that is bio-based rather than fossil-based. Hence, bio-based manufacturers of these chemicals will automatically be exempted from their registration obligations through Annex IV. Since Annex IV is a closed list with clearly named and CAS numbered substances and substance groups, this exemption provides legal certainty to those companies involved. Although Annex IV is open for future amendment, e.g. with other substances of biological origin, this is considered unlikely as the scientific evidence base for such amendments will be demanding and any proposal would trigger substantial policy debate.

To illustrate – chemicals similar to exempted substances (questions considering registration; Article 2, Annex IV exemptions)

The Dutch REACH helpdesk received several questions from bio-based companies (roles presumably manufacturer or importer) specifically on Annex IV and in many cases combined with Annex V. All queries were on compounds that were considered similar (not identical) to those listed on Annex IV and on the need to be registered.

If a compound is identical to the substances listed in Annex IV and it has the same CAS number, it does not need to be registered. It is the responsibility of the company to check the sameness of his chemical with the exempted one. In doing this he should assess whether his substance contains constituent or impurities that would force him to conclude the substance is not the same as the Annex IV substance in accordance with the REACH guidance on data sharing [28]. If an Annex

IV chemical were contained in a multi-constituent substance or UVCB, it would not impact the need to register these chemicals.

3.2.4 *Exemption from registration for (groups of) substances included in Annex V*

According to article 2.7(b), substances covered by Annex V are exempted from registration. Registration for these substances is deemed inappropriate or unnecessary. Hence, in its nature the exemption of registration through Annex V is different from Annex IV. Annex IV substances are by definition exempted because their intrinsic properties pose a minimum risk, while the Annex V exemptions are partly based on other considerations such as the appropriateness of requiring registration from an actor in the supply chain. Furthermore, some Annex V exemptions are conditional; apply to groups of chemicals rather than single chemicals and some exemptions focus on processes through which chemicals may be formed. Hence, in its scope Annex V is much broader than Annex IV. Annex V currently contains 13 entries⁶. A range of exemptions apply generically. Examples are the exemption for byproducts (Annex V.5) that are not placed on the market themselves (see illustration box below) or reaction products that are formed upon end-use of other substances. From the perspective of bio-based manufacturers, four entries of Annex V are of specific relevance (V.8, V.9, V.10 & V.12). These are discussed below.

To illustrate – byproducts, Annex V.5 (questions considering registration; Article 2, general exemptions)

A company produces biofuel from fatty acids. During distillation a byproduct, bioheating oil (BHO), is formed unintentionally. Does this BHO also need to be registered?

All fuels and residual fractions fall within the scope of REACH and, in principle, need to be registered, irrespective whether they are biofuels or not. If a by-product is placed on the market itself or as constituent of another substance or component of a mixture, it is not exempted from registration, although unintentionally produced. It should be noted that for uses of substances as fuels some exemptions apply under REACH such as the exemption from the need to request authorization for fuel uses of substances that are placed on Annex XIV.

Annex V.8: Substances which occur in nature that are not chemically modified.

In order to benefit from this exemption, the substance must be naturally occurring and either unprocessed or processed only by physical or mechanical means such as flotation or extraction with water. Substances occurring in nature as such are defined in article 3.39 of REACH. Furthermore, these substances may not be chemically modified (as defined in article 3.40). This means that in order to benefit from this exemption, the chemical structure of the naturally occurring substance should remain unchanged in the process of extracting it from the natural

⁶ Pending any future amendment of Annex V

source, or from the waste source. Substances extracted from leaves or seeds of a plant through cold extraction or steam distillation yielding a range of substances in the extract that are also originally present in the leaves, would typically meet this requirement.

On top of this requirement, the naturally occurring substance should not have hazardous properties (i.e. not fulfill the criteria for classification under the EU CLP Regulation (Regulation (EC) No 1272/2008)). As it is well-known that substances which are naturally occurring may have hazardous properties, it is obvious that this criterion may be very relevant for bio-based companies. Extracting and concentrating such substances from a natural source may even make these properties more pronounced. For assessing the possible hazards, the burden of proof rests with the manufacturer or importer of the substance covered by the Annex V.8 entry. In the scope of CLP, any company placing on the market a substance (or mixture) is obliged to classify, label and package the substance in accordance with the criteria provided and based on all information available, independent from the fact that the substance should be registered or is exempted from registration.

Furthermore, the substance should not be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) (i.e. not fulfill the criteria for classification set out in Annex XIII of REACH). Such self-classification assessment is in general challenging since it requires information on the environmental fate and behaviour of the substance manufactured. Such information may not be available, especially for new chemicals. In such cases bio-based manufacturers will have to draw up an evidence-based assessment using all information available from literature and based on the information gathered and assessed to establish the classification and labelling following the CLP Regulation requirements. The evidence supporting the conclusion on the PBT/vPvB properties should be documented and presented to inspectorates upon request.

A final criterion is that the substance extracted should not in REACH be listed as a substance of very high concern (SVHC) (article 57 (f)) at least two years previously. In order to verify this, the company should regularly check the candidate list⁷ for (new) placement of substances on it.

In summary, to be exempted from registration, complying with annex V.8, a substance has to be naturally occurring, should not be chemically modified and should be proven not to be hazardous (i.e. not be classified according to CLP), not meet the PBT or vPvB criteria, and not be listed as SVHC.

⁷ <https://www.echa.europa.eu/nl/candidate-list-table>

**To illustrate – mixture retrieved from food waste
(question considering Registration; Article 2, Annex V.8
exemption)**

A company obtains a mixture from food waste. This mixture contains 45% of content that is not intentionally produced. The food is a natural product. The intentionally retrieved fraction (55%) is a (bio)polymer, not chemically modified.

Is the 55% fraction of the mixture (intentionally retrieved) a naturally occurring substance (Article 3, 39 or 40) and exempted from registration?

Answer: For this, both the criteria of 'a substance that occurs in nature' and 'not chemically modified' have to be fulfilled (Article 3 (39) and (40)). Thus, the company has to show that the mixture constituents are identical to naturally occurring substances. In addition, the regular requirements apply that the substances should be proven not hazardous (i.e. not classified according to CLP), not meet the PBT or vPvB criteria and not listed as SVHC on the candidate list.

Notwithstanding the above, the recovery from waste exemption from registration may also apply (as explained in section 3.2.2). Finally, as the fraction contains biopolymers it should be noted that polymers themselves do not need to be registered, rather the monomer or other substances that are chemically bound to the polymers require registration (see section 3.2.6).

Annex V.9: A limited list of substances obtained from natural sources

Entry 9 differs from entry 8 in that it lists a limited number of specific substances that are exempted if they are obtained from natural sources. The chemicals retrieved from these natural sources may not be themselves chemically modified. The exemption applies only to vegetable- or animal fats, oils and waxes, fatty acids (C6-C24) (including their K, Na, Ca and Mg-salts) and glycerol. These chemicals are exempted from registration as long as they are obtained from a natural source. The process through which these substances are obtained may be other than physical or mechanical means, even including chemical reactions (e.g. the breakdown of triglycerides into fatty acids and glycerol). In this exemption 'obtained from a natural source' means that the original source should be a natural material (of plant or animal origin). 'Not chemically modified' means that the substances, for which this exemption applies, once obtained from the natural source, should not be further chemically modified [19]. The substance itself however, once obtained from the natural source, may not be further chemically modified (i.e. it has to be chemically identical to the either of the chemicals listed in V.9). In order to establish chemical 'sameness' of the chemical that is retrieved from a natural source with an Annex V.9 listed substance, a bio-based manufacturer would need to have proper knowledge on the feedstock. First, he would need to ascertain whether his feedstock meets the definition of a natural source. Normally any plant- or animal origin is a natural source including genetically modified organisms. It should be noted though that the definition of 'obtained from a natural source' is not the same as 'occurring in nature'.

Furthermore, he would need to know the chemical identity of the substance obtained and compare it with the Annex V.9 chemical. In order to establish sameness, he would need to have knowledge on any other constituent or impurities present in the substance. Typically, presence of hazardous impurities in a concentration >0,1% by weight may lead to a negative conclusion on sameness and hence, a need to register. The company is responsible for checking sameness and may need to consult guidance and find support by the European Chemicals Agency in order to draw conclusions. The natural source normally constitutes materials of plant or animal origin. The European Commission has taken the position that genetically modified plants also meet the definition of a natural source [19]. Hence, entry V.9 is relevant for bio-based manufacturers if they produce any of the compounds covered.

Similar to substances falling under entry V.8, the substances under V.9 may not be classified as hazardous⁸, assessed as PBT or vPvB or identified as SVHC based on article 57(f). If either one of these criteria is met, the substance still has to be registered.

To illustrate – question considering registration; article 2, Annex V.9 exemption

Is there an obligation to register oil synthesized from fatty acids obtained from palm oil? A company produces oil based on fatty acids and glycerol that are derived from palm oil. The oil is chemically identical or similar to a vegetable oil. Vegetable oils and glycerol are exempted from REACH registration requirements through REACH Annex V, entry 9. Is the oil that is produced also exempted from registration?

The produced oil is not exempted from registration. The synthesis is such that it requires a chemical reaction (esterification) to manufacture a new oil based on building blocks, although these are themselves obtained from a natural source. The oil that is manufactured is not regarded as a vegetable oil.

Annex V.10 process gases and others

The following substances, if they are not chemically modified, are exempted from registration through this entry: liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia. From the perspective of bio-based manufacturers, process gases may be of relevance as in accordance with the guidance these are not naturally occurring substances and the term is used as an umbrella for all kinds of gases produced during certain technical processes. As an example the guidance refers to blast furnace gas produced during the reduction of iron ores and sinter with coke in blast furnaces in the iron and steel industry. Clear criteria and guidance are however lacking (e.g. is it not clear what is meant with 'certain technical processes'). Bio-based companies producing synthesis gas (syngas) through gasification of biological material, could probably benefit from the exemption. This especially applies if the gas would be

⁸ With the exception of those only classified as flammable, skin irritant or eye irritant

chemically the same to the gases specifically included in this exemption. It could be argued that such synthesis gas is intentionally produced and not a byproduct of another technical process and hence, it would not qualify as a process gas covered by this exemption. Existing guidance provides no clarity on this point. Companies would need to assess their specific process and provide a rationale for any use of the process gas exemption.

Annex V.12 compost and biogas

According to the waste framework Directive compost and digestate are made from bio-waste. Compost that is no longer considered to be waste in accordance with the end-of-waste criteria, technically becomes a product falling under the scope of REACH. In 2014 European Commission experts developed end-of-waste recommendations for compost and digestate [29]. To date these recommendations have not yet been implemented at EU level which means that end-of-waste decisions should still be taken by national authorities. End-of-waste compost is unconditionally exempted from registration via Annex V entry 12.

The European Commission recently proposed to add also anaerobic digestate to this entry based on similar grounds and because it is regarded as an anaerobic analogue to compost made from bio-waste. However, to date no decision has been taken and the anaerobic digestate is currently not exempted.

The exemption from registration also applies to biogas, which is gas produced by the biological breakdown of organic matter in the absence of oxygen. Biogas consists mainly of methane. The REACH guidance on Annex V [19] provides no further explanation on the use of this entry. In practice, we expect biogas that is produced by anaerobic digestion to have a composition of limited variability containing in any case primarily methane but also some other gases such as carbon dioxide, ammonia, hydrogen sulphide and water vapour. The likelihood of other hazardous or even SVHC substances being present in biogas is considered negligible. The biological breakdown of organic matter should be considered as a naturally occurring process the products of which are consequentially exempt from REACH registration.

Annex V, summarizing

In general, Annex V includes several relevant exemptions for bio-based substances. However, the fact that a substance is natural, or bio-based, does not automatically imply exemption from registration. Natural substances also need to be registered unless they specifically comply with the listed REACH exemptions from registration. It is the responsibility of the manufacturer or importer to determine first of all their substance identity and second, based on this and the knowledge on their process, whether REACH exemptions for registration apply. Knowledge on substance identity is crucial as in many cases one would need to ascertain the sameness of the manufactured material with the exempted substance. Typically, presence of additional impurities in a concentration >0.1% by weight would lead to a negative conclusion on

sameness and hence, a need to register. The company is responsible for checking sameness and may need to consult guidance and find support by the European Chemicals Agency in order to draw conclusions.

To illustrate – fertilizers (questions considering registration; article 2, Annex V.12 exemptions)

A company imports fertilizer (vegetal and mineral components), do they need to register their product?

Specific natural substances that do not have to be registered are listed in Annex V (such as natural gas, crude oil and coal). If the fertilizer is identical to the substances described in this annex, it is exempted from registration. In general, artificial (anthropogenic) fertilizers are considered substances (or mixtures) which, just as regular substances, should be registered under REACH, unless sameness with a natural substance listed in Annex V can be demonstrated. Therefore in most cases companies that produce or import artificial fertilizers have to register these substances. Companies placing fertilizers on the EU market also need to comply with Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilizers.

Perspective – registration exemptions Annex V

- Annex V.8 offers a broad exemption from registration for many bio-based companies extracting substances from renewable feedstock as long as the substances occur as such in nature and are not chemically modified. Annex V.9 also exempts substances such as vegetable and animal oils and fats;
- Substance identification is crucial. In many cases companies will need it to show a lack of hazardous substances and SVHC content and hence justifying the use of an exemption;
- Bio-based products compost and biogas are exempted from registration through Annex V. This exemption applies unconditionally to a large number of companies. In the future, also digestate may be exempted though currently the situation is not legally clear.

3.2.5 *Exemption from registration for isolated intermediates*

Non-isolated intermediates are not covered by the scope of REACH (article 2.1(c)). Intermediates that are isolated from the contained reaction vessel, either used on-site or transported and used on other sites are covered by REACH. However, to substances used as on-site or transported isolated intermediates a reduced registration regime applies (cfr. article 17 and 18). Furthermore, these isolated intermediate uses are exempted from authorization requirements.

No bio-based specific queries have been received dealing with isolated intermediate uses. Hence, based on information available this exemption is likely to apply equally to bio-based as to fossil-based chemicals.

3.2.6 *Exemption from registration for polymers*

Polymers are in the scope of REACH but they are exempted from registration and evaluation provisions. This means that companies importing or manufacturing polymers do not have to file a registration dossier. However, they would have to do so for monomers or other

chemically bound substances in the polymer that make up more than 2% by weight of the polymer and if the annual volume of these substances is above 1 tonne. Registration would not be necessary if the substances have already been registered higher up in the same supply chain.

It should be noted that according to the review clause (article 138.2), the Commission may reconsider the polymer registration exemption if a practicable and cost-efficient way of selecting polymers becomes available and a report is issued on the risks of polymers and on the need to register groups of polymers taking into consideration environmental health and safety aspects as well as competitiveness and innovation. Early 2015 the European Commission published a study looking into the need to change the registration requirements on polymers [30]. The main recommendation of the authors is to introduce in the EU the (OECD-based) concept of Polymers of Low Concern (PLC) and a grouping approach. The PLC approach is based on a decision tree for determining whether a polymer can be considered of low concern (eligibility criteria (e.g. hazard classification), molecular weight and oligomer content, reactive functional groups and polymer class (e.g. polyesters)). The European Commission is expected to take these recommendations into consideration in the framework of the Regulatory Fitness Programme (REFIT) for the chemicals policy area, a final report of which is expected in 2017.

To illustrate – byproducts and polymers (questions considering registration; article 2, general exemptions)

A company obtains a mixture from food waste. The food bio-waste is a natural product. This mixture contains 45% of content that is not intentionally produced. The intentionally retrieved fraction (55%) is a (bio)polymer, not chemically modified. Polymers do not need to be registered, but their monomers may need to be.

Is the 55% biopolymer fraction of the mixture which is intentionally retrieved exempted from registration because the monomers can be considered as 'non-isolated intermediates' (Article 2 (9))?

The feedstock from which the biopolymer is produced is stated to be food waste. Hence, the scope of the question is that of recovery of a mixture, containing a range of substances, from waste. Exemption from registration in accordance with article 2.7 (d) could apply (See paragraph 3.2.2). In addition, it could also be argued that the food waste is a natural material and hence substances retrieved from it, without chemical modification could benefit from registration exemption in accordance with article 2.7(b) (See paragraph 3.2.4). This could apply for instance to unprocessed and non-contaminated food crops that are discarded off because of insufficient quality. Such exemption would only apply if the biopolymer material is not hazardous according to criteria set in Annex V.8 and the biopolymer is extracted from the feedstock without chemical modification. The latter is unlikely to be applicable in this case.

As these exemptions are likely to be applicable to the biopolymer that is retrieved, it is not necessary to further elaborate on the registration

obligations that apply to the monomers and other chemically bound substances that make up more than 2% of the weight of the polymer. It should be noted though that in accordance with article 6.3 of REACH, monomers will never have the status of intermediates. Hence, the biopolymer fraction may be exempt from registration but not due to its monomers being regarded intermediates as this is a misinterpretation of the REACH Regulation.

Given the complex nature of the fractions that are retrieved from the feedstock, the manufacturer would first have to ascertain a substance identity. The material could be regarded a mixture as the question states but there is also a rationale to describe the material as a whole as a multi-constituent substance or a so-called substance of unknown or variable composition, complex reaction product or biological material (UVCB). The latter could for instance apply in case both fractions in practice are not separated but retrieved from the feedstock in a manufacturing process and marketed as a whole. The company is advised to consult ECHA starting with the guidance on registration and the guidance on substance identification [18]. Many recovered materials consist of two or (many) more substances but also have typical characteristics of UVCB substances. For this reason, the alternatives to characterize the substance(s) are to a certain degree interchangeable. It is up to the manufacturer or importer to decide which of the two options best fits the characteristics of the material. Reference is made to the REACH guidance on waste and recovered substances [17], p.12.

3.2.7 *Exemption from registration for substances used in scientific research and development (R&D) and in product and process orientated R&D (PPORD)*

One of the aims of REACH is to enhance competitiveness and innovation (recital 2). In order to achieve its innovation goals REACH defines *scientific R&D* as 'any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year' (article 3.23). It is presumed implicitly that scientific R&D is considered normally to take place using volumes below 1 tonne per year and, as such, is exempted from registration as is any other production or import at such low volumes. Bio-based manufacturers hence are allowed to develop small scale production processes up to the level of 1 tonne (manufactured product) without having the obligation to register. Furthermore it is noted that obligations following authorization and restriction do not apply to substances used for scientific R&D (REACH article 56.3). Hence, if the activities of a bio-based manufacturer are taking place as scientific R&D and (hence) remain below the 1 tonne threshold, any restriction or authorization provisions (if relevant) would not affect them. It should be noted that scientific R&D will often extend beyond the scope of the 1 tonne annual limit. In such cases he will find the REACH definition of scientific R&D not fit for his purpose as exceeding the legal 1 tonne import or manufacturing threshold will place his activities automatically outside the scope of scientific R&D and into the scope of registration obligations. In such cases, he may want to revert to a conditional exemption from registration for R&D purposes (see below).

To encourage innovation, REACH introduced an exemption from registration for product and process oriented R&D (PPORD). This type of R&D is defined as any scientific development related to product and production process development or the further development of a substance, on its own, in mixtures or in articles. The PPORD activities may comprise of pilot plant or production trials used to develop the production process and/or to test the fields of application of the substance. The exemption applies for 5 years with a possible extension to 10 years. The PPORD use is not bound to tonnage thresholds. In order to be allowed a PPORD exemption companies should file a notification in accordance with article 9.2. The information to be submitted is limited to the identity of the manufacturer, the identity of the substance, the hazard classification of the substance (if any), the estimated quantity and the list of customers. Hence, PPORD information requirement is very limited but authorities may decide to impose conditions in order to ascertain that risks are adequately controlled, the product will not be made available to consumers and that remaining quantities will be re- collected for disposal after the exemption period. PPORD may be applicable in cases where a substance is not yet intended to be placed on the market to an indefinite number of customers, for instance because its application in mixtures for specific use still requires further R&D. The PPORD activities may be performed by the potential registrant himself or in cooperation with a limited number of known customers.

PPORD exemption in theory may also be applicable to SVHC substances as REACH does not lay down the lack of SVHC status as a condition for PPORD exemption. For SVHC substances that are placed on Annex XIV, authorization applies normally also to PPORD uses. However, in accordance with article 56.3, the Commission may exempt PPORD uses from authorization for a corresponding maximum quantity. This exemption so far has not been applied in Annex XIV.

To illustrate –Less obligations for innovation stage (questions considering Registration; Article 9)

- Some bio-based companies are not aware of the possibilities for R&D under REACH and presume they have to register their substance during the innovation stage. They hold back on exploring bio-based options, because they think it will cost too much time and money (pers. comm.). However, the PPORD exemption does provide the option to develop, test and optimize substances and processes, without having to register for REACH.
- • Laboratory scale research and development below 1 tonne goes without registration obligations and is not affected by authorization and restriction. Transition from scientific R&D to larger scales or even industrialization increases legal obligations, but a temporary (5 year) PPORD exemption from registration may be appropriate for bio-based companies. PPORD exemptions may help to smoothen the transition from laboratory scale to large scale production and use in cooperation with selected customers. However, the final products should not be made available to the general public during the PPORD period.

Perspective – Registration exemptions for Research and Development

- Up to use volumes of 1 tonne annually no registration is required and if bio-based companies with such limited volumes innovate through scientific research and development they are also exempted from the authorization and restriction titles of REACH.
- PPORD exemptions from registration offer the possibility at laboratory scale or industrial scale to explore product development and process optimization. The PPORD exemption may be applied for without limitation to tonnage and in cooperation with selected customers in order to develop, test and improve the process and their products. These exemptions may be granted for 5 and up to 10 years. PPORD information requirements are very limited. However, ECHA and member state enforcement authorities may evaluate and request further information and lay down conditions if deemed necessary.

4 Chemical safety assessment by bio-based companies

Above annually manufactured or imported volumes of 10 tons, registrants have the obligation to perform a chemical safety assessment (CSA) as part of their registrations and report it in the chemical safety report (CSR). The CSA consists of a hazard assessment and for substances classified as hazardous (selection of hazard classes) or concluded to be PBT/vPvB, an additional assessment is required of the exposure and risks to humans and the environment. The registrant has the obligation to assess all uses of his substance that are covered by his registration for the whole supply chain. A key element of the CSA is the exposure assessment, with one or more so-called exposure scenarios for each identified use. The exposure scenarios lay down the (operational) conditions of use and risk management measures which, if adhered to for a certain use, ascertain an adequate control of risks. The exposure scenarios are communicated downstream in the supply chain through an Annex to the safety datasheet.

Establishing such exposure scenarios for bio-based uses and specifically for bio-based production processes may open a chapter in the REACH guidance that currently not exists. Exposure scenarios are developed based on standardized approaches for fossil-based production processes, while bio-based production processes may be substantially different in many respects. The question is whether the REACH exposure scenarios and the so-called use descriptor system defining and categorizing the uses are fit for purpose, taking into account a transition to bio-based production. This is one of the issues raised in a report by Royal Haskoning DHV commissioned by RIVM [22]. The report addresses the REACH Environmental Release Category no. 1 (ERC-1) that covers bio-based production processes as well as fossil-based production processes. The ERC calculates the releases of the manufactured substance to air, water and waste. They concluded that the bio-based production route in general may lead to different emissions (of the produced chemical or of auxiliary chemicals) to the environment compared to the conventional production route. The main differences are the feedstock used, the energy consumption, sustainability aspects but also health and safety issues, e.g. due to the use of other types of auxiliary agents and different emissions and exposures. The REACH ERC concept provides a generic approach, not differentiating between various types of (new) manufacturing processes.

5 REACH authorization and restriction for bio-based companies

REACHS allows authorities to initiate measures on substances of very high concern or in case of unacceptable risk identified at EU level. They can decide to manage at EU level the risks of a single use, several uses or the production and placing on the market of a substance based on unacceptable risk or hazards. Unacceptable risks may be tackled through a restriction proposal that after scrutiny by ECHA's scientific committees for risk assessment (RAC) and socio-economic analysis (SEAC) and subsequent policy decision making may result in an amendment of Annex XVII of the regulation. Another regulatory management option affecting uses of substances at the EU level is authorization. The authorization requirement applies only to substances that are of very high concern based on specific hazard properties and are placed on the candidate list and subsequently on Annex XIV of REACH. Prolonged use of these substances (if not exempted) requires prior authorization which is time-limited and reviewed if necessary.

5.1 Authorization

REACH stimulates the quest for alternative and safe substances for substituting those chemicals that are of highest concern due to their hazardous properties or risks to man and the environment. Authorization is targeted towards substituting these substances. Use of these substances is prohibited after a fixed date (so-called sunset date), unless a company has applied for a specific authorization for his use. The aim of authorization according to article 55 is 'to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable'. Currently Annex XIV of REACH contains a limited number of 31 chemicals but this list will expand as REACH progresses. Analysis by the European Chemicals Agency has shown that for approximately 50% of the substances currently on Annex XIV no applications for authorization were filed. This means that the uses of these substances in the EU are either substituted by introducing alternative substances or technologies or the uses are non-existing or have become redundant. The idea of reverting to safe bio-based alternatives for replacing functions that were in the past performed by SVHC chemicals in general is too simplistic as SVHC properties will often have a close relation with the function performed by the chemical. Finding a bio-based drop-in chemical replacement that does not have the SVHC properties but nevertheless fully takes over the function requested in most cases is not realistic. Chances lie in integrated approaches focusing on benign material design and new technologies.

Manufacturers, importers and downstream users may apply for authorization and in doing this they need to analyze the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution. Authorization will normally be granted if the

company shows that the risks to man and the environment resulting from his use(s) are adequately controlled (article 60.2). This adequate control routing normally applies only to those substances listed in Annex XIV based on hazardous properties for which a threshold of effects may be established. For substances included in Annex XIV on the basis of their non-threshold hazards (i.e. genotoxic carcinogens), the applicant has to apply for authorization using the socio-economic route (article 60.4). Authorization may be granted to him if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies.

Since most substances on Annex XIV are on this list because of non-threshold effects, authorization relies heavily on socio-economic analysis. To date, experience with granting authorizations from the start of the application to opinion making and final decision making is still relatively new but ECHA's scientific committees are catching up rapidly. In 2015 and 2016 the number of applications for authorization processed reached a peak level. Many applications were received on chromates and solvents currently on Annex XIV and for which the sunset dates were near. Several tens of dossiers were scheduled for opinion agreement at each single committee meeting. Experience shows that the three parts of the application, the chemical safety report, the analysis of alternatives and the socio-economic analysis should be carefully aligned and they should contain sufficiently detailed information balanced against the scope of the use applied for. As can be deduced from the legal text in article 60.4, the analysis of alternatives plays a crucial role in the application for authorization. Above all, it is needed to justify the claim that no alternatives are available for the use applied for at the sunset date. Without such justification, the applicant in fact has no legal basis for requesting authorization. Furthermore, experience has shown that the analysis of alternatives provides a rationalized starting point of the socio-economic analysis as it clarifies what would happen if authorization was not granted (the so-called non-use scenario). This non-use scenario is an essential part of the socio-economic analysis (SEA). In the SEA, the socio-economic costs in the non-use scenario are compared with the socio-economic benefits (i.e. reduced health impacts).

The central role of the analysis of alternatives is based on the substitution principle. Thus substances subject to Authorization (on Annex XIV), should be phased out eventually. The application for authorization process therefore also includes a public consultation. During the public consultation, the analysis of alternatives provided by applicants may be scrutinized and any additional information on alternatives from interested third parties can be identified. This has to be for the specific use of the substance, for which the authorization is applied for. Any relevant information on alternatives submitted has to be taken into account in the analyses by ECHA's scientific committees. These consultations show that REACH provides a window of opportunity for bio-based producers to develop sustainable alternatives. It should be noted though that the consultations are only one of the very last steps in a process towards authorization. The authorization process starts many years before, when the substance is taken forward by authorities

to identify its risk management options or when the substance is included in the SVHC roadmap. Since development of alternatives for specific uses may take substantial time, companies aiming at substitution as a window of opportunity would need to get information on substances targeted towards substitution as soon as possible. Hence, they would need to closely follow early SVHC developments under REACH.

***To illustrate – bio-based as safer substances?
(questions considering authorization, Annex XIV)***

- *Companies reported they wanted to submit information on alternatives in a public consultation. However, they noted they had to provide a substantial amount of information and the procedure was complicated while the time window was very limited. Hence, instead they focused on their own marketing of alternatives through communicating in their supply chains. What is the most effective approach?*

Answer: Taken from the point where the discussion on an application for authorization is initiated in ECHA's scientific Committees, the timeframe in which the information on alternatives should be submitted is indeed limited and it is only practicable if alternatives manufacturers have prepared their interventions far in advance based on expected future authorizations. In addition, in practice, the use description in some cases may be too broad or unspecific to allow third parties to come forward with the right targeted information. It is noteworthy that use description in the scope of application for authorization has developed recently and will further develop into a more specific description than the standardized use description used in the scope of registration.

- *In REACH companies that manufacture (e.g. plastic) granulates from recycled materials have to check the registration status of the substances they use and consider the need to register (see section 3.2.2). Substances that are on the authorization list may not be allowed in the recovered granulates, unless authorization is granted. Recyclers claim that for them it is not possible to apply for authorization because of the information needs and associated costs. Hence, authorization is perceived as a limitation to recycling.*

Answer: In general, authorization does not affect recycling of materials that are free of chemicals of concern that are on Annex XIV of REACH (currently just over 30). If however, a mixture that is recovered from waste contains an SVHC substance in a concentration above the limits given by REACH (e.g. equal to or greater than 0,1% for a substance classified as a carcinogen), the company may need to apply for authorization in order to continue its business after the sunset date. Just like any other company applying for authorization, they would have to justify their prolonged use based on prove of adequate control of risks or a lack of alternatives being available and a socio-economic analysis. Hence, if their recycling activity concerns a waste

stream that contains an SVHC substance, they are affected by authorization as any other user. In addition, also production itself (recovery) is not covered by authorization and there are a range of additional exemptions (such as research and development). The recovery operator has the responsibility to establish the identity of the recovered material.

Finally, it should be noted that if a company manufactures new articles directly from waste feedstock, they would not be affected by authorization since the recycling company treating the waste would in the scope of REACH be a producer of articles. The article production in such case (if purely made from waste), would not involve the use of an Annex XIV substance, but rather waste containing such substance. This is a theoretical case and as a result of pending policy debate on the relation between REACH and the European waste legislation, specifically the end-of-waste status, its practical application and implications are as of yet unknown.

Perspective – REACH authorization and bio-based alternatives

- The public consultation offers a window of opportunity for companies to submit information on bio-based alternatives. Submission of such information needs to be addressed by ECHA's scientific Committees in the opinion making on the authorization requests and where relevant it may play a role in the decision making on authorization (i.e. in the most extreme case authorization could be refused due to an alternative presented). Hence, manufacturers of bio-based alternatives of Annex XIV substances could include such interventions in REACH public consultations in their marketing strategy.
- Since the window of opportunity as described above involves a limited calendar time it is advised that manufacturers of potential alternatives regularly check the candidate list and even earlier communications by ECHA and member states regarding substances that are directed towards Annex XIV. This provides opportunities for early development and marketing of alternatives and communication.

5.2 Restrictions

A restriction (Annex XVII) on the production, marketing and use of chemicals for which an unacceptable risk at EU level is shown provides another steering mechanism for innovating towards safe and sustainable alternatives. Some restrictions primarily focus on implementing risk management measures and hence do not place a direct ban on the production, marketing or use of a substance. Other restrictions do in fact prohibit a single use or marketing and use as a whole. For the latter group of chemicals and their specific applications, a range of alternatives will normally be needed. Some will be chemical alternatives taking over the function of the restricted chemical; others may constitute different processes rendering the restricted use as redundant. Hence, also the restriction process under REACH provides opportunities for bio-based companies.

In the scientific assessment of restriction proposals, the availability of alternatives plays a less prominent role compared to the authorization process. However, the availability of alternatives (or the lack of it) for the restricted use(s) of a substance may play an important role in the final decision-making by policy makers. This is illustrated by the Bisphenol-A case as described below. In the decision-making, ready availability of suitable alternatives will normally be favorable for reaching agreement on restricting the use.

To illustrate – re-use old wood and restrictions (questions and issues considering restrictions, Annex XVII)

Can a consumer (private use) use old wood from a railroad track in his garden?

The wood is treated with creosote. The application of creosote on wood is currently a forbidden use under REACH (Annex XVII, restrictions). The restriction also applies to the re-use of creosote treated wood for indoor purposes, as well as in parks and gardens (amongst others) where there is a risk of frequent skin contact. The restriction does not apply to re-use and the second hand market of wood already placed on the market before 31 December 2002. Thus, in this case, the use by a consumer would be permitted if the wood was already placed on the market before the end of 2002. Nevertheless, it would be advisable to consumers to remove such wood or otherwise avoid skin contact.

Information on alternatives will affect regulatory decision making; the Bisphenol-A case.

During the public consultation on the restriction proposal by France on the use of Bisphenol-A as a dye developer in thermal printing paper, RIVM submitted additional information on alternatives. In a study commissioned by RIVM the analysis of alternatives submitted by France as part of the restriction dossier was scrutinized and based on a review of literature, patents and an expert assessment it was shown that one of the alternatives taken forward was not technically feasible, some alternatives were likely to be feasible substitutes but with limited gain as regards their hazards and risks. Finally also some additional alternatives were identified some of which were produced from renewable feedstock (bio-based chemical production). The information submitted by RIVM in the public consultation did not result in any change in the dossier and the opinions of ECHA's scientific Committees. Nevertheless, the information contributed to the overall picture on alternatives that played its role in the decision making.

Perspective – REACH Restriction

- Restriction other than authorization does not have a primary focus on substituting substances of very high concern. However, in some cases restrictions may constitute a ban with a limited or broad scope. In other cases, restrictions will be focused on strengthened risk management. Also in these cases, there will be a level of pressure on the supply chains to either invest in the mandatory risk mitigation measures, or transition to alternative processes or substances. Hence, similarly to authorization, bio-

based companies could also approach restrictions under REACH as a window of opportunity.

6 Reflection and perspective for action

Companies producing or using bio-based chemicals operate at the interface between agriculture, forestry, waste treatment, and chemical production. At this interface, it is not always easy to understand whether and how REACH applies. We have assessed REACH and the BBE and conclude that, although REACH applies to bio-based chemistry as it does to fossil-based chemistry, there is still a distance between the world of bio-based companies and REACH. It is difficult for some of these companies to gain information and understand the scope of their obligations and the opportunities REACH offers. The use of biomass comes with some specific challenges when dealing with REACH. In this report, we discussed key challenges such as the link between REACH and waste legislation and the accurate identification of substances to ease compliance with legal obligations. In the transition to a circular economy, both biotic and abiotic materials need to be reused and recycled, giving these challenges an even broader scope than BBE. Also, we conclude that REACH is probably not yet perfectly ready for the transition to a BBE, but REACH reaches out to the BBE, and it does so to a higher degree than may be perceived at first sight. Analyzing the various REACH processes more closely shows that next to the legal obligations and associated costs and administrative workload, REACH offers several opportunities. Both these challenges and opportunities will be discussed below.

6.1 Link between REACH and waste regulation

We have encountered bio-based companies that have questions about REACH and recycled or retrieved substances from waste (section 3.2). Waste itself is not a substance, mixture or article under REACH, but REACH gives the opportunity for recovery operators to be exempted from registration if they recover a substance that has already been registered. This places them in a favorable position compared to manufacturers and importers of the same substance from non-waste feedstock. This not only applies to bio-based producers, but also stimulates waste reduction and resource efficiency in general and thereby the circular economy. It may apply to metal scrap from which (e.g.) copper is recovered but also to ethanol being manufactured through biochemical digestion of biological waste material. If the recovered substance is the same as a registered one, the manufacturer (recovery operator) is exempted from registration.

We note that policy discussions on the so-called end of waste criteria for specific waste streams are still ongoing and this hampers an easy interpretation by companies regarding their role in the supply chain and legal obligations following REACH, waste legislation and other product legislation. Another issue often encountered by companies handling waste and recovering materials is the 'sameness' question (see following paragraph about substance identity). In order to be able to make use of the exemption from registration for recovered substances, the sameness of the recovered substance compared to an already registered substance should be proven. For single (mono constituent) substances with a

distinct CAS number this will normally not be a major hurdle. However, many recovered materials will be multi-constituent or UVCB substances and for these categories proving sameness may not be easy. We know from companies (personal communication) that they have ongoing discussions with ECHA on substance identity and sameness in the scope of the recovery exemption. A difference of 0.1% impurity contained in a recovered substance compared to a substance already registered may already lead to a negative conclusion on sameness.

All such perceived issues on whether or not REACH applies to certain substances, can partially be resolved by clear guidance and support from ECHA and the government [7, 15]), as does this report by explaining the legal context and providing specific examples. Also, the national and international REACH helpdesks can be consulted for any REACH related issue, including those from the bio-based industry [20, 21].

6.2 Substance identity

The accurate identification of substances is important under REACH. It enables the sharing of test data to prevent animal testing and costs. If a compound is identical to the substances listed in Annex IV or V or it is a recovered substance identical to a substance already registered, it does not need to be registered. It is the responsibility of the company to check the sameness of his chemical with the registered or exempted one or the group, process or category exempted. The REACH guidance on data sharing provides help to companies by describing the steps to take and the information needed to ascertain the identity. ECHA and member states helpdesks may offer help. Difficulties with substance identification can arise when companies are dealing with variable and heterogeneous feedstock. This may typically be the case for renewable feedstock, but also for recovering substances from heterogeneous waste streams. Evidently, this means that the better companies are in separating, identifying and/or purifying their input and output streams, the easier it is to comply with regulation. Relatively pure or multi-constituent chemicals may be produced but also so-called UVCBs, substances of unknown or variable composition, complex reaction products or biological materials. The identification of these UVCBs is largely done based on process description rather than on chemical identification of its constituents, although some information on concentration ranges of constituents is required.

For recyclers in general it is known that substance identification can be an issue [7, 24] (see section 3.2.2 on the link between REACH and waste legislation). Information on the substance is often lost down the supply chain or not provided. Many recyclers do not have the capacity to control or identify their incoming materials, but do have the obligation under REACH to check and report the use of harmful substances (i.e. SVHCs). This can hold back the re-use of certain waste streams, hampering a circular economy [7, 24, 25].

6.3 Registration costs and room to experiment and innovate

High registration costs can be a hurdle, especially for smaller companies or start-ups (section 3.1). REACH does not differentiate between fossil-based and bio-based substances. Both need to comply with the same safety standards embedded in REACH and companies have the same set of legal obligations. The Fee Regulation ((EC) No. 340/2008) however differentiates according to company size, hence allowing smaller companies to profit from much smaller fees (e.g. for registration) than larger companies.

Registration is not required at low tonnage levels (below 1 tonne annually). Therefore, in the early stages of scientific research and development, where bio-based substances are manufactured at laboratory scale, registration costs do not play a role. And even at larger scale, companies may decide to request for an exemption from the obligation to register in order to progress on product or process orientated research and development (PPORD). This PPORD notification (REACH article 9) will allow manufacturers to explore for five years (with a possibility of extension) the feasibility of a production process and uses of chemicals. They may do this in collaboration with selected customers without limitation to tonnage and with very little information requirements. In this way, REACH enhances competitiveness and innovation, also for bio-based industries.

In the commercial phase, companies manufacturing the same substance will normally team-up for a joint registration through a substance information exchange forum (SIEF) in which they have to share key information such as toxicological study results and classification and labeling. Through the SIEFs also costs are shared [16]. Although competitiveness may hold back companies from providing data to one another, sharing information can significantly bring down the registration costs [15]. This, of course, holds not only for BBE, but also for the industry in general. It is noted that registrants have the option not to share certain proprietary information such as detailed information on the use description and exposure assessment. Some SMEs consider the costs to enter the SIEF (the so-called letter of acceptance) as high. ECHA may mediate between SMEs and companies already in the SIEF. Further, the national governments can facilitate (BBE) companies in several ways, especially SMEs and start-ups that are less familiar with REACH or have less capacity. Suggestions as SDS preparation support, simplifying guidance and facilitating digital information sharing have been brought forward by the industry as a way of reducing the additional costs that often accompany registration [15].

6.4 Opportunities for bio-based chemicals

During our investigation, we noted a lack of awareness of exemptions that may apply to bio-based companies. Through these exemptions, it becomes clear that REACH could be more stimulating towards innovations by bio-based companies than perceived by them. In addition, the processes of authorization and restriction, may offer a window of opportunity for the production of safe substitutes for the substances of the highest concern. In the following section, we summarize the opportunities offered by REACH.

REACH applies to all substances in the same way, irrespective the origin of the substance being either bio-based or fossil-based. However, several specific REACH registration exemptions exist that are applicable for bio-based chemicals (as explained in chapter 3). As BBE is a rapidly developing field, exemptions related to R&D are given as well:

- Generic registration exemptions for uses such as in medicinal products and food and feeding stuffs may be highly relevant for some bio-based industry sectors focusing on these markets (bio-based production of chemicals that are used for other purposes in other industrial sectors, will need to be normally registered)
- PPORD notification in order to be exempted from the obligation to register. This gives companies the possibility for a maximum of five years (with an optional extension to 10 years) to (further) develop a product or process (see paragraph 3.2.7).
- REACH provides specific room for substances available in nature or taken from natural sources (see paragraph 3.2.3 and 3.2.4 for examples). Under certain conditions these substances may be fully exempted from registration through Annexes IV and V.
- When substances, mixtures or articles are recovered from waste streams, REACH gives the opportunity for recovery operators to be exempted from registration if they recover a substance that has already been registered (see paragraph 3.2.2).
- Authorization or restriction of substances may stimulate the gradual replacement of these SVHCs by less hazardous alternatives or technologies. This so-called substitution principle is strongest for authorization as any use of a substance placed on the authorization list will be prohibited after the sunset date, unless exempted or authorization is granted (or decision on such authorization is pending). Restriction proposals may be broad or targeted towards certain high risk uses focusing on mandatory risk management in order to limit exposure and risk. Not for all restrictions the analysis of alternatives therefore plays a prominent role. Hence, we see a significant window of opportunity for manufacturers of alternatives, especially for substances under control of REACH authorization. Manufacturers of (BBE) alternatives for substances (or uses of these) under authorization or restriction are advised to be proactive in gathering information in the early stages of risk management options analysis by member states or the European Chemicals Agency. During these stages, ECHA and European member states often communicate on their plans. When a substance is listed on Annex XIV and applications for authorization are submitted or a restriction proposal is discussed in ECHA's scientific Committees, the public consultation allows third parties to come forward, especially with information on alternatives. We note that this information on alternatives is of extreme importance in these processes as the final policy decision on granting authorization or the proportionality of the restriction proposal will depend heavily on the availability of alternatives. Signals from companies able to make new (bio-based) alternatives, indicate that the procedure to announce alternatives is not well known and it is difficult to judge their substitution potential, as information on required functionality is not understood or too broadly described. Providing such information in a more comprehensive and

structured way would significantly strengthen the authorization and restriction procedures.

We note that the numerous guidance documents currently available pay ample attention to differences between fossil-based chemical production and bio-based chemical production and associated supply chains. Questions by bio-based companies are increasing and this will become even more so in years to come as we progress towards a transition to BBE. We therefore plea for more guidance specifically focused on issues bio-based supply chain actors may come across.

6.5 Sustainability and REACH

Looking at BBE and REACH together, we conclude that REACH is probably not yet perfectly ready for the transition to a BBE but REACH reaches out to the BBE, and it does so to a higher degree than may be perceived at first sight. The REACH regulation aims to ensure a high level of human health and environmental protection, and in doing this it contributes to sustainable development (recitals 3,4 & 131 [6]). The basic paradigm of REACH is that chemicals are produced and used in a way leading to minimization of significant adverse effects on human health and the environment. In this way, REACH contributes to an overarching sustainability goal. Sustainability is however a very broad concept and encompasses many more aspects than safety for humans and the environment. There are several additional ways to fulfil sustainability goals and these have not yet been given a role in the leading interpretation of REACH. The regulation offers the possibility for a broader societal view including sustainability aspects in the socio economic analysis of authorizations and restrictions. However, to date the analysis of costs and benefits of proposed measures focuses only on issues directly related to chemical safety for humans and the environment. We strongly support a discussion on options for introducing broader sustainability aspects in the socio economic analysis in the light of the transition to BBE.

Bio-based substances, products and processes are not by definition safer, more sustainable, and without dispute as compared to fossil-based manufacturing practices. However, the potential sustainability benefits of bio-based chemicals are outstanding; less greenhouse gas emissions [1, 27], less depletion of and dependence on fossil and mineral resources [3], sustainable and efficient agriculture [12], stimulating innovation [12], re-use of waste streams [3] and providing jobs [12]. Thus if there is a safe and sustainable bio-based alternative to any SVHC it should be embraced by REACH as its use would contribute in many ways to its sustainability goals.

In the current setting of the socio-economic analysis and analysis of alternatives that are assessed for authorization applications and restriction proposals, there is ample opportunity to take into account these other considerations. Ideally, any sustainability gains (other than safety-related) due to transition to a bio-based alternative would have to be included in the comparison of the societal costs and benefits of a measure. On the other hand, the question raises how to deal with substances that do provide sustainability benefits as mentioned before,

but may score less well on for instance ecotoxicity. In a broader view, similar discussions are going on about recycled materials containing SVHCs. From a sustainability perspective, recycling may be a good way of keeping feedstock in the production cycle (e.g. PVC). However, from a safety perspective the prolonged presence of SVHCs in the material is undesirable (e.g. phthalate plasticizers or lead as stabilizer). With the current transition to a circular economy, it is expected that the need for an integral assessment of safety and sustainability will increase. In the Dutch Government-wide Program for a Circular Economy [3], the need for developing an integral policy framework for decisions on recycling or discarding material waste streams containing SVHCs is laid down as one of the key goals. The REACH Regulation should by no means compromise on the safety standards protecting human health and the environment. The main challenge is how to make REACH fit for purpose to assess sustainability aspects of alternatives in socio-economic analysis and weigh these aspects together with safety gains which currently are the main paradigm. This would stimulate companies not only to search for safer alternatives, but also to include sustainability and circularity in their product design. A starting point could be to make sustainability issues that are concerned with a substitution more transparent. This makes clear that in REACH also choices can be made as to how the sustainability goals are fulfilled in other ways than through ensuring safe use of chemicals only.

7 Conclusions and recommendations

The development of a bio-based economy triggers a discussion on how bio-based chemicals are covered by the European chemicals legislation REACH. In general, bio-based chemicals are no different than chemicals manufactured from fossil feedstock. However, bio-based manufacture does trigger new discussions on exemptions and perspectives for bio-based supply chains. We have analyzed questions received by the Dutch REACH helpdesk, other information sources and interviews with bio-based companies. We analyzed the typical questions on registration, authorization and restriction, corresponding answers provided to companies and the pitfalls and uncertainties that are still waiting for a solution. Looking at the queries from a broader perspective allowed us also to provide some initial reflections on the bio-based economy and the way REACH addresses its sustainable development goals. The following main conclusions and recommendations are taken forward:

- REACH applies to bio-based chemistry as it does to fossil-based chemistry but there is still 'a distance between the world of bio-based companies and REACH';
- For bio-based companies REACH obligations do not come naturally and may easily be perceived as rather an administrative burden. The challenge is to focus on perspectives for action and windows of opportunity;
- REACH is probably not yet perfectly ready for the transition to bio-based economy but reaches out to this development, more so than perceived at first sight. Use description and exposure scenario definition need development specific for bio-based manufacturing processes;
- Recovery from waste exemptions may specifically apply to some bio-based manufacturers placing them in a favorable position compared to fossil-based manufacturers;
- Pending policy discussions on end-of-waste criteria and difficulties interpreting substance identity and sameness in the scope of REACH hamper easy understanding by companies of their obligations. There is a sense of urgency to resolve these issues;
- Below 1 tonne annually, bio-based manufacturers do not need registration and, in addition, REACH offers possibilities for innovations through PPORD and R&D exemptions of which BBE stakeholders may not be aware (note: in general REACH obligations other than registration are also applicable below 1 tonne);
- Authorization and restriction offer a window of opportunity for the production of safe substitutes for substances of highest concern;
- As the transition towards a bio-based economy is expected to progress, we plea for more guidance specifically focusing on issues bio-based supply chain actors may come across;
- REACH contributes to overarching sustainable development goals by minimizing significant adverse effects to human health and the environment. We strongly support a discussion on options for introducing broader sustainability aspects in the socio-economic analysis to be prepared for a transition to BBE.

Annex I. REACH-helpdesk questions, RIVM, 2013-2015

The Dutch REACH-helpdesk (at RIVM) archived all received questions between 2013 and 2015 in a database, together with the Dutch CLP (Classification, Labelling and Packaging) and “chemicals risks” (“risico’s van stoffen”) helpdesks. This database was screened with a non-exhaustive search, using several identified relevant BBE keywords in English and/ or Dutch, see Table 1.

Table 1: BBE related keywords. In the Dutch REACH-helpdesk database all inquiries (between 2013 and 2015) were searched for these keywords.

| English | Dutch |
|--------------------------|-------------------------|
| algae | alg(en) |
| animal | dier(lijk) |
| bio | bio |
| bio-based | bio-based |
| biogas | biogas |
| biomass | biomassa |
| bioplastic | bioplastic |
| biorefinery | bioraffinage |
| biotic | biotisch |
| byproduct | bijproduct |
| carbon dioxide | koolstofdioxide |
| cellulose | cellulose |
| climate friendly | klimaatvriendelijk |
| climate neutral | klimaatneutraal |
| environmentally friendly | milieuvriendelijk |
| fat | vet |
| fermentation | fermentatie, vergisting |
| glucose | glucose |
| green | groen |
| green chemistry | groene chemie |
| lignin | lignine |
| microorganisms | micro-organismen |
| natural | natuurlijk |
| oil | olie |
| organic | organisch |
| organic waste | gift, organisch afval |
| PLA (polylactic acid) | PLA (polymelkzuur) |
| renewable | hernieuwbaar |
| residue | reststroom |
| starch | zetmeel |
| sugar | suiker |
| sugarbeet | suikerbiet |
| sugarcane | suikerriet |
| sustainability | duurzaamheid |
| sustainable | duurzaam |
| vegetable | plantaardig |
| waste | afval |
| wood | hout |
| yeast | gist |

Inevitably there are many more BBE relevant queries, however this first scan was performed as a pilot to scout whether BBE specific issues pop up at the REACH helpdesk or not. The results from this exercise are used in a semi-quantitative way. They give an impression on the number of questions on BBE related issues raised by Dutch companies between 2013 and 2015. For thorough quantitative analysis, additional study would be required. The automated search results from this inventory were manually checked for BBE relevance and categorized. This resulted in 52 types of questions relevant for the bio-based economy, originating from 48 different companies. One question may address several issues (sub questions). A total of about 400 questions per year were asked at the REACH helpdesk between 2013-2015 (BBE and not BBE related), thus about 1200 inquiries in three years. This means that, merely based on this semi-quantitative exercise and the particular keywords searched, about 4% of the questions can be directly linked to BBE.

For each question, the helpdesk analyzed the role in the supply chain of the company (importer, manufacturer, distributor, downstream user (e.g. user, formulator, etc.)) based on information provided in the inquiry. The companies were not specifically asked to state their role. Companies may have more roles in the supply chain and for the purpose of this evaluation, the role relevant for the question the company raised was used in the database.

No questions from distributors were captured with the search results. One inquiry from a consumer was included. BBE related questions were asked most frequently from an importers perspective, followed by producers and downstream users (Figure 4). From the 48 companies that asked a question, 5 companies had multiple (>1) roles in the supply chain (based on the information provided).

The search results show that producers, importers and downstream users all ask questions about Article 2 exemption rules (annex IV/V, annex V and food or feeding stuffs), obligations, waste or import. These categories are all represented in a similar percentage for each role. Almost half of all questions are about Article 2 exemptions. Then most inquiries are done on general obligations under REACH, followed by waste, import, labelling and MSDS in similar percentage (see Figure 5).

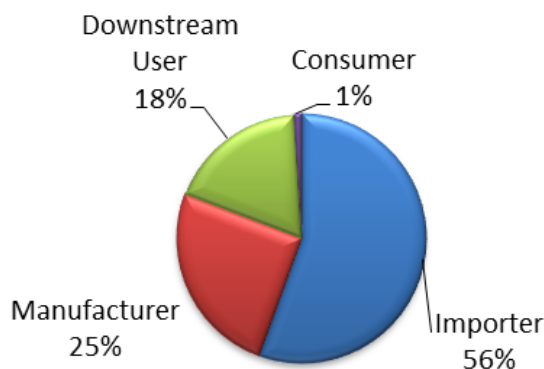


Figure 4: REACH-helpdesk questions related to BBE (2013-2015): categorized by role in the supply chain.

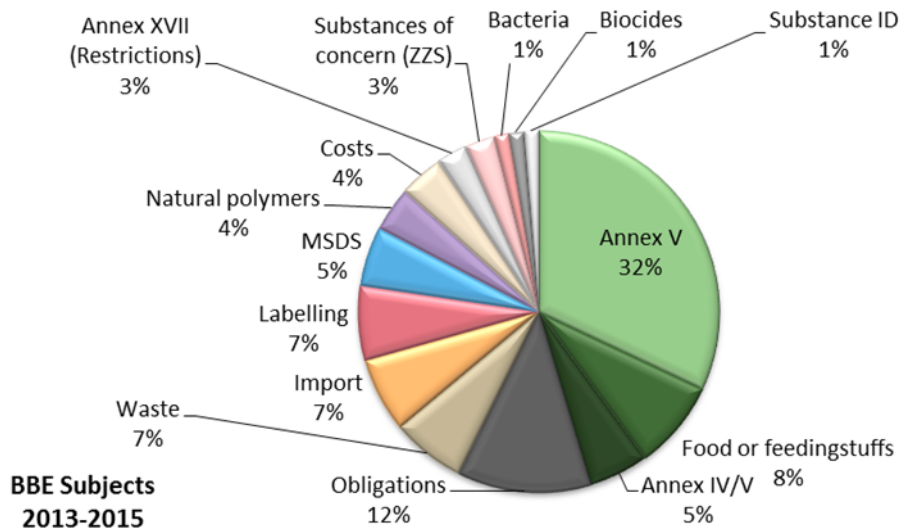


Figure 5: REACH-helpdesk questions related to BBE (2013-2015): categorized by subject

Table 2: BBE relevant REACH helpdesk questions, categorized by subject.

In the first column the subject is stated with the number of total question received, followed by how many different companies asked these questions (in brackets). The second column gives examples of these types of questions and the third column shows the roles of the companies in the supply chain. These (and more) questions are discussed (specifically or general) in the chapters 3 to 6 of this report.

| Question categories (# questions, companies)* | Examples | Asked by |
|--|---|--|
| Exemptions Article 2 • Annex IV/V (4,4) • Annex V (24,23) • Food or feedingstuffs (6,6) | My compound is similar to one listed in Annex IV, should I register? My compound is a natural product, is it exempted from REACH? If I use food ingredients for other applications (pure, mixed or modified) than consumption, do I need to register? | • (Annex IV/V) Importers, Producers • (Annex V) Importers, Producers, Downstream Users • (Food) Importers, Producers, Downstream Users |
| Obligations (9,9) | What do I have to do to comply to REACH? | Importers, Producers, Downstream Users |
| Waste (5,5) | I recycle/re-use waste, do I need to register for REACH? | Importers, Producers, Downstream Users |
| Import (5,5) | Do I need to register cut wood, wooden products, bacteria, (raw) natural materials if / when I'm importing? | Importers, Producers, Downstream Users |
| Labelling (5,5) | Do I need to label? Is my label correct? | Importers |
| MSDS (4,4) | Which emergency number should I report? Which ingredients need to be on the MSDS? | Importers, Producers |
| Natural polymers (3,3) | Do I need to register my polymer | Importers, Producers |

| Question categories (# questions, companies)* | Examples | Asked by |
|--|--|----------------------|
| Annex XVII (Restrictions) (2,2) | and/or its constituents/impurities from natural origin? My compound is natural, does it need to be registered? What are the allowed applications for a certain restricted compound? | Downstream Users |
| Substances of concern (ZZS) (2,2) | A substance of concern is/maybe used up the chain: will it cause exposure? Do I need to report this substance? | Importers |
| Bacteria (1,1) | Do I need to register for REACH when importing bacteria? | Importers |
| Biocides (1,1) | Do approved biocides need to be registered for REACH? | Importers, Producers |
| Substance ID (1,1) | I've found several consortia that have registered a natural group of substances, but with all different EINECS numbers, what can be done? | Importers |

* Please note that there may well be more BBE relevant questions asked than listed in this table. The inquiries listed here were found because they could be linked directly to the bio-based economy, based on the keywords listed in Table 1. The results presented here are semi-quantitative.

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