Letter to customers outside the European Economic Area (EEA)

Dear customer,

Subject: REACH and DuPont

DuPont’s intention to support customers outside the European Economic Area (EEA)

This communication related to REACH focuses on the intend of DuPont to support customers located outside the European Economic Area (EEA). We have compiled some typical situations and have outlined the response of DuPont to ensure that our customers comply with the REACH regulation.

Important remarks:
The following comments refer to DuPont Performance Materials business only. Other DuPont Businesses may operate in other business environments and therefore may have to adopt other approaches than our Polymers Businesses.

We are assuming that none of the chemicals we use in our polymer compounds is listed on the ‘Candidate List of Substances of Very High Concern for Authorisation’. If a substance present in our materials is or becomes reportable through the ‘Candidate List’, we will contact our customers.

We are assuming that none of our polymer compounds contains substances which, based on the function of typical articles produced, are intended to be released under reasonably foreseeable conditions of use of such articles.

We provide the information below for use of our polymers / polymer compounds on their own without addition of other chemicals.

The following situations describe typical relationships between DuPont and its customers. With the globalisation of our businesses, products sold anywhere in the world may end up in Europe and consequently may fall under the REACH regulation.

Our intentions indicated below provide the general approach DuPont will follow for its Polymers Businesses. Exceptions may exist. Please contact your DuPont representative as early as possible if DuPont needs to get involved in your REACH activities as per described situations.
Situation 1:
A Non-European customer purchases our polymer compound and produces 'Articles' outside the European Economic Area (EEA). These articles are then imported back into the European Economic Area (EEA). Our polymer compound has been produced in the European Economic Area (EEA) and exported by DuPont to the non-European country in which our customer operates.

-> 'Articles' (under the above assumptions) are exempt from REACH and therefore REACH will not impact the non-European customer or the importer of the articles into the European Economic Area (EEA). The origin of the polymer compound is not relevant. In this situation, the raw material manufacturer(s) already have made the pre-registration / registration of the substances used in the European Economic Area (EEA) to produce the polymer compound. The article manufacturer has no obligation for compositional disclosure or the importer for registration under REACH.

Situation 2:
A Non-European customer purchases our polymer compound and produces 'Articles' outside the European Economic Area (EEA). These articles then are imported into the European Economic Area (EEA). Our polymer compound has been produced outside the European Economic Area (EEA).  

-> 'Articles' (under the above assumptions) are exempt from REACH and therefore REACH will not impact the non-European customer or the importer of the articles into the European Economic Area (EEA). The origin of the polymer compound is not relevant. In this situation, neither the raw material manufacturer(s) nor the article manufacturer has an obligation for compositional disclosure or the importer for pre-registration / registration under REACH.

Situation 3:
A Non-European customer purchases our polymer compound in the European Economic Area (EEA), exports the polymer compound and produces 'Articles' outside the European Economic Area (EEA). These articles then are imported into the European Economic Area (EEA). Our polymer compound has been produced in the European Economic Area (EEA).

-> 'Articles' (under the above assumptions) are exempt from REACH and no obligation exists for the non-European customer or the importer of the articles into the European Economic Area (EEA). The origin of the polymer compound is not relevant. In this situation, the raw material manufacturer(s) already have made the pre-registration / registration of the substances used in the European Economic Area (EEA) to produce the polymer compound. The article manufacturer has no obligation for compositional disclosure or the importer for pre-registration / registration under REACH.

Situation 4:
A Non-European customer purchases our polymer compound in the European Economic Area (EEA), exports the polymer compound and produces 'Articles' outside the European Economic Area (EEA). These articles then are imported into the European Economic Area (EEA). Our polymer compound has been produced outside the European Economic Area (EEA) and had been imported by DuPont into the European Economic Area (EEA) prior to customer’s purchase.

-> 'Articles' (under the above assumptions) are exempt from REACH and no obligation exists for the non-European customer or the importer of the articles into the European Economic Area (EEA). Neither the origin of the polymer compound nor the identity of the importer of the polymer compound is relevant. In this situation, DuPont as the initial raw material importer already has made the pre-registration / registration of the substances contained in the polymer compound. The article manufacturer has no obligation for compositional disclosure or the importer for pre-registration / registration under REACH.
**Situation 5:**
A Non-European customer purchases our polymer compound and produces a 'Preparation' (e.g. master batch) outside the European Economic Area (EEA). This 'Preparation' then is imported into the European Economic Area (EEA). Our polymer compound has been produced in the European Economic Area (EEA) and exported by DuPont to the non-European country in which our customer operates.

Step 1: Polymer compound produced by DuPont (1) in the EEA.
Step 2: Polymer compound exported to non-EU Formulator (2); non-EU formulator uses polymer compound to produce e.g. a polymer master batch in the non-EEA region.
Step 3: Polymer master batch is imported e.g. by an EU-Converter (3), who is the customer of (2); the polymer compound in that master batch thus is re-imported into the EEA.

-> ‘Preparations’ are subject to the REACH regulation. The importer (here the EU-Converter (3), customer of the non-European Formulator (2)) has the obligation to pre-register and to register. Considering that the polymer compound in the 'Preparation' was provided by DuPont (i.e. carrier of the master batch) and as the polymer has been manufactured in the European Economic Area (EEA), all registration obligations will have been completed by DuPont (or its suppliers). DuPont will provide the non-European formulator (2) or the importer (3) with the appropriate information to demonstrate that registration has been completed as well as with use conditions. However, the non-EU Formulator (2) must inform DuPont of the re-import of the DuPont polymer compound into the European Economic Area (EEA) in order to obtain this information. There is no requirement for compositional disclosure under REACH.

However, a so called double pre-registration* of the monomers / substances in the re-imported polymer compound is required to be done by the importer (3) until the registration by DuPont (or its suppliers) has been completed.

*Reference: ECHA News Alert: ECHA/PR/08/32
Please contact your DuPont representative as early as possible if this case applies to you!

**Situation 6:**
A Non-European customer purchases our polymer compound and produces a 'Preparation' (e.g. master batch) outside the European Economic Area (EEA). This 'Preparation' then is imported into the European Economic Area (EEA). Our polymer compound has been produced outside the European Economic Area (EEA).

Step 1: Polymer compound produced by DuPont (1) outside the EEA region.
Step 2: Polymer compound used by non-EU Formulator (2) to produce e.g. a polymer master batch in the non-EEA region.
Step 3: Polymer master batch is imported e.g. by an EU-Converter (3), who is the customer of (2); the polymer compound in that master batch thus is imported into the EEA.

-> ‘Preparations’ are subject to the REACH regulation. The importer (here the EU-Converter (3), customer of the non-European Formulator (2)) has the obligation to pre-register and to register. Considering the polymer compound in the 'Preparation' provided by DuPont (i.e. carrier of the master batch) was produced outside the European Economic Area (EEA), no registration will have been made. DuPont will make a business decision whether or not to act as 'Only Representative' for that polymer compound exported by the non-European formulator (2) to the European Economic Area (EEA). In those cases where DuPont shall act as the 'Only Representative', the non-EU formulator (2) should provide import volumes, use and exposure information related to the use of the polymer compound in the European Economic Area (EEA). This includes all downstream uses (formulator’s customer etc. - down the supply chain). DuPont will perform the registration and provide the non-European formulator (2) or the EU-importer (3) with the appropriate information to demonstrate that (pre-) registration has been completed.
DuPont may also decide to disclose the polymer compound composition and other information to the non-EU formulator (2). The non-EU formulator then might decide to appoint an ‘Only Representative’ for the purpose of registering the substances in the polymer compound or pass on the information to his customer, the EU converter (3), to enable (3) to make his own registration of the substances in the polymer compound.

-> Where DuPont decides neither to act as ‘Only Representative’ nor to disclose compositional information, the non-EU formulator (2) on his own behalf could develop the required data on his own where possible and make a registration. For this purpose he will need to appoint an ‘Only Representative’ in the European Economic Area (EEA) (as he is not located in Europe).

Please contact your DuPont representative as early as possible if this case applies to you!

Situation 7:
A Non-European customer purchases our polymer compound and imports the material into the European Economic Area (EEA). Our polymer compound has been produced in the European Economic Area (EEA) and exported by DuPont to the non-European country in which our customer operates.

-> DuPont will offer the customer the possibility of directly purchasing the polymer compound in the European Economic Area (EEA). In this way no registration obligations will fall on our customer, but DuPont will bear this responsibility.

Situation 8:
A Non-European customer purchases our polymer compound and imports the material into the European Economic Area (EEA). Our polymer compound has been produced outside the European Economic Area (EEA).

-> DuPont will ask the customer to directly purchase the polymer compound in the European Economic Area (EEA) (if available from an alternative DuPont source in Europe). If the polymer compound is not produced by DuPont in the European Economic Area (EEA), we will make a business decision whether or not to support the business at this customer by offering a similar product grade i.e. DuPont will initiate production at a European factory or import the polymer compound itself and offer it for sale to the customer within Europe.

-> DuPont in general does not intend to disclose the polymer compound composition and other information the importer would need to make his own registration.

-> Where DuPont is unable to assist the customer in this way, the customer could develop the required data on his own (where possible) and make a registration. For this purpose he will need to appoint an ‘Only Representative’ in the European Economic Area (EEA).

Please contact your DuPont representative as early as possible if this case applies to you!

Definitions:
(Regulation EC 1907/2006, Chapter 2, Article 3)

Substance means:
a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

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Preparation means:
a mixture or solution composed of two or more substances.

Article means:
an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

Should you have any question regarding the content of this letter, or any other REACH related subject, please do not hesitate to contact us.

Yours faithfully,

Dr. Stefan Dully
Regulatory Affairs Manager, DPM, EMEA

This information is based on our current level of knowledge and expresses only our intention. It does not constitute a binding obligation. Whilst the information is provided in good faith, no representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information. As we cannot be aware of all aspects of your business and the impact REACH Regulation may have on your company, we strongly encourage you to get familiar with REACH, its requirements and timelines.

DuPont has no intention to change its product portfolio of polymer offerings due to the introduction of REACH under the condition, that REACH does not impose commercial or technical burden, which could impact the health of our business. However, since DuPont depends on its suppliers, DuPont is not in full control of this decision. Based on industry assessments, it is likely that a certain number of chemicals will no longer be available to the European market. This may necessitate product reformulation, and subsequent product / article re-qualification, or, in more critical cases, to a complete product change.

For your information, please see also the REACH web site of the EU commission: http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm
Attachment

General REACH Information
(Registration, Evaluation, Authorisation of Chemicals)

As part of our communication process, we would like to inform you about the position and the activities that DuPont has undertaken in regard to the proposed EU Regulation on Chemicals called REACH (Registration, Evaluation, Authorisation of Chemicals). For more background information, please consult the webpage of the European Chemical Industry Council CEFIC1).

The REACH Regulation has been finalized as Regulation EC 1907/2006 and has entered into force on 1 June 2007 after being published in the Official Journal of the European Union on 30 December 20062):

DuPont's Businesses are in the process to assess all chemical substances, manufactured or imported in the EEA, that could be subject to any part of the REACH Regulation, whether substances on their own or present in preparations or articles. DuPont is fully committed to work with its customers and suppliers along the entire supply chain to develop workable solutions to comply with REACH.

Consistently with the Responsible Care® code of Product Stewardship, we remain fully engaged in the debate around the implementation rules for REACH to ensure that the final application of the Regulation is targeted towards an acceptable cost/benefit balance, that animal testing is minimised and that the traditional aspects of quality, safety and environmental protection are preserved.

1)  http://www.cefic.org/Templates/shwStory.asp?NID=494&HID=444&PHID=441

European Economic Area (EEA):
The European Economic Area includes the European Union Member States and Iceland, Liechtenstein and Norway.
Supply Chain Related Questions

1. REACH concerns hazardous and non-hazardous chemical substances. Most of our products are either preparations (polymer compounds or paint formulations) or articles (e.g. parts & shapes) under REACH terminology. All the substances in preparations, and some in articles, need to be registered if manufactured in or imported into the European Economic Area (EEA).

2. In principle, REACH does not concern finished products, i.e. articles, even if produced from chemical substances or preparations. However, should a substance in an article be subject to intended release (example: the substance(s) included in a ‘scented’ eraser), then a registration of that particular substance(s) is required.

   For substances, included in an article, which are of very high concern (example CMR’s, or PBT’s or vPvB’s) the authorities need to be informed. This is the case if these substances exceed the concentration threshold of 0.1 weight percent in the article, even though they are not intended to be released. This includes all cases in which the release of such substance(s) be excluded during the waste treatment of the article. The authorities might take the decision to require a full registration of these substance(s).

3. DuPont uses chemical substances, which are often not produced by DuPont, but by other chemical companies. Consequently, the DuPont use depends on the REACH registration of these other chemical companies.

4. If a DuPont supplier is located outside the EEA, then this supplier cannot register the substances in the EEA himself, but only through a legal entity within the EEA. This means an additional burden passes to DuPont as importer of substances into Europe or alternatively on to DuPont’s suppliers (who may want to appoint an “Only Representative” to release DuPont and other customers from the burden of registration). Non-EU suppliers will probably be less knowledgeable about REACH, and it could be difficult to obtain either their decision to register their substances in the EEA or to obtain the information necessary for DuPont to make the registration in a timely manner. This could impact any importer into the EEA and also converters importing directly from outside the European Economic Area (EEA).

5. The REACH registration requirements are stretched out over several years up to 2018, depending on the tonnage put onto the European market.

6. Any substance falling under either ‘authorisation’ or ‘restriction’ based on its hazard characteristics and risk assessment will be limited to or excluded from specific uses.

8. New product developments already consider REACH issues as far as these are known today.

9. At this point in time the industry is working closely together to make REACH workable. Concerning the direct work for substance registration, assessment and approval, industry groups have been formed to share and develop the necessary data and to avoid in that way repetition of data development and animal testing.

10. REACH requires an active communication process up and down the supply chain. This includes the obligation for customers to provide information concerning the use of the products of DuPont.

11. DuPont has developed a structured communication process to assist with interaction with its customers, to enable a smooth implementation of all elements of the REACH regulation. DuPont has established and maintains an active communication process with its customers on relevant REACH matters (www.reach.dupont.com).
12. REACH is a regulation, which concerns the registration of chemical substances for manufacturing in or import into the European Economic Area (EEA). Any substance purchased and used outside the European Economic Area (EEA) is in principle not subject to REACH. Finished or semi-finished products (technical term ‘article’\(^3\)) which are (i) manufactured with materials purchased outside the EEA and (ii) imported into the EEA are not subject to registration under REACH with the following two exceptions if: they contain ‘Substances of very high concern’ (SVHC) or if they contain substances which are intended for release. SVHC and / or substances intended for release may bear obligations in terms of notification, information and registration; the content of these obligations is related to the importer and his operation.

As appears from the above, the REACH regulation is not only linked to chemical substances but also to certain conditions of manufacture, use and import. Therefore, a generic ‘REACH compliance certification’ from the producer for a given substance cannot be provided.

The list of SVHC (‘Candidate List of Substances of Very High Concern for Authorisation’) is published by the European Chemical Agency (ECHA) (http://echa.europa.eu/web/guest/candidate-list-table), DuPont communicates the presence of any SVHC above the regulated threshold limit to its customers, including those located outside the European Economic Area (EEA) and selling their finished or semi-finished articles into the European Economic Area (EEA). The list of SVHC is periodically amended.

From all information provided above it can easily be deduced that raw materials will face increased costs. Additional costs will arise due to the need for material changes, reformulation, changes of manufacturing processes, re-approval of materials and articles. These costs will occur on each step of the supply chain.

\(^3\): Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

If unclear whether your product is considered an article or a preparation, please consult your DuPont partner.

\(^4\) CMR category 1 or 2 substances (as to be considered under REACH Article 57) are either

- substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC
- substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC
- substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

\(^5\) For PBT criteria, please see Annex XIII of REACH Regulation EC 1907/2006.

\(^6\) For vPvB criteria, please see Annex XIII of REACH Regulation EC 1907/2006.