Results of the project:

Model Agreement for a contract between an Only Representative and a non-Community manufacturer pursuant Article 8 REACH

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with the collaboration of the members of the VCI working groups "Legal issues of chemical policy" and "REACH – questions/interpretatations"

Commissioned by the Verband der chemischen Industrie e.V. (VCI)

Frankfurt a.M., July 2008

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N o t e

This Model Consortium Agreement was developed on the basis of the practical and legal experience of the aforementioned law firm and the Project Group. Consequently, the Model Agreement cannot and does not reflect all possible constellations and problems occurring under actual conditions. Therefore, the Model may not be used as a standardised form for a consortium agreement. Rather, it is to be used as a guideline and sample. In each specific case, a separate review must be conducted to determine whether the provisions of the relevant Model Agreement are appropriate under practical and legal aspects and whether any other provisions are required and suitable.

The Model Agreement is based on Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 and on the European law in force (legislation and court rulings). Adjustments may be necessary in order to comply with the national law applicable according to Section VIII. par. 2.1 of the Model Agreement.

Model Contract

for

an Agreement between an Only Representative and a non-Community manufacturer

pursuant to Article 8 REACH

between

1. XY ... [non-EC manufacturer] **- XY -**

und

2. The OR …..
   represented by ..... **- OR -**

I.

Pursuant to the REACH Regulation[2] substances may only be manufactured or placed on the market in the Community if they have been first registered by the manufacturer or importer in accordance with the provisions of REACH. A manufacturer who is not established in the European Community (hereinafter "EC") and who exports or intends to export into the EC (hereinafter "non-EC manufacturer") may, pursuant to Article 8, appoint a natural or legal person established in the EC to fulfil, as his Only Representative, the obligations of importers under REACH. In such case the importers within the same supply chain (hereinafter "importers/customers") shall be regarded as downstream users for the purposes of REACH.

XY's aforementioned headquarters are located outside of the EC; XY is a manufacturer of the substance [HvH1]... *[name of the substance with the chemical name]* [optional: the group of substances ... *[name of the group of substances with the chemical name]* in his production site(s) in .....*[location outside the EC]* . The substance is a phase-in substance within the meaning of Article 3 No. 20. [alternatively: the substance is a non-phase-in substance.]

XY ...
[*Alternative for phase-in substances*: XY exports the substance in annual quantities of .... *[approximation: a figure based on the tonnage bands as found in Article 23 is sufficient]* into EC territory.] The import of the substance is thus subject to (as of June 1, 2008) registration obligation pursuant to Article 5 ff; for pre-registered substances the transition deadlines of Article 23 apply.

[*Alternative for non-phase-in substances*: XY intends to export the substance in annual quantities of.... *approximation: a figure based on the tonnage bands of Article 12 is sufficient]* into EC territory. Registration pursuant to Article 5 ff must take place prior to the first delivery into the customs area of the EC.]

Moreover, the requirements for the information pertaining to the supply chain, pursuant to Title IV (Article 31 ff) must be fulfilled.

OR is established in the EC and has sufficient experience in handling substances as required in Article 8 (2).

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Commission Regulation (EC) No 1488/94, Council Directive 76/796/EEC as well as Council Directive 91/155/EEC, 93/105/EC and 2000/21/EC ("REACH Regulation "), Official Journal No. L 396 of 30.12.2006 p. 1 – hereinafter: "REACH"; any reference to articles in this Agreement, unless otherwise indicated, should be understood as those of REACH.

Now, therefore, XY and OR agree as follows:

II.

1. Mandate and Appointment

(1) XY appoints OR as his Only Representative (pursuant to Article 8) under the terms and conditions of this contract for the substance ..... *[name of the substance with the chemical name, including CAS and EINECS numbers]* in accordance with the specification of the substance laid down in **Annex 1** [HvH2]**(**- hereinafter: the Substance).

(2) OR shall be engaged, as the Only Representative of the Substance, solely for XY [optional: and for following other non-EC manufacturers of the substance affiliated to XY... name and address]. An activity as the Only Representative of other non- EC manufacturers for the Substance requires the prior written consent of XY[HvH3].

(3) [optional: OR will – if and insofar as legally permissible – act as third party representative, pursuant to Article 4, for XY for all proceedings under Article 11, Article 19, Title III and Article 53 and, in this context, shall not disclose the identity of XY [HvH4].]

(4) In order to fulfil its contractual obligations OR is entitled to commission and subcontract with third parties (especially external experts). [Optional: OR commissions, in conjunction with XY, an independent trustee pursuant to the provisions of **Annex 2** ... of this contract to accept information from XY (or from a third party named by XY) and to keep it available and to present it (on behalf of OR) if requested to the European Chemicals Agency (ECHA), to national authorities or even to other third parties; OR shall receive instruction in an anonymous form from the trustee as soon as and to the extent that such information has been obtained by the trustee[HvH5].]

2. Tasks and obligations of OR

(1) OR assumes all rights and obligations of an Only Representative pursuant to Article 8. In particular, OR assumes the obligations as set out in paragraphs (2) – (8) of this section.

(2) *(Alternative for phase-in substances:* OR must pre-register the Substance, in accordance with the provisions of Article 28, and must submit to ECHA the registration dossier no later than three months prior to the deadline (i.e. at the latest on ... Date ...), which pursuant to Article 23 applies to the whole quantity of the Substance directly or indirectly [HvH6]delivered by XY into the EC, as far as covered by this Contract[HvH7].

(Alternative for non-phase-in- substances: OR must submit to ECHA the registration dossier for the Substance by ... [place here the agreed upon date].

(3) For a registration under paragraph (2) above, OR shall compile the registration dossier pursuant to the provisions of Article 10, and in particular:

- make use of the information which XY has provided on Substance properties and on identified uses[HvH8].

- fulfil the legal obligations for data sharing under Title III of REACH, in particular in a SIEF according to Articles 29, 30 of REACH, as well as for the joint submission of data (Articles 11, 19).

- upon request of XY participate in a consortium for the joint registration of the Substance.

- carry out testing activities necessary for the compliance with the registration requirements according to REACH [HvH9]either alone or, dependant on legal or contractual obligations within a consortium provided however such testing cannot be waived under Annex XI of REACH.

- in consultation with XY communicate with the importers/customers which have been directly or indirectly (e.g. from the formulator of a preparation outside of the EC) supplied by XY[HvH10] fulfilling requirements of Title V of REACH (Downstream Users) in order to obtain other information necessary for the compliance with registration requirements (e.g. use and/or exposition data). [optional: The independent trustee commissioned in accordance to section II.1.4 second sentence of this Agreement has to be involved appropriately.]

(4) OR is commissioned and obligated to fulfil the obligations on importers under Title II of REACH (registration), under Title VI of REACH (dossier and substance evaluation) as well as (if relevant) under Title VII (authorisation) and Title VIII (restrictions) of REACH.

(5) OR is commissioned and obligated to update any and all relevant registrations to the extent that such is necessary (Articles 22, 12 (2)).

(6) OR is commissioned and obligated in consultation with XY to provide the importers/customers which have been directly or indirectly (e.g. from the formulator of a preparation outside of the EC) supplied by XY[HvH11] the safety-data sheet according to Article 31 of REACH and to update it[HvH12]; OR must in consultation with XY also take care of other obli-

gations of importers concerning information in the supply chain (Articles 31, 32). OR is commissioned and obligated to notify the importers/customers (upon request) whether and to what extent their imports are covered each year by OR's registration provided importers/customers notify to OR their actual per-year imports – if relevant, confidentially[HvH13]. OR shall distribute, accordingly, certificates for customs clearance and for other regulatory requirements. If importer/customer is not a direct customer of XY, the notification of importer/customer to OR on his actual per-year imports must not be made known to XY. [Optional: The independent trustee established in accordance to section II.1.4 second sentence of this Agreement has to be involved appropriately.]

(7) OR is commissioned and obligated to keep available and up-to-date information

- on the Substance,
- on quantities imported and customers sold to, as well as
- information on the supply of the latest update of the safety data sheet.

In addition OR is commissioned and obligated to assemble and keep available information in accordance to Article 36. [optional: If, according to section II.1.4 second sentence of this Agreement an independent trustee is involved, OR fulfils the obligations laid down to sentence 1 and 2 above within the agreed-upon scope of the trustee.]

[optional: (8) The aforementioned actions of OR are subject to the written approval of XY if requiered by section II. 5 of this Contract[HvH14].]

[optional: (9) OR shall submit without delay, no later than ..., a written measures and time schedule (hereinafter MTS) and shall clear such with XY. The MTS must be based upon the relevant legal requirements. Necessary changes of the MTS shall be agreed upon if needed[HvH15].]

(10) OR shall advise XY on what actions and measures are to be taken by XY for an only representation that meets [optional: the requirements of the MTS as well as]the relevant legal requirements, in particular on the information and cooperation requirements in accordance with section II. 3 of this Contract.

3. Tasks and obligations of XY

(1) XY shall provide OR [optional: without prejudice to the provisions in section II. 5 of this Agreement] all available information regarding the Substance, which is needed for OR to carry out his tasks and duties. This concerns without limitation all information:

- for the compiling and updating of the registration dossier (Article 10, 12 as well as Annexes VI to XI REACH);

- for the compilation and updating of the chemical safety report (Article 14/ Annex I REACH).

- for the compilation and updating of the safety data sheet in accordance with Article 31 and Annex II of REACH as well as for the compilation and updating of the information under Article 32.

The studies (Article 3.27 of REACH) and/or the (robust) summaries (Article 3.No. 28 and 3.No. 29 of REACH) already at the disposal of XY are listed in **Annex 3.**

(2) XY shall provide OR [optional: to OR's trustee under section II.1.4 second sentence of this Agreement] without undue delay [optional: according to MTS] the required information on importers/customers which have been directly or indirectly (e.g. from the formulator of a preparation outside of the EC[HvH16]) supplied by XY. [optional: The current status in this regard is laid down in **Annex 4**.]

(3) XY shall update the information described above immediately as soon as he has access to new information.

(4) XY shall without undue delay inform [optional: via the independent trustee appointed in accordance to section II. 1 (4) of this Contract] the importers/customers which have been directly or indirectly (e.g. from the formulator of a preparation outside of the EC[HvH17]) supplied by XY and which are affected by this Agreement [HvH18]about the appointment of OR as Only Representative pursuant to the model as found under **Annex 5.** XY shall ensure that the importers-customers cooperate with OR pursuant to Article 8. XY shall, therefore, take all measures necessary vis-a-vis the importers/customers.

(5) XY shall support OR in every respect in the performance of his tasks and the fulfilment of his duties as Only Representative, specifically for any relevant required declarations (e.g. authorisation for OR) to be given to importers/customers or third parties.

(6) In the EC, XY shall supply the Substance exclusively according to the specifications corresponding to the information given to OR and to the registration carried out by OR – to be updated if necessary – as well as the data in the safety data sheet provided by OR to importers/customers. XY shall not supply importers/customers, if there is reason to believe that such customers would use the Substance for purposes not foreseen or supported in the registration, unless the importers/customer(s) can provide proof of fulfilment of their obligations to prepare a chemical safety report of the Substance pursuant to Article 37.4 of REACH and to inform ECHA pursuant to Article 38 of REACH. XY shall, in view of the described duties, take hints/advise from OR.

4. Information Exchange and Cooperation

(1) XY and OR shall comprehensively, promptly and in a timely manner cooperate and carry out the exchange of information or coordination [optional: in accordance with the MTS]. For the purposes of implementation, they duly appoint the following contact persons:

- For XY: ...

- For OR: ...

(2) OR shall inform XY in writing on a regular basis, at least once per quarter, of the status of the performance of the mandate, in particular on compliance with the MTS. Additionally, information shall be provided separately on any important matters. Important matters include, in particular but not limited to[HvH19]:

- circumstances that could result in cost-relevant decisions being taken beyond the cost limits;

- circumstances which might necessitate the provision of data or studies to third parties (e.g. pursuant to Articles 11, 19, 27, 30 and/or in a consortia).

(3) OR shall perform his tasks and fulfil his obligations as the Only Representative of XY on his own responsibility. In the event that OR would need to act as a formal representative of XY in legal/contractual matters vis-a-vis a third party, XY hereby grants a power of attorney to OR (see **Annex 6**).

5. [optional: Prior written consent[HvH20]

The following actions of OR are subject to the prior written consent of XY:

- The assumption of the role as Only Representative for another non-EC manufacturer of the substance [optional: with the exception of the companies listed in Section II.2.2 of this Agreement[HvH21]];

- The conclusion of contracts with third parties, which contain the duty to provide confidential information of XY (e.g. exchange of confidential substance data in order to assert the sameness of the Substance in a Pre-SIEF[HvH22]);

- Participation in a consortium for a joint registration of the Substance[HvH23];

- The assumption of the function as "Lead Company" pursuant to Articles 11 and 19;

- Conclusion of contracts for generating new studies or the acquisition of usage rights to existing studies of third parties, which would financially burden XY beyond the scope of the approved budget (as contained in Section II.7.7 of this Agreement]

6. [optional:Only Representative for more than one non-EC manufacturer (multiple representations)

Note:

The present model contract does not contain detailed provisions in the event that OR acts as Only Representative for more than one non-EC manufacturer. With the exception of the representation of more than one non-EC-manufacturer within a group of companies (e.g. the EC based parent company and/or a service enterprise of the parent company takes on the role of the Only Representative for all affiliated non-EC manufacturers of the same substance who export into the EC), the representation of other non-EC-manufacturers seems to be problematic, for in such case, competitors would be required to be integrated together. However, if such representation of other non-EC manufacturers is still desired (outside of a group of affiliated companies), the following provisions are necessary:

- ***Discrimination-free, equal treatment of all non-EC manufacturers by OR;***
- ***Establishment of a communication platform among the non-EC manufacturers, the operation of which must be in accordance with competition law; there must be similar safeguards as in a consortium context;***
- ***Separate documentation for each manufacturer, which shall especially demonstrate that the information on the quantities imported and to customers sold to have to be kept absolutely confidential; if relevant, a penalty clause in the contract in case of breach by OR of such duties;***

- ***Clear provisions on the usage rights and on cost sharing for studies of the various non-EC manufacturers when such studies are used for registration.***
- ***Take into consideration that the current view of the ECHA is that a separate (pre-) registration must be filed for each non-EC manufacturer; an accumulation of the quantities does not take place. Presently, however, there are still problems with the IT-tool for the pre-registration.***

7. Reimbursement of expenditures/Budget[HvH24]

(1) OR shall immediately prepare, no later than ..., a budget for the execution of the Only Representative activities [optional: in accord with the MTS]. [optional: The budget shall not exceed the sum of € ... .]

(2) XY shall reimburse OR for all costs related to the execution of its Only Representative activities in accordance with the budget – expenditures to third parties, including administrative fees – up to the total amount of the budget. Within the framework of the budget, OR is entitled to take measures giving rise to expenditures (including legal and contractual transactions with third parties), in an individual case, up to an amount of € ... . Prior consent of XY is needed for actions giving rise to higher expenditures.

(3) OR shall inform XY promptly if it should become foreseeable that the budget will not be sufficient to cover the necessary expenditures; in such case, OR and XY will together establish the future budget.

(4) If OR should take measures falling outside of the budget or without the prior consent of XY, he shall not be entitled to claim reimbursement t for such expenditures.

(5) The agreed-upon financing for the budget shall be provided by XY in adequate instalments in advance. OR shall render account of the appropriation of the budget at the end of each quarter [calendar year?].

8. Remuneration

OR shall receive from XY, for performing his tasks and fulfilling his duties, a remuneration of € ... [under the following conditions: if relevant, establishing individual remuneration for individual areas of activity]. [optional: The remuneration shall be abated in the event of multiple representations as follows: ...]

9. Confidentiality, rights to information

(1) OR shall keep the information/data, which is supplied by XY to OR, strictly confidential. This shall include that the data shall not be used for other purposes than those in the contract, whether commercial or non-commercial, shall not be made available to third parties, unless legal disclosure requirements apply. OR's employees and experts (under Section II.1.4) or other third-party experts may only have access to information to the extent that this is necessary for implementing the contract and that the named persons have contractually or otherwise committed themselves to such confidentiality; the provisions in section II.1.4 second sentence of this Contract t concerning the involvement of an independent trustee remain unaffected. The above-referenced obligations apply, accordingly, for new data/information obtained by OR from importers/customers in accordance with section II. 2.3 last bullet point of this Contract.

(2) The aforementioned duties do not apply for information which was already available to the public prior to receipt, was made available to the public without the help of OR, or was published or made available to the public by way of a law or administrative action.

[optional: (3) When submitting the registration dossier to ECHA, OR shall (in consultation with XY) apply the legal possibilities for the confidential treatment of data[HvH25].]

(4) Studies made available by XY [HvH26]to OR remain in the ownership of XY. OR shall receive the non-transferable rights to use the (robust) study summaries derived from the studies for registrations under REACH and also to refer to these studies. OR is also entitled to grant rights of usage to third parties for the purposes of REACH within a SIEF or a consortium, unless this has been expressly prohibited by XY when providing the usage rights to OR[HvH27]; any reimbursement of costs collected in this way shall belong to XY.

[optional[HvH28]: (5) So far studies are generated in the performance of this contract by OR either alone or in the context of a SIEF or a consortium, OR shall hold the rights on such studies as trustee for XY; in the relationship between XY and OR, XY is regarded as the beneficial proprietor or co-proprietor. XY shall receive from OR the full study report as soon as this becomes available. Subject to para. (7) upon request by XY, OR shall transfer free of charge his right(s) to such studies to XY or a third party designated by XY, and if it has not already taken place, shall also provide the original studies. Upon XY's request, OR is obligated to inform the authorities – especially the ECHA – in writing (or in another relevant required form) of any such assignment of rights.]

[optional[HvH29]: (6) In as far as OR receives usage rights on the studies of third parties – e.g. in the context of a SIEF or a consortium – for the registration pursuant to REACH, OR shall also hold these rights for XY as a trustee. Subject to para. (7) OR shall transfer, upon XY's request, his rights on these studies to XY or to a third a party designated by XY. OR is obligated, to inform the authorities – especially the ECHA – in writing (or in some other relevant required form) of any such assignment of rights.]

(7) In contractual negotiations with third parties (e.g. in consortium contracts[HvH30]), OR shall be responsible to ensure that:

- a clause is included in the contract where the replacement of OR by another Only Representative is made possible without payment of a "late entrance fee",

- a clause is included in the contract in which it is possible to transfer the usage rights on studies in the event that XY would replace OR by another Only Representative.

10. Compliance with Competition Law

(1) Insofar as an exchange of data and studies (on the part of OR) with competitors of XY is necessary (e.g. pursuant to Articles 11, 19, 27, 30 and in consortia) [optional: and especially in cases of multiple representations of non-EC-manufacturers under Section II.6), OR shall strictly abide by the competition-law rules of Articles 81 and 82 of the Treaty[HvH31].

(2) OR is entitled, within budget provisions as set out in section II. 7 of this Contract , to obtain advice or assistance from external consultants to avoid actions which violate competition law.

(3) [if relevant: penalty clause]

11. Liability and Warranty

(1) OR shall exercise the care that is customary in practice for the performance of the mandate. There shall be no liability on the part of OR in the event that XY does not fulfil (or does not fulfil in due course) his information duties pursuant to section II. 3 of this Contract. OR does not warrant that the ECHA will accept the registration which OR submits, to the extent that such rejection cannot be traced back to a breach of OR's obligations.

(2) XY indemnifies OR, to the extent such indemnification does not contradict applicable laws, from any punishment or fines for violations of laws or administrative regulations which are based upon faulty or insufficient information given by XY or upon insufficient rights of

disposal of XY to information provided to OR. Furthermore, XY indemnifies OR against liability to third parties related to insufficient rights of disposal of XY to information provided to OR.

(3) The liability for financial losses in this contract is limited to € ... . OR hereby assures XY that he has taken third party liability insurance within the above-referenced amount [HvH32][possibility of other or additional securities?].

12. Termination of the Contract[HvH33]

(1) XY has the right to terminate this contract by giving a one-month notice at the end of a calendar month [optional: within the first six months of its entry into force]. In addition, each party has the right to terminate this contract for good cause with six-weeks' notice given at the end of a calendar month [optional: half year]. A good cause is considered to be, in particular:

- the violation of essential duties under this contract, if the one party has already demanded from the other party at least one time (with a deadline) to fulfil its duties.

- the assumption of an additional activity as Only Representative of a non-EC-manufacturer of the substance by OR without the consent of XY.

- the opening of bankruptcy proceedings related to the assets of OR.

(2) If the Substance has not been registered at the point in time when this Contract is terminated, at the request of XY, OR must do everything reasonable to immediately facilitate the transfer of the Only Representation and the registration of the substance within the deadline by another Only Representative appointed by XY[HvH34].

(3) If the Substance has already been registered when this Contract is terminated, OR must do everything reasonable to facilitate the immediate transfer of the registration to an other Only Representative appointed by XY or, if required by law, the immediate registration of the Substance by another Only Representative appointed by XY[HvH35]. OR herewith declares his approval to the update of the registration in the eventuality of a later change to an other Only Representative appointed by XY; XY will be empowered to update the registration pursuant to Article 22.1 (a) to the ECHA on behalf of OR [optional: based on the power of attorney in **Annex 7**]. In as far as required by law XY and the other Only Representative appointed by XY are entitled to refer to the (robust) study summaries as well as to the full study reports submitted to the ECHA.

(4) In the event of termination of this Contract, OR is obliged to surrender all the information/data received within the performance of this contract by XY, third parties or authorities, in particular documents containing information about the Substance, the quantities imported and the customers sold to and other information as well as the documentation compiled by OR (e.g. safety data sheets, registration dossier, drafts of these documents) to XY or to a third party designated by XY. Insofar as OR requires access to such information to meet his legal duties, OR is entitled to keep copies of such information/data.

(5) In the event of termination of this Contract, OR remains obliged to maintain confidentiality pursuant to Section II.9.1 of this Contract for a period of ... years starting from the point in time that such termination became effective.

(6) In the event of termination on grounds for which OR is responsible, OR shall be entitled to a reimbursement of expenses and to the payment of a reasonable proportion of the remuneration. As a result of any circumstances for which XY is responsible, OR shall also be entitled to the full payment of the agreed remuneration.

13. Arbitration Clause

(1) In the event of a dispute arising out of or in connection with this contract, XY and OR shall first attempt (in good faith) to reach an amicable settlement. Should such amicable settlement fail, XY and OR agree to have their disputes definitely decided by arbitration in accordance with the rules of conciliation and arbitration [optional: of the International Chamber of Commerce in Paris]. The arbitral tribunal shall consists of three arbitrators appointed in accordance with these rules of arbitration. The award of the tribunal shall be final and binding on the parties. The arbitral tribunal is also empowered to decide (with final and binding effect) upon the validity of this arbitration clause.

(2) The costs of arbitration shall be borne equally by XY and OR; any out-of-court costs form each party shall be borne by the respective party s. [Optional: The arbitral tribunal shall decide on the cost of arbitration , including the out-of-court costs of each party, in accordance with the outcome of arbitration]

(3) The language of the proceeding shall be ... The place of the arbitral proceeding shall be ...

14. Applicable Law

This Agreement is subject to the laws of ….[insert country] without giving effect to any rules on conflict of laws.

15. Final Provisions

(1) The legal relationships between XY and OR (in view of the object of this contract) shall be governed exclusively by this contract. Agreements to the contrary do not exist or are ineffective. Side agreements, amendments or additions to this contract, including the relevant annexes, must be in writing; this *written-form* requirement can only be waived in writing.

To the extent that one of the provisions of this contract is unclear, the interpretation that shall apply is the one which comes closest to the intention of the parties expressed in this contract; moreover, should the contract prove to be incomplete, this shall apply accordingly for the supplementary interpretation.

(2) To the extent that provisions of this Contract are invalid or unenforceable, the remaining provisions shall remain valid. In such event the Parties shall replace the invalid provisions by valid provisions which comes close to the invalid provisions taking into account the intention of the parties expressed in this contract; in such event, XY and OR must amend the contract in writing (accordingly) without delay.

....., date	Stuttgart, date .....
.....	.....
für XY	für OR

Annexes 1 - 7

Annex 1

Substance definition

[optional: Annex 2

Tasks of the independent trustee]

Annex 3

existing studies on the Substance

[optional: Annex 4

existing information of XY on the quantities imported and the customers sold to]

Annex 5

model letter on information to customers/importers

Annex 6

power of attorney

[optional: Annex 7

power of attorney of OR to XY to update the registration (on behalf of OR) in accordance to Article 22.1 (a) in case of a later change of the Only Representative]

Seite: 3

[HvH1]Even the non-EC manufacturer of a preparation or of an article, in using the substance relevant to the contract, can appoint an only representative pursuant to Article 8.1 REACH. The contract would have to be (in such case) adapted.

Seite: 4

[HvH2]In Annex 1, the substance/substance group must be precisely specified so as to exactly define the objective of the appointment. This specification should, when possible, already fulfil the requirements under Annex VI.2 REACH.

Seite: 4

[HvH3]The ECHA allows the only representative to represent several non-EC-manufacturers of the same substance; in such a case the only representative has to submit separate registration dossiers and to pay a fee for each registration. There are situations where a multiple representation makes sense, e.g. within a group of affiliated companies (e.g.: when an EC parent company (and/or a service provider of an EC parent company) takes on the role of an only representative for all affiliated non-EC manufacturers of the same substance who export to the EC; such a role can be performed besides the registration of the EC parent company for own manufacturing or importing of the substance). However, it should not be overlooked that a multiple representation outside of the context of affiliated companies carries with it significant problems (e.g. maintaining confidentiality, competition law issues, problems with the allocation of usage rights to studies among the non-EU manufacturers, cost sharing). For this reason, it is recommended in this model agreement to subject multiple representation to the prior written consent of the non-EU manufacturer.

Seite: 4

[HvH4]It must be noted that exercising this option will make the only representation more difficult. In consortiums, the contracting partners will put emphasis to ensure disclosure of the non-EU manufacturers by the only representative – and to possibly refuse entrance without this disclosure.

Seite: 4

[HvH5]The use of a trustee serves to protect confidential business information – e.g. concerning the composition of a preparation, information on uses, on quantities imported or customers sold to. In practice there are constellations in which the only representative itself is part of the supply chain (e.g. as a European manufacturer of the specific substance subject to a duty to register) and for this reason should not be the receiver of confidential information (e.g. information on the European customers sold to by a non-EC preparation manufacturer (supplied by the non-EC-manufacturer of the substance within the same supply chain) who exports to the EC). The trustee would receive the information from the non-EC-manufacturer or from a designated third party (e.g. a non-EC preparation manufacturer) on behalf of OR and would keep the information available for the authorities or for another third party. Such action would be in compliance to Article 8 (see *Fischer*, Opinion, "The Only Representative under REACH", commissioned by VCI, May 2008, p. 14). As every case is unique here, it is recommended to regulate the details in an Annex to the contract.

Seite: 4

[HvH6]The official German REACH helpdesk (BauA) (and more or less the ECHA guidance on data sharing) views it as possible, that an OR can be appointed by a non-EC manufacturer of the substance in cases of the delivery of a preparation to the EC produced by a non-EC-formulator using the substance.

Seite: 4

[HvH7]In practice, there will be cases where the non-EC manufacturer exempts certain customers from the only representation; these customers must, therefore, register themselves.

Seite: 5

[HvH8]The identified uses (defined in Article 3 No.26) shall be included in the registration dossier (Article 10(a)(iii)).

Seite: 5

[HvH9]Only testing listed in Annex VII and VIII is required for registration. Concerning data gaps listed Annexes IX and X proposals for testing must be included in the registration dossier (Article 10 (a) (xi).

Seite: 5

[HvH10]The official German REACH helpdesk (BauA) (and more or less the ECHA guidance on data sharing) views it as possible, that an OR can be appointed by a non-EC manufacturer of the substance in cases of the delivery of a preparation to the EC produced by a non-EC-formulator using the substance.

Seite: 5

[HvH11]The official German REACH helpdesk (BauA) (and more or less the ECHA guidance on data sharing) views it as possible, that an OR can be appointed by a non-EC manufacturer of the substance in cases of the delivery of a preparation to the EC produced by a non-EC-formulator using the substance.

Seite: 5

[HvH12]Pursuant to Article 8.2 sentence 1, OR shall also comply with all other obligations of importers under REACH. Thereby, OR is responsible (under public law) for the conveyance of the safety data sheet to the customers of XY. From a civil law perspective, however, it is only XY who is responsible for all of this (as per the delivery contract with its customer) – this also includes responsibility for the conveyance of the safety data sheet. Hereby the re-conciliation with XY as set out in section II.2 (6) is necessary in order to connect both the public and the civil law spheres.

Seite: 6

[HvH13]OR must treat the information on quantities imported confidential if requested from the importers.

Seite: 6

[HvH14]The clause in section II.2 (8) concerning the prior consent of XY concerning specific actions of OR may be inapplicable in cases of sole representation within a group of affiliated companies.

Seite: 6

[HvH15]The clause concerning the MTP can be inapplicable in cases of sole representation within a group of affiliated companies.

Seite: 7
[HvH16]The official German REACH helpdesk (BauA) (and more or less the ECHA guidance on data sharing) views it as possible, that an OR can be appointed by a non-EC manufacturer of the substance in cases of the delivery of a preparation to the EC produced by a non-EC-formulator using the substance.

Seite: 7
[HvH17]The official German REACH helpdesk (BauA) (and more or less the ECHA guidance on data sharing) views it as possible, that an OR can be appointed by a non-EC manufacturer of the substance in cases of the delivery of a preparation to the EC produced by a non-EC-formulator using the substance. However, it would also be required in such cases that the non-EC manufacturer of the substance notifies the EC customers (of the formulator) of the appointment (Article 8.3). Pursuant to Section II.1.4 second sentence, if a trustee is commissioned, to whom information on the directly or indirectly serviced customers flows, then the notification to the customers concerning the appointment of OR as Only Representative (under Article 8.3) must be carried out by this trustee.

Seite: 7
[HvH18]In practice, there will be cases where the non-EC manufacturer exempts certain customers from the only representation; these customers must, therefore, register themselves.

Seite: 8
[HvH19]These examples may be inapplicable in cases of sole representation within a group of affiliated companies.

Seite: 8
[HvH20]The prior consent clause may be inapplicable in cases of sole representation within a group of affiliated companies.

Seite: 9
[HvH21]See comment 3.

Seite: 9
[HvH22]These types of contracts may, for example, be necessary to determine after the pre-registration whether the substances (submitted for pre-registration) are the same. If not the pre-registrants do not belong to the same SIEF.

Seite: 9
[HvH23]No consent is needed for the participation in the SIEF (as, OR, by law, is a participant in SIEF as long as he has pre-registered) nor for the joint submission of core data under Article 11/19, as this concerns a legal duty. The participation in a consortium takes place, on the other hand, via a contract and normally goes beyond the legal duties set out in Title III REACH and/or Article 11/19.

Seite: 10
[HvH24]In cases of sole representation within a group of affiliated companies, it would seem that modifications of Section II.7 of the Agreement are required, especially when the EC parent company takes on the role of the only representative for its non-EU affiliate.

Seite: 11
[HvH25]See Article 10(a)(xi) REACH.

Seite: 11
[HvH26]In cases of sole representation within a group of affiliated companies (e.g.: an EC parent company takes over the role of the only representative for all non-EC manufacturers of the same substance which export to the EC), this clause would normally not play a role; for normally only the EC parent company disposes of the studies.

Seite: 11
[HvH27]The only representative is, by law, the "previous registrant" under Articles 26 and 27; he is also, after the pre-registration, a participant in SIEF. On the other hand, he is not the "owner" (within the meaning of Article 30) of the studies that XY made available. For this reason, it is questionable whether or not, for example, the obligations as found under Article 30 (to provide studies to other participants in a SIEF) apply to OR. Yet, OR can hardly just play the role of a "receiver" in SIEF; he will also have to be the "provider" if he uses the usage rights on studies of XY for registration. This is even clearer when OR participates in a consortium. For this reason, OR should be empowered in the contract to grant usage rights on such studies to third parties. Only in cases where such right has been expressly refused by XY other solutions (if needed) have to be sought.

Seite: 11
[HvH28]In cases of sole representation within a group of affiliated companies (e.g.: an EC parent company takes over the role of the only representative for all non-EC manufacturers of the same substance which export to the EC), this clause would have to be changed. The EC parent company may be manufacturer of the substance itself and thus has the duty to register. In such case studies that were lacking have to be generated or obtained from third parties in its own interest; the parent company (and not the non-EC affiliate) may become, thus, the owner of this new study. In such cases, therefore, the optional set-up clause does not apply.

Seite: 12
[HvH29]The same goes here as in comment 26.

Seite: 12
[HvH30]It is recommended that the non-EC manufacturer, along side his appointed only representative, may himself become a member in a consortium whereby he may de facto be represented by his only representative. He can also in this way make sure that the replacement of the only representative takes place without complications.

Seite: 12
[HvH31]Here, the "Cefic REACH competition law compliance guidance" can be consulted and used.

Seite: 13
[HvH32]If relevant, XY can require OR to present confirmation that liability insurance exists.

Seite: 13
[HvH33]The termination of the contract cannot be excluded, if this is associated with good cause. Of particular note is that upon the appointing of an only representative under Article 8.1 the importers become downstream users (Article 8.3), and thus do not have to register themselves. This important legal consequence does not apply any longer when the appointment of the only representative is terminated. To protect the importers from such legal effects and avoid problems with the appointment of a new only representative, it is recommended that the importers, in any case, submit the pre-registration themselves; they can then take advantage of the transition periods under Article 23, e.g. if the pre-registration by the only representative fails or (in the event that the representative is replaced) the pre-registration by the new only representative is somehow legally not possible – the application of Article 28.6 is disputed.
For only representatives in cases of sole representation within a group of affiliated companies, diverging provisions (pursuant to section II. 12(1)) are potentially appropriate.

Seite: 13
[HvH34]The new only representative is only a member of SIEF when he has pre-registered or has the right to a late pre-registration pursuant to Article 28.6 REACH. The effect of entering into an existing consortium, in which the former only representative had been a member, will depend upon the contractual terms. At any rate, the replacement of an only representative prior to registration will bring with it problems.

Seite: 13
[HvH35]The ECHA guidance on registration at present (June 2008) views a replacement of an only representative as requiring a new registration; a transfer of the registration to the new only representative is hold not possible. It seems, however, that this position of ECHA changed (see presentation of *Otto Linher*, European Commission, DG Enterprise and Industry, at Cefic REACH Implementation Workshop III, Brussels, 24 June 2008). Now it seems to be sufficient that the earlier only representative agrees to the replacement and the registration is updated pursuant to Article 22.1 (a) REACH (see also *Fluck*, in: Fluck/Fischer/von Hahn, REACH+Stoffrecht, Art. 8 REACH paragraph 22 and *Fischer*, Opinion commissioned by VCI) . The clause in section II.12. (3) of the contract prepares the eventuality of a later change of OR. In addition, it should be considered to issue and sign a power of attorney of OR to XY (**Annex 7)** so that XY can have the change reported (pursuant to Article 22.1 (a) REACH) to the ECHA on behalf of OR.
As a means of precaution, the clause ensures, that XY and the new only representative are entitled to refer to the (robust) summaries as well as to the full study reports registered already by the earlier only representative. So a new registration via the new only representative can be obtained quickly, if necessary.