

IUCLID5

最新情報

2008/07/10

於: デュッセルドルフ商工会議所

日本化学工業協会REACHタスクフォース/JCCE

日化協REACHタスクフォース 島 久治



REACHの目的

- 化学物質の安全な取扱を図ること (Riskベース)
- 域内の自由な物流
- EU内化学産業の強化発展
- 動物愛護

手段

No Data No Market (No registration no market)



当局との情報伝達が重要

Registration(Preregistration),

Notification,

C&L submission,

Authorization submission,

Use submission,

Update of information to ECHA



商流内の情報伝達が重要

Communication in the Supply Chain in REACH

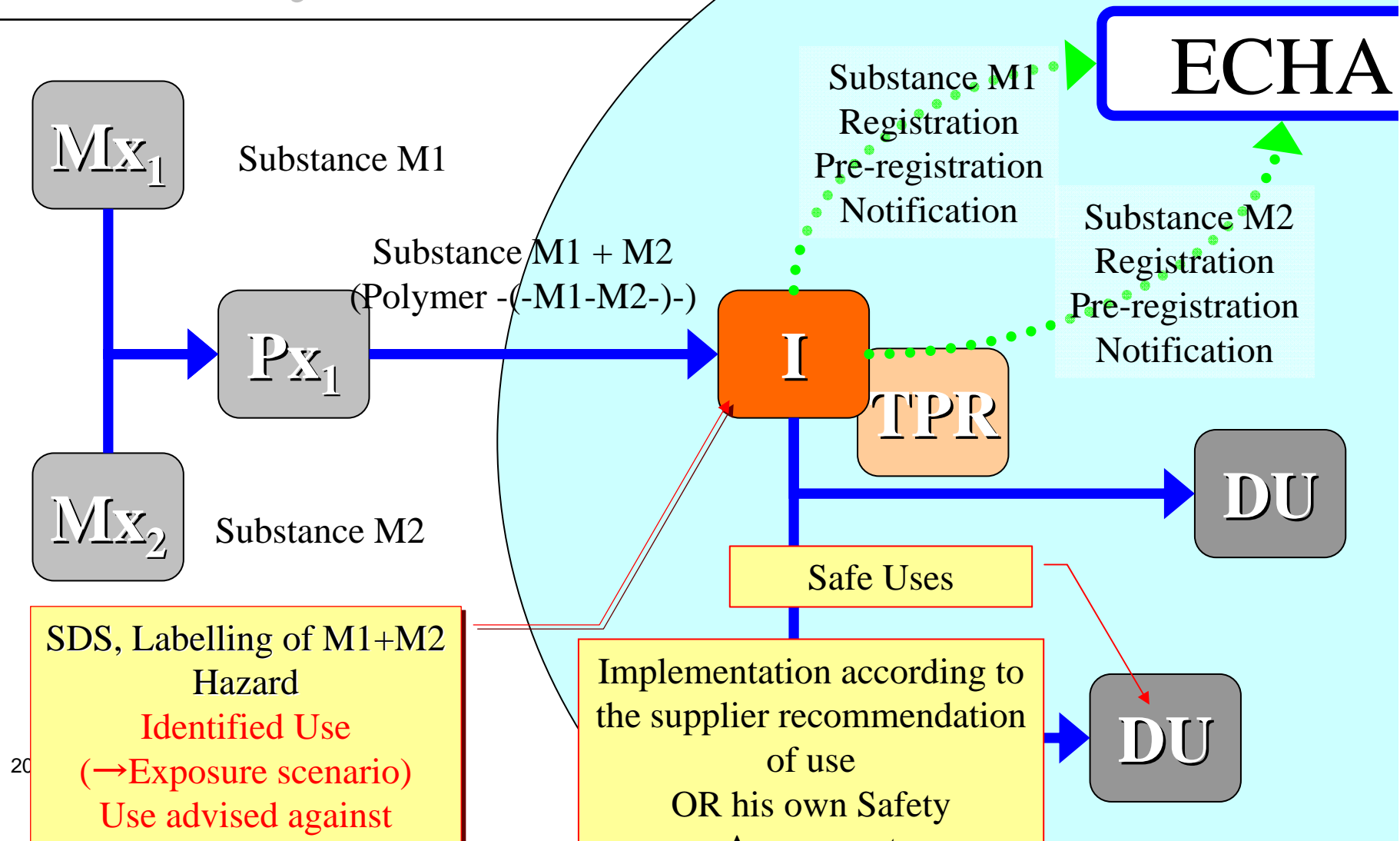
- Hazard Information of the chemical.
 - Classification
 - Dangerous properties (DSD/DPD) - Classification
 - PBT, vPvB, 同等の危険性
 - Labelling, SDS
- Exposure/Use information
 - Identified Uses
 - Uses advised against



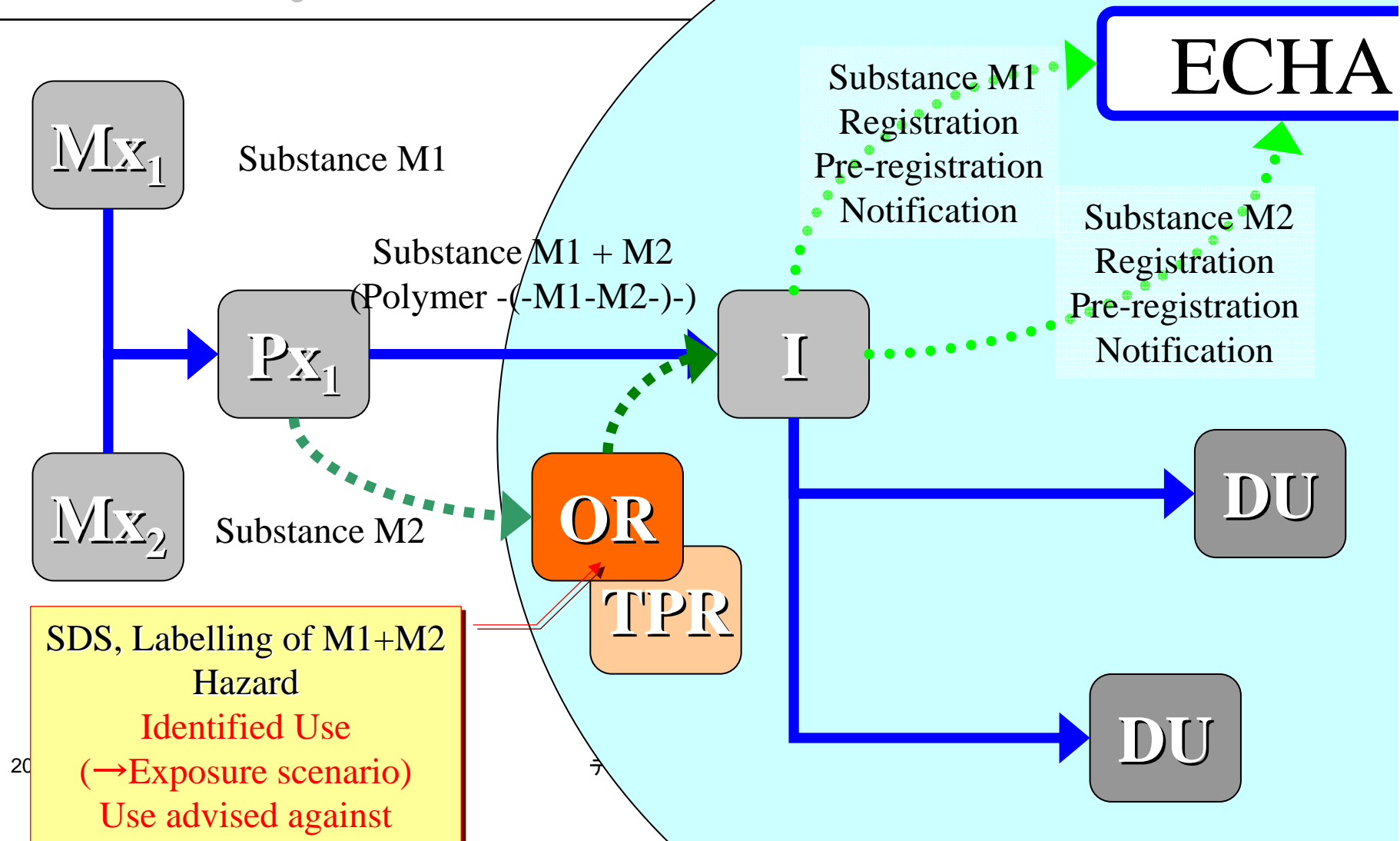
Your Role in REACH

- 御社EUのREACHの中での役割は?
 - 製造業者 (Manufacturer)
 - 輸入業者 (Importer)
 - 唯一の代理人 (**OR**)
 - 第三者代理人 (**TPR**)
 - Downstream User (**DU**)
 - ✓ 第三者代理人は域外でも可能。それ以外は全てEU域内。
 - ✓ 二つを兼ねる場合もある。

What's your role in REACH?

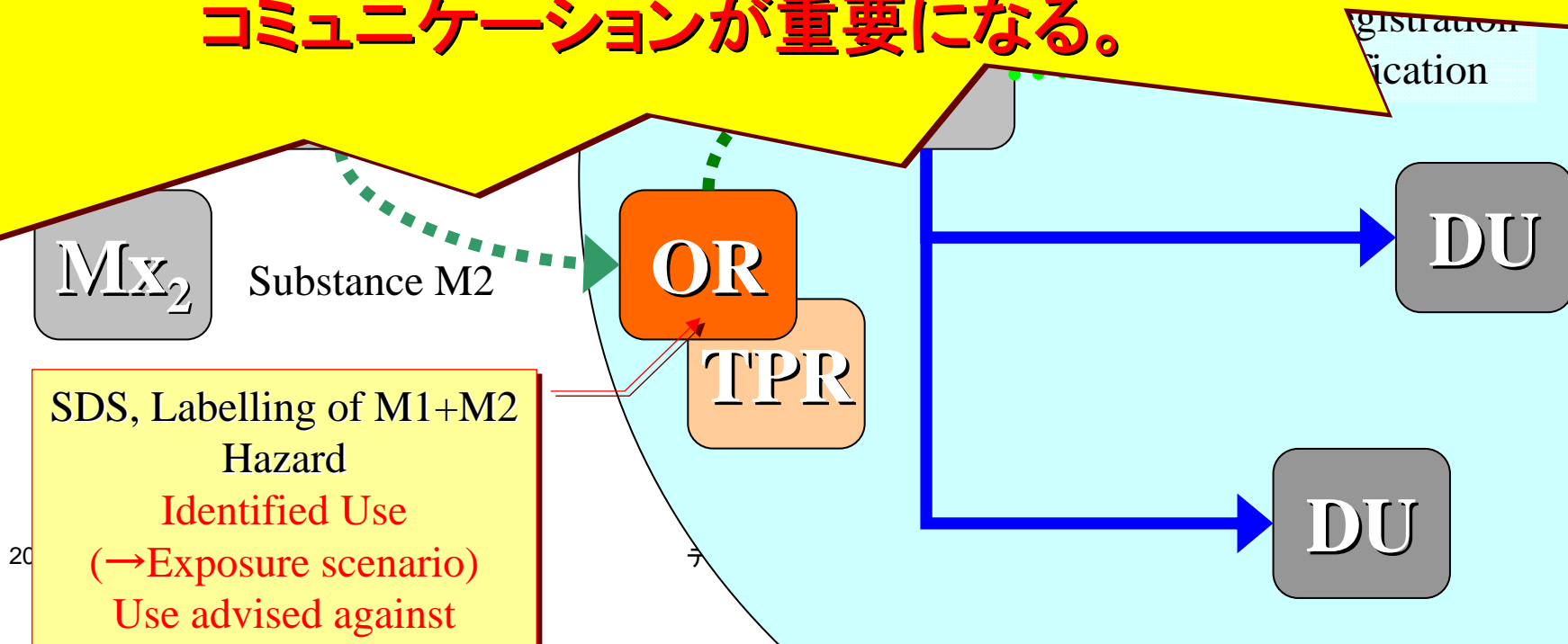


What's your role in REACH?



What's your role in REACH

欧州顧客との安全に関する情報のひとつ、
安全な取扱い方法(含: Safety Phrase)、
どんな取扱いがなされているかの
コミュニケーションが重要になる。



IUCLIDトピック

補足：
Useに係るIUCLID5の章は改訂される。

ECHAは現行のIUCLID5のUseの書き方については暫定的なマニュアルが7/9に公表され、その中で2009年はじめにIUCLID5.1(改訂版)をpublishすると公表しました。

[IUCLID 5 Guidance and Support / How to report identified uses for REACH in IUCLID 5.0](#)

1. Use情報

- IUCLID5 3.2, § 3.3関係
 - 7月9日 ECHA Useに関する入力手引き発行
 - IUCLID5.1の2009年はじめの発行を案内

2. サプライチェーン情報

- IUCLID5 § 1.7関係
 - サプライチェーン情報
(ORを立てた場合に当局へ通知として)

1. IUCLID5→5.1 section 3.5, 3.6

The screenshot shows the 'Identified use' form in IUCLID 5.0. It contains several fields and sections, each with a red circle and an arrow pointing to a replacement in IUCLID 5.1:

- Application technique / Activity:** A text field with a red circle and arrow pointing to the text "To be replaced by the 'Process Category' (PROC)".
- Use category:** A dropdown menu with a red circle and arrow pointing to the text "To be replaced by the 'Product Category' (PC)". Below it are two checkboxes: "Available as substance" and "Substance in mixture".
- Industry category:** A dropdown menu with a red circle and arrow pointing to the text "To be replaced by the 'Sector of Use' (SoU)".
- Type of article:** A dropdown menu with a red circle and arrow pointing to the text "To be replaced by the 'Article category' (AC)".

Source: ECHA (July 2008): [IUCLID 5 Guidance and Support / How to report identified uses for REACH in IUCLID 5.0](#)
(IUCLID5 > Get Support > Documentation)

4.2. Exposure Scenarios

When an ES has been attached, then a row in the table will be created. It will not be possible for the transfer of data to link an ES to an identified use.

Exposure scenario

ES 3- formulation of adhesive xxx

Description: ES 3- formulation of XXXX

Document: identified uses.xls / 74.5 KB

Identified Use reference	Sector of Use (SU)	Product Category (PC)	Subst/ Prep	PROcess Category (PROC)	Article Category (AC)	Exposure Scenario reference	Attachment
[CBI, xxxxxxxx] EU: REACH						ES 3- Formulation of xxx	ES- 3.doc / 23.5 KB

DRAFT

Source: ECHA (July 2008): [IUCLID 5 Guidance and Support / How to report identified uses for REACH in IUCLID 5.0](#)
(IUCLID5 > Get Support > Documentation)

2. Section 1.7 Suppliers of IUCLID 5.

The screenshot displays the IUCLID 5 software interface. The main window title is "Substance: test2 / 3,4,5,6-tetrachloro-2-(1,4,5,8-tetrabromo-6-hydroxy-3-oxoxanthen-9-yl)benzoic acid / 2',4',5',7'-tetrabromo-4,5,6,7-tetrachloro-3',6'-dihydroxy-3H-spiro[5.5]undec-2-en-1-one". The left sidebar shows a "Section tree" with 13 categories, where "1.7 Suppliers" is selected. The main area is titled "Suppliers" and contains a search bar, a "Manufacturer / Importer / Formulator" section with "Name" and "Remarks" fields, and an "Only representation information" section with "Official assignment from non EU manufacturer" and a table for "Other importers". The table has columns for "Name" and "Agreement". At the bottom of the main area are "Add...", "Edit...", and "Delete" buttons. A dialog box titled "Importer information" is open, showing "Add a new importer" with "Name" and "Agreement" fields and "OK" and "Cancel" buttons.

Navigation: Query results | Section tree

REACH Registration above 1000 tonnes

0 Related Information

1 General Information

- 1.1 Identification
- 1.2 Composition
- 1.3 Identifiers
- 1.4 Analytical information
- 1.5 Joint submission
- 1.6 Sponsors
- 1.7 Suppliers**
- 1.8 Recipients

2 Classification and Labelling

- 2.1 GHS
- 2.2 DSD - DPD

3 Manufacture, use and exposure

4 Physical and chemical properties

5 Environmental fate and pathways

6 Ecotoxicological Information

7 Toxicological information

8 Analytical methods

11 Guidance on safe use

12 Literature search

13 Assessment Reports

Suppliers

Manufacturer / Importer / Formulator

Name

Remarks

Only representation information

Official assignment from non EU manufacturer

Name	Agreement
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Add... Edit... Delete

Importer information

Add a new importer

Name

Agreement

OK Cancel

Fields in IUCLID § 1.7 for *Supplier*

Manufacturer/Importer/Formulator

- ❑ **Name** (Link to LEO)
- ❑ **Remark** (Free text)

“The OR designated by non-EU polymer manufacturer should enter the polymer manufacturer’s LEO.” (reachcentrum)

Only representation information

- ❑ **Official assignment from non EU manufacturer**
(Attachment)
- ✓ Other importers (table-view block)
 - ✓ Importer information
 - ❑ **Name** (Link to LEO)
 - ❑ **Agreement** (Attachment)

“The Agreement should be MANDATORILY made between the importers and the non EU manufacturer.”
“ (reachcentrum)

Necessary (reachReady)

Not Necessary (ECHA)

Fields in IU

Manufacturer/Im

- ❑ **Name** (Link)
- ❑ **Remark** (Free text)

Only representation

- ❑ **Official assignment from non EU manufacturer**
(Attachment)
- ✓ Other importers (table-view block)
 - ✓ Importer information
 - ❑ **Name** (Link to LEO)
 - ❑ **Agreement** (Attachment)

補足:

❑がIUCLID § 1.7のフィールド

REACHcentrumの情報によれば、Manufacturer/Importer/Formulator欄には Polymer製造業者がORを指名した場合、Polymer製造業者の名前を記載するとよいようです。

REACHcentrumセミナーでは、Other importers欄の合意書(OR指名者-importer間)については添付することが必要と回答を得ました。しかし、合意書を結ぶのはOR-Importers間あるいはOR指名者-OR-importers間(Rreachready)との欧州サイドの見解もあります。また、ECHAからは” There is no need to also provide the text of any contractual agreement together with this list.”との回答も得ています。

“The Agreement should be MANDATORILY made between the importers and the non EU manufacturer.”
“(reachcentrum)

Necessary (reachReady)

Not Necessary (ECHA)

section 1.7 Suppliers of IUCLID 5.

Manufacturer / Importer / Formulator

Name

指名した者 (non-official LEO)

Remarks

section 1.7 Suppliers of IUCLID 5.

Only representation information

Official assignment from non EU manufacturer

Other importers

Name	Agreement
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Add... Edit... Delete

Importer information

Add a new importer

Name

Agreement

**DU合意をした輸入者の non-official LEO
合意書を添付(合意数量も?)。雛形がCEFIC
に**

OK Cancel