

MS REACH Reporting Questionnaire

General Information	
Which Member State are you reporting for?	ES
What reporting period are you reporting on?	2010
Primary contact person's name.	Esther Martín / Ana Fresno
Please provide an email address for the primary contact person.	emartind@msps.es / afresno@mma.es

Theme 1 - Information on the Competent Authority	
How many Competent Authorities are responsible for REACH?	There is more than one Competent Authority responsible for REACH.

More than one Competent Authority Responsible for REACH

First Competent Authority	
What is the name of the organisation where the Competent Authority is situated?	Ministerio de Sanidad y Política Social
What is the address of the organisation?	Paseo del Prado, 18-20 28071 Madrid Spain
What is the email address of the organisation?	sgsasl@msps.es
What is the telephone number of the organisation?	+34 915962084 / +34 915952085
What is the fax number of the organisation?	+34 913601341
What part of REACH does this part of the Competent Authority deal with?	Evaluation Restriction CLP Risk Assessment Other (please list)
Please list the other parts of REACH that this part of the Competent Authority deals with here.	Enforcement coordination. Authorisation. Contact the previous notifier of new substances in order to deliver IUCLID-5 files once they have requested the Registration Number. Members in the following ECHA groups: - Member State Committee - Forum - Risk Communication Network
From what part of Government does this part of the Competent Authority have authority from?	Health Consumer protection
Are employees in the Competent Authority directly employed by Government (civil servants)?	Yes
What skills do staff in this part of the Competent Authority have?	Chemistry Toxicology Enforcement Legal Policy Exposure CLP

What other chemical legislation are the staff of the REACH CA involved in?	Biocides Pesticides Other
If Other, please list the different legislation here	Drinking Water

Second Competent Authority	
What is the name of the organisation where the Competent Authority is situated?	Ministerio de Medio Ambiente y Medio Rural y Marino
What is the address of the organisation?	Plaza San Juan de la Cruz, s/n 28071 Madrid Spain
What is the email address of the organisation?	afresno@mma.es / buzon_sgcamai@mma.es
What is the telephone number of the organisation?	+34 91 453 53 62 / +34 91 453 53 79
What is the fax number of the organisation?	+34 534 05 82
What part of REACH does this part of the Competent Authority deal with?	Evaluation Restriction Helpdesk CLP Risk Assessment Other (please list)
Please list the other parts of REACH that this part of the Competent Authority deals with here.	Authorisation Members in the following ECHA groups: - Management Board - Risk Communication Network - Helpnet Adviser in the following ECHA groups: - Forum
From what part of Government does this part of the Competent Authority have authority from?	Environment Other (please list)
Please list the other parts of Government that this part of Agriculture Livestock the Competent Authority has authority from.	
Are employees in the Competent Authority directly employed by Government (civil servants)?	Yes
What skills do staff in this part of the Competent Authority have?	Chemistry Ecotoxicity Legal Policy Exposure CLP
What other chemical legislation are the staff of the REACH CA involved in?	Biocides Pesticides Food Other
If Other, please list the different legislation here	GMOs EMAS ECOLABELLING
Are there any more Competent Authorities responsible for REACH?	No

Theme 2 - Information on Cooperation and Communication with other Member States, the European Chemicals Agency (ECHA) and the Commission

How effective is communication between MS for REACH? 7

How could effectiveness of communication between MS be improved?	
How effective is collaboration between MS for REACH?	6
How could effectiveness of collaboration between MS be improved?	
Are there any special projects/cooperation on chemicals that the MS participates in with other MS outside of REACH?	Yes
Please provide further information.	Most of the projects carried out by CLEEN network. IMPEL network COPHES (Consortium to perform Human biomonitoring on a European Scale) SUBSPORT (Substitution support portal: moving towards safe alternatives)
How effective is MS communication with ECHA?	6
How could effectiveness of communication with ECHA be improved?	Sometimes communication with ECHA seems to be unilateral. In some cases consultation is difficult due to there is no direct contact person for specific issues.
How effective is MS collaboration with ECHA?	7
How could effectiveness of collaboration with ECHA be improved?	
How effective is MS communication with the Commission (specifically Article 133 Committee)?	7
How could effectiveness of communication with the Commission be improved?	
How effective is MS collaboration with the Commission (specifically Article 133 Committee)?	7
How could effectiveness of collaboration with the Commission be improved?	
Has use been made of the safeguard clause of REACH (Art. 129)?	No

Theme 3 - Operation of the National Helpdesk and Provision of Communication to the Public of Information on Risks of Substances

Please provide the name of the organisation responsible for operating the National Helpdesk for REACH.	Ministerio de Medio Ambiente y Medio Rural y Marino
What is the address of the Helpdesk?	C/ Doctor Esquerdo, 138, 3º Dcha 28007, Madrid
What is the web page address of the Helpdesk?	www.reach-pir.es / www.portalreach.info
What is the email address of the Helpdesk?	info@reach-pir.es
What is the telephone number of the Helpdesk?	+34 914 34 57 30
What is the fax number of the Helpdesk?	+34 91 434 57 20
Are there any more organisations responsible for operating the National Helpdesk for REACH?	No

Please indicate the number of each type of staff that are involved in the Helpdesk.

Toxicologist	1-5
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Ecotoxicologist	1-5
Chemist	1-5
Risk Assessor	
Economist	
Social Scientist	
Exposure Assessor	1-5
Other (please list)	1-5
If you have specified that there are a number of other staff that are involved in the Helpdesk, please list the type of staff here.	Environmental sciences IT-tools
Is the same Helpdesk used to provide help to Industry on CLP?	Yes
Does the Helpdesk receive any non-governmental support?	No
How many enquiries does the Helpdesk receive per year?	101-1000
In what format can enquiries be received by the Helpdesk?	Email Phone Other (please list)
Please list the other format(s) of enquiries that can be received by the Helpdesk.	Information request form available at our website
How are the majority of enquiries received?	Other
Do you provide specific advice to SME's?	Yes
Who are the majority of enquiries from?	Small-medium enterprises
What type of enquiries does the Helpdesk receive?	Pre-registration SIEFs Registration REACH-IT IUCLID5 Authorisation Downstream user obligations Restriction Obligations regarding articles Testing Safety Data Sheets Enforcement SVHC CSR preparation Other (please list) CLP
Please list the other types of enquiries that the Helpdesk receives.	Scope (general information about REACH, exemptions, monomers and polymers) Importation (Only representatives)

For each type of enquiry received, please provide the proportion in percentage of the total enquiries.

Pre-registration (%)	5
Registration (%)	25
Authorisation (%)	1
Restriction (%)	1
Testing (%)	3
Enforcement (%)	2
CSR preparation (%)	2
CLP (%)	15
SIEFs (%)	2
REACH-IT (%)	2
IUCLID5 (%)	1
Downstream user obligations (%)	3
Obligations regarding articles (%)	3
Safety Data Sheets (%)	4
SVHC (%)	2
Other (%)	Scope 29%, Importation (Only Representatives) 1,4%

What proportion of enquiries received are deemed to be 1) straight forward, 2) complex, OR No information

Straight forward (%).	20
Complex (%).	20
No information (%).	5

How long, on average, does it take to respond to the following types of questions?

Straight forward questions	4 hours
Complex questions	1 week
Are any types of enquiry outsourced?	Yes
What types of enquiry are outsourced?	SVHC CLP
Does the Helpdesk seek feedback on its performance?	Yes
Does the Helpdesk review its performance and consider ways to improve its effectiveness?	Yes

What level of cooperation is there between Helpdesks?

What level of cooperation is there between Helpdesks under REHCORN?	4
What level of cooperation is there between Helpdesks outside REHCORN?	4
How frequently do you use RHEP?	Daily
Has the MS carried out any specific public awareness raising activities?	Yes

What type of activities have been carried out?	Other (please list) Speaking events
Please list the other types of activities that have been carried out.	Information on website

How effective was each type of activity?	
Speaking events	4
Other	4
Do you have a REACH webpage/website?	Yes
Do you have a single webpage for REACH or multiple pages?	Single webpage
How frequently is the REACH webpage visited (per month)?	No information
Please describe the scope of the number of REACH webpage visits.	There is not a record of visits

Theme 4 - Information on the Promotion of the Development, Evaluation and Use of Alternative Test Methods	
Does the MS contribute to EU and/or OECD work on the development and validation of alternative test methods by participating in relevant committees?	Yes
What has been the overall public funding on research and development of alternative testing in your MS each year?	Euros 100,001-1,000,000

Theme 5 - Information on Participation in REACH Committees (FORUM, MS, RAC, SEAC, CARACAL, PEG, RCN, REHCORN)	
On a scale of 1-10, how effective do you think the work of the Committees associated with REACH are?	8
How could the effectiveness of the Committees be improved?	In order to reduce the number of meetings, videoconferences/teleconferences or written procedures could be considered.

Theme 6 - Information on Substance Evaluation Activities

2010 Reporting
Please name the organisations/institutions that are involved in the evaluation process.

Please indicate the number of each type of staff that are involved in substance evaluation.	
Toxicologist	1-5
Ecotoxicologist	6-10
Chemist	6-10

Risk Assessor	1-5
Socio-Economic Analyst	
Exposure Assessor	6-10
Other (please list)	1-5
If you have specified that there are a number of other staff that are involved in substance evaluation, please list the type of staff here.	Q(SAR) expert
Please list the names of the substances covered in the dossiers that the MS has commented upon.	
Please list the names of the substances covered in the dossiers where a draft decision has been made.	
Please list the names of the substances covered in the dossiers that the MS has rapporteured.	
Please list the names of the substances covered in the dossiers that the MS has completed.	
How long, on average, does evaluation of a dossier take?	
How many transitional dossiers has the MS completed?	
How many substances has the MS added to the Community Rolling Action Plan?	
How many of ECHA's draft decisions on dossier evaluation has the MS commented on?	1-3

Theme 7 - Annex XV Dossiers

How many of each type of dossier has the MS prepared?

CLP	0
Restriction	0
Identification of SVHC	1-3
Is the time spent following up your MS dossiers reasonable?	5
Space is available below to provide further comments on how reasonable the time spent following up your MS dossiers was.	

How many of each type of dossier are rapporteured?

CLP	0
Restriction	0
Identification of SVHC	1-3
Is the time spent following up rapporteured dossiers reasonable?	7

Space is available below to provide further comments on how reasonable the time spent following up your rapporteured dossiers was.

We have understood "Rapporteured" as all activities related with the Annex XV dossier preparation and follow up / collaboration with the Committees involved.

How many of each type of dossier are co-rapporteured?

CLP	0
Restriction	0
Identification of SVHC	0
Is the time spent following up co-rapporteured dossiers reasonable?	5

Space is available below to provide further comments on how reasonable the time spent following up your co-rapporteured dossiers was.

We have understood "Co-rapporteured" as all activities related with the Annex XV dossier preparation and follow up / collaboration with the Committees involved.
Answer to question Is the time spent following up co-rapporteured dossiers reasonable?: Not applicable

How many dossiers prepared by other MS has the MS contributed to or commented upon?

CLP	0
Restriction	0
Identification of SVHC	0

How many dossiers prepared by ECHA has the MS contributed to or commented upon?

Restriction	0
Identification of SVHC	0

What expertise is available for preparing dossiers?

Chemist	4-6
Toxicologist	4-6
Ecotoxicologist	7-9
Economist	
Enforcement	4-6
Legal	4-6
Policy	4-6
Exposure	4-6

CLP	4-6
Other (please list)	
If you have specified that there is other expertise is available for preparing CLH dossiers, please provide details here.	
Is the MS able to access external specialists?	Yes
What types of external specialists does the MS have access to?	Toxicologist Ecotoxicologist Chemist Expert in nanomaterials, Q(SAR) and omics
Is the MS satisfied with the levels of access to expertise?	4
Has there been any industry involvement in the preparation of MS dossiers?	No

Theme 8 - Information on Enforcement Activities

General Information

Please enter the MAIN enforcing authority for REACH within the Member State.	
Is there more than one enforcing authority for REACH within the Member State?	Yes
Please provide details on the other enforcing authorities for REACH within the Member State.	Junta de Andalucía Gobierno de Aragón Gobierno del Principado de Asturias Gobierno de Canarias Gobierno de Cantabria Junta de Comunidades de Castilla-La Mancha Junta de Castilla y León Generalidad de Cataluña Junta de Extremadura Junta de Galicia Gobierno de las Islas Baleares Gobierno de La Rioja Comunidad de Madrid Región de Murcia Gobierno de Navarra Generalidad Valenciana Gobierno Vasco

Enforcement Strategy

Has an overall strategy (or strategies) been devised and implemented for the enforcement of REACH?	Yes
If Yes, is the strategy (or strategies) in line with the strategy devised by the Forum?	Yes

Please outline the enforcement strategy within the Member State in a maximum of 2000 characters.

The regulatory regime for REACH enforcement is clearly assigned by the Spanish Sanctions Regime Law. (Ley 8/2010, de 31 de marzo. BOE 1 de abril de 2010). REACH enforcement in Spain is the responsibility of the regional authorities (Autonomous Communities), as it is mentioned in this Law. On the central level there are two Competent Authorities responsible for the implementation of REACH, the Ministry of Health and Social Policy and the Ministry of the Environment and Rural and Marine Affairs. These two authorities ensure the coordination between all Spanish Enforcement Authorities. In order to reach uniform, coordinated and effective enforcement, the Law establishes that both MSCAs and Enforcement Authorities shall supply and share criteria, information and any other issue useful for the normal application of their duties. In this cooperation, policy objectives and priorities are defined. Both MSCAs and Enforcement Authorities shall share information obtained in order to ensure the application of the Spanish Law, including the results of the inspections, investigations and formal enforcements in an annual basis. In the scope of Health Administration, a National Network for Surveillance, Inspection and Enforcement and a Fast Information Exchange System for chemicals has been developed, allowing Enforcement Authorities to disseminate obtained data, to alert the rest of Autonomous Communities of any risk when it is deemed necessary and compile all the information available deciding how it can be used. In addition, the Spanish REACH enforcement Law establishes that proposals and projects coming from the ECHA Forum should be specially taken into account in the activities related with inspections and enforcement of REACH. The Ministry of Health and Social Policy has coordinated REACH-EN-FORCE 1 in Spain.

Co-ordination, co-operation and exchange of information

<p>Please outline of the mechanisms put in place to ensure good cooperation, coordination and exchange of information on REACH enforcement between enforcing authorities and the Competent Authority.</p>	<p>The main mechanisms established in Spain are defined in the Spanish Sanction Regime Law (Ley 8/2010): Article 3 is dedicated to information exchange between Autonomous Communities. Both Spanish Competent Authorities and Spanish Enforcement Authorities shall provide and share criteria, information or any other mechanism available in order to carry out their duties in a correct way. In the scope of Health Administration, the Law establishes that the “National Network for Surveillance, Inspection and Enforcement” has to be used. By this network, uniform, coordinated effective actions for enforcement are achieved. Furthermore, to ensure the dissemination of sanitary alerts between Enforcement Authorities, there is a “Fast Information Exchange System for chemicals” that forms part of the Network. Both mechanisms have been working actively before REACH came into force. On the other hand, in the scope of Environment Administration, the Law puts in place two mechanisms: “Conferencia Sectorial de Medio Ambiente” and “Red de Directores Generales de Calidad y Evaluación Ambiental” Moreover, the Law establishes that other measures can be used in order to achieve an effective coordination of actions to prevent risk and the fulfilment of the Law. All these activities will be coordinated by an administrative body where there are representatives from all competent authorities. Annually, all Authorities shall share the information of activities carried out for the fulfilment of the Law.</p>
<p>Describe how these mechanisms have operated in practice during the reporting period (e.g. regular meetings, joint training, joint inspections, co-ordinated projects and so on).</p>	<ul style="list-style-type: none"> - Regular meetings between Competent Authorities for the implementation of REACH (Ministry of Health and Social Policy and Ministry of the Environment and Rural and Marine Affairs) and other ministries related with REACH Regulation (Ministry of Labour and Ministry of Industry). - Regular meetings between the Competent Authorities for the implementation of REACH and Competent Authorities for enforcement. - Organization of joint trainings for inspectors. - Co-ordination of inspection projects (REACH-EN-FORCE-1, CLEEN)

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<p>Describe the inspection and investigation strategy and methodology.</p>	<p>Previously to the participation in REACH-EN-FORCE-1, inspections of the SDS had been carried out. Inspectors training has been an important activity during these years.</p>
<p>Describe the level and extent of monitoring activities.</p>	<p>Monitoring activities in this first period has been related mainly with pre-registration process. Most Spanish regional governments (Comunidades Autónomas) have participated in REACH-ENFORCE-1. Previous inspections of SDS have also been carried out.</p>

Describe sanctions available to enforcing authorities.	Enforcement is regulated in Spain by Law "Ley 8/2010". Briefly, administrative penalties are the following: Severe (muy grave): from 85,001 to 1,200,000 Euros; Serious (grave): from 6,001 to 85,000 Euros; Light (leve): up to 6,000 Euros. Exceptionally, closure of premises up to five years can complete the fines for infringements classified as severe. There are no criminal penalties. Until 2010, most of the enforcement efforts were to inform dutyholders about their REACH obligations.
Describe the referrals from ECHA.	No referrals from ECHA
Describe the referrals from other Member States.	No referrals from other Member States
Describe any other measures/relevant information.	

2007

Dutyholders

Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	
Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.	
What was the total number of inspections and investigations carried out by enforcing authorities in which REACH was discussed and/or enforced for this year?	351
State the number of manufacturer dutyholders subject to inspections and investigations.	0
Were these mainly:	No information
State the number of importer dutyholders subject to inspections and investigations.	0
Were these mainly:	No information
State the number of distributors subject to inspections and investigations.	0
Were these mainly:	No information
State the number of downstream users subject to inspections and investigations.	0
Were these mainly:	No information

Inspections

State the number of inspections that addressed registration.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed information in the supply chain.	291
State the number these cases which were non-compliant.	

State the number of inspections that addressed downstream use.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed authorisation.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed restriction.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed other REACH duties.	0
State the number these cases which were non-compliant.	

Investigations	
State the number of investigations prompted by complaints and concerns raised.	0
State the number of investigations prompted by incidents or dangerous occurrences.	0
State the number of investigations prompted by monitoring.	70
State the number of investigations prompted by results of inspection/follow up activities.	0
State the number of inspections and investigations resulting in no areas of non-compliance.	154
State the number of inspections and investigations resulting in verbal or written advice.	0
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	31
State the number of inspections and investigations resulting in initiation of legal proceedings.	0
State the number of convictions following legal proceedings.	

Enforcement	
State the number of manufacturers subject to formal enforcement.	0
Were these mainly:	No information
State the number of importers subject to formal enforcement.	0
Were these mainly:	No information
State the number of distributors subject to formal enforcement.	0
Were these mainly:	No information

State the number of downstream users subject to formal enforcement.	0
Were these mainly:	No information

2008

Dutyholders	
Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	
Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.	
What was the total number of inspections and investigations carried out by enforcing authorities in which REACH was discussed and/or enforced for this year?	426
State the number of manufacturer dutyholders subject to inspections and investigations.	0
Were these mainly:	No information
State the number of importer dutyholders subject to inspections and investigations.	0
Were these mainly:	No information
State the number of distributors subject to inspections and investigations.	0
Were these mainly:	No information
State the number of downstream users subject to inspections and investigations.	0
Were these mainly:	No information

Inspections	
State the number of inspections that addressed registration.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed information in the supply chain.	392
State the number these cases which were non-compliant.	
State the number of inspections that addressed downstream use.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed authorisation.	0
State the number these cases which were non-compliant.	

State the number of inspections that addressed restriction.	25
State the number these cases which were non-compliant.	
State the number of inspections that addressed other REACH duties.	0
State the number these cases which were non-compliant.	

Investigations	
State the number of investigations prompted by complaints and concerns raised.	0
State the number of investigations prompted by incidents or dangerous occurrences.	0
State the number of investigations prompted by monitoring.	34
State the number of investigations prompted by results of inspection/follow up activities.	0
State the number of inspections and investigations resulting in no areas of non-compliance.	217
State the number of inspections and investigations resulting in verbal or written advice.	0
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	21
State the number of inspections and investigations resulting in initiation of legal proceedings.	0
State the number of convictions following legal proceedings.	

Enforcement	
State the number of manufacturers subject to formal enforcement.	0
Were these mainly:	No information
State the number of importers subject to formal enforcement.	0
Were these mainly:	No information
State the number of distributors subject to formal enforcement.	0
Were these mainly:	No information
State the number of downstream users subject to formal enforcement.	0
Were these mainly:	No information

2009

Dutyholders

Provide an estimate of the total number of dutyholders who are likely to have duties imposed on them by REACH.	
Provide an estimate of the above dutyholders who are likely to constitute registrants as defined by REACH.	
What was the total number of inspections and investigations carried out by enforcing authorities in which REACH was discussed and/or enforced for this year?	726
State the number of manufacturer dutyholders subject to inspections and investigations.	159
Were these mainly:	No information
State the number of importer dutyholders subject to inspections and investigations.	116
Were these mainly:	No information
State the number of distributors subject to inspections and investigations.	196
Were these mainly:	No information
State the number of downstream users subject to inspections and investigations.	173
Were these mainly:	No information

Inspections	
State the number of inspections that addressed registration.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed information in the supply chain.	671
State the number these cases which were non-compliant.	89
State the number of inspections that addressed downstream use.	143
State the number these cases which were non-compliant.	46
State the number of inspections that addressed authorisation.	0
State the number these cases which were non-compliant.	
State the number of inspections that addressed restriction.	30
State the number these cases which were non-compliant.	
State the number of inspections that addressed other REACH duties.	220
State the number these cases which were non-compliant.	4

Investigations	
State the number of investigations prompted by complaints and concerns raised.	2
State the number of investigations prompted by incidents or dangerous occurrences.	0
State the number of investigations prompted by monitoring.	53
State the number of investigations prompted by results of inspection/follow up activities.	0
State the number of inspections and investigations resulting in no areas of non-compliance.	405
State the number of inspections and investigations resulting in verbal or written advice.	63
State the number of inspections and investigations resulting in formal enforcement short of legal proceedings.	31
State the number of inspections and investigations resulting in initiation of legal proceedings.	0
State the number of convictions following legal proceedings.	

Enforcement	
State the number of manufacturers subject to formal enforcement.	0
Were these mainly:	No information
State the number of importers subject to formal enforcement.	0
Were these mainly:	No information
State the number of distributors subject to formal enforcement.	0
Were these mainly:	No information
State the number of downstream users subject to formal enforcement.	0
Were these mainly:	No information

Theme 9 - Information on the Effectiveness of REACH on the Protection of Human Health and the Environment, and the Promotion of Alternative Methods, and Innovation and Competition	
Do you think that the effects of REACH would be better evaluated at a Member State (MS) or EU level?	EU
What parameters are available at MS level that could be used to assess the effectiveness of REACH in a baseline study?	R&D&I focused on the replacement of substances of very high concern and the development of alternative Technologies. Industrial sectors affected by REACH and level of compliance.

Theme 10 - Other Issues/Recommendations/Ideas

Please provide any further information on the implementation of REACH that the MS considers relevant.

Many activities promoting and informing about REACH Legislation have been carried out by Spanish MSCAs. For instance, MSCAs have organised workshops aimed at all dutyholders. Furthermore, several seminars about REACH have been celebrated all-around Spain since 2005. The Ministry of Health and Social Policy Website has been modified to provide deep information about REACH processes. In addition, we have sent leaflets to inform potential registrants of their obligations.

Do you wish to upload documents in support of this submission

Yes

Please provide a brief description of the documents that you are uploading. Note: You may upload more than one document.

Clarification document.

Meta Informations

Creation date	31-05-2010
Last update date	
User name	ReachES
Case Number	939357139581215110
Invitation Ref.	
Status	N