

# Proposal to adapt monitoring strategy

August 23 2021

## Introduction

Six transgenic carnation events have marketing approval (for import as cut flowers only) into the EU. A requirement of the consents for marketing approval of these events is that annual monitoring reports are provided and since 2008 a general monitoring strategy has been used. That strategy comprises four methodologies to identify any new or historical incidences of escape of carnation from cultivation:

- A review of the scientific literature.
- A review of online floras, herbaria, and vegetation mapping databases.
- Contact with breeders and botanist experts engaged to focus on looking for carnation during their regular fieldwork.
- A mail out by letter and email. This strategy is referred to as an “institutional mail out” in the monitoring plans provided with the consents. The mail out has been primarily to botanical gardens, herbaria, universities, government agencies, and research institutions but also to “citizen scientists” and individual scientists.

Based on the outcomes and experience of following the general monitoring strategy the consent holders have determined the value of the institutional mail out has diminished. The purpose of this document is to propose and request that the mail out component of the monitoring strategy is removed from 2023, and the general monitoring scheme adapted accordingly.

In sequence, this document covers a) the type of entity contacted and amount of contact as part of the mail out b) information on the type of entity responding to the mail out and nature of response c) a rationale and proposal to adapt the monitoring plan by removal of the mail out.

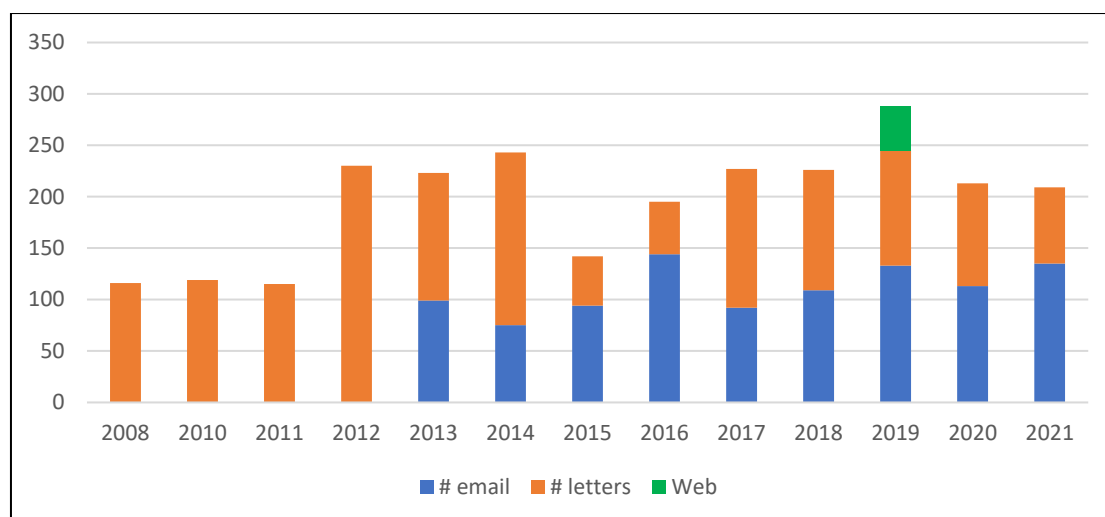
## Institutional mail out requests

Since 2008 2,571 letters and emails have been sent in the institutional mail out process. In these communications information has been sought in the context of researching the possibility that genetically modified *Dianthus caryophyllus* (carnation) might establish into the environment via inadvertent disposal or hybridisation. The mail out has made clear that representations are from a private company working on transgenic carnation, providing a link to the company database, and including printed or electronic brochures describing the transgenic varieties. The mail out has also expressed interest in any records of carnation, *Dianthus caryophyllus*, or other *Dianthus* species. Where clarification has been sought on what was meant by “carnation” this has been provided.

Communication has been by post (letter), email and via a web-based French online flora<sup>1</sup>. Since 2012 written communication has been in French, Italian, Spanish, Bulgarian and English and since 2018 (with the aid of translation software) in the language of the respondent. Figure 1 provides a breakdown of the number of communications each year. In total, 882 different entities were contacted i.e., many entities were contacted more than once, whether or not a response was received. Where an entity was contacted more than once, this was generally in separate years. There were 33 instances when an entity was contacted twice in the same year.

---

<sup>1</sup> <https://www.tela-botanica.org/en/>



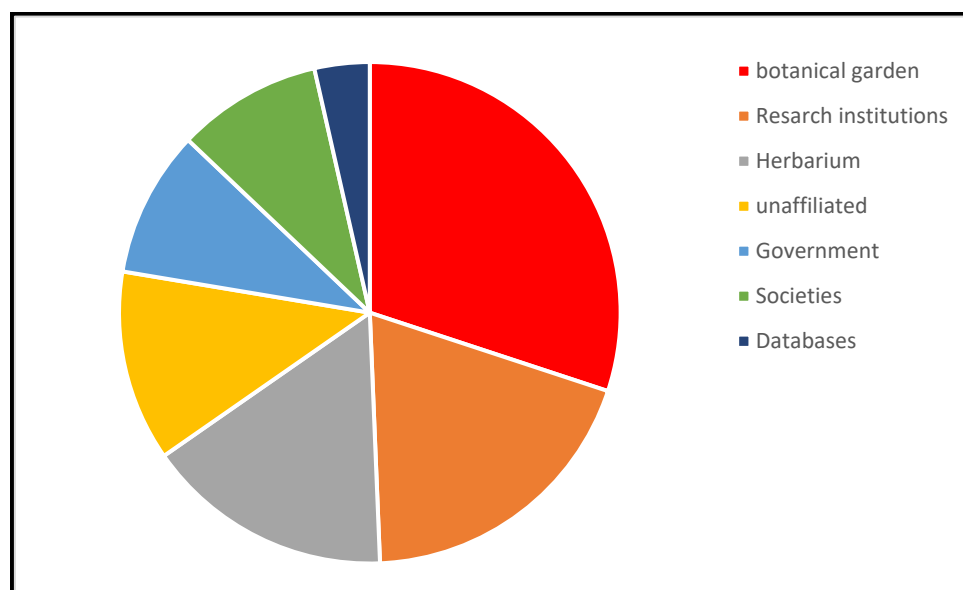
**Figure 1. Number of mail-out enquiries each year since 2008. A mail-out was not carried out in 2009.**

#### Failed contact requests

2.37% of the communications sent (61 contacts made to 37 entities) were misdirected, returned or undeliverable leaving a balance of 2,510 contacts to 845 entities.

#### Type of entity contacted

The distribution of the 845 entities by entity type is shown in figure 2.



**Figure 2. Distribution of the 845 entities contacted, by type of entity.**

Approximately half the entities contacted were botanical gardens and herbarium. In the latter case the herbaria were often associated with universities. Some botanical gardens also had herbaria. The research institution definition of entity included university departments and museums. Unaffiliated entities were largely individuals contacted through the French website TelaBotanica<sup>2</sup> but also to individuals contacted through other websites and to retired scientists. Government agencies were largely plant protection agencies, with a particular focus on Italy (approximately one third of the entities in this category). The majority of the societies contacted were national botanical

<sup>2</sup> <https://www.tela-botanica.org/en/>

societies and the national representatives of the European weed society. The majority of the databases contacted were the administrators of European-based vegetation databases.

#### Geographical distribution of entities

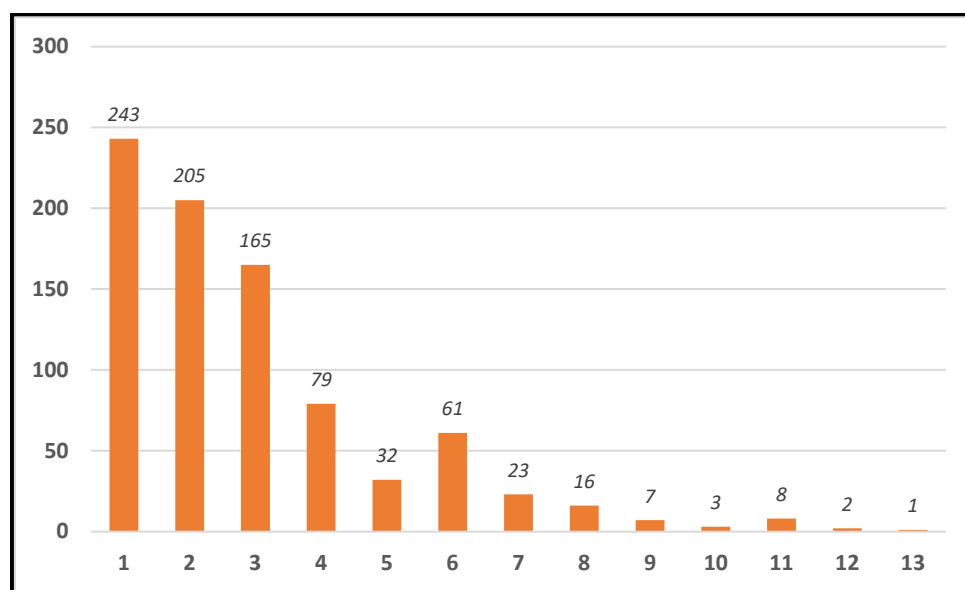
Though there was a deliberate bias towards France, the Balkans and Italy entities contacted were located across Europe. The focus on France, the Balkans and Italy was because these are areas of Europe with high numbers of *Dianthus* species and so arguably might be areas where hybridisation with carnation would be most likely to occur.

Aside from the category of unaffiliated, which was biased towards France, and the category government, which was predominantly centred on Italy, there was generally an even geographic spread within each type of category. Table 1 (page 9) tabulates the number of entities contacted by country.

#### Contacts per entity

Table 1 shows for each country the mean number of times that the entities within that country were contacted over the 2008 – 2021 monitoring period.

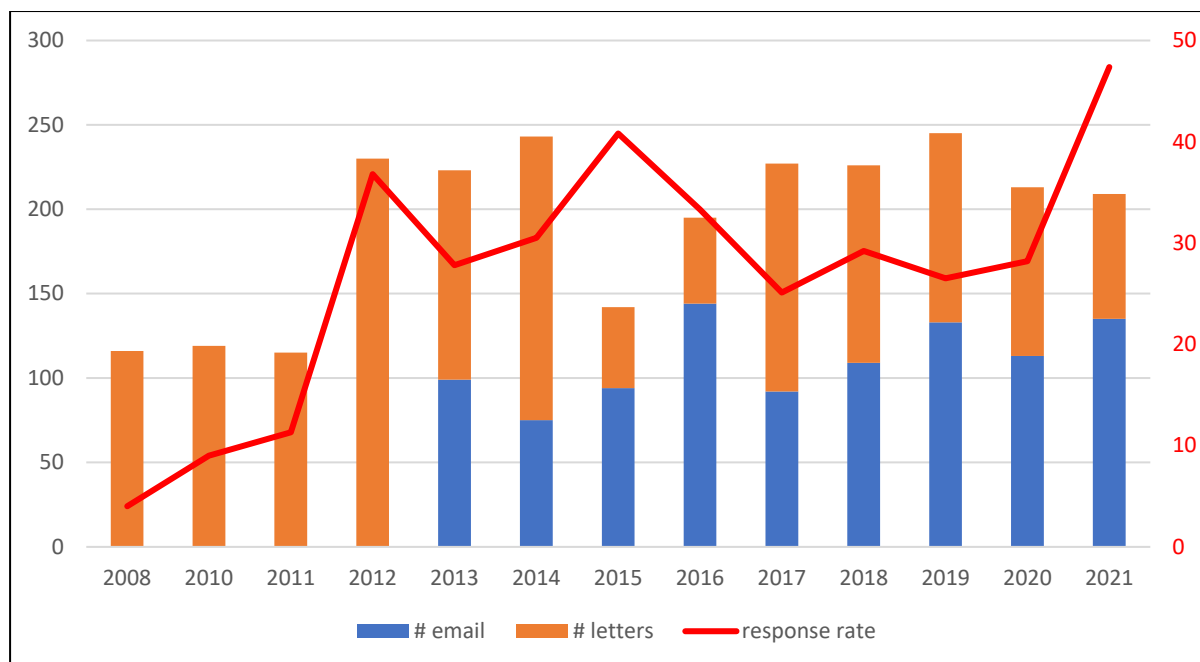
The number of times each entity was contacted during 2008 – 2021 ranged from once (in cases for example, where the entity could not help, an entity asked not to be contacted in future, a contact was only recently made) to an almost annual basis (where the entity willingly co-operated with regular yearly contact). Figure 3 shows the distribution data for number of contacts per entity.



**Figure 3. Distribution data for number of contacts per entity. The data shows the number of times that an entity was contacted over the period 2008 – 2021 (x-axis). The y-axis is number of entities.**

#### **Institutional mail out responses**

Over the whole period 2008 – 2021 there were 817 responses. Some entities responded in more than one year and overall, responses were obtained from 53.1% of all the entities contacted (449 out of 845 entities). On an annual response basis, the response rate to letters and emails varied from 4% in 2008 to 47% in 2021 (figure 4).



**Figure 4. Number of postal and email enquiries each year since 2008 (left hand side axis) and overall response rate as a percentage (right hand side axis). Response rate is calculated from the response to emails and letters. Mean response rate for the period 2008 – 2021 was 32.5%.**

#### Response rate by entity type

Table 2 shows responders by entity type. Aside from the entity type *botanical gardens*, where the response was 43%, more than 50% of the entities within other entity types provided a response. There was therefore a good spread of response across the different entity types.

**Table 2. Response rate by entity type.**

Entity type	No. of entities responded	Response as percent of all entities contacted within entity type
Databases	19	63.3%
Government	50	62.5%
Unaffiliated	62	59.6%
Research institutions	93	57.1%
Societies	44	55.7%
Herbarium	72	53.3%
Botanical garden	109	42.9%

#### Response rate by country

Table 3 (page 10) shows responders by country. With three exceptions (Bosnia and Herzegovina, Gibraltar, and Moldova) responses were obtained from at least one entity in every country contacted. Though the data shows a significant range, response rate was at least 50% in 29 of the 40 countries contacted. In addition, the rate was over 40% in the Czech Republic and Italy. These two countries had a relatively high number of responding entities (table 3). Table 3 demonstrates a good geographical spread of responding entities.

Type of responses

Detailed summaries of the responses to mail outs have been provided in the annual monitoring reports sent to the EU since 2008. Table 4 provides a summation of responses, made by categorising the type of response.

**Table 4. Categorisation of the 817 responses received.**

Category		Percentage of all responses
Provision of a relevant record	A wild type <i>Dianthus caryophyllus</i> observation in past 12 months	8.7%
	A historical wild type <i>Dianthus caryophyllus</i> report (older floras, or an observation noted before 2008)	2.3%
	A wild type <i>Dianthus caryophyllus</i> herbarium specimen(s). Pre 2008	3.4%
	A wild type <i>Dianthus caryophyllus</i> herbarium specimen(s). Post 2008	0.5%
	<b>A carnation observation or description of any type</b>	<b>0.7%</b>
Provision of a statement of no record	No records of <i>Dianthus caryophyllus</i> or carnation	30.7%
	No records of <i>Dianthus caryophyllus</i> or carnation but provided records of other <i>Dianthus</i> species	10.9%
	No records of <i>Dianthus caryophyllus</i> or carnation but provided information about <i>Dianthus</i> genus	1.2%
	Not heard of or seen naturalised carnation	0.7%
	Never seen <i>Dianthus caryophyllus</i> or carnation during field work	1.5%
	Carnation is not present in environment, the botanical record or vegetation in their area.	1.1%
	<i>Dianthus caryophyllus</i> is not present in environment, the botanical record or vegetation in their area.	5.9%
Provision of a statement on cultivated status	Provided an opinion that carnation cannot survive outside cultivation	1.5%
	Unaware of any records of occurrence of carnation or of hybridisation to other species	3.1%
	Stated <i>Dianthus caryophyllus</i> is only found in cultivation	0.6%
	Stated carnation is known in cultivation only	1.5%
Provision of information	Provided reference material (papers, floras) on <i>Dianthus caryophyllus</i> or <i>Dianthus</i> genus	4.8%
	Provided information that <i>Dianthus caryophyllus</i> is not defined as a weed, pest and/or invasive species	1.3%
Provision of website link	Provided links to website(s) and/or database(s) to access information	3.3%
Unable to assist	Unable to aid. No further explanation provided	3.8%
	Unable to aid. Cited lack of expertise and/or resources	6.0%
	Unable to aid. Suggested alternate contacts	6.5%

16% of responders kindly advised us that they were unable to assist (table 4). The remaining responses may be broadly summarised as:

- Just over 50% of responses provided information that carnation and *Dianthus caryophyllus* were absent from the local environment or were not present in records. 7% of respondents advised carnation was only found in cultivation and some proffered a view that carnation could not escape cultivation.

- Dozens of reports were received of observations (many supported with photographs) and records of unimproved, wild type *Dianthus caryophyllus* in the environment, floras, and herbarium collections. This information enhanced baseline knowledge of the distribution, habitat, and taxonomy of *Dianthus caryophyllus* in Europe.
- 6 of the 449 entities (from France, Belgium, Sweden, Hungary, Spain, and Germany) provided a carnation observation or description. On further investigation five were found to be either plants in cultivation or in and near gardens. One case was a herbarium specimen of a cut flower from cultivated carnation. None of the information identified a carnation population established outside of cultivation. In 2019 amateur botanists in France, Germany, Belgium, and the Czech Republic who were familiar with *Dianthus caryophyllus* (having accurately recorded the species) were asked if they had ever seen a wild population of carnation – of those that responded (17 of 52 contacted), none had.

### **Proposal to adapt the monitoring plan by removal of the institutional mail out**

#### Conclusions from the institutional mail out

The mail out response was comprehensive, as it was geographically widespread (entities were spread over 243 cities in 37 countries, in addition to individuals) and included all the different type of entities contacted. Many entities responded more than once.

The mail out was effective. It provided multiple records on the distribution of wild type *Dianthus caryophyllus* as well as local flora literature. All herbarium specimens of *Dianthus caryophyllus* (reviewed through digital records) were wild type *Dianthus caryophyllus*, bar one.

Over the 12-year period, the institutional mail out did not result in identification of recent or historical populations of carnation outside of cultivation. Some respondents advised carnation had never been found in certain areas and others suggested there was no capacity for escape or survival outside of cultivation because of adverse winter conditions in Northern Europe.

The results of the mail out served to reinforce a view that carnation has not escaped from cultivation in Europe. This was expected because of the theoretical low risk of gene flow extrapolated from the biology of the plant (and the even lower risk from harvested flowers). The results of the literature and database reviews carried out alongside the mail out painted a similar picture i.e., no evidence of populations of carnation outside of cultivation.

#### Rationale for removing mail out from monitoring strategy

The position of the consent holder(s) is that the institutional mail out has been comprehensive enough and carried out over long enough period to have reached the conclusions outlined above. Based on the biology of carnation and the results of the mail out, the chance of carnation escaping cultivation is low. Therefore, naturalised populations, if they exist, will be rare and not likely to be identified through continuation of the mail out unless such a mail out were expanded to a very much larger, individual contact, scale. Aside from the cost and effort of such an exercise such an expansion is not a justifiable option for two reasons. Firstly, the mail out is not an efficient process. Secondly, the database reviews and literature reviews are as or more comprehensive and are known to be effective.

The institutional mail out is not efficient because:

- 47% of all entities contacted failed to respond. On a mean annualized basis, less than one-third of contacts responded. Lack of response may be due to unwillingness (hesitancy to communicate to industry, entities from outside Europe or GMO-related businesses for example) or lack of interest, knowledge and/or resources. After repeated contact asking for the same information, some entities asked not to be contacted again.
- Some of the entities contacted have stated there are no records and have explained that carnation is not known outside of cultivation. With this information, it does not make sense contacting those entities again or contacting entities in the same geographical areas.

- Taxonomically, “carnation” can be a loosely interpreted term, sometimes interchangeable with “pinks” and sometimes used generically to refer to the *Dianthus* genus. The taxonomy of *Dianthus caryophyllus* is also confusing as there are more than a dozen synonyms for the species<sup>3</sup>. In the course of the mail out there have been instances where photographs of other *Dianthus* species have been recorded as carnation or *Dianthus caryophyllus* by respondents. Other respondents have understood “carnation” to mean any *Dianthus* sp.

The literature and database reviews are adequate tools for general monitoring. As time has progressed the database review particularly has become increasingly important and has proven itself to be more valuable than the institutional mail out:

- Responders provided information on many databases as a result of mail out, increasing the breadth of information sources to an extent greater than has been achieved through responses to the mail out.
- New databases have been established since the start of the institutional mail out, replacing the role of mail out with some entities. 56 mail out respondents who provided a record of *Dianthus caryophyllus* did so by using a publicly available herbaria and flora databases and providing us a link to the database. In subsequent monitoring reports the databases suggested were used, with no need to contact the entity through the mail out.
- Databases and literature are fully accessible, which removes the redundancy of contacting entities who do not respond.
- Large “naturalist/citizen botanist” flora databases such as TelaBotanica and i-naturalist have now been established. The majority of recent observations of *Dianthus caryophyllus* have come from these sites. It would be very difficult to replicate contact with the membership of these large associations by direct mail out.
- Any identification problem or confusion can be resolved when photographs are reviewable on databases or collectors can be contacted directly.
- Any follow ups made from the database review and literature review is specific, to people who are knowledgeable of the genus *Dianthus*.

#### Proposal to remove the institutional mail out from the monitoring plan

The proposed amendment to the monitoring plan is:

- In early June 2022 contact will be made entities that have never responded by letter (this will be approximately 140 entities), using email instead. In 2021 a trial of this approach was carried out, emailing 20 entities who had never responded to letters. As 11 of the 20 responded, 60 – 70 responses are expected from 140 entities. The purpose of this final mail-out is to expand the number of responding entities, so adding more comprehensiveness to the overall outcome of the institutional mail out.
- In early June 2022 contact will be made to all entities who have responded regularly advising them that a) though a mail out will no longer be made the general monitoring will continue b) provide contact details for them to voluntarily advise of any observations of escape carnation populations in future years.
- The institutional mail out will not be carried out in 2023 and will be discontinued from the 2023 monitoring reports onwards. Direct communication will continue on an annual basis with literature authors, vegetation databases and collectors as necessary to confirm they have not observed, recorded, or noted carnation populations.

The proposal outlined above applies to all six transgenic carnation marketing consents.

#### Adaptation of the general monitoring plan

The proposed adaptation of the monitoring plan is in accordance with the consents for the six transgenic carnation events as the expected outcomes from the general monitoring plan are

<sup>3</sup> <http://www.theplantlist.org/tpl1.1/record/kew-2764005>

unchanged. Literature review and database review are proven to be effective means of general monitoring and expansion to include vegetation databases and direct communication to authors and individual collectors will substitute for information potentially gained from the institutional mail out.

The adaptation is within the framework for the monitoring plans specified in the consents:

- There is no impact on the provision of annual reports of the results of the monitoring activities. These will continue to be provided at the end of July each year.
- The requirement to provide evidence of monitoring activity is provided more comprehensively through database and literature review as URLs, reference dates and citations are provided alongside any observations noted.
- Where databases are publicly available It can be guaranteed that the relevant information will be provided before the submission date of the annual reports.

August 23 2021



**Table 1. Distribution of 845 entities contacted, by country.**

Country	No. of entities	Percentage of total	Average contacts per entity
France	203	24.0%	2.4
Italy	135	16.0%	2.8
Germany	60	7.1%	2.9
Spain	55	6.5%	3.4
United Kingdom	48	5.7%	3.6
Czech Republic	35	4.1%	2.1
Switzerland	21	2.5%	2.3
Croatia	18	2.1%	3.4
Hungary	18	2.1%	4.2
The Netherlands	18	2.1%	3.0
Slovakia	16	1.9%	2.9
Slovenia	16	1.9%	2.9
Austria	15	1.8%	3.8
Bulgaria	15	1.8%	2.7
Portugal	13	1.5%	3.9
Romania	13	1.5%	2.7
Greece	12	1.4%	4.3
Poland	12	1.4%	2.6
Belgium	11	1.3%	3.5
Sweden	11	1.3%	3.1
Latvia	10	1.2%	3.1
Finland	9	1.1%	3.8
Russia	9	1.1%	2.7
Serbia	9	1.1%	3.0
Estonia	8	0.9%	3.4
Denmark	7	0.8%	5.1
Norway	7	0.8%	1.7
Ireland	5	0.6%	3.8
Lithuania	5	0.6%	3.8
Republic of North Macedonia	5	0.6%	2.2
Cyprus	4	0.5%	4.5
Malta	4	0.5%	7.8
Ukraine	4	0.5%	1.0
Bosnia and Herzegovina	3	0.4%	3.0
Luxembourg	3	0.4%	5.3
Albania	2	0.2%	3.5
Iceland	2	0.2%	2.5
Montenegro	2	0.2%	2.0
Gibraltar	1	0.1%	2.0
Moldova	1	0.1%	3.0
<b>Total</b>	<b>845</b>	<b>100.0%</b>	<b>3.0</b>

**Table 3. Response rate by country.**

Country	No. of entities responded	Response as percent of all entities contacted within that country
Denmark	7	100.0%
Iceland	2	100.0%
Malta	4	100.0%
Ireland	4	80.0%
Serbia	7	77.8%
Poland	9	75.0%
Norway	5	71.4%
United Kingdom	33	68.8%
Luxembourg	2	66.7%
Spain	35	63.6%
Portugal	8	61.5%
Croatia	11	61.1%
The Netherlands	11	61.1%
Latvia	6	60.0%
Republic of North Macedonia	3	60.0%
Greece	7	58.3%
France	113	55.7%
Finland	5	55.6%
Sweden	6	54.5%
Austria	8	53.3%
Bulgaria	8	53.3%
Switzerland	11	52.4%
Albania	1	50.0%
Cyprus	2	50.0%
Estonia	4	50.0%
Germany	30	50.0%
Montenegro	1	50.0%
Slovakia	8	50.0%
Ukraine	2	50.0%
Czech Republic	16	45.7%
Italy	57	42.2%
Romania	5	38.5%
Belgium	4	36.4%
Hungary	6	33.3%
Slovenia	5	31.3%
Russia	2	22.2%
Lithuania	1	20.0%
Bosnia and Herzegovina	0	0.0%
Gibraltar	0	0.0%
Moldova	0	0.0%