



**INTERNATIONAL FEDERATION  
OF FERTILITY SOCIETIES**

# IFFS Surveillance 2013

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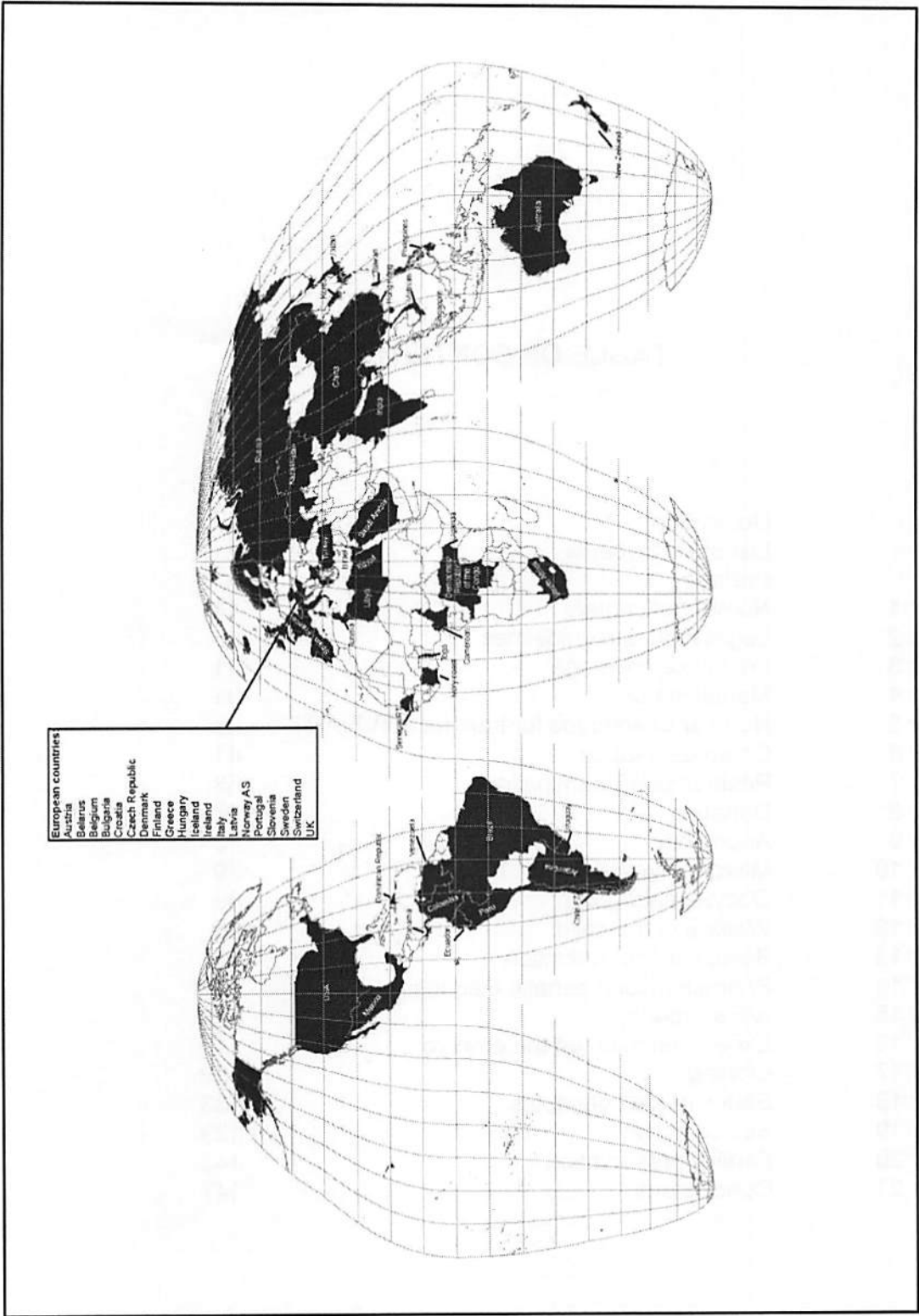
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## **Surveillance 2013 Dedication**

**The 2013 edition of Surveillance is dedicated to Dr. David Healy, late IFFS president, whose premature loss made this edition of Surveillance particularly challenging. Professor Healy made substantial academic, inspirational, executive, and financial contributions to this project at the outset, and we profoundly regret that he was not able to see the final product that he had so passionately championed.**

## List of Participants (Survey Respondents)

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Saudi Arabia	Samar Hassan
Senegal	Rokhaya Thiam Ba
Singapore	P C Wong
Slovenia	Tomaz Tomazevic
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Spain	Charo Buxaderas Sanchez
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South Africa	Paul Le Roux
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## **Preface 2013**

The current version of this IFFS Surveillance Report (Surveillance 2013) has undergone considerable evolution. The highly accomplished leaders, Drs. Howard Jones, Jr., Ian Cooke, Roger Kempers, and Doug Saunders, have retired from their editorial duties after committing over a decade to the inception, development, and production of the IFFS Surveillance Report. Their vision, insights, and extraordinary productivity made Surveillance an ongoing successful activity for IFFS. Of the 2010 editors, only Dr. Peter Brinsden has continued. A larger editorial board was assembled for this edition of Surveillance, and Paul Devroey and I were enthusiastically supported by the talented writing group of Drs. Manish Banker, Peter Brinsden, John Buster, Moïse Fiadjoe, Marcos Horton, Karl Nygren, Hirshikesh Pai, Paul Le Roux, and Elizabeth Sullivan. We wish to gratefully acknowledge the superb technical support and external review by Sheryl van der Poel from the World Health Organization. We also wish to thank the IFFS officers, Board of Directors, and administrative staff for their excellent support and assistance.

Surveillance remains a triennial report released on the occasion of the IFFS Congress. The transition of Surveillance to a Web-based survey progressed considerably for the 2013 edition. Redshift Technologies, a data management/IT firm, was engaged to develop and refine a custom online survey based on the previously used questionnaire with the intent to be accessible to all national society participants, worldwide. The advantages of this system included the ability to create a more user-friendly survey with internal validation systems and data analysis in place. The system created an enormous multinational database and facilitated the extraction of data for producing this report. It provided central data analysis immediately available to the editorial group. The Surveillance 2013 editors are very appreciative of Ethan Wantman at Redshift Technologies, whose imagination and energetic commitment to the project were essential to the report's completion. In addition, the editors are deeply indebted to Kathleen Miller who solved the hitherto insurmountable problem of converting the large cumbersome Excel spreadsheets into concise, legible, print format-ready tables. The current format and final product reflect the skill and thoroughness of our copy editor, Jill Vandermeulen.

For the Surveillance 2013 survey, requests to participate were emailed to 216 individuals who potentially represented over 150 countries. This list was primarily developed from past participants, who were contact sources representing the professionals from their respective National Societies. Ultimately, respondents from 60 countries who had partially or fully completed the survey provided sufficient information to be used in the analysis. The number of responses to individual questions from participants ranged from 0 to 205 with a minimum of 32 survey responses required for inclusion of their survey results in the report. Most of the chapters reflect a variable number of responses from the 73 respondents representing the 60 countries. Although the total number of respondents that logged onto the website was comparable to the response noted in the Surveillance 2010 survey, the 60 countries included this year are fewer than the 105 reported within the Surveillance 2010 but consistent with the 59 national participants in 2007. However, response rates for some topics, such as insurance coverage, were more extensive for this year's iteration. A



top priority for the next version will be to secure broader representation of additional National Fertility Societies or their equivalent through our status as a nongovernmental organization (NGO) in official relations with the World Health Organization (WHO).

Surveillance offers a snapshot of assisted reproductive technology (ART) *in vitro* fertilization (IVF) applications worldwide, as they existed in the fall of 2012. The data presented in this report, attests to consistencies in practice around the world and highlights local differences that reflect cultural, religious, and other preferences. The data compiled herein reflect the understanding of one or two well-informed individuals concerning the professional practice and status of ART within their country. As such, we acknowledge that there are likely intrinsic potential bias and errors of omission and commission that are inherent in this collection methodology.

Trends noted in the Surveillance 2013 depict a more modest growth in the number of new IVF facilities over previous intervals. Laws and guidelines enacted over the past three years seemed to have shown a significant (75% positive) salutary effect on the practice of ART. Although considerable variation in approaches to safety and quality control is noted by regulation or between professionals practicing in countries, there appears to be a consistent overall trend towards broader access to ART with increased safeguards for the stakeholders.

Steven J. Ory

Editor-in Chief, Surveillance 2013

## **Chapter 1: Number of centers**

### **INTRODUCTION**

Generating an accurate estimate of the number of IVF centers which provide ART in the world is problematic for a number of reasons. In countries in which clinics are registered, licensed, or otherwise regulated, reasonable calculations exist. However, some of the most populous countries do not have any relevant registries or have incomplete or inconsistent tallies/outcomes. Countries where a first IVF clinic is just being established may not be identified for this analysis, and the opening of new centers and closing of older ones is an ongoing dynamic process, worldwide.

### **ANALYSIS OF THE SURVEY**

The 2013 Surveillance survey was initiated in the fall of 2012, and invitations to participate were sent to 216 individuals. Ultimately, 73 responses representing expert-informed data from 60 countries, of which 59 provided information about the number of centers, were received and deemed sufficient for analysis (Table 1.1). In 2010, representatives from 104 countries provided data regarding the number of IVF units in their respective countries. One representative new to the survey provided data on Kazakhstan for the 2013 survey, and 45 previous participants did not. Despite the absence of data from the previous 45 participants, the survey notes that based only on participants from 60 countries, there is an increase in the total number of IVF centers, with most participants noting a modest increase in their total when compared to their 2010 tally. For the most part, the same respondents have provided the data in both survey years (2010 and 2013), and the changes noted may reflect genuine trends.

The current survey estimates that the number of IVF centers is approximately 3,706-3,895 compared to a range of 3,528-3,877 reported in 2010. The 45 participants in the 2010 study who did not contribute data this year accounted for approximately 550 centers that were cited in the 2010 total (thus unable to correct for new or clinic closures.) Nonetheless, these numbers are higher than the IVF Worldwide recent continent-by-continent estimate of 3,352 centers, which was an increase from the 3,055 total that they had noted in December 2009.

### **REFERENCE**

IVF Worldwide: <http://www.ivf-worldwide.com/>

<b>Table 1.1 Number of centers</b>			
<b>Country</b>	<b>2010 (N)</b>	<b>2013 (N)</b>	<b>Comments</b>
Argentina	23-25	30-44	
Australia	63	Not reported	
Austria	25	25	
Belarus	4	4	
Belgium	16-30	31	
Brazil	150	200	
Bulgaria	16	23	
Cameroon	2	2	
Chile	8-9	7	
China	102-300	>200	The number of centers approved by the Ministry of Health is about 200, but others are approved by health departments of provinces.
Colombia	19-21	27	
Croatia	7-11	13	
Czech Republic	30	38	
Democratic Republic of the Congo	1	1	
Denmark	18-22	18-21	
Dominican Republic	4	5	
Ecuador	6-8	11	
Egypt	52-55	58	
Finland	19-20	18	
France	90-106	100	
Greece	50-60	~ 60	
Hong Kong	7	9-12	
Hungary	12	14	

<b>Table 1.1 Number of centers (continued)</b>			
<b>Country</b>	<b>2010 (N)</b>	<b>2013 (N)</b>	<b>Comments</b>
Iceland	1	1	
India	500	500-600	
Ireland	7	7-8	
Israel	24-30	29	
Italy	360	350	
Ivory Coast	3	2	
Japan	606-618	591	
Kazakhstan	Not reported	12	
Latvia	4-5	4	
Libya	9-10	8-10	
Mexico	Uncertain	~ 30	
New Zealand	7	7	
Norway	11	10	
Panama	7	9	
Peru	5-7	6	
Philippines	4	5	
Portugal	24	28	
Russia	80	110-130	
Saudi Arabia	24-30	30	
Senegal	2	2	
Singapore	9	11	
Slovenia	3	3	
South Africa	12-15	15	
South Korea	142	150	

<b>Table 1.1 Number of centers (continued)</b>			
<b>Country</b>	<b>2010 (N)</b>	<b>2013 (N)</b>	<b>Comments</b>
Spain	177-203	>100	
Sweden	15-16	16	
Switzerland	26	26	
Taiwan	72-78	76	
Togo	1	1	
Tunisia	8	12	
Turkey	112-116	131	
Uganda	1	2	
United Kingdom	66	71 -117	
Uruguay	4	4	
United States	450-480	430	
Venezuela	17-18	10	
Vietnam	11-12	13	
<b>Totals</b>	<b>3,524 - 3,870</b>	<b>3,701 - 3,890</b>	

\* Multiple replies submitted for the country but only one response included in table.

## **Chapter 2: Legislation and guidelines**

### **INTRODUCTION**

The practice of ART is extensively influenced by cultural, religious, and political exigencies in each of the locales in which it is practiced. All nations have a legitimate interest in promoting the safety and welfare of its citizens undergoing new medical therapy, and the practice of ART has endured special scrutiny in its regulation. The attention devoted to implementing new ART legislation appears to exceed that given to other medical disciplines. While the plethora of different national laws across the globe may try to ensure safety and implement best practices, they can be influenced by cultural norms, religious ideology, preferences of local officials, ethical opinion, and general public perception. For example, the Catholic Church's view, published in the 1987 "Donum Vitae" document, is that IVF is morally illicit; this view has profoundly influenced legislation in some countries. This position has not been modified. Other religions endorse IVF but are not supportive of certain applications such as use of donor gametes or surrogacy. ART practitioners and reproductive medicine societies have a unique insight into the field of IVF and infertility patients but often may have either a varied or limited role in the enactment of legislation promulgated in different countries.

The previous IFFS 2010 Surveillance Report documented an increase in ART legislation between 2007 and 2010. In countries where IVF has been more recently introduced, there is often no legislation or "quasi-legislation," but over time most countries appear to have either developed or have begun to develop guidelines and dedicated ART legislation. The intent of some forms of newer legislation has not, for example, been consistently realized and sometimes has produced unintended consequences, such as motivating patients to travel abroad in search of higher success rates or specific treatments otherwise unavailable, a practice that has been defined as "reproductive tourism" or "cross-border reproductive care."

Increased medical negligence claims, as well as harsher penalty violations for breach of ART law, has put pressure on ART clinicians and embryologists to be more vigilant and compliant with existing national guidelines and legal statutes. Guidelines at the Society level as well as national level, are often written to protect and guide ART practitioners with the intent to provide best practice and to better ensure avoidance of possible medical negligence claims.

This chapter surveys the global landscape with respect to legislation and guidelines and, in particular, addresses changes since the 2010 publication.

### **ANALYSIS OF THE SURVEY**

There were 73 respondents from 60 countries that contributed reliable data to this survey. Of these, 31% used only legislation to regulate ART, 21% used only guidelines to regulate ART, 37% used both legislation and guidelines, and 9% had neither regulations nor guidelines. See Table 2.1. There was a licensing body to regulate the practice of ART in 74% of the countries where participants were surveyed. There are various methods for the implementation of legislation, and the respondents were asked how clinical surveillance was carried out in their country. In 16%, an on-site inspection took place, 6% submit to a periodic report, 29% had both an on-site inspection and periodic reports, and 2% used other methods. In 24%, no surveillance was undertaken and it was unknown in 8%. In summary, approximately two thirds of the respondents replied that there were checks in place to implement enacted legislation directly with the practicing clinics.

There are penalties for violation of the statutes in 67% of the respondents' countries. In 54%, it was recorded that penalties are carried out by health officials, 17% by medical officials or unofficial agencies, and 20% by both health and medical officials. In 9%, the respondents did not know who enforced the penalties.

Laboratories are not always included in the surveillance of the ART clinics; therefore, respondents were asked separately about laboratory surveillance. However, the results obtained were similar to the clinical surveillance data. In this study, 77% had some form of surveillance (22% on-site inspection only, 8% periodic reports only, 31% both on site and periodic reports, and 16% other methods).

Laboratory accreditation was done in 69%, 65% had laboratory certification, and 68% had quality control systems. There were also specific penalty violations noted in the legislation for laboratory procedures in 57% of the respondents surveyed. Some countries used the International Organization for Standardization (ISO) accreditation system or complied with the European Union (EU) tissue directive legislation. Voluntary accreditation via a national reproductive society was reported as a common method of laboratory assessment.

In this 2013 survey, the respondents were asked about whether there had been an update in the legislation in 2012 since the previous IFFS surveillance data were collected in 2009. In 43%, there had been an update in the legislation. Where legislation was updated, 77% concluded that it has been an improvement, 5% a regression, and 18% had no opinion. In some countries, whole new Health Acts incorporating ART were introduced (e.g., South Africa and Russia). In other countries, specific legislation was introduced to address important issues; for example, in the United Kingdom, there was the introduction of legislation to increase donor compensation. In Brazil, Croatia, Taiwan, and Turkey, there were laws passed about the number of embryos to transfer. In August 2012, the European Court of Human Rights invalidated one provision of the restrictive Italian law on ART. The Court ruled that a part of the law prohibiting non-infertile couples from accessing embryo screening (preimplantation genetic diagnosis [PGD]) was a violation of the right to privacy and family life (1). In Argentina, Czech Republic, and Latvia, legislation relating to insurance or government payment toward IVF was instituted. Law on oocyte donation and sex selection was updated in Israel. In Denmark, anonymous and non-anonymous gamete donation was legalized, and single women were allowed access to treatment. In Belgium, the implementation of the EU tissue directive was implemented, which increased administrative costs but was of questionable benefit to patients.

Respondents were asked about the publicity given to penalty violations for breach in ART practice. Twenty-five percent of respondents replied that there was increased publicity given to the violations, 41% replied that there was no increase in publicity, and the remainder replied that it was not applicable or unknown. Penalties for failure to comply with ART legislation or guidelines varied from revocation of a physician's license to practice or deregistration of a clinic in some countries, to fines and imprisonment in other countries.

New legislation often devolves around well-known topics, and in this survey, China, India, South Africa, Argentina, Croatia, Belarus, and Czech Republic all had legislation introduced relating to the number of embryos that can be transferred. In Austria and Denmark, new legislation was introduced relating to single embryo transfer in IVF. In Belgium, there was no change in the restrictive 2003 law, but reimbursement is now linked to the number of embryos transferred. However, changes in legislation or guidelines regarding

other important key areas were infrequent. Only 22% of countries introduced new legislation relating to cryopreservation procedures, 8% for donor anonymity, and 4% for child welfare laws.

### **DISCUSSION**

ART remains a highly regulated medical discipline. In this survey, 90% of the respondents surveyed reported some regulation of ART via either legislation or guidelines or a combination of both. Legislation was updated in 43% of the respondent's countries, demonstrating the continued role of government in regulating the practice of ART. The ultimate benefit and harm of regulation continues to be intensely debated, but the widespread acceptance of the legitimacy of ART and society's role in promoting its safe and ethical application are now well established. Globally, there seems to be an emerging consensus regarding availability and best practices, although considerable regional variation still exists. The rapidly evolving technology and inherent ethical issues integrally associated with ART mean that some degree of guidance for physicians is essential. There will unfortunately always be some physicians who act unethically and merit sanctions, but the majority could be hindered by excessive restrictive oversight.

Some of the more controversial legislation enacted includes limits on the number of oocytes that can be fertilized and restrictions on use of donor oocytes and donor compensation. It was encouraging to note that 77% of countries replied that new legislation drafted in the last 3 years has improved existing legislation. There has been an increase in media attention for violations of ART legislation reported in 25% of the countries. This change in addition to the increase in public awareness of medical negligence litigation may be reassuring to the general public, but can also be destructive if it discourages transparency and responsible, corrective actions on the part of the clinics when errors and mishaps occur.

The high rate of 65%-75% for laboratory accreditation, certification, and surveillance also can be viewed as a positive development. This trend has continued and is now clearly international global norm.

### **SUMMARY**

The IFFS 2013 survey incorporated more detailed data being reported from respondents from 60 countries than in previous IFFS reports. Most countries used legislation, guidelines, or a combination to regulate ART practice (90%). In 43% of countries, there was a reported update in legislation over the last 3 years. There was evidence that the drafting and implementing of new legislation was often influenced by the views of religious ideology, politicians, and health officials rather than only medical personnel. There are trends identified that depict increased surveillance of IVF laboratories, stronger penalties for ART violations, and increased publicity of these violations. In two thirds of countries, IVF laboratories are accredited, are certified, and/or have surveillance by authorities.

### **REFERENCE**

1. <http://www.presseurop.eu/en/content/news-brief/2601161-echr-condemns-italian-law-assisted-reproduction>



Table 2.1 Legislation and guidelines					
Country	Legislation	Guidelines	Licensing body	Laboratory accreditation	New legislation since 2009
Argentina	+	+	-	+	+
Australia			+		
Austria	+	+	+	+	-
Belarus	+	+	+	-	-
Belgium	+	-	+	+	+
Brazil	+	+	+	+	+
Bulgaria	+		+	+	+
Cameroon	-	+	-	+	+
China	+	+	+	+	-
Chile	-	-	-	+	-
Colombia	+	-	-	-	-
Croatia	+	-	+	+	+
Czech Republic	+	-	+	+	+
Democratic Republic of the Congo	-	-	-	-	-
Denmark	+	-	+	+	+
Dominican Republic	+	-	-	-	-
Ecuador	-	-	-	-	-
Egypt	-	+	+	+	-
Finland	+	-	+	+	-
France	+	+	+	+	+
Greece	+	-	+	+	-

Table 2.1 Legislation and guidelines (continued)					
Country	Legislation	Guidelines	Licensing body	Laboratory accreditation	New legislation since 2009
Hong Kong	+	+	+	+	-
Hungary	+	-	+	+	-
Iceland	+	-	+	-	-
India	-	+	-	+	-
Ireland	+	+	+	+	-
Israel	+	+	+	+	+
Italy	+	+	+	+	+
Ivory Coast	-	+	-	+	-
Japan	-	+	-	-	-
Kazakhstan	+	+	+	+	+
Korea	+	+	+	+	+
Latvia	+	+	+	-	+
Libya	+	-	+	-	-
Mexico	-	-	+	-	-
New Zealand	+	+	+	+	+
Norway	+	+	+	-	-
Panama	-	-	+	-	-
Peru	-	-	+	+	-
Philippines	-	+	-	-	-
Portugal	+	-	+	+	+
Russia	+	+	+	-	+
Saudi Arabia	-	-	-	+	-

Senegal	-	-	-	+	-
Table 2.1 Legislation and guidelines (continued)					
Country	Legislation	Guidelines	Licensing body	Laboratory accreditation	New legislation since 2009
Singapore	-	+	+	+	+
Slovenia	+	-	+	+	-
South Africa	+	+	+	+	+
Spain	+	+	-	-	-
Sweden	+	+	+	+	-
Switzerland	+	+	+	+	-
Taiwan	+	+	+	-	+
Togo	-	-	+	-	-
Tunisia	+	-	-	+	+
Turkey	+	+	+	-	+
Uganda	-	-	-	+	+
United Kingdom	+	+	+	+	+
Uruguay	-	-	-	-	-
United States	+	+	+	+	-
Venezuela	-	-	-	+	-
Vietnam	-	+	+	+	+

\* Multiple replies submitted for the country but only one response included in table.