

### A Study on Infectious Biological Materials Import/Export Permit Process at Taipei Regional Center of Taiwan Centers for Disease Control, 2015–2017

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#### Abstract

With the rapid development of biomedical technology, the number of applications for import or export permit of infectious biological materials have increased year by year. Among them, around 50%–60% was examined by the Taipei District Control Center of Taiwan Centers for Disease Control (Taiwan CDC). However, there were some problems when applying for the import/export permit, such as misunderstanding the permit requirements. The purpose of this study is to identify the errors and to investigate the causes.

Our study was divided into two parts. First, we linked and analyzed data collected from January 1, 2015, to December 31, 2017, through the Infectious Biological Materials Import/Export Permit System and the Electronic Official Document System of Taiwan CDC. Second, we conducted an applicant satisfaction survey. The results of this study would facilitate policy revision to improve the efficiency of the application process.

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The Taipei District Control Center examined 2,164 applications for the import and export of infectious biological materials from 2015 to 2017. The most frequently mistaken field in the application form was a characteristic description of infectious biological materials. The text errors in the correspondence and accompanying documents were mostly inconsistent, incomplete, unclear, or insufficient. The results of the questionnaire survey demonstrated the gaps between the respondents' perception and the regulations and guidance. Therefore, it is necessary to improve the readability and clarify the application process of the guidance, and the interface and management of Infectious Biological Materials Import/Export Permit System.

Biotechnology has been developing rapidly in recent years. To cope with the increasing number of import or export applications, we suggest that the Infectious Biological Materials Import/Export Permit System should be updated and its user friendly convenience for applicants be improved.

**Keywords:** Infectious Biological Materials, Import/Export Permit System, satisfaction

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Weekly Data of Notifiable Inases (by week of diagnosis)

Case diagnosis year		Week 50★		Week 1-50			
Classification	Disease Diagnosed	2021	2020	2021		2020	
				Total cases★	Imported cases	Total cases★	Imported cases
Category I	Plague	0	0	0	0	0	0
	Rabies	0	0	0	0	0	0
	SARS	0	0	0	0	0	0
	Smallpox	0	0	0	0	0	0
Category II	Acute Flaccid Paralysis	0	1	28	0	31	0
	Acute Viral Hepatitis type A	0	0	71	0	73	8
	Amoebiasis	1	1	188	59	236	122
	Anthrax	0	0	0	0	0	0
	Chikungunya Fever	0	0	1	1	3	3
	Cholera	0	0	0	0	1	0
	Dengue Fever	0	1	12	12	141	68
	Diphtheria	0	0	0	0	0	0
	Enterohemorrhagic E. coli Infection	0	0	0	0	0	0
	Epidemic Typhus Fever	0	0	0	0	0	0
	Hantavirus Pulmonary Syndrome	0	0	0	0	0	0
	Hemorrhagic Fever with Renal Syndrome	0	0	9	0	11	0
	Malaria	0	0	2	2	2	2
	Measles	0	0	0	0	2	2
	Meningococcal Meningitis	0	0	3	0	7	0
	Paratyphoid Fever	0	0	2	0	0	0
	Poliomyelitis	0	0	0	0	0	0
	Rubella	0	0	0	0	0	0
Shigellosis	3	2	121	0	149	24	
Typhoid fever	0	0	3	1	9	3	
West Nile Fever	0	0	0	0	0	0	
Zika virus infection	0	0	0	0	2	2	
Category III	Acute Viral Hepatitis type B	5	0	137	2	106	2
	Acute Viral Hepatitis type C	24	18	547	0	575	4
	Acute Viral Hepatitis type D	0	0	1	0	0	0
	Acute Viral Hepatitis type E	0	0	5	0	8	0
	Congenital Syphilis	0	0	0	0	0	0
	Congenital Rubella Syndrome	0	0	0	0	0	0
	Enteroviruses Infection with Severe Complications	0	0	1	0	7	0
	Haemophilus Influenza type b Infection	0	0	1	0	3	0
	Japanese Encephalitis	0	0	28	0	21	0
	Legionnaires' Disease	6	4	349	1	277	8
	Mumps	3	4	394	1	467	6
	Neonatal Tetanus	0	0	0	0	0	0
	Pertussis	0	1	0	0	9	0
Tetanus	0	0	5	0	7	0	
Category IV	Botulism	0	0	0	0	1	0
	Brucellosis	0	0	0	0	0	0
	Complicated Varicella	0	0	51	0	48	0
	Endemic Typhus Fever	0	0	31	0	21	0
	Herpesvirus B Infection	0	0	0	0	0	0
	Influenza Case with Severe Complications	0	0	1	0	548	6
	Invasive Pneumococcal Disease	1	7	185	0	230	0
	Leptospirosis	0	0	80	0	84	0
	Listeriosis	0	0	157	0	130	0
	Lyme Disease	0	0	1	1	0	0
	Melioidosis	0	0	20	0	17	1
	Q Fever	0	1	8	0	14	0
	Scrub Typhus	5	12	296	0	406	1
Toxoplasmosis	1	0	16	0	16	0	
Tularemia	0	0	1	0	0	0	
Category V	Ebola Virus Disease	0	0	0	0	0	0
	Lassa Fever	0	0	0	0	0	0
	Marburg Hemorrhagic Fever	0	0	0	0	0	0
	Middle East Respiratory Syndrome	0	0	0	0	0	0
	Coronavirus Infections	0	0	0	0	0	0
	Novel Influenza A Virus Infections	0	0	1	0	0	0
	Rift Valley Fever	0	0	0	0	0	0
Severe Pneumonia with Novel Pathogens	68	39	15997	1454	733	678	
Yellow Fever	0	0	0	0	0	0	

- ★The weekly and cumulative total numbers include indigenous and imported cases of notifiable infectious diseases.
- MDR-TB, Tuberculosis, Syphilis, Gonorrhoea, HIV Infection, AIDS, Hansen's Disease and Creutzfeldt-Jakob Disease are excluded from the table.
- Numbers of mumps and tetanus cases are summed up by the week of report.
- Since 2020/1/15, "Severe Pneumonia with Novel Pathogens" was listed as a Notifiable Infectious Disease.

## Suspected Clusters

- Fourteen clusters related to diarrhea (10), tuberculosis (3) and varicella (1) were reported during week 50.

## Imported Infectious Diseases

- There were 62 imported cases from 20 countries during week 50.  
**Severe Pneumonia with Novel Pathogens** : 62 ( Vietnam 12, USA 9, UK 9, the Philippines 8, Cambodia 5, Thailand 2, Indonesia 2, Nigeria 2, Singapore 2, Ireland 1, Canada 1, Czech Republic 1, India 1, UAE 1, Myanmar 1, Spain 1, Maldives 1, Mongolia 1, Malaysia 1, Bangladesh 1 ).
- During week 1–50, there were 1534 imported cases from 84 countries. The top three countries are Indonesia (322), the Philippines (228), and USA (218).
- During week 1–50, the three notifiable diseases with the highest number of imported cases are Severe Pneumonia with Novel Pathogens (1454), Amoebiasis (59), and Dengue Fever (12).

## Summary of Epidemic

- **Severe Pneumonia with Novel Pathogens** : There have been COVID-19 clusters linked to quarantine hotel and the imported cases and inbound passengers are increasing. In addition, Taiwan continues to detect imported cases of Omicron variant. The risk of locally-acquired and imported SARS-CoV-2 infection in Taiwan is rising.

### Weekly Data of Notifiable Infectious Diseases (by week of diagnosis)

Case diagnosis year		Week 51★		Week 1-51			
Classification	Disease Diagnosed	2021	2020	2021		2020	
				Total cases★	Imported cases	Total cases★	Imported cases
Category I	Plague	0	0	0	0	0	0
	Rabies	0	0	0	0	0	0
	SARS	0	0	0	0	0	0
	Smallpox	0	0	0	0	0	0
Category II	Acute Flaccid Paralysis	0	3	28	0	34	0
	Acute Viral Hepatitis type A	0	2	71	0	75	8
	Amoebiasis	1	5	189	59	241	122
	Anthrax	0	0	0	0	0	0
	Chikungunya Fever	0	0	1	1	3	3
	Cholera	0	0	0	0	1	0
	Dengue Fever	0	1	12	12	142	69
	Diphtheria	0	0	0	0	0	0
	Enterohemorrhagic E. coli Infection	0	0	0	0	0	0
	Epidemic Typhus Fever	0	0	0	0	0	0
	Hantavirus Pulmonary Syndrome	0	0	0	0	0	0
	Hemorrhagic Fever with Renal Syndrome	0	0	9	0	11	0
	Malaria	0	0	2	2	2	2
	Measles	0	0	0	0	2	2
	Meningococcal Meningitis	0	0	3	0	7	0
	Paratyphoid Fever	0	0	2	0	0	0
	Poliomyelitis	0	0	0	0	0	0
	Rubella	0	0	0	0	0	0
Shigellosis	1	3	122	0	152	24	
Typhoid fever	0	0	3	1	9	3	
West Nile Fever	0	0	0	0	0	0	
Zika virus infection	0	0	0	0	2	2	
Category III	Acute Viral Hepatitis type B	1	2	138	2	108	2
	Acute Viral Hepatitis type C	11	13	558	0	588	4
	Acute Viral Hepatitis type D	0	0	1	0	0	0
	Acute Viral Hepatitis type E	0	0	5	0	8	0
	Congenital Syphilis	0	0	0	0	0	0
	Congenital Rubella Syndrome	0	0	0	0	0	0
	Enteroviruses Infection with Severe Complications	0	0	1	0	7	0
	Haemophilus Influenza type b Infection	0	0	1	0	3	0
	Japanese Encephalitis	0	0	28	0	21	0
	Legionnaires' Disease	8	7	357	1	284	8
	Mumps	7	13	401	2	480	6
	Neonatal Tetanus	0	0	0	0	0	0
	Pertussis	0	0	0	0	9	0
Tetanus	0	0	5	0	7	0	
Category IV	Botulism	0	0	0	0	1	0
	Brucellosis	0	0	0	0	0	0
	Complicated Varicella	0	0	51	0	48	0
	Endemic Typhus Fever	0	0	31	0	21	0
	Herpesvirus B Infection	0	0	0	0	0	0
	Influenza Case with Severe Complications	0	0	1	0	548	6
	Invasive Pneumococcal Disease	1	5	186	0	235	0
	Leptospirosis	1	0	81	0	84	0
	Listeriosis	0	5	157	0	135	0
	Lyme Disease	0	1	1	1	1	1
	Melioidosis	1	1	21	0	18	1
	Q Fever	0	0	8	0	14	0
	Scrub Typhus	3	5	299	0	411	1
Toxoplasmosis	0	0	16	0	16	0	
Tularemia	0	0	1	0	0	0	
Category V	Ebola Virus Disease	0	0	0	0	0	0
	Lassa Fever	0	0	0	0	0	0
	Marburg Hemorrhagic Fever	0	0	0	0	0	0
	Middle East Respiratory Syndrome	0	0	0	0	0	0
	Coronavirus Infections	0	0	0	0	0	0
	Novel Influenza A Virus Infections	0	0	1	0	0	0
	Rift Valley Fever	0	0	0	0	0	0
Severe Pneumonia with Novel Pathogens	110	30	16107	1563	763	708	
Yellow Fever	0	0	0	0	0	0	

1. ★The weekly and cumulative total numbers include indigenous and imported cases of notifiable infectious diseases.  
2. MDR-TB, Tuberculosis, Syphilis, Gonorrhoea, HIV Infection, AIDS, Hansen's Disease and Creutzfeldt-Jakob Disease are excluded from the table.  
3. Numbers of mumps and tetanus cases are summed up by the week of report.  
4. Since 2020/1/15, "Severe Pneumonia with Novel Pathogens" was listed as a Notifiable Infectious Disease.

## Suspected Clusters

- Twenty-six clusters related to diarrhea (19), tuberculosis (4), varicella (2) and upper respiratory tract infection (1) were reported during week 51.

## Imported Infectious Diseases

- There were 109 imported cases from 27 countries during week 51.  
**Severe Pneumonia with Novel Pathogens** : 109 (USA 45, Vietnam 14, Kazakhstan 11, UK 5, Indonesia 4, Italy 3, Cambodia 3, the Philippines 3, France 2, Germany 2, Japan 1, Netherlands 1, Poland 1, Brazil 1, Ukraine 1, Singapore 1, Malaysia 1, Colombia 1, Thailand 1, Russia 1, South Africa 1, Dominicana 1, Pakistan 1, Lithuania 1, Cameroon 1, Canada 1, UAE 1 ).
- During week 1–51, there were 1644 imported cases from 86 countries. The top three countries are Indonesia (326), the Philippines (262), and USA (231).
- During week 1–51, the three notifiable diseases with the highest number of imported cases are Severe Pneumonia with Novel Pathogens (1563), Amoebiasis (59), and Dengue Fever (12).

## Summary of Epidemic

- **Severe Pneumonia with Novel Pathogens** : The domestic epidemic of COVID-19 is under control. The COVID-19 pandemic remaining serious globally and the imported cases and inbound passengers are increasing in Taiwan. In addition, Taiwan continues to detect imported cases of Omicron variant. The risk of locally-acquired and imported SARS-CoV-2 infection in Taiwan is rising.

### Weekly Data of Notifiable Infectious Diseases (by week of diagnosis)

Case diagnosis year		Week 52★		Week 1-52			
Classification	Disease Diagnosed	2021	2020	2021		2020	
				Total cases★	Imported cases	Total cases★	Imported cases
Category I	Plague	0	0	0	0	0	0
	Rabies	0	0	0	0	0	0
	SARS	0	0	0	0	0	0
	Smallpox	0	0	0	0	0	0
Category II	Acute Flaccid Paralysis	0	0	28	0	34	0
	Acute Viral Hepatitis type A	2	2	73	0	77	8
	Amoebiasis	3	4	192	60	245	125
	Anthrax	0	0	0	0	0	0
	Chikungunya Fever	0	0	1	1	3	3
	Cholera	0	0	0	0	1	0
	Dengue Fever	0	0	12	12	142	69
	Diphtheria	0	0	0	0	0	0
	Enterohemorrhagic E. coli Infection	0	0	0	0	0	0
	Epidemic Typhus Fever	0	0	0	0	0	0
	Hantavirus Pulmonary Syndrome	0	0	0	0	0	0
	Hemorrhagic Fever with Renal Syndrome	0	0	0	0	0	0
	Malaria	0	0	2	2	2	2
	Measles	0	0	0	0	2	2
	Meningococcal Meningitis	0	0	3	0	7	0
	Paratyphoid Fever	0	0	2	0	0	0
	Poliomyelitis	0	0	0	0	0	0
	Rubella	0	0	0	0	0	0
	Shigellosis	1	3	123	0	155	24
Typhoid fever	0	1	3	1	10	3	
West Nile Fever	0	0	0	0	0	0	
Zika virus infection	0	0	0	0	2	2	
Category III	Acute Viral Hepatitis type B	2	1	140	2	109	2
	Acute Viral Hepatitis type C	10	15	568	0	603	4
	Acute Viral Hepatitis type D	0	0	1	0	0	0
	Acute Viral Hepatitis type E	0	0	5	0	8	0
	Congenital Syphilis	0	0	0	0	0	0
	Congenital Rubella Syndrome	0	0	0	0	0	0
	Enteroviruses Infection with Severe Complications	0	0	1	0	7	0
	Haemophilus Influenza type b Infection	0	0	1	0	3	0
	Japanese Encephalitis	0	0	28	0	21	0
	Legionnaires' Disease	3	18	360	1	302	8
	Mumps	5	15	406	2	495	6
	Neonatal Tetanus	0	0	0	0	0	0
	Pertussis	0	0	0	0	9	0
Tetanus	0	0	5	0	7	0	
Category IV	Botulism	0	0	0	0	1	0
	Brucellosis	0	0	0	0	0	0
	Complicated Varicella	1	0	52	0	48	0
	Endemic Typhus Fever	1	0	32	0	21	0
	Herpesvirus B Infection	0	0	0	0	0	0
	Influenza Case with Severe Complications	0	0	1	0	548	6
	Invasive Pneumococcal Disease	0	1	186	0	236	0
	Leptospirosis	1	0	82	0	84	0
	Listeriosis	2	2	159	0	137	0
	Lyme Disease	0	0	1	1	1	1
	Melioidosis	0	1	21	0	19	1
	Q Fever	0	0	8	0	14	0
	Scrub Typhus	4	3	303	0	414	1
	Toxoplasmosis	0	0	16	0	16	0
Tularemia	0	0	1	0	0	0	
Category V	Ebola Virus Disease	0	0	0	0	0	0
	Lassa Fever	0	0	0	0	0	0
	Marburg Hemorrhagic Fever	0	0	0	0	0	0
	Middle East Respiratory Syndrome	0	0	0	0	0	0
	Coronavirus Infections	0	0	0	0	0	0
	Novel Influenza A Virus Infections	0	0	1	0	0	0
	Rift Valley Fever	0	0	0	0	0	0
	Severe Pneumonia with Novel Pathogens	154	20	16261	1715	783	727
Yellow Fever	0	0	0	0	0	0	

5. ★The weekly and cumulative total numbers include indigenous and imported cases of notifiable infectious diseases.  
6. MDR-TB, Tuberculosis, Syphilis, Gonorrhoea, HIV Infection, AIDS, Hansen's Disease and Creutzfeldt-Jakob Disease are excluded from the table.  
7. Numbers of mumps and tetanus cases are summed up by the week of report.  
8. Since 2020/1/15, "Severe Pneumonia with Novel Pathogens" was listed as a Notifiable Infectious Disease.

## Suspected Clusters

- Eight clusters related to diarrhea (5) and tuberculosis (3) were reported during week 52.

## Imported Infectious Diseases

- There were 153 imported cases from 33 countries during week 52.
  - Severe Pneumonia with Novel Pathogens** : 152 ( USA 78, Vietnam 14, France 7, UK 4, Thailand 4, Canada 4, Laos 3, Germany 3, the Philippines 3, Argentina 3, UAE 2, Hong Kong 2, Ukraine 2, Cambodia 2, Switzerland 2, Kazakhstan 2, Nicaragua 1, India 1, Cameroon 1, Guatemala 1, Finland 1, Saudi Arabia 1, Kenya 1, Greece 1, Honduras 1, Hungary 1, Haiti 1, Nigeria 1, Australia 1, Romania 1, Korea 1, Indonesia 1, Egypt 1 ).
  - Amoebiasis** : 1 Indonesia.
- During week 1–52, there were 1797 imported cases from 89 countries. The top three countries are USA (341), Indonesia (327), and the Philippines (234).
- During week 1–52, the three notifiable diseases with the highest number of imported cases are Severe Pneumonia with Novel Pathogens (1715), Amoebiasis (60), and Dengue Fever (12).

## Summary of Epidemic

- **Severe Pneumonia with Novel Pathogens** : There have been domestic cases of COVID-19 clusters linked to quarantine hotel and airport staff, the risk of locally-acquired cases is expected to increase. The COVID-19 pandemic remaining serious globally and the imported cases and inbound passengers are increasing in Taiwan. The risk of locally-acquired and imported SARS-CoV-2 infection in Taiwan is rising.

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