

RAPID RISK ASSESSMENT

Zika virus transmission worldwide

9 April 2019

Main conclusions

Symptoms associated with Zika virus (ZIKV) infection are generally mild and most people who become infected do not develop any symptoms. However, since the 2015–2017 epidemic in the Americas, ZIKV has been recognised as being associated with severe neurological disorders, mainly Guillain-Barré syndrome in adults and congenital Zika syndrome in foetuses and infants, along with other complications including pre-term birth and miscarriage.

Since the epidemic in the Americas peaked in the early spring of 2016, a continuous decline in the number of reported ZIKV disease cases has been observed in the majority of countries throughout the Americas and the Caribbean. Moreover, virus transmission appears to have been interrupted in several island territories since 2017 and early 2018. In Asia, retrospective investigations and epidemiological surveillance suggest a wide geographical distribution of ZIKV. In Africa, information about ZIKV circulation remains limited.

The travel-related risk of infection primarily depends on the risk of mosquito-borne transmission at the destination, although sexual transmission is also a possible factor. The risk of infection may be high during epidemics, but ongoing virus circulation is expected to be lower in areas where ZIKV circulation is considered endemic. In such endemic areas the risk of exposure is low to medium. As a precautionary principle, areas where ZIKV circulation has been reported historically (but where there is limited capacity for ZIKV disease surveillance and therefore a lack of evidence concerning the current level of transmission) can be considered as having low-to-moderate transmission risk.

Most of the European Union (EU) Outermost Regions (OMRs) and Overseas Countries and Territories (OCTs), where the main mosquito vector, *Aedes aegypti*, is present, have reported autochthonous transmission in the past. In those areas where transmission has been interrupted, re-introduction of the virus may occur, but the probability of large outbreaks is currently low due to herd immunity in the population.

In EU OMRs and OCTs outside of the Caribbean with no previous ZIKV circulation, but where potentially competent vectors are present, such as Madeira and Mayotte with *Aedes aegypti*, or Réunion with *Aedes albopictus*, there is a low risk of local transmission if the virus were to be introduced, as local vector transmission has not been documented to date.

In continental parts of the European Union/European Economic Area (EEA), there are two mosquito vectors that have been shown to be competent for ZIKV in laboratory studies: *Aedes albopictus* and *Aedes japonicus*. Nevertheless, their vector competence has been demonstrated to be lower than *Aedes aegypti*. The probability of mosquito-borne transmission of ZIKV is therefore very low in the European¹ parts of EU/EEA during the spring. However, during the summer and autumn, when temperatures and vector abundance are higher, autochthonous transmission in the European parts of the EU/EEA is possible, if the virus were to be introduced by a viraemic traveller.

¹ Refers to geographical Europe

Options for response

EU/EEA Member States should consider communicating the risks of ZIKV to the general public. This should include information on the possibility of transmission by mosquitoes, as a result of sexual activity, or from substances of human origin (SoHO). All residents of, and travellers to areas with ongoing or historical transmission should apply measures to prevent mosquito bites, and be able to make informed decisions on whether to abstain from sex, follow safer sex practices, or avoid/delay pregnancy.

In order to prevent transmission through SoHO, restrictions on the importation of blood, tissues and cells from areas with ongoing transmission should be considered. In special circumstances, these may be imported but should be tested for the presence of ZIKV. The importation of organs from areas with active transmission should be based on an individual risk assessment which should take into account factors such as the risk of virus transmission to any potential recipient, the possibility of performing nucleic acid testing (NAT) testing for ZIKV and the risks and benefits to the patient.

EU/EEA Member States should ensure that medical practitioners in travel clinics maintain awareness of the current ZIKV epidemiology in order to inform pre-travel individual risk assessments. As ZIKV infection during pregnancy can result in severe foetal brain defects and microcephaly, pregnant women and their partners and couples planning pregnancy should be provided with comprehensive information about the risk associated with ZIKV infection, prevention strategies and the risk of Zika transmission in the geographic area to be visited. They should also be informed about the risk of acquiring other infectious agents which may impact pregnancy and cause foetal development disorders, the so-called TORCH agents (e.g. *Rubella* virus, cytomegalovirus and *Toxoplasma gondii*) which are distributed worldwide.

Clinicians should remain alert to the risk of ZIKV infection in travellers returning from areas with ongoing or past transmission and the risk to their sexual contacts in the EU/EEA, and consider testing for ZIKV infection of those with compatible symptoms according to national guidelines. Confirmed ZIKV infections should be reported to the European Surveillance System (TESSy).

Health professionals providing antenatal care, obstetricians and paediatricians should maintain awareness of current ZIKV epidemiology in order to identify and investigate pregnant women exposed to ZIKV during their pregnancy and monitor the neurological development of their children.

Source and date of request

ECDC Internal Decision, 20 March 2019.

Public health issue

This rapid risk assessment was triggered by the evolution of the ZIKV epidemic, the recent update of World Health Organization (WHO) guidelines for the prevention of sexual transmission of ZIKV, the recent identification of three Zika travel-associated cases in travellers from Denmark and Norway returning from Thailand, and one case of sexual transmission in the partner (EU/EEA citizen) of one of the returning travellers. The rapid risk assessment addresses the risk for EU/EEA travellers, the risk for pregnant women, the risk related to sexual transmission, the risk related to SoHO and the risk of importation into EU/EEA.

Consulted experts

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Disease background information

ZIKV disease is a mosquito-borne disease caused by ZIKV. The *Aedes aegypti* mosquito is the main vector but other *Aedes* species can also transmit the virus.

Most infections are either asymptomatic or cause a mild illness. The duration is usually 2–7 days without severe complications and a low hospitalisation rate. ZIKV-associated fatalities are rare [1]. However, according to WHO [2], ZIKV infection during pregnancy can cause infants to be born with microcephaly and other congenital malformations, and it is a trigger of Guillain-Barré syndrome, neuropathy and myelitis, particularly in adults and older children.

ZIKV is also transmitted from mother to foetus during pregnancy, through sexual contact, transfusion of blood and blood products, and organ transplantation.

There is no prophylactic or curative treatment or vaccine to protect against ZIKV infection. Therefore, preventive personal measures are recommended to avoid mosquito bites during the daytime.

More information about ZIKV disease is available in the ECDC <u>factsheet for health professionals</u>, in <u>previous ECDC</u> <u>risk assessments</u> and in the <u>WHO Zika virus factsheet</u> [3-8].

Epidemiological developments

WHO has published a list with epidemiological profiles of vector-borne Zika virus transmission in countries and territories [9]. Although the list is no longer active, it has been replaced with periodic epidemiologic updates [10] to guide public health programmes and traveller health. This section gives an overview of ZIKV epidemiology in the aftermath of the epidemic in the Americas which peaked during the early spring of 2016. Since then, the majority of countries in the Americas and the Caribbean have seen a continuous decline in the number of reported cases, with apparent interruption of virus transmission documented in several island territories. In Asia, results from retrospective investigations and epidemiological surveillance suggest a wide geographical distribution of ZIKV circulation. In Africa, information about ZIKV circulation remains limited due to heterogeneity in the diagnostic capabilities and in arbovirus surveillance systems across the continent. Recent epidemiological developments are reported below by world region. Cases are autochtonous unless otherwise stated.

It should be noted that ZIKV surveillance capacity and coverage varies considerably across the globe, with many areas not having proper surveillance or only patchy coverage. Therefore, the information below is the best available at present and has a significant level of uncertainty. The non-mention of specific countries does not necessarily infer lack of local transmission.

South America

In 2018, according to the Pan American Health Organization (PAHO), Brazil reported 19 020 cases of ZIKV disease. Of these, 1 379 were laboratory confirmed [11]. According to the Brazilian Ministry of Health, 2 062 probable cases of ZIKV disease had been reported in 2019 as of week 9, compared to 1 908 cases reported over the same period in 2018 [12].

According to PAHO, in addition to Brazil, the countries in South America that reported the majority of ZIKV disease cases in 2018 were Bolivia (1 736), Peru (984) and Colombia (857). In Bolivia, 486 cases were laboratory confirmed, and in Colombia 607 were laboratory confirmed.

In 2019, as of 16 March, Peru and Colombia remain among the countries with the highest numbers of ZIKV disease cases, reporting 275 and 110 cases, respectively [11].

Central America and Mexico

In 2019, as of 16 March, Mexico reported 13 confirmed cases of ZIKV disease compared with 39 for the same period in 2018 [13]. For the whole year in 2018, Mexico reported 860 confirmed cases of ZIKV disease which represents a significant decrease in cases compared to 2017 when 3 260 confirmed cases were reported [14].

In 2018, Guatemala was one of the countries in the region reporting the highest number of cases. According to PAHO, 2 300 ZIKV disease cases were notified during 2018, compared to 703 cases reported in 2017. Of these cases, 106 were reported as confirmed in 2018 and 164 in 2017.

In 2018, El Salvador reported 481 cases of ZIKV disease. This represents a slight increase in the number of cases compared to 2017, when 450 cases were reported. In 2019, as of week 11, 128 ZIKV disease cases had been reported, compared to 66 cases for the same period in 2018 [15].

Continental United States of America

In 2016 and 2017, the United States reported around 230 cases of locally-acquired ZIKV disease in Florida and Texas. Of these cases, the majority were reported in Florida in 2016 [16].

The most recent mosquito-infected autochtonous case in the continental United States was reported in Hidalgo County, Texas in December 2017 [17]. Since then, and as of 6 March 2019, no autochthonous mosquito-borne transmission has been reported in the continental United States [18].

A significant decrease in Zika travel-related cases returning to the continental United States has been observed for the same period, from 4 897 cases in 2016 to 72 cases in 2018 [18].

The Caribbean

In 2018, according to PAHO, Cuba reported 873 cases of ZIKV disease.

According to PAHO, in 2018, Puerto Rico reported 146 ZIKV disease cases, while in 2019, as of 16 March, two confirmed cases had been reported [11].

As of 27 March 2019, according to PAHO data the US Virgin Islands reported their last confirmed cases of ZIKV disease in June 2018, while Saint Lucia reported its last cases in 2016, followed by Grenada, Anguilla and Dominican Republic in 2017 [11].

European Union Outermost Regions and Overseas Countries and Territories in the Caribbean and South America

The British Virgin Islands reported its last cases in 2016 [11].

The epidemic in Martinique, Guadeloupe and Saint Martin abated between July 2016 and early 2017. According to the French health authorities, as of February 2018 [19], Martinique and Guadeloupe reported the last confirmed ZIKV disease case in week 5 and week 1 of 2017, respectively. The last confirmed ZIKV disease cases in Saint Martin and Saint Barthélemy were reported in week 8 and 6 of 2017. The last confirmed ZIKV disease cases in French Guyana were reported in April 2017 [20].

In 2018, according to PAHO, the island of Aruba in the Netherlands Antilles reported three confirmed cases of ZIKV disease [11]. According to PAHO, as of December 2017, Sint Maarten and Curaçao reported their last cases in May and June 2017, respectively.

To conclude, in the presence of continued and robust surveillance, the majority of the European Union Overseas Countries and Territories (OCTs) and Outermost Regions (OMRs) from the Caribbean have no apparent active circulation of ZIKV, and therefore can be considered as locations without ongoing transmission.

Africa

Multiple countries in Africa are considered to have current or past ZIKV transmission [10]. In recent years, ZIKV transmission has been reported in Angola, Cabo Verde and Guinea Bissau.

In 2016, Guinea-Bissau reported four cases of ZIKV infection and five cases of microcephaly. Later investigations did not detect Zika RNA, but ZIKV IgG was highly prevalent in samples from infants born with microcephaly and their mothers [21]. Between September and December 2017, 42 microcephaly cases with suspected ZIKV disease as the cause were reported across Angola [22]. Additionally, between October 2015 and March 2016, 7 490 suspected ZIKV disease cases were reported in Cabo Verde [23].

According to the WHO Eastern Mediterranean Regional Office, no ZIKV disease cases have been recorded in the countries belonging to the WHO EMRO Region since August 2018 [24].

Asia

In November 2018, 159 confirmed ZIKV disease cases were reported in Rajasthan state, in India. According to the same sources, ZIKV disease cases were also recorded in Gujarat and Tamil Nadu states in February and July 2017, respectively [25]. In addition, according to media sources, 127 ZIKV disease cases were reported in Madhya Pradesh state during late 2018 [26].

ZIKV disease cases have also been reported in Thailand in recent years. In 2018, 568 ZIKV disease cases were reported across the country [27] and in 2019, as of 12 March, 48 ZIKV disease cases had been reported [28].

In Singapore, four ZIKV disease cases and one ZIKV disease case were reported in 2019 [29] and 2018 respectively [30]. No information was available concerning the probable place of infection for these cases.

In 2019, as of 28 February, Taiwan had reported one confirmed case with probable place of infection in Vietnam. During the period 2016–2018, Taiwan reported travel-related cases from Asia with probable places of infection stated as Vietnam (5), Thailand (4), Malaysia (2), the Philippines (2), Singapore (1) and Indonesia (1) [31].

In October 2018, media quoted health authorities as having reported one confirmed ZIKV disease case in a traveller returning to China having visited the Maldives [32].

In 2018, Australia reported a case with probable infection in Indonesia [33].

Pacific region

ZIKV disease cases have been reported among returning travellers from the Pacific region. In 2018, Australian health authorities reported two imported cases with the probable place of infection being Fiji and Vanuatu, respectively [33].

Overseas Countries and Territories (OCTs) in the Pacific

A large Zika outbreak in French Polynesia lasted until week 19 of 2014 [34]. In week 11 of 2019, one suspected ZIKV disease case in a returning traveller from French Polynesia was reported by Korean health authorities [35].

The other OCTs from the Pacific region have no active circulation of ZIKV. The last ZIKV disease cases in New Caledonia were reported in 2017.

Europe

No vector-borne locally acquired ZIKV disease cases had been reported by EU/EEA countries in Europe as of week 12, 2019.

Between 2015 and week 12 of 2019, 22 EU/EEA Member States reported 2 398 travel-associated ZIKV infections through the European Surveillance System (TESSy)1. France reported 48% of the cases, Spain 15% and the UK 9%. The latest week of disease onset reported was week 4, 2019. Since 2015, 12 countries have reported 139 travel-associated Zika cases among pregnant women. Two cases of microcephaly associated with these pregnancies, one from Spain and one from Slovenia, were reported in the literature [36,37]. An additional case of congenital ZIKV infection was reported in the pregnancy of a Finnish woman [38].

An overview of the number of laboratory-confirmed travel-associated ZIKV disease cases by year and probable place of infection is presented in Annex 1. The number of travel-associated cases has substantially decreased since 2016 when 2 059 travel-associated cases were reported. During the peak of the outbreak in 2016, the majority of the travel-associated cases were reported in travellers returning from Guadeloupe (n=463; 22%), Martinique (n=413, 20%) and the Dominican Republic (n=153; 7%).

In 2017, 264 travel-associated cases were reported to TESSy and only 47 in 2018. In 2017 and 2018, most cases were reported from Cuba (n=116; 44% (2017) and n=20; 43% in (2018)). In 2019, three cases were reported to TESSy as of week 12 in 2019. The travel-related cases from 2019 reported to TESSy up to week 12 have all been reported in travellers returning from Thailand: two from Denmark and one from Norway (see Annex 1).

In addition, 25 sexual transmission events from returning travellers to their partners in the EU/EEA have been reported in TESSy. These event were reported by eight Member States during the period 2015–2019. Of these, the majority were reported as occurring in 2016 (n=21; 84%). One was reported in 2017, two in 2018 and one in 2019. The case from 2019 contracted the infection from a partner who was infected in Thailand, presumably as a result of mosquito-borne transmission.

¹ In March 2016, an interim case definition for surveillance of ZIKV infection was approved and EU surveillance was initiated, allowing countries to report their cases to TESSy. Retrospective data were reported by countries as far back as possible. A formal case definition of ZIKV disease was added to the Commission Implementing Decision (EU) 2018/945 of 22 June 2018.

ECDC threat assessment for the EU/EEA

Prior to the epidemic in the Americas, ZIKV disease was historically known to cause sporadic outbreaks of mild febrile illnesses in Africa and south-east Asia, with one isolated outbreak in Yap in the Pacific region. The expansion of ZIKV circulation to new areas of the Pacific regions, the Americas and the Caribbean between 2013 and 2016 has been a serious public health concern, mainly due to congenital Zika syndrome in neonates. During 2017 and 2018, virus circulation in these regions decreased markedly, as exemplified by the decline in the number of cases reported by national surveillance in the affected countries (see *Epidemiological developments* above) and the decline in the number of travel-associated cases (see Annex 1).

Silent and/or low virus circulation remains possible but does not constitute a major public health threat for the general population, as the majority of the symptomatic cases have mild febrile illnesses and the risk of infection is expected to be low. Moreover, the risk can be further reduced by applying appropriate personal protective measures. In historical endemic areas, such as south-east Asia, viral circulation is expected to vary seasonally (following a seasonal pattern of other *Aedes*-borne diseases) with possible local resurgences and outbreaks.

Outbreaks of chikungunya virus disease and dengue in the European region confirm that autochthonous transmission of arboviruses, for which *Aedes albopictus* is a competent vector, is possible in Europe. However, there is limited evidence of the role of *Aedes albopictus* in ZIKV transmission in the field. Nevertheless, the south of Europe has a suitable period for transmission during the summer and autumn seasons in areas, with established competent vector populations.

Travel-related risk for EU/EEA citizens

Areas with ongoing or known previous transmission

The travel-related risk is dependent on the risk of ongoing mosquito-borne transmission in the traveller's destination area. In areas with enhanced ongoing ZIKV circulation, the main mode of transmission is through the bite of an infected mosquito, although sexual transmission has been reported in a small number of cases. In such areas, as illustrated during the epidemic in the Americas and the Caribbean, the ZIKV disease attack rate in a naïve population can be high, and as a consequence, travel-associated cases are expected during such an outbreak (see Annex 1).

In areas with lower levels of ongoing virus circulation, the likelihood of infection is lower. For travellers, the probability is expected to be even lower than for the resident population, due to the shorter exposure period. Lower levels of ongoing virus circulation are expected in countries or territories where ZIKV circulation is considered to be endemic, as demonstrated by sero-surveys, regular reports of cases by national ZIKV disease surveillance systems, and reports of sporadic travel-associated cases (e.g. south-east Asia). As observed for other arboviruses (e.g. dengue fever), the seasonal variation in competent vector densities is expected to shape seasonal transmission of ZIKV, with an increased risk of local resurgence and localised outbreaks during certain periods of the year with high vector density [39].

As a precautionary principle, areas where ZIKV circulation has been reported historically but where there is limited capacity for ZIKV disease surveillance (and therefore a lack of evidence about the current level of transmission) may be considered areas of ongoing transmission. For these areas, it is expected that the level of viral circulation in the local population is low-to-moderate. For travellers applying personal protective measures against mosquito bites, the risk is low but the possibility of infection still exists. In such regions, where epidemiological surveillance capacities are limited, the reporting of any travel-associated cases might provide important additional evidence of ZIKV transmission. It should be noted that ZIKV disease is a communicable disease under EU epidemiological surveillance in accordance with Commission Implementing Decision (EU) 2018/945 of 22 June 2018 [40].

Areas with interrupted ZIKV transmission and without ongoing transmission

Areas without ongoing transmission include locations where the vectors of ZIKV are not present and locations with past transmission where appropriate epidemiological and laboratory ZIKV disease surveillance of arboviruses is in place and it has been possible to document the (continued) interruption of ZIKV transmission [41]. Following the spread of the ZIKV epidemic across several Pacific islands (2013–2014) and the Caribbean region (2015–2017), numerous island territories were able to document apparent interruption of transmission [11]. In such settings the likelihood of exposure for residents and travellers is considered to be negligible. However, there is a level of uncertainty due to the varied quality of the surveillance and these areas remain suitable for circulation of arboviruses, including ZIKV, if the virus were to be reintroduced - for example from nearby areas with ongoing ZIKV transmission - because of the presence of competent *Aedes* mosquito vectors. In addition, the possibility of ZIKV circulation in non-human primates cannot be excluded [42,43].

Areas with mosquito presence but without ever reported transmission

In general, in any area with a competent vector but where no autochthonous mosquito-borne ZIKV transmission has ever been reported, the risk of exposure for a traveller is negligible. As a general principle, applying personal protective measures against mosquito bites is still recommended, especially during periods of high mosquito activity, as mosquitoes can transmit several other viruses and parasites.

Risk for pregnant women

Symptoms associated with ZIKV infection are generally mild and most people with ZIKV infection do not develop symptoms [44]. However, for certain groups there is an increased risk of medical complications. For example, for pregnant women and their developing foetus there is a risk of congenital Zika syndrome and other complications, including pre-term birth and miscarriage. A study carried out by the US CDC together with state, territorial, and local health departments on the US Zika Pregnancy and Infant Registry (USZPIR) monitored pregnancy and infant/child outcomes among pregnancies with laboratory evidence of confirmed or possible ZIKV infection. The study found that approximately 6% of the children with congenital ZIKV exposure had Zika-associated birth defects and more children had neurodevelopmental abnormalities, possibly associated with congenital ZIKV infection, among those identified during follow-up care [45]. A recent systematic literature review on travel-associated ZIKV infections also revealed that 5–7% of pregnant travellers with ZIKV infection experienced adverse foetal outcomes [46].

The risk of congenital Zika syndrome is higher during the first and the second trimester of the pregnancy (8% and 5%, respectively) than the third trimester (4%)[47]. Consequently, options for the prevention of Zika infection are primarily focused on pregnant women, their partners and couples planning pregnancy, travelling to areas with ongoing transmission.

Due to the severe impact of congenital Zika infection, pregnant women should be provided with comprehensive information about the risk associated with ZIKV infection and prevention strategies. Pregnant women planning to travel to countries where *Aedes*-borne arbovirus transmission is ongoing or has been reported should always seek pre-travel health advice to assess the risk of infection based on the local situation. They should also pay strict attention to personal protective measures against mosquito bites, should they chose to travel.

During the pre-travel health assessment, pregnant women should be informed about the risk of adverse pregnancy outcomes associated with ZIKV infection during pregnancy. They should also be informed of the risk to the foetus from other infectious agents that are distributed worldwide, the so-called TORCH agents (e.g. *Rubella* virus, human cytomegalovirus (*Human betaherpesvirus 5*), *Toxoplasma gondii*). The number of reported rubella and congenital toxoplasmosis cases in the EU/EEA countries in 2015–2017 varied between 696–2 161 and 40–288, respectively. The risk of microcephaly linked to congenital infections with TORCH agents can be higher (1–50%) than the risk associated with ZIKV congenital infection [48]. Information about several other infectious agents (including malaria, influenza A virus, varicella-zoster virus, parvovirus B19, etc. [49]) that can cause pregnancy complications and potential prevention measures can be considered as an element of travel advice.

Risk of sexual transmission

Although not a common mode of transmission, ZIKV can be transmitted through sexual contact. Sexual transmission has predominantly been reported from men to women, but transmission from women to men and from men to men has also been documented. Half of the cases of sexually acquired ZIKV infection developed symptoms within 12 days of the onset of symptoms in their sexual partner, with the longest reported duration between onset of symptoms in the two sexual partners being 44 days [41]. This is consistent with reports of infectious ZIKV being detected in semen for a median duration of 12 days (95%CI: 1–21 days) and a maximum duration of 69 days [50]. ZIKV RNA has also been detected in male and female genital secretions for a longer median and maximum duration, although the significance of this for sexual transmission is less clear. In semen from male cases, ZIKV RNA was present for a median duration of 34 days (95% CI: 28–41 days) in one cohort study, for 35 days (no CI given) in another cohort study and for 40 days (95% CI: 30–49 days) among male case reports and case series [50]. The maximum reported duration of ZIKV RNA detection in human semen is 370 days. ZIKV RNA was detected in vaginal fluid from infected women for a median duration of 14 days (95% CI: 7–20 days) and a maximum of 37 days [50].

WHO recently published an executive summary of updated guidelines for preventing sexual transmission of ZIKV [41]. The revised recommendations take into account the results of a recent evidence review indicating that the infectious period for sexual transmission of ZIKV is shorter than previously estimated by viral RNA detection studies performed earlier during the outbreak [50]. The recommended duration for correct and consistent use of condoms or abstinence from intercourse to prevent sexual transmission of ZIKV from an infected partner to a sexual contact has been reduced by WHO from six to three months for men, and two months for women. In order to reduce the risk of sexual transmission of ZIKV from an infected or exposed partner to a pregnant woman and to prevent

potential infection of the foetus, the consistent use of condoms or abstinence continues to be recommended for the whole duration of an ongoing pregnancy. Nonetheless, the new recommendations more explicitly refer to risk groups: women or couples planning to conceive or having sex that can result in conception and pregnant women. WHO recommendations refer to both individuals living in areas with ongoing transmission of ZIKV, and individuals living in areas without ongoing ZIKV transmission but travelling to or from areas with ongoing ZIKV transmission. The recommendations are summarised under the section *Options for response*.

While sexual transmission will not contribute significantly to the overall number of cases in areas with ongoing mosquito-borne transmission of ZIKV, the use of condoms and other barrier methods for vaginal, anal and oral sex, or the practice of temporary abstinence will have a substantial impact on the risk of returning travellers transmitting the virus to their sexual contacts in ZIKV-free areas. It is therefore essential for EU/EEA residents travelling to or returning from areas with ongoing transmission and their sexual partners in the EU/EEA to be provided with information about the risk of sexual transmission and safer sex practice.

Risk of ZIKV transmission via substances of human origin (SoHO)

Data, though limited, indicate that there is a risk of ZIKV transmission through SoHO, especially through blood transfusion [51,52]. The high proportion of asymptomatic cases [53-56], the documented occurrence of Zika RNA-positive blood donations [57-59], and the reports of probable transfusion-transmitted (TT) cases [60,61] indicate that Zika-positive blood, donated by an asymptomatic infectious donor, may enter the blood supply and could be transfused to a patient. However, the low number of TT cases, all without clinical consequences in recipients, preclude a more accurate risk assessment. Cases of donor-derived ZIKV-associated Guillain–Barré syndrome (GBS) have not been reported, and the likelihood of maternal and foetal exposure to blood products and presumably to other SoHO is very low [62]. Cases of ZIKV transmission through infectious non-reproductive tissues and cells, and reproductive cells such as donated semen and oocytes have not been reported. Since the risk of ZIKV transmission through SoHO cannot be excluded, precautionary measures should be taken in order to prevent possible transmission with potential consequences to a SoHO recipient's health, such as congenital malformations and GBS. SoHO recipients may be immunosuppressed and at risk of developing more severe illness following ZIKV transmission via infectious SoHO products, but conclusive data are lacking.

Risk of importation and transmission in EU Outermost Regions and Overseas Countries and Territories

The probability of spread after introduction or re-introduction is related to the proportion of susceptible (naïve) individuals in the human population, presence of competent vectors and the suitability of the climate. *Aedes aegypti* mosquitoes are present in the EU Overseas Countries and Territories (OCTs) and Outermost Regions (OMRs) in the Americas and the Caribbean, and most of them have reported autochthonous transmission. In the Caribbean region and the Americas, interruption of ZIKV transmission has been observed in several countries and territories (see *Epidemiological development*s above).

In the EU OMRs and OCTs of the Caribbean with previous transmission, re-introduction of the virus might occur, however it is expected that herd immunity in the human population would reduce the probability of large outbreaks, given the intense viral circulation observed during the 2016–2017 period. The current risk of ZIKV infection in residents and travellers in the EU OMRs and OCTs in the Caribbean with previous transmission is probably low; however, active transmission has been reported as recently as December 2018 in Aruba [11].

In the EU OMRs and OCTs outside of the Caribbean where there was no previous ZIKV circulation, but where potentially competent vectors are present, such as Madeira and Mayotte with *Aedes aegypti*, or Réunion with *Aedes albopictus*, further local transmission is possible should the virus be introduced [63,64]. It should be noted that *Aedes aegypti* is also present in Réunion but persists only as residual populations, mainly found in natural habitats, such as ravines located on the west coast [65]. However, this risk currently seems to be low, as local vector transmission has not been documented to date [65]. A laboratory vector competence study of *Aedes albopictus* from Réunion artificially infected with a ZIKV strain isolated from a 2014 case in New Caledonia did not find dissemination of the virus beyond the mosquito gut [66]. Nevertheless, the possibility that local mosquitoes might be a competent vector for other ZIKV strains cannot be excluded. For Madeira, a vector competence study showed that only one out of 20 (5%) *Aedes aegypti* mosquitoes from a population in Funchal had virus in its saliva at day 9 and 14 post feeding on blood infected with a ZIKV strain isolated from a 2014 case in New Caledonia, and no virus was detected in 20 *Aedes aegypti* mosquitoes from Paul do Mar [67].

Risk of importation and transmission within European parts of the EU/EEA

Mosquito-borne transmission

In European parts of the EU/EEA, there are two mosquito vectors that have been shown to be competent for ZIKV in laboratory studies: *Aedes albopictus* and *Aedes japonicus*. Maps of their current known European distributions can be found here: <u>www.ecdc.europa.eu/en/disease-vectors/surveillance-and-disease-data/mosquito-maps</u>. Other European mosquitoes such as *Culex p. molestus, Culex p. pipiens, Culex torrentium* and *Aedes caspius* are not known to be competent vectors [68-70].

Vector competence of *Aedes albopictus* is generally low. In France, only one out of 24 (4%) *Aedes albopictus* mosquitoes from Bar-sur-Loup, tested 14 days post feeding on blood infected with ZIKV isolated from a 2014 case in New Caledonia, had the virus in its saliva, whereas no virus was detected in 24 *Aedes albopictus* from Nice. Mosquitoes were kept at 28°C [67]. Another study [71] reported a transmission rate of 29% at day 10 after infection and 25% at day 14 post feeding on infected blood for an *Aedes albopictus* population from Nice with a ZIKV strain from French Polynesia kept at a temperature gradient from 22°C (during a night of eight hours) to 25°C (during a day of 16 hours).

In Italy, ZIKV was found in saliva of two out of 40 (5%) *Aedes albopictus* mosquitoes from Calabria, 11–21 days post feeding on blood infected with a ZIKV strain from French Polynesia. Mosquitoes were kept at 26°C [72]. Another study [68] found virus in the saliva of four out of 31 (12.9%), and two out of 29 (6.9%) *Aedes albopictus* from Calabria tested 14 and 21 days post feeding, respectively. Mosquitoes were fed on blood infected with an American ZIKV strain and kept at 27°C. Mosquitoes kept at 18°C did not have virus-positive saliva.

In Germany, the virus was found in saliva of four out of 31 (12.9%) and six out of 34 (17.6%) *Aedes albopictus* from Freiburg tested 14 and 21 days post feeding, respectively [68]. Mosquitoes were fed on blood infected with an American ZIKV strain and kept at 27°C. Mosquitoes kept at 18°C did not have virus-positive saliva.

In Spain, Gutiérrez-López and colleagues [69] found virus in the saliva of two out of 21 (10.5%), two out of 27 (7.4%), and four out of 18 (22.2%) *Aedes albopictus* from Barcelona, Spain tested at day 7, 14 and 21 post feeding, respectively. Mosquitoes were fed on blood infected with a Cambodian ZIKV strain and kept at 27°C [73]. However, with a ZIKV strain from Puerto Rico, no virus was found in the saliva of 33 mosquitoes (0%), none of 30 (0%), and nine out of 26 (34.6%), at day 7, day 14 and day 21, respectively.

For *Aedes japonicus* from south-west Germany, Jansen and colleagues [74] reported virus in saliva in two out of 21 (9.5%), where *Aedes japonicus* was tested 14 days post feeding on blood infected with an American ZIKV strain and kept at 27°C. However, no mosquitoes that were kept at 21 and 24°C had virus-positive saliva 14 days post feeding, and they had much lower infection rates overall.

The probability of mosquito-borne transmission of ZIKV infection is very low in the EU/EEA during the spring as the climatic conditions do not support large *Aedes* mosquito populations and at average temperatures below 20°C the virus does not replicate fast enough for the vector to become infectious [75]. However, during the summer and autumn when temperatures and vector abundance are higher, autochthonous transmission in the EU/EEA following the introduction of the virus by a viraemic traveller is possible [64] in areas where *Aedes albopictus* and *Aedes japonicus* are established.

According to the Interim Risk Assessment issued by WHO's Regional Office for Europe in May 2016, overall the capacity to contain ZIKV transmission at an early stage is good in the countries of the WHO European Region [76,77].

Sexual transmission

Although rare cases of ZIKV infection can occur in European residents as a result of sexual transmission with returning travellers, sustained chains of sexual transmission or sexually transmitted Zika outbreaks are so far just a theoretical possibility and have not been documented, even in highly dense sexual networks [78]. Modelling studies indicate that the reproduction number is below the value of one and thus sexual transmission cannot sustain an outbreak [50,79,80].

SoHO transmission

There is a risk of ZIKV infection importation into the EU through SoHO donated by asymptomatic travellers returning from affected areas and their sexual partners, or via imported infectious SoHO products. Therefore, in addition to measures already applied to travellers in order to prevent the transmission of other arboviruses and malaria, SoHO safety interventions related to donor selection and donation/donor screening have also been proposed (See Table 2).

Options for response

Risk communication

Risk communication is a core public health tool for response and important in managing risk. Uncertainty about risk and prevention measures, low public risk perception and a lack of urgency about Zika are among the main challenges in the EU/EEA Member States.

To address these challenges, WHO published a response guide [81] to Zika risk communication designed to assist public health authorities in response to possible outbreaks of the ZIKV in European countries, based on the experience in the Americas. The report offers options and advice for countries on how to apply the principles of risk communication to their Zika response activities, including how to build a risk communication plan and how to proactively communicate about sexual transmission of Zika virus and the threat it can pose to unborn babies.

Information to healthcare providers in the EU/EEA

EU/EEA Member States should consider the following:

- Ensure that, when providing pre-travel health advice, clinicians and medical practitioners are aware of the current ZIKV epidemiology in order to:
 - perform a comprehensive pre-travel risk assessment and advise travellers accordingly;
 - detect ZIKV infections among travellers returning from areas with ongoing transmission (see Algorithm for public health management of cases under investigation for ZIKV infection) [82,83];
 - consider ZIKV infection in their differential diagnosis for travellers coming from any area with competent vectors (areas within an intertropical range where *Aedes albopictus* and *Aedes aegypti* are present) or for symptomatic individuals who have not travelled but have had sexual contact with a person residing in or returning from areas with ongoing transmission.
- Ensure that health professionals providing antenatal care, obstetricians and paediatricians maintain awareness of current ZIKV epidemiology in order to:
 - detect ZIKV infections among travellers returning from areas with ongoing transmission;
 - identify and investigate pregnant women exposed to ZIKV during their pregnancy (see Algorithm for public health management of cases under investigation for ZIKV infection) [82,83];
 - monitor the neurological development of children born to women exposed to or infected by ZIKV during their pregnancy.
- Ensure timely detection and reporting to the European Surveillance System (TESSy) of confirmed cases imported to EU/EEA Member States in order to provide information about areas with ZIKV transmission.

Options for prevention of ZIKV disease by population type

EU/EEA residents in areas with ongoing transmission

In principle, all residents should apply measures to prevent mosquito-borne diseases [84] when residing or visiting countries with historical ZIKV circulation or areas with ongoing transmission. Given that sexual transmission of ZIKV has been described in areas with ongoing transmission, albeit at low levels [80], residents should be informed of the possibility of sexual transmission so they can make informed decisions on whether to abstain from sex or follow safer sex practices and prevent or delay pregnancy.

In the updated WHO guidelines for prevention of ZIKV sexual transmission recommendations are set out for individuals living in areas with ongoing transmission, specifically for i) all sexually active women and men, ii) women or couples who are planning to conceive or having sex that could result in conception and iii) pregnant women and their sexual partners [41]. A summary is presented below.

All sexually active women and men residing in areas with ongoing transmission

- should, as a matter of principle, always apply measures to prevent mosquito-borne diseases;
- should receive information about the risks of sexual transmission of ZIKV and options for prevention of sexual transmission (i.e. abstinence, correct and consistent use of male or female condoms);
- should be offered a full range of contraceptives and be counselled to allow them to make informed decisions, including whether and when to prevent pregnancy in order to avoid possible adverse outcomes of ZIKV infection during pregnancy;
- should be informed about the possible risk of sexual transmission of ZIKV during the three months after known or presumptive infection for men, and during the two months after known or presumptive infection for women. Men and women should be informed about the correct and consistent use of condoms or abstinence during the respective time periods to prevent ZIKV infection through sexual transmission.

Couples planning to conceive or having had sex that could result in conception residing in areas with ongoing transmission

Women or couples planning to conceive should receive information about the possible risk of vertical transmission of ZIKV to the foetus and about options to delay conception until the risk of ZIKV infection in the local area has substantially decreased, in accordance with local risk assessment. Women should avoid sex that could result in conception for two months and men for three months after known or presumptive infections. Further details on recommendations for couples planning to conceive or having sex that could result in conception are available in WHO's guidelines for the prevention of sexual transmission of ZIKV [41].

Pregnant women and their sexual partners residing in areas with ongoing transmission

- Pregnant women should consult their antenatal care provider for medical advice and pregnancy follow-up and consistently follow measures to prevent mosquito-borne diseases.
- Pregnant women and their sexual partners should correctly and consistently use condoms, or abstain from sex for the whole duration of the pregnancy to prevent ZIKV infection through sexual transmission and possible adverse outcomes of the infection during pregnancy.

EU/EEA travellers to or returning from areas with ongoing transmission

All travellers

In principle, all travellers should <u>apply measures to prevent mosquito-borne diseases</u> [84] when visiting countries with past or current ZIKV circulation.

Although sexual transmission of ZIKV remains an infrequent mode of transmission, sexually active travellers should be made aware of this possibility and advised to consider measures to reduce the risk of sexual transmission, such as abstaining from sex or engaging in safer sex practices [85] for the duration of the trip. Upon return, to prevent sexual transmission to their sexual partners in the EU/EEA and because ZIKV infection can develop without symptoms, they should abstain from sex or correctly and consistently use condoms and other barrier methods for vaginal, anal or oral sex for a duration of three months if the returning traveller is a man, for a duration of two months if the returning traveller is a woman, and for the whole duration of pregnancy if the partner in the EU/EEA is pregnant.

Pregnant women, women of childbearing age, women considering pregnancy and their partners

Travellers who are pregnant or considering pregnancy and their partners should take special precautions to prevent ZIKV infection. Pregnant women in particular, should consult their healthcare provider for an individual assessment of risk, and consider delaying non-essential travel to areas with ongoing ZIKV transmission. Table 1 below presents a general overview of the updated options for Zika prevention by population group and areas of travel.

Table 1. Options for prevention of ZIKV infection for pregnant women, women of childbearing age and their partners planning to travel to or returning from areas with ongoing* transmission

Type of population	Options for prevention				
Pregnant women	 Prior to travel, should consult their healthcare provider for individual assessment of risk and consider delaying non-essential travel to areas with ongoing transmission; During the trip, should strictly follow measures to prevent mosquitoborne diseases; During the trip, should abstain from sex or correctly and consistently use condoms to prevent ZIKV infection through sexual transmission for the whole duration of pregnancy; Upon return, should inform their antenatal care provider of their trip to an area with ongoing transmission and seek medical advice if they develop Zika-compatible symptoms. 				
Partners of pregnant women	 Upon return, should abstain from sex or correctly and consistently use condoms with their pregnant partner for the duration of the pregnancy; Should seek medical advice if they develop Zika-compatible symptoms and consider informing the antenatal care provider about possible exposure as a result of travelling. 				
Women of childbearing age and women considering pregnancy	 Prior to travel, should be informed about the adverse outcomes of ZIKV infection during pregnancy and options for prevention of mosquito-borne and sexually transmitted ZIKV infection so they can make an informed decision about avoiding pregnancy for the duration of the trip and for two months after return. 				
Partners of women of childbearing age and of women considering pregnancy	 Male sexual partners returning from areas with ongoing ZIKV transmission should use condoms correctly and consistently or abstain from sex for at least three months after the last possible exposure to prevent ZIKV infection through sexual transmission and reduce the risk of conception. Testing of returning travellers for ZIKV infection may be considered, in accordance with national guidelines. 				

* In the presence of limited capacity for ZIKV disease surveillance and as a precautionary principle due to uncertainties about the active circulation of the ZIKV, areas of ongoing transmission can include areas where historical circulation (syn. 'previous/past transmission') has been reported.

Options for prevention of ZIKV transmission through SoHO

In order to prevent transmission through SoHO, the restriction of importation of blood, tissues and cells from areas with ongoing transmission should be considered. In special circumstances or for life-saving procedures, these may be imported but should be tested for the presence of ZIKV. The importation of organs from areas with active transmission should be based on an individual risk assessment which should consider factors such as infection transmission to any potential recipient, the possibility of NAT testing for ZIKV, and the risks and benefits for the patient. In order to apply Zika safety measures, SoHO establishments should refer to available global epidemiological data.

Proposed SoHO safety measures (Table 2) have been published in ECDC's guidance [86] and are updated in this risk assessment in accordance with the latest WHO recommendation on the sexual transmission of ZIKV [41].

Type of SoHO	Area without active transmission	Area with active transmission				
Whole blood and blood components	Deferral of donors for at least 28 days (i) after cessation of symptoms in the event of confirmed ZIKV infection, and (ii) after return from areas with active transmission, and (iii) after sexual contact with a man diagnosed with ZIKV infection in the three months preceding sexual contact or with a woman diagnosed with ZIKV in the eight weeks preceding the sexual contact OR NAT screening AND/OR application of plasma and platelet pathogen inactivation techniques. (This should also be applied to red blood cells or whole blood, if possible).	OR temporary suspension of local blood donations and importation of blood components from areas without active transmission, AND/OR application of plasma and platelets pathogen inactivation techniques. (This should also be applied to red blood cells or whole blood if possible).				
Plasma for fractionation	It is not essential to exclude blood donors who have returned from active transmission areas wishing to donate plasma for fractionation. It is also not essential to screen plasma for fractionation which was collected in areas without active ZIKV transmission.	It is not essential to exclude blood donors who have returned from active transmission areas wishing to donate plasma for fractionation. It is also not essential to screen plasma for fractionation which was collected in areas with active ZIKV transmission.				
Sperm	Deferral of donors for three months (i) after cessation of symptoms in the event of confirmed ZIKV infection, and (ii) after return from active transmission risk areas, and (iii) after sexual contact with a man diagnosed with ZIKV infection in the three months preceding the sexual contact, and (iv) after sexual contact with a woman diagnosed with ZIKV infection in the eight weeks preceding the sexual contact OR NAT screening of sperm donation, if available.	NAT screening of sperm donation if available OR temporary suspension of local donation and importation of sperm donated from an area/country without active transmission.				
Non-reproductive tissues and cells	Deferral of donors for at least 28 days (i) after cessation of symptoms in the event of confirmed ZIKV infection, and (ii) after return from areas with active transmission, and (iii) after sexual contact with a man diagnosed with ZIKV infection in the three months preceding the sexual contact or with a woman diagnosed with ZIKV infection in the eight weeks preceding the sexual contact OR NAT screening OR/AND pathogen inactivation, if applicable.	NAT screening of donors OR suspension of local donation and importation of tissue and cell materials from areas without active transmission OR/AND pathogen inactivation, if applicable.				
Organs	Individual assessment of organ donors, while carefully weighing the benefits against the risks for the potential organ recipient; final decision lies with the transplant team.	Individual assessment of organ donors, while carefully weighing the benefits against the risks for the potential organ recipient. NAT testing may be used in donors to identify the pathogen.				

Table 2. Options for prevention of ZIKV transmission SOHO

Vector management

A regional framework and vector borne disease response guide has been developed by WHO with the purpose of developing preparedness activities, updating national response plans, harmonising surveillance of vector-borne diseases and mobilising resources to implement an integrated vector management approach [81,87-90].

Disclaimer

ECDC issues this risk assessment document based on an internal decision and in accordance with Article 10 of Decision No. 1082/13/EC and Article 7.1 of Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (ECDC). In the framework of ECDC's mandate, the specific purpose of an ECDC risk assessment is to present different options on a certain matter with their respective advantages and disadvantages. The responsibility on the choice of which option to pursue and action to take, including the adoption of mandatory rules or guidelines, lies exclusively with EU/EEA Member States. In its activities, ECDC strives to ensure its independence, high scientific quality, transparency and efficiency. This report was written with the coordination and assistance of an Internal Response Team at the ECDC. All data published in this risk assessment are correct to the best of our knowledge at the time of publication. Maps and figures published do not represent a statement on the part of ECDC or its partners on the legal or border status of the countries and territories shown.

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Annex 1. Number of travel-associated cases of ZIKV disease by probable place of infection, beginning of 2015 to week 4 (date of onset) 2019⁺

Probable place of infection	2015	2016	2017	2018	2019	Total	Travellers to EU/EEA in 2017*
Africa							
Sub-Saharan Africa							
Angola	0	1	2	0	0	3	276,319
Burkina Faso	0	0	2	0	0	2	81,344
Cabo Verde	0	2	0	0	0	2	651,985
Cameroon	0	1	0	0	0	1	200,049
Nigeria	0	0	1	0	0	1	550,902
Americas							
Latin America and the Caribbean							
Antigua and Barbuda	0	12	0	0	0	12	79,87
Aruba	0	2	1	0	0	3	107,958
Bahamas	0	2	0	0	0	2	86,62
Barbados	0	54	2	0	0	56	319,289
Belize	0	3	0	0	0	3	23,44
Bolivarian Republic of Venezuela	4	48	0	0	0	52	149,34
Bonaire, Sint Eustatius and Saba	0	3	0	0	0	3	52,40
Brazil	2	72	3	0	0	77	2,531,79
British Virgin Islands	0	2	0	0	0	2	7,18
Cayman Islands	0	2	0	0	0	2	20,76
Colombia	4	82	4	0	0	90	825,01
Costa Rica	0	19	9	0	0	28	332,65
Cuba	0	17	116	19	0	152	1,115,77
Curaçao	0	22	4	0	0	26	218,32
Dominica	0	2	0	0	0	2	10,25
Dominican Republic	0	153	2	1	0	156	1,208,93
Ecuador	0	6	19	0	0	25	314,82
El Salvador	1	5	0	0	0	6	55,70
French Guiana	0	29	0	0	0	29	166,11
Grenada	0	14	0	0	0	14	30,96
Guadeloupe	0	464	0	0	0	464	591,89
Guatemala	1	16	0	0	0	17	118,67
Guyana	0	2	0	0	0	2	8,45
Haiti	0	11	1	0	0	12	31,54
Honduras	0	29	1	0	0	30	68,21
Jamaica	0	40	1	0	0	41	374,77
Martinique	0	426	0	0	0	426	5,037,37
Mexico	1	86	3	0	0	90	2,239,69
Nicaragua	0	57	1	0	0	58	77,72
Panama	0	4	2	0	0	6	182,23

Probable place of infection	2015	2016	2017	2018	2019	Total	Travellers to EU/EEA in 2017*
Paraguay	0	1	0	0	0	1	65,054
Peru	0	0	3	0	0	3	560,446
Plurinational State of Bolivia	0	15	2	0	0	17	117,115
Puerto Rico	0	8	2	0	0	10	128,075
Saint Barthélemy	0	16	0	0	0	16	No data
Saint Lucia	0	17	2	0	0	19	88,200
Saint Martin (French part)	0	29	0	0	0	29	No data
Saint Vincent and Grenadines	0	3	0	0	0	3	10,247
Sint Maarten (Dutch Part)	0	6	0	0	0	6	96,016
Suriname	11	37	1	0	0	49	134,294
Trinidad and Tobago	0	14	1	0	0	15	63,926
Antigua and Barbuda; Montserrat	0	0	1	0	0	1	
Bahamas; Ecuador; Mexico	0	0	1	0	0	1	
Northern America	-			-	-		
							5,196,639**
United States of America	0	3	0	0	0	3	
ASId							
South-eastern Asia							
Cambodia	0	0	1	0	0	1	143,010
Indonesia	0	2	0	0	0	2	1,104,639
Malaysia	0	1	0	0	0	1	785,172
Myanmar	0	0	1	0	0	1	108,95
Philippines	0	3	5	2	0	10	898,47
Singapore	0	0	1	0	0	1	1,322,08
Thailand	0	3	4	3	3	13	3,795,39
Viet Nam	0	3	4	1	0	8	842,69
Cambodia; Lao People's Democratic Republic; Malaysia; Thailand***	0	0	0	1	0	1	
Southern Asia							
	-	0	-	0	0	-	3,585,86
India	0	0	2	0	0	2	408,23
Maldives Sri Lanka	0	4	1	1	0	6	685,30
Oceania	0	0	1	0	0	1	
Melanesia/Polynesia							
Fiji	0	1	0	0	0	1	8,98
Vanuatu	0	1	0	0	0	1	20
Fiji; Papua New Guinea; Solomon Islands; Tonga; Samoa***	0	1	0	0	0	1	
Unknown place of infection	1	203	57	6	0	267	
Total number of cases	25	2,059	264	34	3	2,385	33,100,817

* Source: International Air Transport Association (IATA)

** Florida, Texas, US Virgin Islands and U.S. Pacific Trust Territories and Possessions

*** Case travelled to these destinations

† Reporting of ZIKV disease to TESSy has been mandatory since 2018