Annex A: Health Protection (Notification) Regulations 2010 – proposed amendments

Schedule 1 - 'notifiable diseases': Registered medical practitioners (RMPs) have a statutory duty to notify the 'proper officer' at their local council or local health protection team (HPT) of suspected cases of certain infectious diseases.

Schedule 2 - 'causative agents': All laboratories in England performing a primary diagnostic role must notify PHE on the confirmation of a notifiable organism.

Disease	Surveillance already conducted (Y/N)	Should it be added to England Notifiable list? If so, what Schedule?	Rationale
Middle East Respiratory Syndrome	**YES**	**YES Schedule 1 & Schedule 2**	Middle East Respiratory Syndrome (MERS) is a recognised high consequence disease and a concern for public health due to the associated case fatality and the potential for large clusters to occur, particularly in the context of healthcare settings. Therefore, it appears incongruous that this is not a notifiable disease in a similar way to other high consequence infectious diseases (HCIDs) such as Viral haemorrhagic fever. Notifiable Disease – "Middle East Respiratory Syndrome" Rationale: Prompt notification before laboratory confirmation facilitates public health actions such as reinforcement of relevant infection prevention and control measures, and preparation for wider responses such as contact tracing. Relying on reporting as a causative agent alone (below) may delay implementation of these controls. It is acknowledged that not all suspected cases will be confirmed on testing; however, this could also trigger appropriate advice for other infections. For instance, a number of cases of Legionnaires' disease with travel to the United Arab Emirates were identified only after testing for MERS-CoV, as the former is often overlooked in this context Causative Agent – "Middle East Respiratory Syndrome Coronavirus"

			Rationale: Acts as a contingency in case notification above has not occurred, to ensure that public health measures are taken. This is very important as MERS-CoV can be tested through a number of commercial test kits. In the context of a potential cluster or outbreak, laboratory notification will be an important core dataset Additional burden that making these changes will have on health and care system (costs) There are existing recommendations in place to test for these infections which are based on clinical presentation and patient risk factors, and there will be no change in these approaches. Clinically suspected cases of MERS-CoV and Influenza of zoonotic origin are relatively infrequent and therefore the burden on clinicians to notify is proportionate to the public health risk posed by these. Diagnostic laboratories have established relationships with public health agencies in relation to data flows for reporting, and these relationships have been strengthened further through the pandemic. These workflows will be able to adapt to these changes. Public Health England (PHE) does not hold information on costs of these changes. Pros and cons during a pandemic – e.g. not the time to be placing an additional burden – but equally pandemic has highlighted the need and DHSC thinks this will help protect public health Implementing these changes now will be arguably more successful as there is a heightened awareness about respiratory infections and the potential for these to cause outbreaks and potentially pandemics. Despite being in a pandemic, PHE still maintains its public health services and response capabilities for these infections, as does the National Health Service (NHS); the reason for this is to avoid the additional burden of other outbreaks. Delaying changes until the pandemic ends will risk losing the awareness that has developed across healthcare workers.
Avian Influenza/ Swine Influenza / Influenza from other potential animal reservoirs	**YES**	**YES** **Schedule 1** **&** **Schedule 2**	There is a high level of vigilance currently applied to emerging influenza viruses arising from animal reservoirs and causing infections in humans in order to promptly detect viruses which may have epidemic or pandemic potential. Early identification allows implementation of public health measures as well as triggering wider processes such as risk assessment. In the context of a suspected zoonotic source, notification will also facilitate information being provided to animal health colleagues in the Animal and Plant Health Agency and Department for Environment, Food and Rural Affairs (DEFRA), in order to facilitate further investigations and risk assessment. This will support the one health approach to managing disease risks.

			Notifiable Disease – "Influenza of Zoonotic Origin" Rationale: Early notification of suspected cases will accelerate the public health investigation of suspected cases which will assist with identifying potential risk exposures and facilitate rapid information sharing with animal health. Notification also allows control measures to be implemented such as reinforcement of appropriate infection prevention and control measures. A broad term such as "*Influenza of Zoonotic Origin*" is suggested to ensure the terminology in the regulations is sufficiently flexible to adapt to potential changes in animal reservoirs identified over time. Specific Avian Influenza subtypes associated with severe human disease are already designated as HCIDs and adoption as a notifiable disease would be ensure this is consistent. Causative Agent – "Non Human Influenza A subtypes" Rationale: This approach will allow emerging influenza A viruses from potential animal reservoirs such as avian and swine species to be reported and enable public health follow-up of these cases to identify potential sources of exposure. In turn, this will allow more comprehensive surveillance data to be reported at a national level and support our capabilities to report under the International Health Regulations (2005). This has been modified from the approach below related to unsubtypeable as there is a potential for the reporter to incorrectly report a Flu A detection where subtyping has not been completed perhaps due to insufficient material from the sample being tested being available. Additional burden that making these changes will have on health and care system (costs) There are existing recommendations in place to test for these infections which are based on clinical presentation and patient risk factors and there will be no change in these approaches. Clinically suspected cases of MERS-CoV and Influenza of zoonotic origin are relatively infrequent and therefore the burden on clinicians to notify is proportionate to the public health risk posed by these. Diagnostic laboratories have established relationships with public health agencies in relation to data flows for reporting, and these relationships have been strengthened further through the pandemic. These workflows will be able to adapt to these changes. PHE does not

			hold information on costs of these changes, however the cost of failure to notify the first human case of an untypeable zoonotic influenza could be very high. Pros and cons during a pandemic – e.g. not the time to be placing an additional burden – but equally pandemic has highlighted the need and DHSC thinks this will help protect public health Implementing these changes now will be arguably more successful as there is a heightened awareness about respiratory infections and the potential for these to cause outbreaks and potentially pandemics. Despite being in a pandemic, PHE still maintains its public health services and response capabilities for these infections, as does the NHS; the reason for this is to avoid the additional burden of other outbreaks. Delaying changes until the pandemic ends will risk losing the awareness that has developed across healthcare workers.
Chickenpox (Varicella)	**YES**	**YES** **Schedule 1**	Notifiable Disease – "Chickenpox" There are 3 key arguments for the inclusion in schedule 1: **1. To enable prompt risk assessment and post exposure management of high-risk contacts** Varicella zoster immunoglobulin (VZIG) or antivirals are recommended for high risk susceptible individuals exposed to chickenpox /shingles, based on a clinical diagnosis. For immunosuppressed and young babies, VZIG should be administered with seven days of exposure. For pregnant women, post exposure prophylaxis with antivirals should be commenced at day seven post exposure. VZIG for pregnant women should be administered within 10 days of exposure. Therefore, the management requires prompt notification to enable the risk assessment, which requires serological testing using appropriate assays to ensure that VZIG / antivirals can be delivered and administered within the recommended time frame. **2. Surveillance to estimate burden of disease** Live attenuated varicella vaccines have been licensed and available since the 1980s. Currently the United Kingdom (UK) offers selective vaccination to high risk groups e.g. susceptible healthcare workers and household contacts of immunosuppressed individuals. In many countries routine childhood varicella vaccine programmes have been successfully implemented. The UK Joint Committee on Vaccination and Immunisation (JCVI) is currently reviewing varicella control strategies which requires accurate estimates on the burden of disease to inform cost

			effectiveness analyses. Currently burden data is available for selective General Practitioner consultations through a sentinel surveillance scheme. In addition, data on hospital admissions are available but are known to significantly underestimate burden due to coding issues. **3. Establish baseline data to evaluate impact of a future vaccine programme** Following the potential introduction of a childhood varicella vaccine programme, it will be critical to have population wide baseline data to accurately monitor trends and evaluate the impact and effectiveness of the programme. Given that varicella is a clinical diagnosis and laboratory investigations are not routinely undertaken, notification data will provide the key source of information for the early evaluation of the programme. **Additional burden that making these changes will have on health and care system (costs)** Notification of clinical chickenpox cases by general practitioners (GPs) (or other health professionals) to Health Protection Teams (HPT) could be done by completing a form and submitting it by email to the HPT for upload onto HPZone. GP practices are already setup to do this for a wide range of infectious diseases and the addition of chickenpox would only add minimal burden which will likely fall on administrative staff. The burden would vary throughout the year as chickenpox is a seasonal infection. Follow up of vulnerable contacts of chickenpox cases is already a requirement / included in public health guidance – so no additional burden there. **Pros and cons during a pandemic** – The addition of chickenpox to the notifiable infections would ensure that data start to trickle through. We expect it to take time to bed in so signalling the change now is preferable rather than waiting until the pandemic is 'over'. The early availability of routine surveillance data for chickenpox through this route would provide JCVI with evidence to take into account in their deliberations on the introduction of a varicella immunisation programme. In addition, as the pandemic has disrupted normal transmission of infections, we may see different patterns of disease with important public health implications and it will be even more important to have a handle on this if we have additional pressure on top of COVID-19.
Norovirus	**YES**	**YES** **Schedule 2**	Causative Agent – "Norovirus"

			Norovirus is the most common gastrointestinal infection in the UK and is most disruptive in health and social care settings, contributing notably to 'winter pressures' each year in the NHS. A robust surveillance system, including the reporting of all norovirus confirmed laboratory by frontline diagnostic laboratories and referral of representative samples to the reference laboratory for further molecular characterisation is critical for timely detection of strain replacement events and temporally unusual levels of activity to inform preparedness planning and assessment of the potential impact on healthcare systems. Reporting is currently voluntary, with significant under-ascertainment and batch reporting limiting the ability to carry out effective surveillance in near real-time, but inclusion in Schedule 2 of the Regulations would help address these limitations. The additional burden that making these changes will have on the health and care system (and costs) Inclusion only in Schedule 2 is recommended. There are existing workflows for the reporting of norovirus (voluntary reporting into second generation surveillance system with the majority of frontline diagnostic laboratories reporting some/most laboratory confirmed cases at this current time) alongside the mandatory reporting of other gastrointestinal pathogens included in Schedule 2 such as *Salmonella*, Shiga toxin-producing E. Coli etc. There are already existing recommendations in place to test for viral gastrointestinal infections which are based on clinical presentation, patient risk factors and for outbreak detection/management and there will be no proposed change in these approaches. PHE does not hold information on costs of these changes. The pros and cons during a pandemic – e.g. not the time to be placing an additional burden - but equally pandemic has highlighted the need and DHSC thinks this will help protect public health. Surveillance for gastrointestinal pathogens, including norovirus, continued despite the pandemic with detection of outbreaks which require a public health response and detection of unusual or heighted norovirus activity being particularly important (most recent report **here**). The recommendation for inclusion of norovirus as a Schedule 2 agent is especially important because the non-pharmaceutical interventions (NPIs) implemented to reduce COVID-19 transmission are also effective in reducing norovirus transmission and there has been very low activity since the emergence of COVID-19, with a concurrent increase in the proportion of the population now with

			reduced immunity to norovirus a key consideration. With recent easing of some of these measures, norovirus activity is increasing and outbreaks, especially in education settings have significantly increased compared to pre-pandemic years. There is mounting evidence to support the increased risk of temporally unusual and increased norovirus activity across all settings in the community following the relaxation of COVID-19 NPIs, which could also be an applicable consideration in future pandemics where similar NPIs are implemented. In the absence of norovirus being designated as a Schedule 2 agent, the impact of under-reporting cannot be estimated and this hampers both current attempts to quantify changes in norovirus surveillance indicators during the pandemic and, even prior to emergence of COVID-19, effective national level surveillance was negatively impacted by variable reporting across the country (therefore national representativeness/ population coverage was impacted). Norovirus outbreaks have a particularly disruptive impact in hospitals due to staff sickness, ward closures and bed days lost; contributing to 'winter pressures' in the NHS every year. There is also a significant impact in social care settings and educational settings each year and norovirus is the subject of media interest every winter, particularly around the "peak" of activity and the associated disruption caused to NHS and social care services. Changes in the timing of the seasonal increase can lead to unexpected burdens in hospital and community settings making planning for risk mitigation difficult. Analysis and communication of the outputs of effective, comprehensive, representative surveillance data is key to help mitigate 'winter pressures', especially where there may be early and unexpected increases in norovirus activity. Therefore waiting for the end of the pandemic is not recommended. Building on the heighted awareness resulting from the pandemic on the importance of effective surveillance systems for communicable diseases, especially those such as norovirus and influenza that cause a significant burden on health and social care, seems timely in terms of maximising take-up.
Echinococcosis	Yes (only laboratory surveillance)	**YES** **Schedule 2**	Causative Agent – "Echinococcus granulosus and Echinococcus multilocularis" UK acquired human cases of *E.granulosus* are increasing, the disease very has high morbidity, and only species *E.multilocularis* is notified by vets routinely (some data available from slaughterhouse which could be incorporated into national risk assessment).

			Echinococcus (all species) – there was a mandatory requirement for monitoring (in animals) – previously as per the Directive 2003/99/EC Annex A - as considered a priority zoonoses. We understand some surveillance is carried out in the livestock/ animal sector in the UK but not specifically/robustly for imported food commodities, so this supports a 'yes' for adding to Schedule 2 together with above justification. Suggest lack of 'specific' clinical symptoms make it not suitable for Schedule 1 'Notifiable Diseases' It would be useful to make this notifiable as a causative agent in order to ensure that the risk of infections (particularly E. granulosus) can be monitored. However, it is only tested for at two labs in England currently (HTD in London and LSTM in Liverpool), both of which are in close liaison with PHE for surveillance. Ensuring that all cases are notified will ensure that any new locally acquired cases of E. multilocularis are identified, although it is likely that any diagnosed human case would be reported to PHE for further One Health investigations and follow up. Additional burden that making these changes will have on health and care system (costs) *Echinococcus granulosus* and *E. multilocularis* are usually only detected in two specialist laboratories that PHE works closely with. These laboratories have systems in place to report in to PHE and this will be strengthened through this change. Pros and cons during a pandemic – e.g. not the time to be placing an additional burden – but equally pandemic has highlighted the need and DHSC thinks this will help protect public health The laboratories involved in the diagnosis of echinococcus spp (more than one species) are specialist parasitology laboratories. It is important to understand potential changing epidemiological trends in these two infections and ensuring that appropriate public health investigations and measures can be put in place if a locally-acquired case of *E. multilocularis* is detected.
Congenital syphilis	Yes	**YES** **Schedule 1**	Notifiable Disease – "Congenital syphilis" Cases are increasing, the majority are UK born, and many of the mothers screened negative during antenatal testing in early pregnancy – acquiring syphilis later in pregnancy. Case prompts assessment of whether public health actions are needed locally – to address syphilis within the

			wider local population. Current surveillance (including recently strengthened infectious diseases in pregnancy surveillance) is not detecting all cases. Notifiable cases should include syphilitic still birth. The additional burden that making these changes will have on the health and care system (and costs) Reporting these additional cases will be an additional burden for the medical practitioners involved, however congenital syphilis cases are rare (with less than 10 cases per year). The aim of notification is for better surveillance of these rare cases to inform action to reduce the number of cases to zero. The overall burden to the health system will be low. The pros and cons during a pandemic – e.g. not the time to be placing an additional burden - but equally pandemic has highlighted the need and DHSC thinks this will help protect public health. Syphilis cases have not declined substantially during the pandemic while disruption to sexual health services, where pregnant women with or at risk of acquiring syphilis are managed increases the argument for enhanced vigilance at this time.
+ to add neonatal herpes	No	**YES** **Schedule 1**	Notifiable Disease – "Neonatal herpes" Primarily for information flows and surveillance. Poor understanding of the overall burden of this condition. No regular surveillance. A condition that can lead to significant morbidity and death. Limited evidence available suggests that cases are increasing. Better information required to understand and prevent this outcome. Currently subject of a British Paediatric Surveillance Unit study to measure burden (limited duration) – support groups have advocated to make notifiable. The additional burden that making these changes will have on the health and care system (and costs) Reporting these additional cases will be an additional burden for the medical practitioners involved, however neonatal herpes cases are uncommon (with around 100 cases per year). The aim of notification is for better surveillance of these cases to inform action to reduce them. The overall burden to the health system will be low.

			The pros and cons during a pandemic – e.g. not the time to be placing an additional burden - but equally pandemic has highlighted the need and DHSC thinks this will help protect public health. Genital herpes cases have not declined substantially during the pandemic while disruption to sexual health services, where pregnant women with or at risk of acquiring genital herpes are managed increases the argument for enhanced vigilance at this time.
Tick-borne viral encephalitis	No	**YES Schedule 2**	Causative Agent – "Tick borne encephalitis virus" Tick-borne encephalitis virus (TBEV) was detected in ticks within the UK for the first time in 2019 and there have been two probable locally acquired cases detected in humans to date. The infection does not transmit from person to person but is transmitted by ticks, can be severe, and is widespread in central Europe; we may be seeing the start of emergence of this virus in the UK. The public health response to locally acquired cases is around increased tick bite awareness measures in the local area and, importantly, ensuring health professionals are aware to identify further cases and consider vaccination of at-risk individuals. Additional burden that making these changes will have on health and care system (costs) The diagnosis of TBEV is carried out at the PHE Rare and Imported Pathogens Laboratory and this will not change based on the inclusion of this virus in schedule 2. Pros and cons during a pandemic – e.g. not the time to be placing an additional burden – but equally pandemic has highlighted the need and DHSC thinks this will help protect public health The first case of locally acquired TBEV was reported in 2019 and it is important that awareness is maintained for further cases in order to fully understand the risk within the UK. The infection is spread via tick bites and people will continue to visit areas identified with potential risk (based on detection of the virus within tick populations) during the pandemic.
Congenital toxoplasmosis	Yes (laboratory surveillance toxoplasma as a whole,	**YES Schedule 1 & Schedule 2**	Notifiable Disease – "Congenital toxoplasmosis" Extremely poor clinical outcome, emerging threat and no currently robust surveillance framework, needs statutory notification and enhanced clinical and serological surveillance

	not congenital specifically)		Causative Agent – "Toxoplasma gondii" For general/ all clinical presentations of toxoplasmosis due to international studies indicating a high burden of disease, ACMSF opinion on Toxoplasma spp and also the fact if congenital included in Schedule 1 – this will provide context to the Schedule 1 notifications. No currently structured surveillance for toxoplasmosis in UK livestock sector Suggest lack of 'specific' clinical symptoms for general toxoplasmosis make it not suitable for Schedule 1 'Notifiable Diseases' **SUGGEST -** Agree that this is an important clinical problem but the challenge in making this notifiable is in making a congenital toxoplasmosis diagnosis. This will usually be reliant on the mother being diagnosed initially and maternal infection does not always lead to congenital/foetal infection. Where there is clinical suspicion of Toxoplasmosis in the mother, this will always be followed up with laboratory tests to make the diagnosis, inform clinical management of both mother and foetus, and try to reduce any unnecessary anxiety in the pregnant woman. For this reason, it may be more helpful to include this diagnosis under schedule 2 rather than schedule 1. Public health actions based solely on unconfirmed cases may generate additional anxiety at a difficult time during the pregnancy. PHE receives surveillance data from the Toxoplasma Reference Laboratory on a quarterly basis to monitor diagnoses of congenital toxoplasmosis and toxoplasmosis generally. Additional burden that making these changes will have on health and care system (costs) Inclusion only in Schedule 2 is recommended. If notifications are made based on clinical suspicion under schedule 1, then a new workflow will need to be established to collect this data. This may cause an increased burden on clinicians to report these infections under schedule 1 and there is not a specific public health intervention that can necessarily be enacted at this point. There is one reference laboratory in the UK that tests for toxoplasmosis and there is already a reporting mechanism for providing data to PHE. Pros and cons during a pandemic – e.g. not the time to be placing an additional burden – but equally pandemic has highlighted the need and DHSC thinks this will help protect public health This may lead to an additional workload on clinicians and local health protection teams at the current time if the organism is added to schedule 1.

Trichinellosis	No	**YES** **Schedule 2**	Causative Agent – "Trichinella spp" Although very few cases are currently reported annually, and these are all imported cases – consideration of possible changes in food supply chains post EU exit and to be in position to monitor for emergence of this zoonoses if fell under Schedule 2 requirements is recommended. Additionally, we understand that there is a reasonably sized outdoor pig population and wild boar population in parts of the country (under surveillance by Defra/FSA including fox population monitoring) as there was a mandatory requirement for monitoring (in animals) – previously as per the Directive 2003/99/EC Annex A - as considered a priority zoonoses. No specific/robust surveillance for imported food commodities currently PHE monitor and report the small number of trichinellosis cases reported annually and would support the mandatory reporting of these diagnoses to ensure the public health risks of such infections can be followed up promptly. All cases reported in the UK to date have been linked to imported cases or pork products, but this would ensure that any local foci for infection could be investigated and others who may be exposed identified. Additional burden that making these changes will have on health and care system (costs) While this infection is generally detected in specialist parasitology laboratories, this would ensure that any other cases detected in other laboratories are reported in to PHE for public health follow up. These cases are not common and therefore the additional burden is likely to be low. Pros and cons during a pandemic – e.g. not the time to be placing an additional burden – but equally pandemic has highlighted the need and DHSC thinks this will help protect public health This is not currently a common infection, but it would help establish changing trends in the epidemiology of infections, related to local acquisition or imported food products.
Enteritis due to Yersinia enterocolitica or Yersinia pseudotuberculosis	Yes	**YES** **Schedule 2**	Causative Agent – "Yersinia enterocolitica and Yersinia pseudotuberculosis" Emerging infection, significant increase in cases in UK (due to better molecular diagnostics), outbreaks in other countries, agent of food poisoning, high morbidity and long term sequalae. The fourth most commonly reported in EU in 2019 (https://www.efsa.europa.eu/en/efsajournal/pub/6406)

			No currently structured surveillance for yersiniosis in UK livestock sector or imported food commodities. Suggest lack of 'specific' clinical symptoms make it not suitable for Schedule 1 'Notifiable Diseases'. The additional burden that making these changes will have on the health and care system (and costs) Inclusion only in Schedule 2 is recommended. There are existing workflows for the reporting of yersiniosis (voluntary reporting into second generation surveillance system already in place) alongside the mandatory reporting of other gastrointestinal pathogens included in Schedule 2 such as *Salmonella*, Shiga toxin-producing E. coli etc. There is no change proposed to clinical decision criteria for diagnostic testing. PHE does not hold information on costs of these changes. The pros and cons during a pandemic – e.g. not the time to be placing an additional burden - but equally pandemic has highlighted the need and DHSC thinks this will help protect public health. Surveillance for gastrointestinal pathogens, including yersiniosis (on a voluntary reporting basis), continued despite the pandemic with detection of outbreaks which require a public health response being the key aim.
Respiratory syncytial virus (RSV)	Yes	**Yes schedule 2**	Causative Agent – "respiratory syncytial virus" Rationale 1. Surveillance Strengthening of burden of disease estimates nationally could be facilitated through RSV having the status of a notifiable causative organism. RSV exhibits regional variation in the timing of epidemic peaking and burden of disease. Sub-national surveillance and regional health system response could be supported by inclusion as a notifiable organism. 2. Baseline data for immunisation programmes Introduction of any new vaccination or immunisation programmes or changes to the current palivizumab prophylaxis programme would be supported by strong data on diagnosis in NHS laboratories.

			The additional burden that making these changes will have on the health and care system (and costs) Inclusion only in Schedule 2 is recommended. There are existing data flows for the reporting of RSV. It is already listed as a "core" list pathogen for voluntary but expected reported into PHE's second generation surveillance system. **We would welcome discussion with the DHSC policy team on the scope and implications for notifiable disease reporting of negative results particularly in the context of lighthouse laboratory multiplex piloting.** The pros and cons during a pandemic – e.g. not the time to be placing an additional burden - but equally pandemic has highlighted the need and DHSC thinks this will help protect public health. Pros There is minimal additional burden on NHS services from this reporting. RSV is a potential contributor to post-unlocking rebound pressures on the NHS with some estimates in the range of 50% to 100% more cases than in a typical season. If multiplexing proceeds in pillar 2 lighthouse laboratories in 2021-22 then notifiable causative agent status would give the strongest legal basis. Lighthouse multiplexing would tend to favour inclusion of negative RSV reports in notifications to provide surveillance signal. Cons Moving RSV from the "core" to "notifiable" list might not result in any surveillance changes. By the time RSV is added to the notifiable diseases list, a high proportion of the 2021-22 cases may have occurred. 2021-22 data may not be representative of typical years due to rebound into a more susceptible than usual population. Notifiable disease status is intended to enable the *prompt investigation, risk assessment and response to cases of infectious disease*, with longer-run surveillance a secondary function. However, there are multiple notifiable causative organisms which do not have an acute public health response.