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Compilation of National Research Council (NRC) Recommendations on Biosolids

NRC Recommendation (OA= overarching,, OACS= overarching chemical standards, OACP= overarching chemical/pathogen standards, OAPS= overarching pathogen standards, OAHE= overarching health effects, OACP= overarching chem,ical/pathogen , CH#-#= chapter#-recommendation #)	Category
Survey	
OA-2. Conduct a new national survey of chemicals and pathogens in sewage sludge. The committee endorses the recommendation of a previous NRC committee that a new national survey of chemicals be performed. The committee further recommends a survey of pathogen occurrence in raw and treated sewage sludges. The survey should include a careful examination of management practices to ensure that risk-assessment principles are effectively translated into practice. Data from the survey should be used to provide feedback for continuous improvement in the science and technology of biosolids applied to land.	Survey Risk Assessment
OAPS-1. EPA should conduct a national survey of pathogen occurrence in raw and treated sewage sludges. Important elements in conducting the survey include use of consistent sampling methods, analysis of a broad spectrum of pathogens that could be present in sewage sludge, and use of the best available (preferably validated) pathogen measurement techniques.	Survey
OACS-2. As recommended by an earlier NRC committee, a new national survey of chemicals in biosolids should be conducted. EPA should review available databases from state programs in designing a new survey. Other elements that should be included in the survey are an evaluation of the adequacy of detection methods and limits to support risk assessment; consideration of chemical categories, such as odorants and pharmaceuticals, that were not previously evaluated; and assessment of the presence of multiple species of certain metals, such as mercury and arsenic, that have different toxicity end points. Data from this survey should be used to identify any additional chemicals for potential regulation.	Survey Risk Assessment
CH5-3. The committee endorses the recommendation of the previous NRC committee (NRC 1996) that a new national survey of chemicals in biosolids be conducted. It recognizes that more recent survey data are available through many state programs and recommends that EPA consider those databases in the course of designing a new national survey. Other elements that should be included in a new survey are the following: evaluation of the adequacy of analytical methods and detection limits to support risk assessment; consideration of categories of chemicals of current concern that were not previously evaluated (e.g., odorants, surfactants, and pharmaceuticals); and assessment of the possible presence of multiple species of mercury, arsenic, and other metals that have different toxic end points.	Survey Risk Assessment
CH5-8. In addition to the recommendations above for a new biosolids survey and chemical selection process, it is recommended that a research program be developed for pharmaceuticals and other chemicals likely to be present in biosolids that are not currently included in routine monitoring programs. This included chemicals eliminated from Round 1 and Round 2 evaluations because of data gaps. The research program should have the goal of identifying additional chemicals that should be included in routine biosolids surveys, and in future risk assessments. For odorants, research is needed to identify the odorants present in various kinds of biosolids. For odorants commonly present in biosolids, EPA should move more aggressively to develop acute toxicity values for use in assessing the risks posed by these chemicals and should support research on the interaction between these chemicals and pathogens in causing human disease.	Survey Exposure Risk Assessment

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CH6-1. EPA should conduct a national survey of pathogen occurrence in raw and treated sewage sludges. Important elements in conducting the survey include use of consistent sampling methods, analysis of a broad spectrum of pathogens that could be in sewage sludge, and use of the best available (preferably validated) pathogen measurement techniques.	Survey
Exposure	
OACS-3. Aggregate exposure assessments should be performed. A conceptual site model should be used to identify major and minor exposure pathways for various application scenarios. Special consideration should be given to identifying the application practices and environmental conditions that are likely to result in the greatest human exposure. Risks from long-term low-level exposures, as well as short-term episodic exposures, such as those that can occur with volatile chemicals should be evaluated.	Exposure
OACS-4. An RME individual, rather than an HEI, should be evaluated for each exposure pathway. Use of the RME is a more informed and reasonable estimate of exposure than the HEI because it reduces reliance on the subjective application of default assumptions and reflects improved methods of characterizing population exposure. When the RME individual is likely to be exposed by more than one pathway, exposures should be added across pathways.	Exposure
OACS-5. Fate and transport models and exposure parameter assumptions used in the risk assessment should be updated to reflect the most current information on the RME individual for each exposure pathway.	Exposure
CH3-2. Biosolids exposure-assessment studies. Such studies should characterize the exposures of workers, such as biosolids appliers and farmers, and the general public who come into contact with constituents of biosolids either directly or indirectly. The studies would require identification of microorganisms and chemicals to be measured, selection of measurement methods for field samples, and collection of adequate samples in appropriate scenarios. A possible exposure-assessment study would be to measure endotoxin exposure of workers at biosolids production and application sites and of communities nearby.	Exposure Human Health Studies
CH5-5. A new risk assessment should include separate exposure scenarios that represent substantial differences in exposure potential (e.g., land reclamation and forestry applications). For each scenario, a conceptual site model approach should be used to identify major and minor exposure pathways and routes of exposure. Risks from short-term episodic exposures should also be evaluated for volatile chemicals, such as odorants.	Exposure
CH5-6. A comparable reasonable maximum exposure (RME) should be evaluated for each exposure pathway in each exposure scenario, and where the same receptor is likely to be exposed to more than one pathway, exposures should be added across pathways. Such considerations are applicable for both deterministic and probabilistic exposure assessment approaches. Multiple highly conservative assumptions should be avoided; however, care should be taken to ensure that the risks are assessed for the high-end population and that the most sensitive conditions for biosolids application are considered. For example, for the groundwater infiltration pathway, if biosolids application is likely to occur in areas of sandy soil or karst topography with shallow groundwater, those conditions should be used in the risk assessment.	Exposure
CH5-7. The most recent EPA reviews and new studies reported in the literature should be used to identify updated assumptions for exposure parameters for use in risk assessment. Updated fate and transport models should be used to estimate exposure point concentrations. For each exposure pathway, fate and transport models and exposure parameter assumptions should be selected so that pathway exposures reflect the RME.	Exposure Risk Assessment

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CH6-5. As recommended in Chapter 5 for chemicals, EPA should develop a conceptual site model to identify the major and minor exposure pathways (including secondary transmission) by which humans might come into contact with pathogens in biosolids.	Exposure
CH7-2. Research should be conducted to synthesize existing information on potential interaction of chemicals and pathogens that might be associated with biosolids exposures and lead to an increased susceptibility to infection, particularly by inhalation.	Exposure Risk Assessment
Risk Assessment	
OA-1. *Use improved risk-assessment methods to better establish standards for chemicals and pathogens.* Risk-assessment methods for chemicals and pathogens have advanced over the past decade to the extent that (1) new risk assessments should be conducted to update the scientific basis of the chemical limits, and (2) risk assessments should be used to supplement technological approaches to establishing regulatory criteria for pathogens in biosolids.	Risk Assessment
OACS-1. Using current risk-assessment practices, EPA should reassess the standards for the regulated chemicals and conduct another chemical selection process to determine whether additional chemicals should be considered for regulation. On the basis of the revised risk assessments and chemical selection, EPA can determine whether the standards or risk-management process should be revised and whether additional chemicals should be regulated. Because the land-application standards are to be relevant nationally, it is important that the revised risk assessments reflect regional variations in climate, hydrology, and biosolids use and characteristics, and that standards are protective of populations reflecting reasonable estimates of maximum exposure. The chemical standards should be reevaluated and updated periodically to ensure that they are supported by the best available scientific data and methods. B, C	Risk Assessment
OAPS-2. QMRAs should be developed and used to establish regulatory criteria (treatment requirements, use restrictions, and monitoring) for pathogens in biosolids. For example, EPA could stipulate an acceptable risk level for a particular pathogen. QMRA could then be used to estimate the concentration of that pathogen in biosolids either at the point of application (where there is immediate potential for exposure) or following any required holding period. EPA could then determine experimentally based relationships between the maximum acceptable pathogen concentration and the process conditions (e.g., time, temperature, pH, chemical doses, and holding times) and/or the pathogen indicator concentrations (either density or reduction through treatment). On the basis of those relationships, regulatory criteria and monitoring for land application can be updated or developed to ensure consistent attainment of target pathogen concentrations. To conduct QMRAs, a conceptual site model should be used to identify all potential routes of exposure; additional input data (e.g., dose-response and pathogen-survival data) should be collected; and consideration should be given to potential secondary transmission of infectious disease. QMRAs also can be used to analyze sensitivity and to ascertain what critical information is needed to reduce uncertainty about the risks from exposure to pathogens in biosolids. The pathogen standards should be reevaluated and updated periodically to ensure that they are supported by the best available scientific data and methods and to ensure that anecdotal information is not being used for the predication of past, current, or future regulations.	Risk Assessment Pathogens Regulatory Activities
OACS-6. Representatives of stakeholders should be included in the risk-assessment process to help identify exposure pathways, local conditions that could influence exposure, and possible adverse health outcomes.	Risk Assessment Exposure

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CH4-1. Because of the significant changes in risk-assessment methods and policies over the last decade, EPA should revise and update the Part 503 rule risk assessments. Important developments include recognition of the need to include stakeholders throughout the risk-assessment process, improvements in measuring and predicting adverse health effects, advances in measuring and predicting exposure, explicit treatment of uncertainty and variability, and improvements in describing and communicating risk. EPA should consider how the updated risk assessments would change the risk-management process. A similar approach can be taken with the issue of biological agent risks.	Risk Assessment
CH4-4. Because there are no guidelines to ensure that conditions assumed in the risk assessment actually transpire, the committee recommends that the Part 503 rule provide guidance for periodic reassessments that will be used to ensure that the demographic and operational conditions of biosolids land application are consistent with the assumptions of the applicable risk assessment.	Risk Assessment Regulatory Activities
CH5-1. A revised multipathway risk assessment should be performed for the currently regulated pollutants, with particular attention paid to arsenic and to indirect exposure pathways for cadmium and mercury. Additionally, new survey data should be used to identify any additional inorganic or organic pollutants that might need to be included in a risk assessment.	Risk Assessment
CH5-2. Risk-based standards for land application of biosolids should be reevaluated on a regular basis to take into account new information regarding the identity and properties of chemicals present in these mixtures and current approaches to evaluating the risks of exposure to such mixtures. Stakeholders should be included in the process, particularly in the development of the exposure assessments.	Risk Assessment Exposure
CH5-4. Selected persistent, bioaccumulative, and highly toxic chemicals should be retained in the risk assessment even if they are detected relatively infrequently or if some chemical-specific fate and transport parameters are missing. An uncertainty assessment should be performed to evaluate the significance of eliminating chemicals from the risk assessment because of lack of toxicity data or other parameters.	Risk Assessment
CH6-7. QMRAs should be developed and used to establish (or validate) regulatory criteria (treatment processes, use restrictions, and monitoring) for pathogens in biosolids. They can also be used for sensitivity analyses and identifying critical information that is needed to reduce uncertainty about the risks from pathogens in biosolids. To conduct these risk assessments, consideration must be given to assessing risks from all potential routes of exposure (e.g., bioaerosols, groundwater), dose-response relationships, pathogen survival, and secondary transmission of disease. In some cases, research will be needed to fill gaps in knowledge of those inputs. As additional information is gathered on exposure, dose-response relationship, and pathogen survival, the risk assessments should be reviewed and updated as necessary.	Risk Assessment Survey Pathogens Regulatory Activities
CH7-3. As outlined in Chapters 5 and 6, future risk assessments of biosolids components should be conducted using the most current methods and data. For pathogens, it is important that risk assessments include an evaluation of the potential for secondary transmission of disease. Representatives from all stakeholders should be included in future risk assessments. Stakeholders can provide information and insights into the use of biosolids in practice and the potential health problems, which are particularly important in the development of exposure assessment. Involving stakeholders throughout the risk-assessment process provides opportunities to bridge gaps in understanding, language, values, and perspectives.	Risk Assessment Pathogens
Methods Development	
OAPS-3. EPA should foster development of standardized methods for measuring pathogens in biosolids and bioaerosols.	Methods Development

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OAPS-4. EPA should promote research that uses improved pathogen detection technology to better establish the reliability of its prescribed pathogen treatment processes and biosolids-use controls to achieve and maintain minimal exposure over time. In setting pathogen treatment requirements, it might be useful to establish metrics for typical (mean) treatment performance and concentrations not to be exceeded.	Methods Development
CH4-2. Many of the measures of risk used in developing the Part 503 rule guidelines cannot be monitored. Because of that inability to monitor, the committee acknowledges that EPA must perform theoretical risk assessments. Nevertheless, there is a continuing need to provide some measures of performance that can be monitored (e.g., concentrations of selected chemicals in exposure media, such as indoor air, house dust, or tap water of residences near land-application sites; and exposure biomarkers in the blood or urine of nearby residents). Recent improvements in health surveillance and exposure monitoring provide new opportunities for EPA to develop more explicit and measurable metrics of performance for biosolids land-application practices.	Methods Development Survey
CH6-6. EPA should foster development of standardized methods for measurement of pathogens in biosolids and bioaerosols. EPA should include round-robin laboratory testing to establish method accuracies and precisions at the various pathogen concentrations expected in raw sewage sludge and partially and fully treated biosolids. These new detection methods should be used to verify that EPA's prescribed pathogen reduction techniques are reliable in achieving their intended goals. Mechanisms should be developed for incorporating new methodologies into the verification process as they become available.	Methods Development
Pathogens	
OAPS-5. Research should be conducted to assess whether other indicator organisms, such as *Clostridium perfringens*, could be used in regulation of biosolids. Such indicators, along with traditional indicators and operational parameters, may be suitable for monitoring day-to-day regulatory compliance.	Pathogens
CH2-5. The PEC should be funded, supported, and officially sanctioned as an integral part of the federal biosolids program. The following are important in supporting the PEC: • The PEC members should have a formal portion of their time allocated to PEC responsibilities. • Travel funds should be put at the disposal of the PEC to enable meeting attendance and visits to selected sites of petitioners. • There is a perception on the part of PEC members that EPA's Cincinnati laboratories do not include biosolids as a formal part of their mission statement. This needs to be clarified and rectified. • A formal procedure for designation of backup members should be devised.	Pathogens Biosolids Management
CH2-8. Provisions for allowing distribution Class A biosolids in bags or other containers (weighing less than 1 metric ton) should not be allowed when they do not meet pollutant concentration limits (i.e., all biosolids sold or given away should be EQ).	Pathogens Regulatory Activities
CH2-10. EPA should conduct national field and laboratory surveys to verify that Class A and Class B treatment processes perform as assumed by their engineering and design principles. Determinations should be made of pathogen density and elimination across the various accepted treatment processes and in the biosolids or environmental media over time.	Pathogens Survey
CH2-13. EPA should support development, standardization, and validation of detection and quantification methods for pathogens and indicator organisms regulated under the Part 503 rule. The sufficiency of these methods and their results should be considered in conducting and interpreting future risk assessments and used to develop applicable risk-management technologies.	Pathogens Methods Development

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CH2-15. Research is needed on the following topics: • Pathogen survival in processing or emissions during the treatment process. • Vectors carrying pathogens and toxins. • Bioaerosols and other chemical aerosols. • Test-method development and validation for various organisms in sewage sludge and biosolids. • Field verification of efficacy of Class A and Class B treatment processes (including data to directly relate process controls to initial and final pathogen and indicator densities). • Development of indicator pathogens for assessment of impact and attenuation in field situations.	Pathogens Survey Risk Assessment
CH6-2. Additional indicator organisms, such as Clostridium perfringens, should be considered for potential use in regulation of land-applied biosolids. Such indicators and other operational parameters (e.g., time, temperature, pH, and chemical dose) may be suitable for assessing day-to-day compliance with the regulations.	Pathogens
CH6-3. Site restrictions, buffer zones, and holding periods for land-applied Class B biosolids, should consider geographic and site-specific conditions that affect pathogen fate and transport.	Pathogens
CH6-4. Studies should be conducted to determine whether the site restrictions specified for Class B biosolids in the Part 503 rule actually achieve their intended effect with regard to pathogen levels.	Pathogens
Human Health Studies Human Health Studies	
OAHE-1. Although routine human health surveillance of all populations exposed to biosolids is impractical, the committee recommends that EPA promote and support response investigations, targeted exposure surveillance studies, and a few well-designed epidemiological investigations of exposed populations. This recommendation is intended to provide a means of documenting whether health effects exist that can be linked to biosolids exposure. The committee recommends the following types of studies: *Studies in response to unusual exposures and unusual occurrences of disease*. Occasionally, the occurrence of unusual events can provide information on the agents of disease. For example, an outbreak or a symptom of disease might occur following a known exposure or an unusual exposure scenario. In both instances, exposure and health outcomes should be determined. *Preplanned exposure-assessment studies.* Such studies should characterize the exposures of workers, such as biosolids appliers and farmers, and the general public who come into contact with constituents of biosolids either directly or indirectly. The studies would require identification of microorganisms and chemicals to be measured, selection of measurement methods for field samples, and collection of adequate samples in appropriate scenarios. A possible exposure-assessment study would be to measure endotoxin exposure of workers at biosolids production and application sites and of communities nearby. *Complete epidemiological studies of biosolids use*. These studies should be conducted to provide evidence of a causal association, or a lack thereof, between biosolids exposure and adverse human health effects. They should include an assessment of the occurrence of disease and an assessment or measurement of potential exposures. An example of a longitudinal epidemiological study would be	Human Health Studies Exposure

an evaluation of health effects in a cohort of biosolids appliers These workers should be characterized by duration and level of exposure, and given appropriate follow-up. Because complete epidemiological studies are expensive and require extensive data analysis, priority should be given to studies that can address serious or widespread problems and help reduce uncertainty.	
CH3-1. Studies in response to unusual exposure and unusual occurrence of disease. On occasion, unplanned events occur that can provide information on the agents of disease. An example might be an outbreak or a symptom of disease following a known exposure or an unusual exposure scenario. In both instances, exposure and health outcomes should be determined.	Human Health Studies
CH3-3. Complete epidemiological studies of routine biosolids use. These studies should be conducted to provide evidence of a causal association, or a lack thereof, between biosolids exposure and adverse human health effects. They should include an assessment of the occurrence of disease and an assessment or measurement of potential exposures. An example of a longitudinal epidemiological study would be an evaluation of health effects in a cohort of biosolids appliers; these workers should be characterized by duration and level of exposure, with appropriate follow-up.	Human Health Studies
Regulatory Activities	
CH2-6. Studies should be conducted to determine whether the management practices specified in the Part 503 rule (e.g., 10-meter setback from waters) achieve their intended effect.	Regulatory Activities
CH2-7. Additional risk-management practices should be considered in future revisions to the Part 503 rule, including setbacks from residences or businesses, setbacks from private and public-water supply wells, slope restrictions, soil permeability and depth to groundwater or bedrock, and reexamination of whether a greater setback distance to surface water is warranted.	Regulatory Activities
CH2-9. Exemptions from nutrient management and site restrictions for land application of bulk EQ biosolids should be eliminated.	Regulatory Activities
CH2-11. Standard treatment design criteria should be adopted nationally to ensure compliance with existing biosolids regulations.	Regulatory Activities
CH2-12. Stabilization controls need to be further refined and directly correlated to metabolic techniques (e.g., SOUR test, carbon dioxide metabolic release, methane metabolic release).	Regulatory Activities Pathogens
CH2-14. As part of the process of revising the Part 503 rule, EPA should review biosolids protocols used by other nations. This could provide valuable new perspectives and insights into the scientific, technical, and societal bases for the development and implementation of biosolids regulations.	Regulatory Activities
Biosolids Management	
OA-3. *Establish a framework for an approach to implement human health investigations.* A procedural framework should be established to implement human health investigations, including short-term investigations of unusual episodes of release, exposure, or disease and large-scale preplanned studies of exposures and their association, if any, with disease. The framework should have mechanisms to document state-of-the-art successes, both technological and administrative, in preventing or remediating exposure to pathogens and toxicants and their adverse health outcomes. Further, the framework should include a means for tracking allegations and sentinel events (compliance, management, or health based), investigations, and conclusions. Such tracking should be systematic and developed in cooperation with states.	Biosolids Management

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OA-4. *Increase the resources devoted to EPA's biosolids program.* To remedy the deficiencies and to implement the recommendations described in this report, more funding and staff resources are needed for EPA's biosolids program. EPA should support and facilitate greater delegation of authority to states to administer the federal biosolids regulation. Resources are also needed for conducting needed research and to revise the regulation as appropriate and in a timely fashion.	Biosolids Management Regulatory Activities
OACP-1. EPA should expand its biosolids oversight activities to include procedures for (1) assessing the reliability of the biosolids treatment processes, (2) monitoring compliance with the chemical and pathogen standards, (3) conducting environmental hazard surveillance, and (4) studying human exposure and health. The committee recommends that Figure S-1 be used by EPA as a framework for establishing such a program. The central part of the figure presents the general process by which biosolids are produced and used for land application. Depicted on the left side of the figure are opportunities for conducting environmental hazard surveillance. At these stages, biosolids or environmental samples should be collected and analyzed to verify that (1) treatment technologies for pathogen control are effective (quality control), (2) chemical standards are met (compliance audits), and (3) unanticipated hazards are identified. An important part of this verification process is a review of the management practices required for land application, because the practices are predicated on the assumption that exposure to hazardous agents is further reduced by the implementation of such practices. Studies should be conducted to determine whether the management practices specified in the Part 503 rule achieve their intended effect. Additional risk-management practices should be considered in revising the Part 503 rule. Considerations should include setbacks to residences or businesses, setbacks to private and public water supplies, limitations on holding or storage practices, slope restrictions, soil permeability and depth to groundwater or bedrock, and greater distance to surface water.	Biosolids Management Regulatory Activities
CH2-1. EPA should strengthen its biosolids-oversight program by increasing the amount of funding and staff (technical and administrative) devoted to it.	Biosolids Management
CH2-2. EPA should provide additional funds (not diverted funds) to states to implement biosolids programs and facilitate delegation of authority to states to administer the federal biosolids regulations.	Biosolids Management
CH2-3. Resources are also needed for conducting research into emerging issues and to revise the regulations as appropriate and in a timely fashion (e.g., molybdenum standards should be proposed).	Biosolids Management Regulatory Activities
CH2-4. A process should be established to track allegations and sentinel events (compliance, management, or health based), investigations, and conclusions. Such tracking should be systematic, developed in cooperation with states, and document both positive and negative outcomes.	Biosolids Management
CH4-3. In making revisions to the Part 503 rule risk assessment, EPA must strike a balance between expending resources to carry out site-specific data collection and expending resources to model and assess risk using existing information. In light of improvements in exposure and health monitoring, the committee encourages EPA to consider options carefully for collecting new data in support of risk-assessment assumptions before resorting to another risk assessment that relies only on existing data, models, and default assumptions. Among the data that would be of value are data on proximity of receptors to land-application sites; surveys of activities that could increase direct and indirect exposures; and samples of biosolids, air, vegetation, runoff, groundwater, and soil in environments surrounding land-application sites. In addition, EPA should conduct site-specific surveys of performance (e.g., monitor the extent to which rates and depth of application are consistent with risk-assessment assumptions) and scientifically relevant studies of health complaints.	Biosolids Management Risk Assessment

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CH7-1. Figure 7-1 should be used by EPA as a framework for managing the risks from exposure to biosolids. The framework includes audits of treatment-process performance and management practices, periodic hazard surveillance, and studies of health outcomes, including preplanned studies and studies in response to episodic events. For example, as recommended in Chapters 2 and 6, surveys should be conducted to verify that Class A and Class B treatment processes perform as assumed by engineering principles, and determinations of pathogen density and destruction across the treatment process and in the soil over time should be completed. Recommendations contained in Chapter 5 also address the need for process-performance measures that can be monitored and used in site-specific surveys of performance. In Chapter 3, the nature and objectives of hazard surveillance studies and studies of health outcomes of exposed populations are described more fully. All the recommendations reflect the committee's concern that the complex risk-assessment task posed by biosolids cannot serve as a useful and reliable guide without an ongoing effort to ensure that the assumptions underlying the assessment are valid and that the risk-management procedures put in place in response to the assessment are being routinely implemented. Broad-scale and site-specific feedback, graphically depicted in Figure 7-1, is needed.	Biosolids Management Pathogens Survey