Infrasound

Brief Review of Toxicological Literature

November 2001

Preface

(Revised March 2002)

Recent interest in the potential adverse human health effects of infrasound (generally inaudible sound with a frequency of <20 Hz) arises from health concerns expressed by the residents of Kokomo, Indiana. Several individuals in this community have complained of subjective non-specific symptoms including annoyance, sleep disturbance, headaches, and nausea. These symptoms are perceived by the individuals to be due to a low-frequency hum-like noise in and around their homes that is not clearly audible to everyone. Several local, state, and federal agency officials as well as acoustic experts in the academic community and private sector have been called upon to assist in investigating these health complaints. As yet, no firm conclusions have been reached regarding the relationship between this low-frequency noise and the residents' health complaints.

Subsequent to inquiries from the U.S. Senators from Indiana, the National Institute of Environmental Health Sciences (NIEHS) agreed to review the existing scientific literature on the health effects of infrasound. This review was intended to serve as an initial step in determining whether sufficient information is available to make a reasonable assessment of the potential for adverse human health effects to occur as a result of infrasound exposure. Consequently, the NIEHS is nominating toxicological studies of infrasound for consideration by the National Toxicology Program (NTP) to seek broad federal agency and public input regarding the need for further federal sponsored experimental animal toxicology research on this environmental agent.

This document briefly summarizes studies identified in the open literature relating to the biological and other effects of infrasound exposure in humans and laboratory animals. The literature searches were performed in August-September, 2001 and the search strategy is briefly described in *Section 5.0*. Over one hundred relevant studies were identified that differed widely in their experimental design and selection of endpoints for evaluation. This study variability somewhat limits the conclusions that can be drawn regarding the potential to cause adverse health effects in humans without further expert evaluation and review.

The measurement of intensity of sound is the sound pressure level (SPL), usually given in decibels (dB). Sound is a complex physical phenomenon and no attempt is made here to describe in detail acoustic principles or methods for the measurement of sound. Furthermore, the physiological and psychological effects of higher frequency sound and noise comprise an enormous volume of literature and have not been reviewed at this time. This literature is relevant because effects of different sound frequencies could be similar and because in environmental settings human exposure to infrasound rarely if ever occurs in the absence of exposure to other sound frequencies.

Many of the infrasound studies identified in the literature search are not available in English or are otherwise difficult to acquire, and thus not all articles have been obtained at this time. The individual study summaries are presented as an annotated bibliography and in many cases are based only on review of an English abstract. Attention has not been given to an evaluation of individual study quality or to the strength of the overall evidence regarding potential adverse health effects. This would require a more thorough and independent expert review to draw conclusions regarding adverse human health effects attributable to infrasound exposure. Rather, the document focuses on identifying and describing the available literature regarding reported physiological and/or psychological effects of infrasound. This document has not been formally peer-reviewed at this time.

Experimental studies have been reported where humans or various species of animals (rats, mice, guinea pigs, chinchillas) have been exposed to infrasound in the laboratory. Most of the studies identified involved exposures at 90 dB and higher and ranged from minutes to several months. Of the many animal studies identified, there were none involving long-term (six months or greater) exposure and few that employed modern toxicology testing protocols and pathological assessments. The most common endpoints studied were behavioral, sensory, or simple physiological (e.g. blood pressure) changes. Some studies focusing on biochemical, cellular, or morphological changes in organs and tissues were identified. There were few studies evaluating reproductive function, developmental effects, and immunological effects, and no studies that evaluated carcinogenic effects.

Most studies reported some effects attributed to infrasound exposure, though many studies also reported no observable effects. Among the more consistent findings in humans were changes in blood pressure, respiratory rate, and balance. These effects occurred after exposures to infrasound at levels generally above 110 dB. Physical damage to the ear or some loss of hearing has been found in humans and/or animals at levels above 140 dB. As many studies evaluated endpoints that may or not necessarily be considered adverse, a careful evaluation of the biological significance and reversibility of any reported findings is critical. Due to differences in auditory perception and physiological response to sound, the relevance of animal studies to assessing potential human effects must also be carefully evaluated. An evaluation of consistency in reported effects among the different studies identified is made difficult due to limited details available for this review on methods of generating infrasound, characterization of the experimental exposures, and methods of assessing biological effects. For example, other sound frequencies may have been present in some experiments and effects of exposure to pure tones versus broadband frequency may be different. Thus, it is not clear if "environmental" infrasound, in terms of intensity level, frequency range, and frequency composition, has been adequately reproduced in laboratory experiments.

In summary, though a number of biological effects have been reported that are attributed to infrasound exposure in experimental settings, any assessment of potential adverse human health effects resulting from environmental infrasound exposure is hampered by numerous gaps in our current knowledge. Examples of critical data gaps include a lack of high quality long-term experimental studies of infrasound, and inadequate characterization of environmental infrasound and accompanying higher frequency sound levels in community settings. Thus, this document may serve as a starting point for determining what types of experimental toxicology research or testing may be useful for further characterizing potential adverse health effects of infrasound exposure in humans.

Table Of Contents

Executive Summary

Infrasound is acoustic energy with frequencies up to 20 Hertz (Hz), having wavelengths of 17 m or more. Some definitions give the upper limit of 16 Hz; others restrict infrasound to delivery by air transmission. Infrasound is seldom generated at high sound pressure levels (SPL; usually measured in decibels [dB]) without accompanying audible sound (1). However, hearing protection, e.g. ear muffs and ear plugs, offers little protection against infrasound exposure (2,3).

Infrasound exposure is ubiquitous in modern life. Infrasound is generated by natural sources such as earthquakes (4) and wind; means of transportation such as automobiles, trucks, aircraft, watercraft, and rail traffic (4-6); certain therapeutic devices (which do not meet the restriction of infrasound to airborne delivery) (7-16); numerous industrial sources such as heavy machinery and air compressors; air heating and cooling equipment; and household appliances such as washing machines (1,5,6,17). The potential use in nonlethal acoustic weapons is discussed briefly (18-20).

OSHA guidelines for occupational noise exposure are concerned with SPL limits (90 to 115 dB(A) for 8 hours to 0.25 hour), not frequencies (21). The American Conference of Governmental Industrial Hygienists (ACGIH) recommends that except for impulsive sound with durations of less than 2 seconds, one-third octave levels for frequencies between 1 and 80 Hz should not exceed a SPL ceiling limit of 145 dB, and the overall unweighted SPL should not exceed a SPL ceiling limit of 150 dB; no time limits are specified for these recommended levels (22). NASA criteria for noise exposure in space craft and space stations include a limit of 120 dB for 24-hour exposure to 1 to 16 Hz (23).

Literature retrievals from several biomedical databases, the National Technical Information Service (NTIS) file, and the Internet required the inclusion of the words infrasound or infrasonic. The presentation of the information in the toxicology section is in the style of an annotated bibliography. The human studies subsection is not comprehensive and includes only selected studies identified in the open literature. All of the 59 animal toxicity studies identified in the literature searches are included, but the subsection is not totally comprehensive. A few additional publications were cited in some of the references. A large fraction of the annotations are based on the authors' abstracts in the database records. Annotations for many of the Russian studies were based on limited data extraction from the original [non-English] articles since the database records frequently did not have abstracts.

Summary of Studies in Humans

The literature search identified 69 studies, 34 of which are in English. The records for about half of the foreign-language publications do not have abstracts. Altogether, only two-thirds of the records have abstracts. Twenty-four of the identified human studies are included in the annotated bibliography. Of these, references for 6 citations have been retrieved. English abstracts are available for 15 citations. The effects studied were on the cardiovascular (the myocardium) and nervous systems, eye structure, hearing and vestibular function, and endocrine modulation. Specific CNS effects studied included annoyance, sleep and wakefulness, perception, evoked potentials, electroencephalographic changes, and cognition.

The primary effect of infrasound in humans appears to be annoyance (24-26). To achieve a given amount of annoyance, low frequencies were found to require greater sound pressure than with higher frequencies; small changes in sound pressure could then possibly cause significantly large changes in annoyance in the infrasonic region (24). Beginning at 127 to 133 dB, pressure sensation is experienced in the middle ear (26). Regarding potential hearing damage, Johnson (27) concluded that short periods of continuous exposures to infrasound below 150 dB are safe and that continuous exposures up to 24 hours are safe if the levels are below 118 dB.

There is no agreement about the biological activity of infrasound. Reported effects include those on the inner ear, vertigo, imbalance, etc.; intolerable sensations, incapacitation, disorientation, nausea, vomiting, and bowel spasm; and resonances in inner organs, such as the heart.

Infrasound has been observed to affect the pattern of sleep minutely. Exposures to 6 and 16 Hz at levels 10 dB above the auditory threshold have been associated with a reduction in wakefulness (28). Workers exposed to simulated industrial infrasound of 5 and 10 Hz and levels of 100 and 135 dB for 15 minutes reported feelings of fatigue, apathy, and depression, pressure in the ears, loss of concentration, drowsiness, and vibration of internal organs. In addition, effects were found in the central nervous, cardiovascular, and respiratory systems (29). In contrast, a study of drivers of long distance transport trucks exposed to infrasound at about 115 dBA found no statistically significant incidence of such symptoms (e.g., fatigue, subdued sensation, abdominal symptoms, and hypertension) (30).

Studies have shown that infrasound (6 to 16 Hz at levels ranging from 95 to 130 dB and up to an exposure time of one hour) causes an increase in diastolic blood pressure and decreases in systolic blood pressure and pulse rate (31). Long-term exposure of active Swiss airforce pilots to infrasound with a frequency of 14 or 16 Hz at 125 dB produced the same changes. Additional findings in the pilots were decreased alertness, faster decrease in the electrical resistance of the skin compared to unexposed individuals, and alteration of hearing threshold and time perception (32). However, a whole-body exposure to infrasound at 10 and 15 Hz (level not provided) did not produce changes in respiration, pulse, and blood pressure (33).

In several experiments to assess cognitive performance during exposure to infrasound (7-Hz tones at 125, 132, and 142 dB plus ambient noise or a low-frequency background noise for up to 30 minutes), no reduction in performance was observed in the subjects (34). Sole exposure to infrasound at 10 to 15 Hz and 130 to 135 dB for 30 minutes also did not produce changes in autonomic nervous functions (35). The ability of infrasound (5 and 16 Hz at 95 dB for five minutes) to alter body sway responses suggested effects on inner ear function and balance (36).

Summary of Studies in Laboratory Animals: Acute Exposure Duration
Citations for 31 acute animal studies are annotated in this section; 9 of the references have been retrieved and are available in English. English abstracts are available for an additional 5 references.

Studies of infrasound up to 124 dB for up to four hours found transient effects in behavior, brain chemistry, and effects on blood vessels. Studies at higher SPL induced cochlear damage and other morphological damage in the ear. Thus, rats exposed briefly to infrasound around 120 dB showed changes in concentrations of acetylcholine (37), acetylcholinesterase, brain glutamate (increases) (38), and brain norepinephrine and dopamine (decreases) (39,40). Gastric mucosal blood flow decreased (41) and organ tissue permeability increased (42). At about 100 dB, rats showed reduced endurance in already poor treadmill performers (43), performance decrements in acquisition and retention of conditioned reflexes, and somnolence (44). Acute exposure of mice to ethanol plus infrasound reduced time to submersion in forced swimming tests (45-47). A one-hour exposure to 20 Hz at up to 133 dB SPL did not induce the cochlear and hair cell damage observed in guinea pigs that had been exposed to 163 dB SPL. No morphological changes were observed up to 140 dB (48,49). Infrasound exposure induced endolymph displacement, altered the endonuclear potential (50,51), and reduced the amplitude of the auditory evoked potential and prolonged its latency time in guinea pigs (52). Continuous or intermittent infrasound exposure of chinchillas at 150 to 170 dB induced considerable damage in the ear, including tympanic membrane perforation, bleeding, hair cell damage, saccular wall rupture, Reissner's membrane rupture, and endolymphatic hydrops (53). Continuous exposure was responsible for most of the incidences of several of these endpoints. Too few data were included about rabbit and monkey experiments for summarization.

Summary of Studies in Laboratory Animals: Short-Term Exposure Duration
Twenty short-term studies have been annotated. Full articles in English are available for 8 of the references. Abstracts in English are available for 11 additional citations.

In the short-term animal studies with exposures up to 145 Hz for up to four months, adverse effects were noted on the morphology, histopathology, and histochemistry of the cardiovascular system, nervous system, the ears, the liver, and other organs.

Rats exposed to 8 Hz at 120 dB for up to 45 days showed myocardial cell pathology, microcirculation disturbances, ischemia, and mitochondrial destruction in capillaries (54). Rats exposed to 10 to 15 Hz at 135 to 145 dB for 45 days showed arterial constriction, nuclear deformation, and mitochondrial damage. Regeneration occurred after exposure stopped (55). Rats exposed to 8 or 16 Hz at 120 to 140 dB for up to 40 days showed reduced oxidation-reduction (redox) enzymes in the myocardium, disturbed blood flow, myofibrillar fragmentation, and RNA and DNA changes. Regeneration began within 40 days after infrasound exposure ceased (54,56). Exposure of rats to 8 Hz at 115 and 135 dB for four months induced morphological changes in the myocardial ultrastructure; significant decreases in succinate dehydrogenase and myocardial adenosine triphosphate (ATP) and adenosine diphosphate (ADP); and significant increases in α-ketoglutarate dehydrogenase, myocardial adenosine monophosphate (AMP), and plasma corticosterone (57).

Rats exposed to 8 Hz at 100 dB for up to 60 days showed biochemical and morphological changes in blood and tissues, including dystrophic tissue changes in the lungs, liver, kidneys, heart, adrenals, and testicles. Imidazole treatment reduced the dystrophic tissue changes and changes in enzyme concentrations (58). In studies of infrasound-induced histopathological and morphological changes in the liver after 40-day exposures, the most damage was observed at 8 and 16 Hz at 140 dB. Damage included strongly deformed nuclei, lysis and vacuole formation in the cytoplasm, and lipid granules in the cytoplasm (59). Exposure of rats to 8 Hz at up to 140 dB for 25 to 45 days caused irreversible changes in hepatocytes (60). Exposures of 8 and 16 Hz at up to 140 dB for up to 35 days induced fluctuations in heart and liver enzyme levels.

Exposure of rats to 8 Hz at 110 dB for ten weeks induced transient changes in working capacity and oxygen requirements, increased unconditioned reflexes, and induced immunological effects (61). Exposures to 8 Hz at 120 and 140 dB for up to 40 days induced changes in the heart, neurons, and auditory cortex that increased in severity with length of exposure (62). Exposures to 8 Hz at 100 and 140 dB for up to 25 days affected conjunctival blood vessels. Capillaries initially constricted and an increased permeability of blood vessels led to capillary and tissue swelling (63). Exposure to 4 Hz at 110 dB for 40 days induced ear damage worse than that observed after exposure to 31.5 or 53 Hz at 110 dB for 40 days. Alkaline phosphatase activity was reduced in the blood vessels of the stria vascularis and their permeability was impaired. The infrasound exposure induced neurosensory hearing impairment (64).

Mice exposed to 8 Hz at 120 dB showed erythrocyte-filled acini and thickening of the inter-alveolar septa of the lungs. Exposures of 8 and 16 Hz at 140 dB ruptured blood vessel walls and destroyed acini (65).

Guinea pig short-term studies reported ear damage. Exposure to 4 Hz at 110 dB for 40 days increased alkaline phosphatase concentrations in vessels of tympanic membranes (66). Exposures to 8 or 16 Hz at 90 to 120 dB for up to 25 days induced morphological changes in receptor cells and hair cells of the inner ear. These changes and changes in the endoplasmic reticulum and mitochondria recovered after exposure ended (67).

Rabbits exposed to 10 Hz at 100 to 110 dB for 24 days showed disturbances of enzyme levels of the mitochondria and reduced contractile function of the myocardium (68).

Summary of Other Animal Studies

Synergistic and antagonistic effects were reported in several of the acute and short-term animal studies. Two articles and 3 abstracts are available in English. Diazepam (39), ethanol (46,47,69), imidazole compounds (58), ascorbic acid (69), and microwave radiation (61) moderated the adverse effects of infrasound exposure.

Nine citations covering reproductive and developmental effects, carcinogenicity, genotoxicity, immunotoxicity, and other studies were considered for this report. English abstracts are available for 3 of these studies.

The only finding relating to reproductive effects was dystrophic changes in rat testicles (58).

No studies were identified on subchronic and chronic toxicity, carcinogenicity, anti-carcinogenicity, and initiation/promotion of cancer. Details for a study of genotoxicity in rat bone marrow cells have not been reviewed.

Infrasound pretreatment (10 Hz, 155-160 dB) made guinea pigs less sensitive to antigen induction of anaphylactic shock (70). Infrasound exposure of rats and rabbits to 8 Hz at 115 dB enhanced the immunotoxic effects of gamma radiation on cell and humoral immunity and on autoimmune processes (71).

In an *in vitro* study, ATPase activity in rat whole blood decreased at 16 Hz at 120 dB but increased at 2 Hz. Superoxide dismutase (SOD) concentrations increased with increasing frequency (72).

1.0 Introduction

Infrasound comprises soundlike waves of acoustic energy with frequencies of 20 hertz (Hz), the audible limit, and below. Some sources give the upper limit of infrasound frequencies as 16 Hz. The definition of infrasound may be limited to airborne acoustic energy at these frequencies. The wavelengths of 17 m or more can travel for long distances. The measurement of intensity of infrasound is the sound pressure level (SPL), usually given in decibels (dB). Sound levels are computed in dB-SPL by using the average intensity. One phon is 1 dB-SPL at 1 kHz. Other units for sound pressure levels are explained at the Stanford University web site http://ccrma-www.stanford.edu/~ios/r320/DB_SPL.html (4,73). Perception of low-frequency sound in the range 2 to 100 Hz is comprised of both aural and tactile sensations. High pressure levels may induce resonance responses in body cavities (74).

2.0 Sources and Exposure

Infrasound like all sound is ubiquitous in modern life; e.g., it is generated by motor vehicles, aircraft, watercraft, trains, hydroelectric power stations, compressors, and industrial equipment (6). Intense infrasound exposure is generally accompanied by exposure to intense sounds above 20 Hz (75). In fact, infrasonic acoustic energy does not usually occur in the absence of sounds within the normal audible range due to the processes in which such sounds are generated (1). Ear plugs and ear muffs may not offer sufficient protection (3). Protective equipment usually does not stop penetration of infrasound (2). Ear muffs may even amplify infrasonic frequencies (1).

2.1 Natural Sources

Infrasound is generated by thunder, earthquakes, large waterfalls, ocean waves (< 1 Hz), wind (up to 135 dB at 100 km/h; up to 110 dB at 25 km/h), fluctuations in atmospheric pressure (< 1 Hz at 100 dB), and volcanos (4). Running generates infrasound at frequencies below 2 Hz at levels up to 90 dB; swimming also generates infrasound below 2 Hz, but the pressure is more intense (up to 140 dB).

2.2 Vehicles

Riding in automobiles exposes drivers and passengers to 1 to 20 Hz at up to 120 dB. Exposures while riding in helicopters, other aircraft, submarines, and rockets range from 1 to 20 Hz at 120 to 145 dB. In a free field, diesel engines generate frequencies of 10 to 20 Hz at sound pressure levels up to 110 dB. Jet engines, helicopters, and large rockets generate frequencies of 1 to 20 Hz at 115 to 150 dB (4). In a Finnish survey (5), infrasound levels exceeding 120 dB were found in cars and railway engines. The usual range in vehicles with closed windows was 90 to 110 dB. Infrasound sound pressure levels in aircraft cockpits and cabins ranged from 80 to 100 dB. Ships and aircraft sonic booms are other vehicular sources (1). In Japan, Okada (17) measured infrasound at 83 dB at 20 m from a running truck and 100 dB at 20 m from a running railroad carriage. Thus, persons may be subjected frequently to the annoyance of infrasound exposure if they reside in the vicinity of heavily trafficked areas, railways, airports, or rocket launch sites. Drivers, pilots, and other transportation workers are among those occupations with considerable exposure.

2.3 Therapeutic Devices

Several Russian and European publications report on therapeutic applications of infrasound. A few examples are given in this brief discussion. Infrasound pneumomassage at 4 Hz (daily 10-minute sessions for 10 days) stabilized the progression of myopia in school children (13). Infrasound phonopheresis (frequency and sound pressure level not provided) of antibacterial drugs in the treatment of patients with bacterial keratitis was as effective as local instillation of the same drugs (12). Thermovibration massage at 10 Hz was a useful adjunct in combined treatment of patients with chronic cholecystitis and opisthorchiasis, improving motor-evacuation function of the biliary system (11).

InfraMed, a medical equipment company in the Netherlands, advertised an infrasound device called the SonoMat that may be used to break up arterial blockages (uncertain because the language is apparently Dutch) (16).

Vibrotherapy sources used in medicine generate audible as well as infrasound frequencies (14). At least two hand-held vibrotherapy devices are currently advertised to the public. The Infratronic QGM Quantum device, developed out of scientific research in Beijing, China, is said to focus chi or life energy into patients' bodies and stimulate[s] relaxation and healing. It operates at 8 to 14 Hz, 70 dB, and is said to be "recognized by FDA as a 510k Therapeutic Massager" (10,15). The second device is the Nostrafon Infrasound Wave Massager from Novafon, which is said to provide a 2.25-in. deep massage using mixed-frequency sound waves (7). Such vibrotherapy devices are used for treating horses (76) and athletes (9). [The Chi infrasound device is said to calm race horses by stimulating production of alpha brain waves (8).] The HydroSonic Relaxation System delivers infrasound and other low-frequency sound to the body by water conduction through a heated water mattress. The treatments can be applied through clothing and casts and the low-frequency waves can be programmed to penetrate surface muscles and internal organs to massage deep tissue. Typical treatments last about 30 minutes. The frequencies are generated by a compact disc and amplified. Users are said to include physicians, trainers, physical therapists, chiropractors, and spas (77).

2.4 Industrial Sources

Infrasound exposure is not uncommon in the vicinity of operating heavy machinery. In a Finnish survey of industrial work sites, infrasound pressure levels usually ranged from 80 to 100 dB, significantly higher than in the vicinity of the workplace. Highest infrasound levels were produced by blowers, pumps, oil burners, air compressors, drying towers, and heavy rotating machinery. The highest level (127 dB) was measured 100 m from a crusher at a mine (5).

2.5 Nonlethal Weapons

The U.S. Army has an infrasound weapons program, and infrasound is being considered for riot control and other police actions. [Little evidence was found that infrasound weapons are currently used beyond testing.] The use of infrasound-generating nonlethal weapons is based on the assumption that high-power infrasound will incapacitate those subjected to it with nausea and other gastrointestinal disturbances. Transmission of infrasound energy through the air is not as efficient as transmission through mechanical vibrations at infrasound frequencies. One argument against the feasibility of the use of infrasound in nonlethal weapons is that infrasound's wavelengths (17 m and above) are so long that they spread out too rapidly to be focused (19). A device that can aim parametric infrasound without affecting the user could generate infrasound by mixing two ultrasonic acoustic waves (20). Such a method has been tested in Great Britain. Other infrasound-generation devices may have been used for riot control in Northern Ireland (18).

2.6 Other Sources

Other sources include explosions, bridge vibration, and air heating and cooling equipment (1). Infrasound sound pressure levels of predominantly single frequencies (i.e. tones) were low under a bridge, inside an automobile, and beside a cooling tower. Sound pressure levels were also low beside a refrigerator and inside a computer room. A washing machine in the spin cycle (dehydration process) emitted infrasound at 81 dB. Wooden houses have higher sound pressure levels (highest level > 100 dB) than concrete structures (17).

3.0 Regulations and Criteria

A search of several *Code of Federal Regulations* titles and recent reviews indicated that there are no U.S. or international regulations for permissible exposure limits for infrasound exposure. OSHA (21) in 29 CFR 1926.52, Occupational noise exposure, provides limits based on length of exposure to sound pressure levels of 90 to 115 dBA slow response (eight hours down to 15 minutes or less).

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends that except for impulsive sound with durations of less than two seconds, one-third octave levels for frequencies between 1 and 80 Hz should not exceed a SPL ceiling limit of 145 dB and the overall unweighted SPL should not exceed a SPL ceiling limit of 150 dB; no time limits are specified for these recommended levels (22). Under its occupational guidelines for infrasound exposure, the New Zealand Occupational Safety and Health Service recommended using guidance for safe infrasound exposure given by von Gierke and Nixon (78) and Woodson (79) (both references cited by 80). NASA (23) established criteria for noise exposure applicable to space craft and space stations. The infrasonic, long-term annoyance noise exposure requirements stated that the infrasound sound pressure level in natural and induced environments SHALL be less than 120 dB in the frequency range 1 to 16 Hz for 24-hour exposure. WHO (74) and U.S. EPA (81) did not give any guidance for an upper limit to infrasound exposure.

The "therapeutic" infrasound devices would be subject to regulation by FDA under the Federal Food Drug and Cosmetic act as products meeting the definition of electronic product radiation. According to Section 532 of the Act "the term 'electronic product radiation' means...any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product". 21CFR1000.15 (82) lists "Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968" and includes infrasonic vibrators as "examples of electronic products which may emit infrasonic, sonic, and ultrasonic vibrations resulting from operation of an electronic circuit". No