

# The Connected Product Lifecycle

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**Connected Products Team**  
Keller and Heckman LLP



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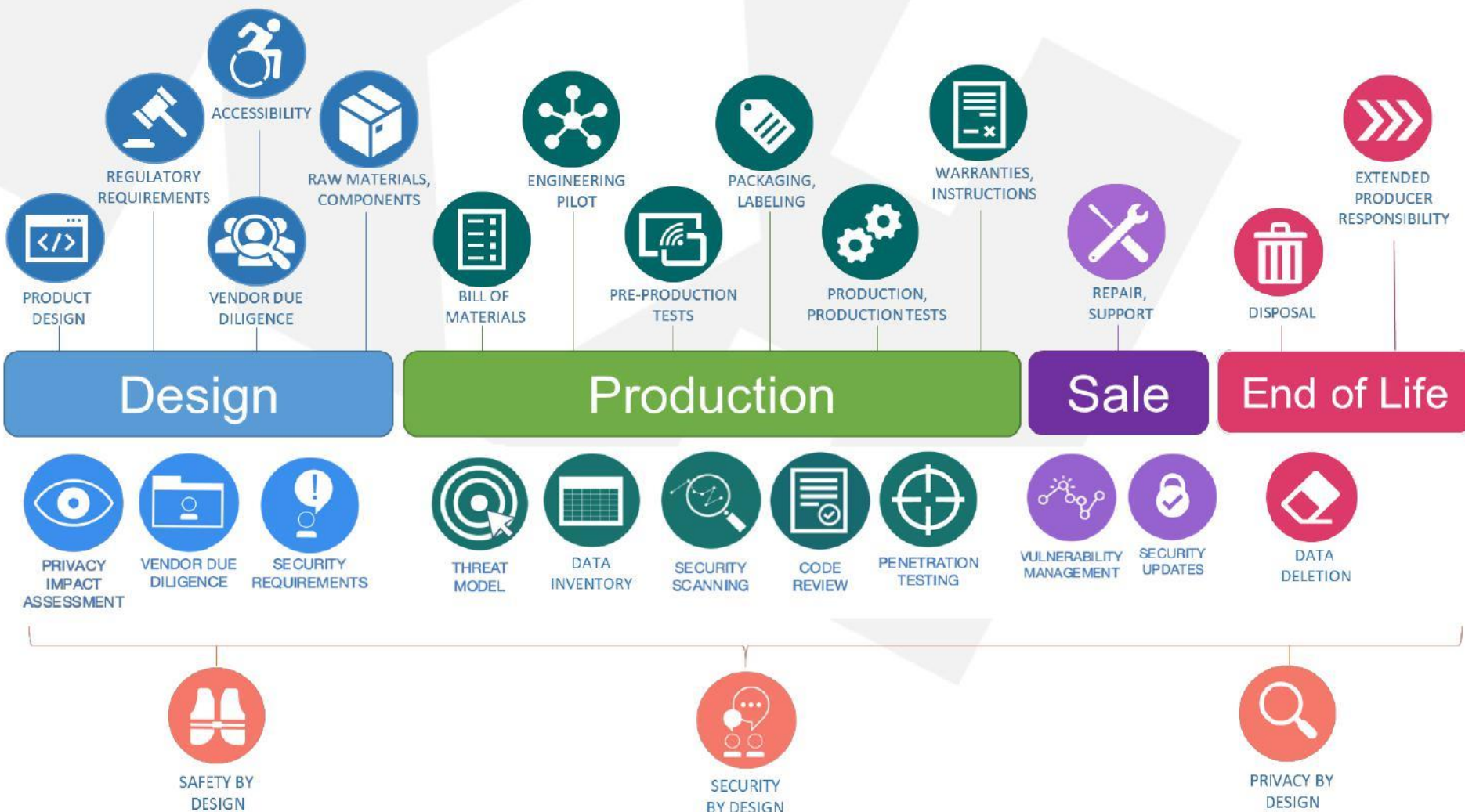
# Today's Session

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- Roundtable discussion of practical issues faced by connected products businesses

# Connected Product Life Cycle





- What kind of device is it?
- Who are target users?
- Where is it being sold?
- What regulatory requirements apply?
- What safety/integrity requirements apply?
  - Could connectivity contribute to hazardization?
- What claims do you want to make?
- What information must be presented to consumers?
- What is the harm to consumers if data is disclosed?
- What's the expected product lifetime?



# Physical + Digital Product Development

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- Physical and digital development schedules must mesh to bring product to market and implicate
  - Contracts with third parties
  - Applicable regulatory frameworks
  - Scope, timing of physical product testing, privacy/security audits, penetration tests
  - Labeling
  - Advertising, marketing, promotions

# Regulatory and Legal Considerations



## Examples:

- Connected Wearables
- Connected Appliances
- Connected Toys
- Connected Baby Monitors

# Concept and Development



- Confirm product category, planned territory for distribution, and target users
- Create framework for regulatory compliance obligations
- ID claims substantiation needs
- Conduct vendor due diligence
- Initial privacy impact assessment

# Final Designs



- Product compliance checklist
- Fault tree/failure modes & effects analysis
- Select product safety test lab
- Website and app development
- Select penetration testing firm
- Preliminary check for energy efficiency
- Preliminary check for RED/FCC
- Refine data map/PIA
- Address physical product ADA compliance

# Tooling & Prototype



- Begin drafting product documents
  - Installation
  - Use
  - Warranty
  - CE Dossier
  - Label copy
- Confirm substantiation for proposed marketing claims
- Prepare web and app privacy policy, terms, EULA development
- Conduct initial penetration tests
- Source packaging

# Parts & Production



- FCC testing & certification
- Safety and performance testing
  - Create CPCs/GCCs and finalize EE dossier
- Complete penetration testing, implement recommended changes
- Finalize consumer-facing documents
- Beta test product
- Pre-launch marketing

# Marketing & Distribution



- Final approval and printing of product documentation
- Website/app go live
- White hat hackers
- Train consumer affairs personnel
- Registrations, product waitlists, and promotions



- Ongoing compliance monitoring
  - Safety agency reporting (CPSC, Health Canada, Member States, etc.)
  - Data breach notifications
  - Marketing claims
- Service and repair
- Software, firmware updates
- Honor consumer access, deletion requests
- Secure data deletion and physical disposal

# Concluding Remarks

# Takeaways

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- Product class, target user, and expected sales region key to identifying physical, digital regulatory obligations
- Test, audit physical and digital and implement recommended changes
- Adopt compliance processes

# Appendix: Background Information

# Privacy and Security

- Data mapping is central to:
  - Privacy impact assessments
  - Security assessments
  - Understanding whether non-PII needs to be secured to promote safe operation

# Common Questions: Privacy & Security



- What is the interplay between international and domestic privacy regulations?
- What should privacy policies cover?
- When should I conduct a penetration test?  
A security audit?
- How do we best communicate about security issues with customers?



- CA AG published draft final regulations to the CCPA and submitted to OAL for approval on 6/1/2020
- Substantively, nothing has changed
- OAL has 90 days to approve draft, but AG has asked to expedite approval
- Enforcement could be delayed until fall but CCPA 12-month look-back in effect as of 1/1/2020

- SB 327, entitled “Information Privacy: Connected Devices”
- Entered into force on January 1, 2020
- Requires manufacturers of connected devices to equip them with reasonable security features to protect the devices and any information they collect from unauthorized access, destruction, use, modification, or disclosure
- These measures are mandatory for all connected devices sold in California

- Judge refuses to approve \$550 million Facebook class action settlement agreement, saying it is less than 2% of the amount that could have been recovered for violation of IL Biometric Information Privacy Act

- On April 8, 2020, Andrew Smith, Director, FTC Bureau of Consumer Protection issued reminder on avoiding risks of AI:
  - Be clear about how you use automated tools
  - Be transparent when collecting sensitive data
  - Information from a third-party vendor used to make decision about consumer may require “adverse action” notice to consumer
  - Explain denials of value based on algorithmic decision making
  - Disclose key factors that affected consumer’s score in order of importance
  - Inform consumers of changes in deal terms based on AI tools
  - Don’t discriminate based on protected classes
  - Give consumers a chance to correct information
  - Ensure shared data for decision-making is accurate and up-to-date
  - AI models should be validated and revalidated
  - Ask :
    - How representative is your data set?
    - Does your data model account for biases?
    - How accurate are your predictions based on big data?
    - Does your reliance on big data raise ethical or fairness concerns?

# Tapplock Settlement with FTC



- On April 6, 2020, smart lock manufacturer Tapplock settled with the FTC over charges the company falsely claimed its locks were “secure” and “unbreakable”
- Locks had serious vulnerabilities that could have been fixed by taking basic standard security measures such as:
  - Conducting penetration tests
  - Detecting and preventing users from bypassing authentication procedures
  - Training employees
  - Implementing written data security standards and procedures



# Communications Testing and Certification

- Certification
  - Primarily for intentional transmitters
  - Test Lab must be FCC accredited
  - FCC accredited labs listed on FCC's website
- SDoC
  - Primarily for unintentional radiators (e.g., devices with digital circuitry)
  - Accredited lab not required
    - lab must maintain record of measurement facilities and record of measurements made
- RF safety testing requirements
  - Different for mobile, portable, and fixed devices



- Two authorization procedures
- Certification
  - Requires approval by Telecommunications Certification Body
  - Application and testing materials made public
    - Some limited confidentiality available
  - Issued certification
- Suppliers Declaration of Conformity
  - No TCB certification required
  - Lab tests not submitted to FCC or made public
    - Responsible Party maintains documentation demonstrating compliance
  - Issued compliance information statement

- FCC has agreements with many countries throughout the world
  - Countries agree to accept test results and/or product approvals performed by labs recognized by other country parties to MRA
  - MRAs with Japan, Hong Kong, Canada, Singapore, EU, Israel, New Zealand, and others
  - Devices must still comply with FCC rules

- FCC generally requires certain device labels and user manual disclosures
- Other disclosures sometimes required by certification conditions such as instructions regarding radio frequency exposure
- Devices authorized by certification labelled with issued FCC ID - Ex. “FCC ID: ABC-1234567”
- Devices authorized by SDoC may use any unique identifier that does not resemble FCC ID

- Importation
  - Device must generally have received equipment authorization
  - Exemptions for importation for testing, product development, demonstrations
    - Limit on number that may be imported

- Marketing/Pilot programs
  - Marketing unauthorized equipment generally prohibited
  - Certain limited exemptions
    - Pilot programs
    - Trade shows
    - Conditional sales
  - Experimental license option

# Product Safety

- Testing, labeling, and certification requirements may apply to:
  - Children’s products and toys
    - “Electrically operated” children’s products and toys have additional warning requirements
  - General use products subject to mandatory safety standards
- No exception for test marketing
- CPSC is focused on battery safety
  - Pay attention to batteries in the product as well as remote control devices



- Is the product a children's product?
  - Is it a toy?
- If the product isn't a children's product, is it subject to any mandatory CPSC safety standards?
- What voluntary standards might apply to the product?

- My product is CE marked and complies with the applicable EN/ISO standard for that category. Do I need to obtain any other certifications to market it in the U.S.?
- Does my product need to be certified by a nationally-recognized testing lab?
- Does a regulatory violation that results in a recall in one jurisdiction automatically require reporting and a recall elsewhere?

# Energy Efficiency, Battery, and Chemical Regulations

- Energy Policy and Conservation Act of 1975, *as amended*, 42 U.S.C. § 6291 *et seq.*
  - Establishes minimum energy efficiency (EE) standards and test procedures for consumer and commercial products
    - Covers various products including refrigerators, air conditioners, clothes washers and dryers, televisions, etc.
    - Connected products are potentially captured by the External Power Supplies and Battery Charger standards
  
- State Standards
  - EPCA generally preempts state regulation
  - States can enforce EE standards on products not covered by regulation

# External Power Supplies—Applicability

- The EPS EE standard encompasses EPS circuits that are used to convert household electric current to DC current or a lower-voltage AC current to operate a consumer product
  - DOE distinguishes between EPS and BCs based on the presence of charge control, which is specific to EPSs
- The U.S. has the most stringent standards for EPSs, enforcing compliance with the Level VI Standard for Direct Operation EPSs
  - Indeed, all external power supplies (with limited exception) manufactured on or after February 10, 2016, shall meet the following standards:

	<b>Class A EPS</b>	<b>Non-Class A EPS</b>
Direct Operation EPS	Level VI: 10 CFR 430.32(w)(1)(ii)	Level VI: 10 CFR 430.32(w)(1)(ii).
Indirect Operation EPS	Level IV: 10 CFR 430.32(w)(1)(i)	No Standards.

# External Power Supplies—Standards



Single-Voltage External AC-DC Power Supply, Basic-Voltage		
Nameplate Output Power ( $P_{out}$ )	Minimum Average Efficiency in Active Mode (expressed as a decimal)	Maximum Power in No-Load Mode [W]
$P_{out} \leq 1$ W	$\geq 0.5 \times P_{out} + 0.16$	$\leq 0.100$
$1$ W < $P_{out} \leq 49$ W	$\geq 0.071 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.67$	$\leq 0.100$
$49$ W < $P_{out} \leq 250$ W	$\geq 0.880$	$\leq 0.210$
$P_{out} > 250$ W	$\geq 0.875$	$\leq 0.500$
Single-Voltage External AC-DC Power Supply, Low-Voltage		
Nameplate Output Power ( $P_{out}$ )	Minimum Average Efficiency in Active Mode (expressed as a decimal)	Maximum Power in No-Load Mode [W]
$P_{out} \leq 1$ W	$\geq 0.517 \times P_{out} + 0.087$	$\leq 0.100$
$1$ W < $P_{out} \leq 49$ W	$\geq 0.0834 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.609$	$\leq 0.100$
$49$ W < $P_{out} \leq 250$ W	$\geq 0.870$	$\leq 0.210$
$P_{out} > 250$ W	$\geq 0.875$	$\leq 0.500$
Single-Voltage External AC-AC Power Supply, Basic-Voltage		
Nameplate Output Power ( $P_{out}$ )	Minimum Average Efficiency in Active Mode (expressed as a decimal)	Maximum Power in No-Load Mode [W]
$P_{out} \leq 1$ W	$\geq 0.5 \times P_{out} + 0.16$	$\leq 0.210$
$1$ W < $P_{out} \leq 49$ W	$\geq 0.071 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.67$	$\leq 0.210$
$49$ W < $P_{out} \leq 250$ W	$\geq 0.880$	$\leq 0.210$
$P_{out} > 250$ W	$\geq 0.875$	$\leq 0.500$
Single-Voltage External AC-AC Power Supply, Low-Voltage		
Nameplate Output Power ( $P_{out}$ )	Minimum Average Efficiency in Active Mode (expressed as a decimal)	Maximum Power in No-Load Mode [W]
$P_{out} \leq 1$ W	$\geq 0.517 \times P_{out} + 0.087$	$\leq 0.210$
$1$ W < $P_{out} \leq 49$ W	$\geq 0.0834 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.609$	$\leq 0.210$

Level VI standards applicable to all direct operation EPS (with limited exception) manufactured on or after Feb. 10, 2016

$49$ W < $P_{out} \leq 250$ W	$\geq 0.870$	$\leq 0.210$
$P_{out} > 250$ W	$\geq 0.875$	$\leq 0.500$
Multiple-Voltage External Power Supply		
Nameplate Output Power ( $P_{out}$ )	Minimum Average Efficiency in Active Mode (expressed as a decimal)	Maximum Power in No-Load Mode [W]
$P_{out} \leq 1$ W	$\geq 0.497 \times P_{out} + 0.067$	$\leq 0.300$
$1$ W < $P_{out} \leq 49$ W	$\geq 0.075 \times \ln(P_{out}) + 0.561$	$\leq 0.300$
$P_{out} > 49$ W	$\geq 0.860$	$\leq 0.300$

- DOE recently issued a Request for Information (RFI) initiating the data collection process to consider whether updates to the EPS standards are necessary
  - In particular, DOE is requesting comment by July 6, 2020 on whether:
    - *Active mode is still the most energy consumptive state of operation for EPSs?*
    - *Design options exist for improving the efficiency of EPSs beyond the Level VI standards? What costs would be associated with these options?*
    - *Specific types of EPS would have trouble meeting more stringent standards?*
  - RFI also seeks input on the emerging network/”smart” technology appliance and equipment market trends and innovations that may be affected by amendments
- CA still maintains regulations for “state-regulated” EPSs or Class A EPSs falling outside the scope of federal regulations

# Battery Chargers (BC)—Applicability



- Device that charges batteries for consumer products, including battery chargers embedded in other consumer products (e.g., cellular and cordless phones, cordless power tools, battery-powered children's toys)
- Applies broadly to products that use DC or AC input voltages of 115 V at 60 Hz, as opposed to the higher voltage of 230 V at 60 Hz that is encompassed by the CEC test procedure:

*As proposed in the NOPR, the scope of the DOE test procedure encompasses products that use DC or AC input voltages of 115 volts (V) at 60 hertz (Hz). 75 FR 16958, 16965. This scope differs from that of the CEC test procedure, which requires, when possible, the testing of units that accept AC line-voltage input at two voltage and frequency combinations: 115 V at 60 Hz and 230 V at 50 Hz. --76 Fed. Reg. 31,750, 31,756 (June 1, 2011).*

*Limiting the scope of the test procedure to encompass BCs with DC or U.S. line-voltage AC input [115 V at 60 Hz] would ensure that all consumer battery chargers intended for use in the U.S. will be covered, while preventing unnecessary testing of industrial BCs or consumer BCs intended for use outside of the U.S.--75 FR 16958, 16965 (Apr. 2, 2010).*



# Battery Chargers (BC)—Standards



- BCs manufactured on or after June 13, 2018 must have a unit energy consumption (UEC) less than or equal to the standard set for the appropriate product class:

Product class	Product class description	Rated battery energy (E <sub>batt</sub> **)	Special characteristic or battery voltage	Maximum UEC (kWh/yr) (as a function of E <sub>batt</sub> **)
1	Low-Energy	≤5 Wh	Inductive Connection*	3.04
2	Low-Energy, Low-Voltage	<100 Wh	<4 V	0.1440 * E <sub>batt</sub> + 2.95
3	Low-Energy, Medium-Voltage		4-10 V	For E <sub>batt</sub> <10 Wh, 1.42 kWh/y E <sub>batt</sub> ≥10 Wh, 0.0255 * E <sub>batt</sub> + 1.16
4	Low-Energy, High-Voltage		>10 V	0.11 * E <sub>batt</sub> + 3.18
5	Medium-Energy, Low-Voltage	100-3000 Wh	<20 V	0.0257 * E <sub>batt</sub> + .815
6	Medium-Energy, High-Voltage		≥20 V	0.0778 * E <sub>batt</sub> + 2.4
7	High-Energy	>3000 Wh		0.0502 * E <sub>batt</sub> + 4.53

- CA maintains regulations that encompass federally-regulated BCs (manuf. after June 13, 2018) and state-regulated small and large battery charger systems (BCS)
  - Imposes CA-specific certification and marking requirements

# Battery Chargers (BC)—Testing



*To demonstrate compliance with the energy conservation standards for battery chargers, manufacturers must develop their certified ratings for each basic model of battery charger by testing a sample of units of that basic model per the battery charger test method – found in Appendix Y to 10 CFR Part 430. The battery charger test method specifies which adapter to use for testing in Section 3.1.4. See relevant text copied below:*

*If a charger is powered by a low-voltage DC or AC input, and the manufacturer packages the charger with a wall adapter, sells, or recommends an optional wall adapter capable of providing that low voltage input, then the charger shall be tested using that wall adapter and the input reference source shall be 115 V at 60 Hz. If the wall adapter cannot be operated with AC input voltage at 115 V at 60 Hz, the charger shall not be tested.*

*If the UUT is designed for operation only on DC input voltage and the manufacturer does not package the charger with a wall adapter, sell or recommend an optional wall adapter capable of providing that low voltage input, it shall be tested with one of the following input voltages: 5.0 V DC for products drawing power from a computer USB port or the midpoint of the rated input voltage range for all other products. The input voltage shall be within  $\pm 1$  percent of the above specified voltage.*

--6/4/2020 DOE Appliance Program e-mail

- DOE recently issued an RFI seeking stakeholder input by June 3, 2020 to determine if an update to the BC test procedure is necessary
  - In particular, the RFI request information on the evolving wireless BC market, including:
    - How wireless chargers – charging mats and “wet environment” products – are used in the field, particularly with regard to the placement of the receiver
    - If DOE should define “wet environment” installations? And if so, how should terminology be used to delineate the scope of wireless BCs subject to the existing BC test procedure and EE standards?
    - Possible approaches for testing wireless BCs other than those designed for “wet” environments (i.e., other than using locating features such as a peg or a cradle)
  - RFI also requests information on the emerging smart technology appliances and equipment market trends and innovations that may be affected by amendments

- EU Ecodesign Directive
  - 31 total categories (8 updated and 2 new in 2019)
  - e.g., electronic displays (>100 cm<sup>2</sup>), various household and kitchen appliances, EPS, motors, ventilators and heaters
  - Stand-by and off mode
- EU Energy Labeling Regulation
  - 15 product groups (mainly consumer electronics) require energy label (scale from A (most efficient) to G (least efficient))

- Restricts placing on the EU market of articles containing certain substances, including:
  - Perfluorooctanoic acid (PFOA) and some other PFCAs
  - DecaBDE (flame retardant)
  - DEHP and other phthalates (7/7/2020)
  - Complete list: <https://echa.europa.eu/substances-restricted-under-reach>
  - Restrictions in the pipeline: <https://echa.europa.eu/registry-of-restriction-intentions>
- Obligation to notify customers (and consumers upon request) of any content of SVHCs in articles above 0.1 % w/w
  - List of SVHCs: <https://echa.europa.eu/candidate-list-table>
- Notification obligation to the new ECHA database of SVHCs in articles from January 2021; it will become available to waste treatment operators and consumers.

# Don't Forget . . .

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- TSCA Inventory status of substances manufactured (or imported) in the U.S.
- Special rules applicable to use of ozone-depleting chemicals and alternatives
- Proposition 65 consumer product warnings
- FIFRA Treated Article Exemption
- State Green Chemistry Laws
- State Electronic Waste Laws
- State Packaging Regulations (e.g., Toxics in Packaging, RPPC)

# Rigid Plastic Packaging Container Law

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- California law with increased investigation/enforcement in this area
- Applies to brand owner/product manufacture for containers:
  - Made entirely of plastic--except incidental parts
  - Relatively inflexible shape or form
  - Capacity or volume: 8 oz to 5 gallon
  - Capable of at least one closure (including during manufacturing)
  - Holds a product sold or offered for sale in California

# RPPC Requirements



- Registration, precertification and compliance certification
- RPPC Compliance option
  - Postconsumer Material Content: at least 25%
  - Source Reduction:
    - Reduced Container Weight: at least 10%
    - Product Concentration: Product within the RPPC must be concentrated by at least 10 percent
    - Product Concentration and Reduced Container Weight Combination
    - Comparison to Similar Products: at least 10 percent less (similar type, material, weight & Shape)
  - Reusable RPPC: reused at least five times to hold a replacement product -- does not refer to a container that is intended to be used or may be used to permanently hold the original product sold in that container
  - Refillable RPPC: routinely returned to and refilled by the product manufacturer at least 5 times
  - Recycling rate: RPPC for a particular type of product/material must be recycled at min. 45%
  - Alternative Container Compliance Method: Product manufacturer or affiliate consumes PCR from California to manufacture product or packaging > 25% PCR content



# FDA

# “General Wellness Product”

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- Has an intended use that relates:
  - (1) to maintaining or encouraging a general state of health or a healthy activity, [i.e., functions associated with a general state of health, but no reference to diseases or conditions], or
  - (2) the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition
  
- Presents a “low risk to the safety of users and other persons”

# “General State of Health” Claims

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- General wellness claims related to:
  - Relaxation or stress management
    - OK: Increase, improve, or enhance the flow of qi
    - Not OK: help treat anxiety disorders
  - Mental acuity
    - OK: Improve instruction-following, concentration, problem-solving, multitasking, resource management, decision-making, logic, pattern recognition or eye-hand coordination
    - Not OK: computer game will help diagnose or treat autism, help reduce effects of Alzheimer’s disease

# “General State of Health” Claims (cont)

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- General wellness claims related to:
  - Self-esteem
    - OK: rejuvenate skin to look younger
    - Not OK: reduces/eliminates wrinkles
  - Sleep management
    - OK: Track sleep trends
    - Not OK: diagnose or treat sleep apnea
  - Sexual function
    - OK: increase or improve muscle size or body tone; tone or firm the body or muscle; enhance cardiac function; or enhance or improve sexual performance
    - Not OK: treat erectile dysfunction

# “Reduce Risk or Impact” Claims

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- “Software Product U coaches breathing techniques and relaxation skills, which, as part of a healthy lifestyle, may help living well with migraine headaches.”
- “Software Product V tracks and records your sleep, work, and exercise routine which, as part of a healthy lifestyle, may help living well with anxiety.”

# “Reduce Risk or Impact” Claims (cont)

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- “Product X promotes physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure.
- “Software Product Y tracks your caloric intake and healthy eating plan to help you maintain a healthy weight and balanced diet (which can help you live well with high blood pressure and type 2 diabetes).”

- Company A markets a connected baby monitor. Can it make claims to help prevent sudden infant death syndrome (SIDS)
- Company B markets video games and consoles. Can it promote its system to help stroke victims improve their physical dexterity as part of their rehabilitation?

# Opportunities for Industry

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- Policy is expansion of FDA's previous (reasonable) position on fitness/exercise equipment
- Reduce uncertainty and open new options for “wearables”
- Ability to make statements about reducing risk or impact of chronic disease/condition is welcome
- Potential for abuse, inappropriate products
- Practical enforcement may now fall to Federal Trade Commission (FTC) and states
- FDA presumably may still take action in appropriate cases



# Americans with Disabilities Act

- Appliances must meet specific standards to be promoted as “accessible”
  - These requirements apply to the ability to reach and manipulate “operable parts”
- Access Board, DOJ, or Uniform Federal Accessibility Standards (UFAS) may apply, depending on intended market
  - These standards differ in key respects; meeting one standard will not necessarily ensure meeting other standards

- Websites and apps should be accessible to consumers with hearing or visual impairments
  - Litigation and regulatory enforcement in this area is growing
- Web Content Accessibility Guidelines (WCAG) 2.0 have been incorporated in U.S. and foreign regulations and adopted as an ISO standard
  - Following WCAG 2.0 will generally ensure compliance with relevant requirements
  - WCAG 2.1 is a newer standard. It does not deprecate or supersede WCAG 2.0
  - CCPA regulations require accessible privacy notices that meet WCAG 2.1

# Advertising and Marketing

- What's different about connected product advertising/marketing?
- What are implications of COPPA's actual knowledge standard for general use connected products?
- Advertising to children
  - Is it a toy? What about items that appeal to mixed audiences?
  - What do we have to watch out for with behavioral advertising?

- Can I create a pre-launch waitlist for orders?
  - Can I charge a fee?
  - Can I offer rewards if people sign up, refer a friend and the friend signs up?
- What happens if I take an order, but my shipment is delayed?



# THANK YOU

**Connected Products Team**  
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