EU Environmental Compliance: An Overview of RoHS and REACH

November 4, 2017
Irvine, California
Agenda

- EU RoHS
  - Evolution – A Timeline
  - Scope
  - Substance Restrictions
  - Homogenous Materials
  - Exemptions
  - EN 50581 – Risk Analysis Requirements

- EU REACH
  - Article 33 - The SVHC Candidate List
  - REACH Annex XIV
  - REACH Annex XVII
  - Producer Responsibilities

- Q&A
EU RoHS

2011/65/EU
WHAT IS THE ROHS DIRECTIVE?


- The directive seeks to reduce the amount of hazardous substances present in EEE (Electrical and Electronic equipment) for the purpose of reducing environmental impact to the waste stream at end of life.

- Limits the amount of certain substances present within materials used to construct EEE.

- The RoHS-2 directive is part of a series of directives used to validate CE Mark compliance for access to the EU market. These include the Electromagnetic Compatibility (EMC) and Low Voltage (Safety) Directives, among others.
### EVOLUTION OF THE ROHS DIRECTIVE

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2006</td>
<td>RoHS Directive 2002/95/EC comes into force</td>
</tr>
<tr>
<td>July 2008</td>
<td>New Legislative Framework adopted</td>
</tr>
<tr>
<td>July 2011</td>
<td>RoHS-2 Directive 2011/65/EU adopted</td>
</tr>
<tr>
<td>July 2016</td>
<td>In vitro diagnostic medical devices come into scope for RoHS compliance</td>
</tr>
<tr>
<td>July 2019</td>
<td>All additional EE which was out of scope for RoHS comes into scope – additional substance restrictions come into effect.</td>
</tr>
<tr>
<td>Nov 2012</td>
<td>EN 50581 standard published in the EU official journal as a harmonized standard</td>
</tr>
<tr>
<td>July 2014</td>
<td>Medical devices and monitoring and control instruments come into scope for RoHS compliance</td>
</tr>
<tr>
<td>July 2017</td>
<td>Industrial monitoring and control equipment comes into scope for RoHS compliance</td>
</tr>
</tbody>
</table>
CE MARKING and THE NEW LEGISLATIVE FRAMEWORK

- CE Marking is a requirement to access the EU market. CE Marking compliance is achieved through the application of product-specific compliance directives, such as the Low Voltage directive, EMC directive, etc...

- The NLF was adopted July 2008, came into effect January 2010

- Package of measures intended to improve market surveillance and quality of conformity assessments. The package includes:
  - **Regulation 768/2008** – provides a template for future legislation, as well as clarity on common documentation requirements.
  - **Regulation 764/2008** – sets procedures relating to the application of certain national technical rules to products marketed in other EU member states.
The NLF is designed to provide consistent approach to conformity validation processes across all applicable EU Directives.

The RoHS directive is not the only directive recast under the NLF. In February 2014, an “alignment package” was adopted consisting of the following new or recast directives:

- Low Voltage Directive 2014/35/EU
- EMC Directive 2014/30/EU
- ATEX Directive 2014/33/EU
- Lifts Directive 2014/33/EU
- Simple Pressure Vessels Directive 2014/29/EU
- Non-automatic Weighing Instruments Directive 2014/31/EU
- Civil Explosives Directive 2014/28/EU
INCLUSION OF THE ROHS-2 DIRECTIVE IN THE NLF RE-ALIGNMENT HAS:

- Brought RoHS Compliance under the CE marking scheme. The CE mark cannot be legally applied to a product in scope with the directive without adequate RoHS compliance validation.

- The Combination of the RoHS directive recast with the NLF regulations has significantly increased the documentation and due diligence expectations placed on manufacturers of electrical and electronic equipment.

- The stakes have been raised for enforcement as well, with all CE Marking non compliance penalties now applicable to RoHS compliance validation.
## ROHS Directive Scope

<table>
<thead>
<tr>
<th>Equipment Category</th>
<th>Description</th>
<th>Mandatory Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Large household appliances</td>
<td>July 1, 2006</td>
</tr>
<tr>
<td>2</td>
<td>Small household appliances</td>
<td>July 1, 2006</td>
</tr>
<tr>
<td>3</td>
<td>IT and telecommunications equipment</td>
<td>July 1, 2006</td>
</tr>
<tr>
<td>4</td>
<td>Consumer equipment</td>
<td>July 1, 2006</td>
</tr>
<tr>
<td>5</td>
<td>Lighting equipment</td>
<td>July 1, 2006</td>
</tr>
<tr>
<td>6</td>
<td>Electrical and electronic tools</td>
<td>July 1, 2006</td>
</tr>
<tr>
<td>7</td>
<td>Toys, leisure and sports equipment</td>
<td>July 1, 2006</td>
</tr>
<tr>
<td>8</td>
<td>Medical devices</td>
<td>July 22, 2014 (standard)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>July 22, 2016 (in-vitro)</td>
</tr>
<tr>
<td>9</td>
<td>Monitoring and control instruments including industrial monitoring and control instruments</td>
<td>July 22, 2014 (standard)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>July 22, 2017 (industrial)</td>
</tr>
<tr>
<td>10</td>
<td>Automatic dispensers</td>
<td>July 1, 2006</td>
</tr>
<tr>
<td>11</td>
<td>Other EEE not covered by any of the categories above</td>
<td>July 22, 2019</td>
</tr>
</tbody>
</table>
ROHS DIRECTIVE SCOPE

The following are explicitly excluded from the requirements of the RoHS Directive:

- Military and Defense Equipment
- Equipment designed to be sent into space
- Equipment designed to be installed and used solely in exempted equipment
- Large-scale industrial tools
- Large-scale fixed installations
- Vehicles (excluding electric 2-wheel vehicles)
- Professional use non-road machinery
- Active implantable medical devices
- Solar panels designed for use as part of a residential, public, commercial, and/or industrial lighting purposes
- R&D Equipment made only made available on a business-to-business basis.
ROHS DIRECTIVE SUBSTANCE RESTRICTIONS

- The following substances are currently restricted, applicable to all in-scope equipment:
  - Lead – 1000 ppm limit
  - Mercury – 1000 ppm limit
  - Cadmium – 100 ppm limit
  - Hexavalent Chromium – 1000 ppm limit
  - PBBs (Polybrominated Biphenyls) – 1000 ppm limit
  - PBDEs (Polybrominated Diphenyl Ethers) – 1000 ppm limit

- Limits (Thresholds) applied at the homogeneous level not part, product, or component level

- There are exemptions available for applications of the above substances where the removal of the substance has been deemed not technologically viable
The following substances will become restricted at the homogeneous level in July 22, 2019 (most categories) or July 22, 2021 (in-vitro medical equipment and monitoring and control equipment):

- Bis(2-ethylhexyl) phthalate (DEHP) – 1000 ppm limit
- Butyl benzyl phthalate (BBP) – 1000 ppm limit
- Dibutyl phthalate (DBP) – 1000 ppm limit
- Diisobutyl phthalate (DIBP) – 1000 PPM limit

Commonly used in PVC, flexible plastics (wire insulation, etc)
ROHS DIRECTIVE SUBSTANCE RESTRICTIONS

- Restrictions do not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE which was placed on the market before the substance restrictions came into effect.

- Restrictions do not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII of the REACH law.
HOMOGENEOUS MATERIALS

- All products must be validated that the restricted substances are not present in the subject product above stated thresholds, applied at the HOMOGENEOUS Material level

- “Homogenous Material” means a material that cannot be mechanically disjointed into different materials. The term homogeneous is understood as "of uniform composition throughout", e.g., individual types of plastics, ceramics, glass, metal, alloys, paper, board, resins and coatings

- The term "mechanically disjointed" means that the materials can, in principle, be separated by mechanical actions such as unscrewing, cutting, crushing, grinding, and abrasive processes
Definition of Homogenous Materials

- Components such as capacitors, transistors and semiconductors packages are not “homogenous materials” but contain several different materials

![BGA Package](image1)

- Multiple homogeneous materials in:
  - **Substrate**: solder mask, BT core etc...
  - **Solder paste**: solder powder alloy, flux mixture
  - **Gold finger**: copper, nickel, gold
  - **Resistor**: substrate, conductive layer, glass layer, termination layer etc...
  - **Capacitor**: inner electrode, ceramic body, conductive layer, barrier layer etc...
EXEMPTIONS

- Certain application-specific exemptions are defined in cases where the commission has determined that meeting the stated threshold is not viable.

- RoHS exemptions are managed separately from the RoHS directive, and exemption updates were not a part of the RoHS-2 recast.

- The exemption list is reviewed and updated every 4 years.

- All Exemptions have defined or default expiration dates, which could be extended at the next review.

- Exemptions are listed in the Annex of the RoHS Directive.
EXEMPTIONS

- Examples:

- Exemption 7(c)-i: Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound
  
  Typically claimed by resistors due to high homogeneous concentrations of lead in glass frit

- Exemption 7(a): Lead in high melting temperature type solders (i.e. lead-based alloys containing 85% by weight or more lead)
  
  Typically claimed by some high-current / high-temperature power components such as inductors, transformers

- Both of the above exemptions were set to expire in July 2016, however, the commission is reviewing them for extensions, so they are still in effect.
EN 50581 – RISK ANALYSIS REQUIREMENTS

- EN 50581 “Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances” was published as a “harmonized standard” to assist manufacturers in determining the due diligence and documentation processes required to adequately validate to the RoHS directive.

- Manufacturers are not required to reference the standard, however, those who demonstrate a process compliant with this standard shall be deemed to be meeting the due diligence requirements of the directive. (Article 16(2) of 2011/65/EU)

- Most companies are referencing EN 50581 when designing or updating their internal RoHS validation processes. Internal processes based on EN 50581 should specifically reference the clauses of the standard throughout.
The specific steps to an EN 50581 compliant process:

- **Step 1:** Determine the Information needed
- **Step 2:** Collect the required information
- **Step 3:** Evaluation of the Information
- **Step 4:** Establish the required technical documentation

*Once all steps of the process have been adequately performed, and the product has been validated against all other applicable EU directives, the declaration of conformity is drawn up and the CE Marking is applied to the product.*
EN 50581 – RISK ANALYSIS REQUIREMENTS

STEP 1: Determine the Information needed

- Per EN 50581:2012, clause 4.3.2, step 1 is a risk analysis process:

  1. You must evaluate the probability of restricted substances being present in the part or material used to construct your product.

  2. You must evaluate and quantify the trustworthiness of the supplier providing the part or material used to construct your product.

- The due diligence performed for each part, material, and/or supplier will be based on the results of the risk analysis performed.
EN 50581 – RISK ANALYSIS REQUIREMENTS

STEP 1: Determine the Information needed

- Evaluating the probability of restricted substances being present in the part or material:
  - Per EN 50581:2012, clause 4.3.2, the manufacturer shall:
    - Apply technical judgement based on information available via the electronics industry and/or…..
    - Perform a literature investigation of the product(s).
  - Some metrics to include in such investigations:
    - Material types typically used in the part or material (or similar parts)
    - Historical record of substances being present in the part (or similar parts)
    - Recently expired exemptions that may impact the part or material.
STEP 1: Determine the Information needed

- Evaluating the trustworthiness of suppliers providing the parts and materials:
  - Per EN 50581:2012, clause 4.3.2, the manufacturer shall:
    - Use their Own Judgement (?)
  - However, the standard does make some suggestions on metrics to use:
    - Historical experience with the supplier organization
    - Results of previous inspections or audits
EU RoHS - Summary

- EU RoHS is a CE-Marking directive and must be validated before applying the CE Mark and importing products into or selling products in the EU.

- EEE not in scope with the RoHS directive now MAY be coming into scope in 2019

- RoHS Exemptions are in flux and impact product compliance and should be tracked for changes and sunset dates

- New substance restrictions coming into effect in 2019 should be reviewed for impact to product compliance.

- The RoHS-2 recast and publication of EN 50581 has added an expectation that a risk analysis based strategy is to be used for compliance assessment. Manufacturers should be performing due diligence based on risk of parts containing the restricted substances, and levels of pre-determined supplier trustworthiness.
REACH

Regulation (EC) No 1907/2006
REACH – What is REACH?

- REACH is the Restriction and Authorization of Chemicals legislation in the EU.
  - Chemical restrictions, authorization requirements, and supply chain communication requirements for all substances and mixtures imported into or manufactured in the EU.
  - INCLUDES substances present in articles (products).
  - An article that expels a mixture or substance (toner cartridge, ink pen) would need be addressed as both an article and a substance / mixture.
  - REACH is an EU law, not a directive, and as such, in not tied to CE Marking in any way.
REACH – Areas of concern for article producers

- Important things to consider when applying REACH requirements to articles such as EEE:
  - Does the article expel any mixtures or substances?
  - Is the article manufactured in the EU or imported into the EU?
  - A clear understanding of the definition of an article is required
  - Which Annex XVII restriction entries apply to your type of product?
  - Regular data updates – every 6 months

- Customer requirements
  - The type of data required by your customers will define what type of data is required from your suppliers
REACH – The SVHC Candidate List

- Producers of articles must evaluate their product for SVHCs present in any article present in the product in amounts greater than 1000ppm.
  - SVHCs present over the stated threshold must be communicated through the supply chain –
    - professional customers only. (Not end users.)
    - At a minimum the name of the SVHC present must be provided.
    - If the amount of the substance imported, used, or manufactured in the EU is above 1 metric tonne per year, some official notification requirements may also be triggered.
- There are currently 174 substances on the list. More substances are added approximately every 6 months. (So any REACH certifications from your suppliers have very short lifespans.)
REACH – What is an “Article”? 

- **Article Definition** – what is an article and how do we calculate substance concentrations?:
  - An article is defined in REACH as “an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.”
  - The original interpretation of this definition was that an article is an end product.
  - A recent EU Court of Justice decision re-interpreted the definition as “one an article, always an article.” The decision was confirmed by a newly released Guidance for Articles publication, released by ECHA June 2017.
  - This means any past REACH compliance validations performed at the product level are no longer viable. Calculations will be performed at a semi-homogeneous level.
  - Manufacturers need to understand the impact of this change and review their process to ensure they are adequately collection data at the correct subpart level.
Changes to Article Definition under REACH

- **Background**
  - Original Definition – Final Article
    - Substance Aggregation at final article (final product)
  - EU Court of Justice decision – 10 Sept. 2015 in case C-106/14
    - Once an Article, Always an Article
  - Guidance document Version 4.0 has been officially released – JUNE 28, 2017
    - Examples of how to calculate the SVHC in an article are provided
    - Subparts of components confirmed to be potential articles
      - Leads of capacitor
      - Lead-frame of IC
      - Body of resistor
      - Transformer core
REACH – Annex XIV

- Annex XIV provides some requirements on certain SVHCs which have restrictions on use applications
  - Annex XIV, while not applicable to articles imported into the EU, is applicable to manufacturers of articles within the EU.
  - The substance must be authorized for its intended use in the article before being manufactured within the EU.
  - Many companies with factories or EMS providers located in the EU are starting to require Annex XIV validation of components from suppliers.
  - Producers of Substances and Mixtures are in scope even if imported from outside the EU.
REACH – Annex XVII

- Annex XVII defines specific substances which are either prohibited from use completely or have restrictions when used in certain pre-defined applications.

- The REACH Annex XVII substance list maintained by the European Chemicals Agency (ECHA) is not all inclusive as the regulation refers to the several classes of substances called out in EU regulation (EC) No 1272/2008 (CLP directive) for some restricted substances.
REACH – Annex XVII

- The Annex includes hundreds of substances as defined by 68 (current) entries to the Annex. Each entry has specific information on scope and applicability.

  - **Example 1:** Entry 66 restricts BPA, but only in Thermal paper made available after Jan 2, 2020. Producers of electronic devices can probably ignore this restriction.
  - **Example 2:** Entry 23 restricts Cadmium in articles containing certain polymers, and painted articles. This requirement may apply to certain electronic or electrical articles, depending on their construction.
  - **Example 3:** Entry 29 restricts substances which appear in Regulation (EC) No 1272/2008 (CLP directive) classified as germ cell mutagen category 1A or 1B or mutagen category 1 or 2. If an article (such as a printer ink cartridge) expels any substance that meets this description, it may be non-compliant.

- Many of the entries do not apply to articles at all. So performing a compliance analysis against the entire Annex XVII is not only very difficult, it is also largely useless without hours of follow up research.
# Producer Responsibilities

<table>
<thead>
<tr>
<th>Condition</th>
<th>Communication Requirements Professional Users</th>
<th>Communication Requirements Consumers (Upon Request)</th>
<th>Notification Requirements</th>
<th>Authorization Requirements</th>
<th>Registration Requirements</th>
<th>Restrictions on use</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVHC not present in Article or sub-article over 1000ppm</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>SVHC Present in Article or sub-article over 1000ppm and as a result over 1 tonne annually of the substance is imported or produced for sale in the EU</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>SVHC Present in Article or Sub-article over 1000ppm and as a result over 1 tonne per of the substance is imported or produced for sale in the EU, and the SVHC is intended to be released during normal article use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Article contains Annex XIV substance which has not been authorized for the specific use. (Articles manufactured in the EU only)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product contains Annex XVII substance which is used in a manner restricted under one or more Annex XVII Entry</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Article 33(1) The name of the substance must be provided as well as any information available to ensure safe use of the article.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Article 33(2) Must provide the name of the substance and if available, safety information about the SVHC and the article.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Article 7(2) Must notify ECHA of the SVHCs present in the article</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Article 7(1) SVHC must be registered with ECHA for use in the article. If not prev registered,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Article 67(1) Substance cannot be used. The Article cannot be imported or produced for sale in the EU.</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

November 4, 2017
EU REACH - Summary

- Producers of articles should be aware of the potential impacts of REACH compliance. It is much more than SVHC certificates....
  - Understand the impact of the re-interpretation of an “Article”
  - Ensure the following have been addressed:
    - SVHC analysis and communication and/or notification responsibilities
    - Annex XIV applicability reviewed and addressed if needed
    - Annex XVII reviewed for applicability to the product and any restricted substances removed from the product
    - Confirmation registration is not required for SHVCs released from the article.
GreenSoft Technology

Who we are and what we do
**GreenSoft Overview**

- Established in 2002, GreenSoft Technology is a leader in the field of environmental compliance management.
- Two business branches:
  - **Data Management Services:** GreenSoft conducts data collection, validation and conversion to any desired format.
  - **Software tool:** For management and reporting of various environmental regulations, such as RoHS-2 & REACH SVHC & Conflict Minerals, from desktop to LAN-based to Internet-based to cloud-based.
- Extensive experience in collecting, formatting and analyzing electronics and compliance data.
- One-Stop Total Solution Provider:
  - From data collection to product-level compliance reporting.
  - Data, software, and reporting solutions for environmental compliance management.
More About GreenSoft

- Headquartered in Pasadena, California, USA with offices in Europe, Israel, Japan, Taiwan and China – 120 employees
- Data factory in Shijiazhuang, Hebei, China. 180 miles south of Beijing
- ISO 9001:2015 certified
Some of our Customers

COMMUNICATIONS
NETGEAR®
Coltix AudioCodes
Corning Mobile Access
Mellanox Technologies
Siklu
Omnicell
Linx
Accton
Multiplay Partnership Work
CoolStream
Qinu
napatech
Newtec
JDSU
radware
Silicom
PacketLight
CASSIDIAN

POWER MODULES
TDK-Lambda Corporation
APC
enLogic
Power-Win Technology Corp.

AEROSPACE
UTC Aerospace Systems
GENERAL DYNAMICS
AEREO
Thales
Airbus

SYSTEMS/SUB-SYSTEMS
Kohler
HP
Logitech
SMART
FabrineT
Honeywell
Vocolect

VIDEO/SECURITY SYSTEMS
NICE
VERINT
ImperX

MEDICAL/LIFE SCIENCES
Abbott
BD
Stryker
Ortho
Tecan
Zaron
ABX
IMP
terus
Cynsure
Hanns
VERATHON
ReSound
Cynosure
Sonesta

SEMICONDUCTOR & TEST EQUIPMENT
Texas Instruments
GLOBALFOUNDRIES
MENTL
Silicon PXL
Winbond
Cavium
Moxtek

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GreenSoft has many years experience in assisting customers with REACH Compliance, but it doesn’t stop there. GreenSoft can assist with any environmental compliance requirements.

Just some of the requirements we help customers address:

1. AD-DSL: International Aerospace Environmental Group (IAEG) – Aerospace and Defense Declarable Substances List (AD-DSL)
2. EU Directive Battery: 2006/66/EC
6. China RoHS: Administrative Measure on the Control of Pollution Caused by Electrical and Electronic Products per standard SJ/T 11363-2006
7. Conflict Minerals – Examine the FMD for Conflict Minerals per 2010 Dodd-Frank Wall Street Reform and Consumer Protection Act
10. EU Regulation - 1005/2009 Ozone Depletion Substances
11. EU RoHS-2: EU Directive 2011/65/EU
14. Low Halogen: EIA JEDEC ECA JS709B
15. Norwegian POHS: No 2010/9016 – 9019/N
17. PFOS: EU Regulation 757/2010/EC
18. Rare Earth Substances
19. REACH Annex-XIV
20. REACH Annex-XVII
21. REACH SVHC: from SVHC(15) to SVHC(174)
The **GreenSoft** Advantage

- GreenSoft offers a customized complete solution for companies of all sizes, markets, and needs.
  - **Data Collection**: Data collection, validation and management services to manage your entire product and materials base.
  - **Software**: Various versions to meet your needs:
    - Hosted GreenData Manager – Hosted on the cloud, no internal IT involvement.
    - On-Premise GreenData Manager – Install your parts database on your servers and have complete control over data security and access.
      - Desktop Edition – Inexpensive single-seat option
      - Workgroup Edition – Collaborative environment for larger compliance groups
      - Browser Edition – Global access to compliance and product data for all global business units
  - **Turnkey Product Compliance**: Just provide us with your BOM(s) or a parts list and specify the compliance requirements (regulations or rules).
    - GreenSoft delivers compliance reports per your requirements with due diligence documents collected from suppliers.
The **GreenSoft** Advantage

- **GreenSoft Component Database**
  - **64 M part numbers** from **27,417 manufacturers** worldwide – Mar 2017

- **Part Numbers Database:**
  - **6.6 M parts** with Full Material Declaration (FMD) Data
  - **REACH SVHC status and Certificates:**
    - **SVHC(161)** – **17M**
    - **SVHC(163)** – **1.19M**
    - **SVHC(168)** – **997K**
    - **SVHC(169)** – **6.92M**
    - **SVHC(173)** – **8.05M**
THANK YOU!